



WIPO-WTO COLLOQUIUM PAPERS: 2018 AFRICA EDITION

**RESEARCH PAPERS FROM THE 2018 REGIONAL WIPO-WTO COLLOQUIUM
FOR IP TEACHERS AND SCHOLARS IN AFRICA**

Compiled by the WIPO Academy

and

the WTO Intellectual Property, Government Procurement and Competition Division

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EDITORS

Antony Taubman, Martha Chikowore, Wolf R. Meier-Ewert, Tana Pistorius, Sheila Mavis SM. Nyatlo and Bassam Peter Khazin. Copy editor: Nishant Anurag.

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Switzerland

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Counsellor
WIPO Academy
World Intellectual Property Organization
Switzerland

PREFACE

This African edition of the *WIPO-WTO Colloquium Papers* marks a new avenue for what has been an invaluable programme of collaboration between the WIPO and the WTO. Intellectual property (IP) scholarship across the African continent has shown impressive growth and range over recent years, and close engagement with the cultural and social realities, and the development challenges, of African communities. We are delighted to put a collection of this remarkable work before an international readership through this special edition, an array of scholarship which exemplifies this trend and demonstrates both the high quality of work and scholars' close engagement with today's legal and policy challenges.

Seemingly ubiquitous in contemporary life, the IP system – together with the many areas of public policy it has bearing on – has undergone an unprecedented phase of globalization and institutionalization within international frameworks. Yet these international developments have only underscored the need for domestic and regional policymakers to adapt and apply the broad principles of IP in balanced and effective ways that promote economic and social development and correspond to the diverse needs and circumstances of individual countries. In turn, as countries address these policy challenges in different ways, these practical experiences offer insights to others grappling with similar challenges elsewhere, that in turn can underpin regional dialogue and cooperation. African nations have displayed increasing dynamism and diversity in the ways they have sought to reform their IP regimes as a means for economic and social development, and better understanding of these trends can illuminate potential ways ahead for cooperation, coordination and mutual learning between like-minded countries.

Today's scholars therefore make an indispensable contribution in analysing these trends, mapping out the specific challenges that confront African nations, and proposing solutions that are better tailored to the reality of diverse social, economic and developmental contexts across the African continent. Accordingly, the authors collected in this volume tackle issues of immediate concern: development through enhanced technology transfer, the recognition of indigenous knowledge systems and traditional cultural expressions, value addition for traditional agricultural and craft products through geographical indication protection, responding to and developing appropriate IP provisions in trade agreements, addressing obstacles to access to medicines and other medical technologies, establishing a balanced and workable approach to the digital economy, and probing the potential of relatively under-utilised forms of IP such as industrial designs and utility models.

These papers had their genesis, and a peer-review dialogue, at the African regional version of the WIPO-WTO Colloquia for academics working in IP law and policy. Jointly convened by our two organisations since 2004, the colloquium series provides a forum for building national expertise and self-sustaining policy know-how, while building networks and collaboration between scholars in developing countries, which in turn bolsters capacity to analyse complex legal and policy issues confronting the domain of IP today. The WIPO-WTO Colloquia are now an invaluable part of the overall strategy to build sustainable IP teaching and research capacity in developing countries and least developed countries. Both WIPO and the WTO aim to empower these countries to use their IP systems ever more effectively as a tool for economic and social development, while simultaneously promoting international and regional cooperation and collaboration. Hence, our two organizations are responding to the growing demand to strengthen the distinct legal and policy expertise available in individual countries, while scholars and teachers have concurrently recognized the value of dialogue, the pooling of ideas and the sharing of experiences from different countries around the world.

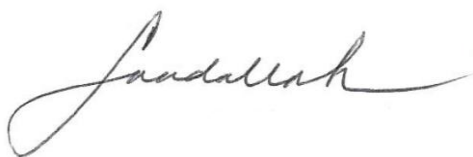
To promote such mutual learning and exchange of ideas, the WIPO-WTO Colloquium has, over the years, brought together an impressive array of scholars from across the globe, and has forged an alumni network that serves to maintain this dialogue and collaboration beyond the formal bounds of the colloquium programme itself. The colloquia have evolved as a clearing house of new ideas, new critical approaches and cutting-edge scholarship, with a unique focus on the developing world. In order to harvest the fruit of this scholarship, and to ensure the sustained impact and greater dissemination of this knowledge, the initiative to publish colloquium participants' papers in an edited, peer-reviewed academic journal, titled the *WIPO WTO Colloquium Papers* was taken in 2010. The *Papers* are published, under the guidance of an editorial board comprising senior international scholars and officials. The six editions of the *Papers* have confirmed the publication's status as an academic journal with a unique focus on emerging policy and legal issues within a wide range of jurisdictions across developing countries.

The WIPO-WTO Colloquium for Africa provided IP academics in the region with a greater understanding of current international developments in IP law and policy, particularly relevant to the Africa context. It also promoted cutting edge

Africa-focused research; and served as a forum to strengthen collaborative networks and academic exchanges across the African region.

All of us who have participated in the colloquium programme have benefited from the hard work and dedication of many colleagues within WIPO and the WTO Secretariat – notably, the WIPO Academy and the WTO's Intellectual Property, Government Procurement & Competition Division, with the invaluable support of the WTO's Institute of Training and Technical Cooperation (ITTC). All have contributed valuably to the design and delivery of this programme, and their spirit of collegiality makes this not only a demanding programme, but also a pleasurable one.

We owe a particular debt of gratitude to the Editorial Board and the editors of this African edition of the *WIPO-WTO Colloquium Papers*, as they have been indispensable in ensuring that the *Papers* can be used as a trusted, academically sound and readable source of cutting-edge IP scholarship from an impressive group of emerging scholars representing a variety of developing countries. They have also served to fulfil the intended contribution of the *Colloquium Papers* initiative towards the capacity building goals of the WIPO Academy and WTO's ITTC, by guiding emerging scholars, where needed, in sculpting their academic writing skills through a participative and interactive dialogue, thus enhancing the potential to add even more diverse perspectives to policy debates in a sustained and credible way. Finally, we record our deep appreciation for the contributions made by individual scholars to this edition of the *Papers*, and its preceding volumes, which we have come to know and respect for their contributions to policy and legal scholarship. We are sure that this active, informed and thoughtful participation in many of the key public policy debates of today will continue, thus exemplifying the important public service role performed by the scholarly community today.



Mr Sherif Saadallah
Executive Director,
WIPO Academy
World Intellectual Property Organization



Antony Taubman
Director
Intellectual Property, Government Procurement and
Competition Division
World Trade Organization

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WIPO-WTO COLLOQUIUM FOR IP TEACHERS AND SCHOLARS IN AFRICA

Class of 2018



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Participants of the WIPO-WTO Colloquium for Teachers of IP Teachers and Scholars in Africa (2018) together with Mr. Antony Taubman, Director, WTO Intellectual Property, Government Procurement and Competition Division (IPD) (left-front); Dr. Yonah Seleti, Chief Director, Science Missions in South Africa's Department of Science and Technology, Pretoria (left-front); Mr. Joseph Bradley, Head, Academic Institutes Program, WIPO Academy (second row-left); Ms. Martha Chikowore, Counsellor, WIPO Academy (front-centre); Professor Irene Calboli, Texas A&M University School of Law and Visiting Professor, Singapore Management University School of Law (front-right); Ms. Florencia Beati Venturini, University of San Andres, Buenos Aires (second row-right); Professor Tana Pistorius, South African Research Chair: Law, Society and Technology, University of South Africa (UNISA), Pretoria; Mr. Wolf Meier-Ewert, Counsellor, IPD, WTO (third row-left); and Mr. Fernando dos Santos, Director General, African Regional Intellectual Property Organization (ARIPO), Harare (third row-centre).

**INTEGRATING INTELLECTUAL PROPERTY, INNOVATION,
TRANSFER OF TECHNOLOGY AND LICENSING
IN KENYA AND AFRICA**

Ben Sihanya*

ABSTRACT

The overarching argument in this essay is that Kenya and Africa have a lot of potential for, and should integrate innovation, technology development, and the protection and promotion of intellectual property (IP). The integration needs to take a three-pronged methodology and approach. First, integration is required on a doctrinal level and IP policy reforms are necessary on a sector-specific as well as an institutional level. Second, integration is necessary through legislative and regulatory reforms. These will help address serious weaknesses or limitations in the legal and regulatory frameworks on and in the interface among IP, innovation and transfer of technology valuation, commercialisation, as well as general corporate and constitutional governance. Third, there is a need for scholarship and practice to integrate business and law in Kenya with licensing, IP, innovation and transfer of technology. This will enable innovators, IP owners and other key stakeholders to benefit from the relevant forms of IP, including copyright, trademark, patent, trade secret, unfair competition, utility model, industrial design, plant or animal breeder's rights, and other forms of IP and innovation that have been developed and need to be nurtured. The key research objective and methodology include review of the legal framework on IP, innovation and transfer of technology, reconceptualization, comparative analysis of how licensing and scholarship affects the status and trends in IP, innovation and transfer of technology in Kenya.

Key words: Technology transfer, Licensing, Kenya, Africa

**1. BACKGROUND TO INTELLECTUAL PROPERTY,
INNOVATION, TRANSFER OF TECHNOLOGY AND
LICENSING IN KENYA AND AFRICA**

My overarching argument is that Kenya needs to integrate intellectual property (IP) protection and promotion, innovation, technology transfer (ToT) and licensing. The integration needs to take a three-pronged methodology and approach. First, integration is required on a doctrinal level and IP policy reforms are necessary on a sector-specific as well as institutional level. Second, integration is necessary through legislative and regulatory reforms. These reforms will help address serious weaknesses or limitations in the legal and regulatory frameworks on and in the interface among IP, innovation and ToT valuation, commercialisation, as well as general corporate and constitutional governance. Third, there is a need for scholarship and practice to integrate business and law in Kenya with licensing, IP, innovation and ToT.

What is IP, innovation and ToT under national, regional and international law? How have international and regional organisations such as the World Trade Organisation (WTO), the World Intellectual Property Organisation (WIPO), the African Regional Intellectual Property Organisation (ARIPO), the African Intellectual Property Organisation (OAPI)¹ and African regional trade agreements, conceptualised and operationalized IP, innovation and ToT? In most cases, the three are not integrated in the relevant laws, in practice and in scholarship.

*Prof Ben Sihanya, JSD (Stanford) is a Scholar, Mentor and Public Interest Advocate on Intellectual Property, Constitutional Democracy and Education Law at the University of Nairobi Law School, Innovative Lawyering and Sihanya Mentoring (IL & SM). He supervises and mentors on PhD, LLM and LLB research and teaches International Intellectual Property, Legal Aspects of International Technology Transfer, and Copyright and Neighbouring Rights Law at LLM level and Intellectual Property Law at LLB level. He is the author of *Intellectual Property and Innovation Law in Kenya and Africa: Transferring Technology for Sustainable Development* and *Intellectual Property and Innovation Law in Kenya and Africa: Cases and Materials* (due 2020). Email: sihanyamentoring@gmail.com; sihanya@innovativelawyering.com; Url: www.innovativelawyering.com

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¹ The *Organisation Africaine de la Propriété Intellectuelle* See Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Transferring Technology for Sustainable Development*, (Sihanya Mentoring and Innovative Lawyering, Nairobi & Siaya, 2016); Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Cases and Materials*, (Sihanya Mentoring and Innovative Lawyering, Nairobi & Siaya, forthcoming 2020).

The instruments under the WTO and WIPO have provided some of the most comprehensive definitions and other provisions on IP. The WTO's 1994 Agreement on Trade Related Aspects of Intellectual Property, (TRIPS Agreement) has a list of seven (7) IP doctrines: copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout designs (topographies) of integrated circuits, protection of undisclosed information, and control of anti-competitive practices in contractual licenses.²

The TRIPS Agreement's definitions are largely similar to those under WIPO. This is partly because the WTO TRIPS Agreement incorporates or legislates, by reference, to some WIPO administered instruments. These include the continuing significance of the WIPO administered Berne Convention for the Protection of Literary and Artistic Works 1886 (1971), the Madrid System 1891 and 1989,³ and the Paris Convention of 1883.⁴

Remarkably, some IP and related regimes crucial to Kenya and Africa are either not prominently captured in the TRIPS Agreement or not reflected at all. These include traditional knowledge (TK) and traditional cultural expressions (TCE),⁵ and utility model (UM) protection.⁶

Relatedly, the transnational IP regime comprehensively integrates ToT. The Draft International Code of Conduct on the Transfer of Technology, 1985 defines transfer of technology (ToT) as 'the systematic transfer of skills for the

manufacture of a product or provision of a service but does not include the sale of a good.'⁷

Technology transfer takes two broad forms. The first is the transfer of skills while the second is the transfer of equipment (or hardware) with appropriate know-how. Another typology relates to contractual, voluntary or consensual technology transfer, compared to compulsory or involuntary technology transfer. The latter may include Government use.⁸

ToT has been a major question even before Kenya's and African independence in the 1950s and 1960s. Numerous transnational and regional instruments have sought to address ToT with varying degrees of success.⁹ These include the various instruments under the treaties administered by WIPO, the TRIPS Agreement, OAPI and ARIPO.¹⁰

Article 7 of the TRIPS Agreement recognizes that the protection and enforcement of IP should contribute to the transfer and dissemination of technology.¹¹ Article 66(2) requires that developed country members under the TRIPS Agreement should provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging ToT to least developed countries (LDCs) in order to enable them to create a sound and viable technology base.¹²

2. TERMINOLOGY RELATED TO INTELLECTUAL PROPERTY IN KENYA AND AFRICA

In Kenya, IP is broadly divided into two categories, namely, copyright and related rights and industrial property rights¹³

² Agreement on Trade Related Aspects of Intellectual Property Rights (1869 UNTS 299; 33 ILM 1197, 1994) [hereinafter TRIPS Agreement].

³ Madrid Agreement on the International Registration of Marks (828 UNTS 391, 1891) and Protocol to the Madrid Agreement 1989.

⁴ Paris Convention for Protection of Industrial Property (21 UST 1583, 828 UNTS 305, 1883).

⁵ Happily, Kenyan and African states are engaged in debates on traditional knowledge and traditional cultural expression at national levels and in the negotiations at WTO, WIPO, UNCTAD, UNESCO, FAO among others.

⁶ Significantly traditional knowledge (TK), traditional cultural expressions (TCE) and genetic resources are actively being debated in the WTO, WIPO, UNESCO, UNCTAD, FAO and WHO as well as under the African IP and trade agreements.

⁷ See Ben Sihanya, *Constructing Copyright and Creativity in Kenya: Cultural Politics and the Political Economy of Transnational Intellectual Property* (Dissertation for the Juridical Science Doctorate (JSD) submitted to Stanford Law School, Stanford, CA, USA, 2003); Ben Sihanya, 'Technology transfer and development in Kenya: issues in regulation and competition law,' (1995) assessed essay submitted

in partial fulfillment of the Master's of Laws Degree, University of Warwick Law School, UK, Dr Andy Clark, Regulation of International Technology Transfer and Intellectual Property on file at Innovative Lawyering and Sihanya Mentoring) Nairobi & Siaya.

⁸ Industrial Property Act 2001 (Kenya) cf. s 80.

⁹ Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Transferring Technology for Sustainable Development*, (Sihanya Mentoring and Innovative Lawyering, Nairobi & Siaya, 2016).

¹⁰ *ibid*.

¹¹ Antony Taubman, Hannu Wager and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (Cambridge University Press, New York, 2012) 24.

¹² *ibid*. Similar ToT debates have taken place in important African and International debates including on environment and development, law of the sea, biodiversity, and climate change.

¹³ Some IP scholars and lawyers claim that PBR or plant variety protection (PVP) is the third distinct doctrine or category of IP and that it is not part of industrial property. They do not account for animal breeder's right (ABR). I treat ABR as significant in Kenya and

Broadly, copyright refers to a set of exclusive rights enjoyed by the author or creator of an original work. These include the right to reproduce (e.g. hand-written, photocopy, print, scan, photograph, snapshot, downloads), distribute or adapt the work. Copyright does not protect ideas, only their expression or fixation. In most jurisdictions, copyright arises upon fixation and does not need to be registered. In Kenya, copyright owners have the exclusive constitutional and statutory right to exercise control over copying and other exploitation of the works for a specific period of time, after which the work is said to enter the public domain.¹⁴

Copyright confers two forms of rights: moral rights¹⁵ and economic rights. Moral rights consist of four categories:¹⁶ the right to be named as author; the right to integrity; the freedom from false attribution; and the right to privacy. Economic rights relate to an author's or entrepreneur's right to secure economic and financial benefits from investing in a work.¹⁷

The second category of IP is industrial property. Industrial property consists of at least ten sets of protected rights¹⁸ Under this, there is patent, which is the certificate granted to an inventor, and the property rights of a patentee. Another protected right is the utility model (UM or petty patent) which is used to protect and promote new and industrially applicable innovations.¹⁹ Some of the utility models (UMs)

granted protection and registered in Kenya include detachable concrete structures, smart GPS alarm, virtual currency or requester device, and virtual currency or mobile device.²⁰

A further right classified under industrial property is trade secret (TS). This is any confidential business information which provides an enterprise a competitive edge. To be protected, it must satisfy three criteria: first, it must be secret in the sense of not being generally known. Second, it must have commercial value because of the confidentiality or secrecy. And third, there must be an obligation to keep the information confidential.²¹ Examples in Kenya include the numerous non-disclosure agreements (NDAs), non-compete agreements, and contracts in restraint of trade in the Kenyan and African sole proprietorship, firms, corporations or organizations dealing with education, training and mentoring; lawyering and litigation; manufacturing; or distribution and delivery of various goods and services.²² An example is the black syrup base of the Coca Cola drink.²³

Moreover, trademark (TM, SM, or ®) as an industrial property is a bundle of intellectual property (IP) rights granted to distinguish the goods and services of one trademark owner, enterprise or undertaking from those of the competitors, while the unfair competition (UC) regime of industrial

Africa and, like PBR, ABR belongs to industrial property rights. In addition, there is need for a clear legal framework on ABR. See Ben Sihanya, *Intellectual Property and Innovation in Kenya and Africa: Transferring Technology for Sustainable Development* (2016).

¹⁴ Moral rights were conferred by s 7(3) of Kenya's Copyright Act 1966 at the end of a section which otherwise dealt more exhaustively with economic rights. s 32 of the Copyright Act 2001 exclusively addresses the 'moral rights of an author.'

¹⁵ Moral rights were conferred by s 7(3) of Kenya's Copyright Act 1966 at the end of a section which otherwise dealt more exhaustively with economic rights. s 32 of the Copyright Act 2001 exclusively addresses the 'moral rights of an author.'

¹⁶ Ben Sihanya, *Intellectual Property and Innovation in Kenya and Africa: Transferring Technology for Sustainable Development* (2016), 193.

¹⁷ *ibid* 194.

¹⁸ Remarkably, the TRIPS Agreement, including Trade in Counterfeit Goods focuses on seven (7) IP doctrines. See TRIPS Agreement, art 1 and ss 1-7 of Part 2. See also Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (Sweet and Maxwell, London, UK, 2003); 'Chapter 3 Categories of Intellectual Property Embraced by TRIPS' in *Resource Book on TRIPS and development* (UNCTAD and ICTSD, Cambridge University Press, London, UK, 2005) 37-60. *ibid*, list and debate this at 39: '1. Literary, artistic and scientific works; 2. Performances of performing artists, phonograms, and broadcasts; 3.

Inventions in all fields of human endeavor; 4. Scientific discoveries; 5. Industrial designs; 6. Trademarks, service marks, and commercial names and designations; 7. Protection against unfair competition and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.'

¹⁹ Industrial Property Act 2001 (Kenya), s 82(2).

²⁰ Kenya Industrial Property, 'Journal of patents, industrial designs, utility models and trademarks' (2016) 19 *Industrial Property Journal*, KIPI, Nairobi, September 2016 <http://www.kipi.go.ke/images/docs/journals/sept_2016.pdf> accessed 18 October 2016. These are included in Annex 1.

²¹ Talhiya Sheikh, 'Trade Secrets and Employee Loyalty' (2015) 7(1) *World Intellectual Property Journal*, Sweet and Maxwell, London.

²² These are included or operate under the Law of Contract Act, Cap 23, and the Contracts in Restraint Of Trade Act, Cap 24. Cf Kenya's Competition Act, 2010; Consumer Protection Act, 2012. Uganda is one of the few African States with a legislative framework on trade secret. See Trade Secrets Act, 2009 (Uganda).

²³ The syrup is not patented but is protected under trade secret law. See Sabra Chartrand, 'Patents; many companies will forgo patents in an effort to safeguard their trade secrets' (*The New York Times*, New York, 5 February 2001) <http://www.nytimes.com/2001/02/05/business/patents-many-companies-will-forgo-patents-effort-safeguard-their-trade-secrets.html?_r=0> accessed 24 October 2016.

property is applied against acts of competition contrary to fair or honest practices in industrial and commercial matters.²⁴

For its part, a geographical indication (GI) is defined under Article 22 of the TRIPS Agreement.²⁵ Clause 2 of the Kenyan Geographical Indication Bill also defines GI stating that:

‘Geographical Indication’ in relation to goods or services, means a description or presentation used to indicate the geographical origin, in the territory of a country, or a region or locality in that territory, where a given quality, reputation or other characteristics of goods or services are exclusively or essentially attributable to geographical environment, including natural factors, human factors or both.²⁶

This relates to situations where indication of the source is a significant factor in terms of quality, sentimental value or association generally.²⁷ For example, Champagne, Chablis and Cognac are French drinks, which derive their names from their geographical origins and relate to certain quality standards.²⁸ Some key examples from Africa include Miombo woodlands of South Africa known for Marula fruits, Penja pepper in Cameroon, Oku honey in Cameroon and Ziamacenta coffee in Guinea. It is notable in this regard that Kenya has a lot of candidate products for GI protection, if only it could enact a law and negotiate these in the international regime. Good examples could include Kisii soapstone (carvings), mnazi (coconut palm, from Coastal Kenya), Kitui or Marigat honey, Kamba carvings, special tea (such as those from Kericho, Nandi and Limuru),²⁹ and coffee (from Mt Kenya region and the Aberdares).³⁰

Another notable industrial property right is mask work or layout design of integrated circuits. This is defined under the Washington Treaty on Intellectual Property in Respect of Integrated Circuits of 1989 as:

The three-dimensional disposition, however expressed, of the elements, at least one of which is an active element, and of some or all of the interconnections of an integrated circuit, or such a three-dimensional disposition prepared for an integrated circuit intended for manufacture.³¹

A generally accepted definition of plant breeder’s rights (PBR) or Plant Variety Protection (PVP) recognises rights granted to the breeder of a new variety of plant that give the breeder exclusive control over the propagating material. Thus, PBR is exclusive rights over the commercial production and marketing of the reproductive or vegetative propagating material of the protected variety.³² In Kenya, PBR and PVP are defined under the Seeds and Plant Varieties Act 2012 at section 2 as ‘rights granted under section 17.’ For protection to be accorded, the seed or plant must be distinct, uniform and stable (DUS). In Kenya, PBR protection has been extended to products, owned by the Kenya Seed Company,³³ Pioneer Hybrid, Monsanto Kenya, and Simlaw seeds.³⁴

The other recognised industrial property is industrial design (ID). This is protected on the basis of the originality of a combination of lines or colours giving rise to the appearance

²⁴ See Kenyan Trade Marks Act, s 5; Competition Act 2010 (Kenya) s 10.

²⁵ TRIPS Agreement, art 22.

²⁶ Kenyan Geographical Indication Bill, Clause 2.

²⁷ Justin Hughes, ‘Champagne, Feta, and Bourbon: The spirited debate about geographical indications’ (2006) 58 *Hastings Law Journal*, at 299.

²⁸ Ben Sihanya, ‘Traditional Knowledge and Traditional Cultural Expressions in Kenya’ (2016) Volume 12, 2016 No. 2 *LSK Journal* (1-38).

²⁹ ‘Farmers must be winners in the tea trade debate’ (*Business Daily*, Nairobi, 4 August 2016) <<http://www.businessdailyafrica.com/Opinion-and-Analysis/Farmers-must-be-winners-in-the-tea-trade-debate/539548-2819848-akgppn/index.html>> accessed 24 October 2016.

³⁰ ‘Brands that could earn farmers more’ (*Daily Nation*, Nairobi, 14 December 2008) <<http://www.nation.co.ke/business/news/-/1006/502166/-/view/printVersion/-/u5br9mz/-/index.html>>

<<http://www.nation.co.ke/business/news/-/1006/502166/-/view/printVersion/-/u5br9mz/-/index.html>> accessed 24 December 2016.

³¹ TRIPS Agreement, art 6 adopts and applies the Washington Treaty on Intellectual Property in Respect of Integrated Circuits, 1989.

³² Significantly, hardly any important IP scholar or lawyer discusses animal breeder’s rights (ABR). They do not account animal breeder’s right. I treat ABR as significant in Kenya and Africa and like plant breeder’s rights (PBRs) belong to industrial property rights.

³³ Some of their products include duma, popo and mbuni for maize seeds; serena and seredo for sorghum seeds; as well as heroe and chozi for wheat seeds.

³⁴ See Kenya Plant Health Inspectorate Service (KEPHIS) website <<https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&cad=rja&uact=8&ved=0ahUKEwiltv60mObPAhXLXRoKHodCBoQFggqMAI&url=http%3A%2F%2Fwww.kephis.org%2F&usg=AFQjCNG3lesECc3H3Yg-mf1YdrIwluiGVA&sig2=my2KWE05Vxx2GysRcCg05w&bvm=bv.135974163,d.d2s>> accessed 19 October 2016.

or look and feel of a product.³⁵ ID includes graphic designs, fashion designs, and textile designs.³⁶ Industrial design can be used to protect shapes, configurations, patterns or ornaments. Other items which may be the subject matter of industrial design include toys, games, and electrical equipment.

3. NOMENCLATURE ON INNOVATION IN KENYA AND AFRICA

What is innovation and how has it been conceptualised, problematised, and contextualised in Kenya and Africa? Innovation has not been significantly conceptualised and integrated into the policies and laws dealing with IP and ToT. For instance, innovation is rarely defined and different terms or concepts are used in similar or relevant contexts. Some of the concepts include creativity, invention, enterprise and entrepreneurship.

A. Linking IP to innovation, industrialization and sustainable development

Historically, social, cultural, economic and political development (especially wealth creation and distribution) were largely associated with the four factors of production known to traditional economics, that is, land, labour, capital, and entrepreneurship.³⁷

Since the early 20th century, the link among IP, innovation and technology in development has become well established, at least in western literature. Developed countries like USA, Japan, and in the European Union (EU) attribute most of their wealth and socio-economic development to the optimal

protection and promotion of IP and innovation. Remarkably, intellectual property and innovation are crucial in health, agriculture or food security, water and sanitation, energy, transport, information, communication, education and entertainment.³⁸

However, in Kenya and most of Africa, emphasis has been on real property and other traditional or tangible assets as the source of wealth. Significantly, a paradigm shift is emerging. Faster industrialization and socio-economic development will be achieved and sustained through a concerted integration of other means of wealth creation like IP and innovation.

In this essay I address the ways the Kenyan and African Governments, companies, civil society organisations (CSOs), other institutions and individuals can integrate IP, innovation and ToT to achieve wealth creation, industrialization and sustainable development.³⁹

B. Nomenclature and conceptualising innovation in Kenya and Africa: what is it?

Many people assume an innovation must be based on a new service or technology. However, innovation does not have to be technical. Technological innovations are important, but so are social and cultural innovations like newspapers, insurance, organizations (like universities), hire purchase or cultural innovations.⁴⁰ In fact, performance contracting increasingly recognises innovation in service delivery.⁴¹

Innovation means developing a new idea and putting it into practice. It is the process of developing a valuable new

³⁵ Industrial Property Act 2001 (Kenya), s 84.

³⁶ Industrial Property Act 2001 (Kenya), s 84.

³⁷ Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Transferring Technology for Sustainable Development*, (Sihanya Mentoring and Innovative Lawyering, Nairobi & Siaya, 2016). Cf. Ben Sihanya, 'Intellectual property and innovation in Kenya: legal and regulatory issues in business incubation,' in Prof Bernard Aduda (Ed) *Science and Technology Park Development for Sustainable Industrial Growth: Proceedings of the National Workshop in Commemoration of the Scientific Revival Day of Africa* (Kenya National Academy of Sciences (KNAS), Nairobi, 2006) 41-58.

³⁸ Ben Sihanya, *How can we Constitutionalize Innovation, Technology and Intellectual Property in Kenya?* (African Technology Policy Studies Network, Nairobi, 2002).

³⁹ Sustainable development here is understood in terms of the sustainable development goals (SDGs), including the preceding millennium development goals (MDGs). That includes social, economic and ecological sustainability: resource production, distribution and use that recognizes intra-generational and inter-

generational equity. See *Our Common Future* (World Commission on Environment Development, Oxford University Press, 1987).

⁴⁰ Peter Drucker, *Innovation and Entrepreneurship: Practice and Principles* (Elsevier Butterworth-Heinemann, 1985); Joseph Schumpeter, *History of Economic Analysis* (Oxford University Press, New York, 1954, 1994) (with a new Introduction by Mark Perlman) (advancing what has been referred to as 'Schumpeterian innovation'); Joseph A. Schumpeter, *Capitalism, Socialism and Democracy* (Routledge, London and New York, 1943, 1994).

⁴¹ Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Cases and Materials* (Sihanya Mentoring and Innovative Lawyering, Nairobi & Siaya, forthcoming 2020). Cf. Phillip Wambua, Gorretti Ofaa & Samuel Otor (eds), 'Performance Contracting and Academic Staffs Administrative Work Systems' for Service Delivery in Selected Kenyan Universities' (2014) *International Journal of Innovative Research & Development* <<http://business.ku.ac.ke/images/stories/docs/Administrative%20Work%20systems%20NOV14019.pdf>> accessed 27 June 2018.

process or product (a good, service or institution) and introducing it into the market or society. This includes the idea or concept formulation stage and the successful launch of the new or improved process or product in the market.⁴²

While innovation in a narrow sense could be defined to mean inventions, innovation in a broader sense includes inventions as well as cultural, institutional and commercial creativity.

4. TYPOLOGY OF INNOVATION IN KENYA AND AFRICA

Innovation may be regarded as falling under a four-pronged typology: technological, cultural, institutional and commercial.⁴³

- (a) Technological innovation. This includes product and process innovation, resulting from scientific or technological R&D. These are usually protected by industrial property doctrines like patent, utility model, industrial design, plant breeder's right, trade secret or unfair competition.
- (b) Cultural innovation. Kenya's and Africa's copyright, creative and cultural industries include book publishing, music, theatre, and film or cinema (or audio-visual works).⁴⁴
- (c) Institutional innovation. In the 1980s and 1990s, the Government of Kenya recognised institutional innovation and established research and development (R&D) institutions, Kenya Industrial Property Institute (KIPI), and the following universities: Moi, Egerton, and Jomo Kenyatta University (College) of Agriculture and Technology (JKU(C)AT), as specialized colleges or universities to emphasize scientific and technological innovation, especially in agriculture and ICT. Some of these, along with the Kenya Institute of Public Policy Research (KIPPRA) focused on the arts, humanities and social sciences as well. However, most of these do not have the desired impact.
- (d) Commercial or business innovation. Successful innovation involves 'going to market.' Trademark, industrial design and

geographical indication play an important role in the marketing process. The strategic use of a combination of IP rights can significantly contribute to higher profits, and related returns on investment.

An invention is the generation of new knowledge aimed at solving a specific technical problem. This relates to both products and processes, characteristically protected by patent law, as covered by section 21 of Kenya's Industrial Property Act, 2001.

Innovation and invention are crucial parameters for Kenya's industrialization, as well as human and socio-economic development. While Kenya and Africa may not effectively compete with countries party to the Organisation for Economic Co-operation and Development (OECD) such as the US, UK, Germany, and Japan on technological innovation, Kenya and Africa have many cultural innovations that can be exploited to benefit the people.

Purposeful and systematic innovation requires an analysis of existing opportunities, such as new knowledge or demographics (changes in population size, age structure, composition, employment, educational status, and income).⁴⁵ Kenyan innovators need to go out and look for innovative opportunities; ask and listen, to determine how the innovation can be utilized to meet an existing opportunity or need.⁴⁶

5. TECHNOLOGY TRANSFER AND THE WTO'S TRIPS AGREEMENT: KENYAN AND AFRICAN PERSPECTIVES

Some of the three contexts in which technology transfer takes place include: first, technology transfer in the context of agriculture and food security (hence the dynamics between biodiversity and biotechnology) in Africa; second, technology transfer in the context of health, especially the pandemics like HIV/AIDS in Kenya and Africa; and third, technology transfer

⁴² Christopher Kalanje, 'The Role of Intellectual Property in Innovation and New Product Development' *op. cit.*; Drucker, *Innovation and Entrepreneurship: Practice and Principles*, *op. cit.*

⁴³ Ben Sihanya, 'Intellectual Property and Mentoring for Innovation and Industrialization in Kenya' (2009) Vol. 5, 2009 No. 1, *Law Society of Kenya Journal* 29-57; Ben Sihanya 'Intellectual Property for Innovation and Industrialisation in Kenya' (October 2008) Vol. 4. No.

2, *Convergence, Journal of the International Bar Association*, London 185-213.

⁴⁴ The three Cs are not coterminous.

⁴⁵ Peter Drucker, *Innovation and Entrepreneurship: Practice and Principles* (Elsevier Butterworth-Heinemann, 1985).

⁴⁶ *ibid.*

in the context of security, defence or military in Kenya and Africa.

ToT has not been dealt with sufficiently under the WTO's TRIPS Agreement, 1994. There are arguments that Article 66(2)⁴⁷ and other provisions of the TRIPS Agreement took a market-based approach to IP, innovation and ToT. Thus, TRIPS has a very limited mandate on a concessionary or preferential approach or the regulation of ToT.⁴⁸ The alternative approach which seeks to promote concessionary terms in technology transfer was a major feature in the following discussions: the quest for a new investment economic order (NIEO) through the Center on Economic Rights and Duties of States;⁴⁹ the United Nations Convention on Law of the Sea (UNCLOS); the Convention on Biological Diversity (CBD); and the United Nations Framework on Climate Change (UNFCCC).

The provisions on ToT in TRIPS have been criticised on two main grounds. First, they seem to regard technology transfer as the transfer of skills and technical know-how primarily to facilitate the implementation and enforcement of TRIPS. Second, TRIPS deals with technology transfer mainly from developed economies to the least developed countries, yet developing countries such as Kenya and other African countries also need technology transfer. And third, there are also challenges in determining exactly what technology is transferred.⁵⁰

The TRIPS Agreement has made fundamental positive changes in the conceptualisation and operationalisation of IP

as Paul Goldstein and others have pointed out above and elsewhere. However, as seen in our discussions, it also poses a number of difficulties for Kenya and other African states regarding the role of IP in innovation, ToT and sustainable development.

First, TRIPS largely embodies Western standards in IP. For instance, provisions on patent, copyright, trademark, and geographical indication (GI) are largely Western. TRIPS generally seems to ignore IP systems which are important to Kenya and other developing countries such as folklore, traditional knowledge (TK), and utility model. These are not dealt with seriously, if at all, in TRIPS, yet they are important in African countries.⁵¹

Second, TRIPS is essentially a patchwork of many IP related agreements especially the Paris Convention, the Berne Convention, and the Washington Agreement on Integrated Circuits of 1989. Many have argued that this is a cut-and-paste or cut-edit job. This approach is sometimes referred to as 'legislation by metaphor' or by reference and maybe an untidy way of promulgating law.⁵² Some argue TRIPS is incoherent because of this.⁵³ But Prof Daniel Gervais and Hannu Wager, among others, have argued that other agreements can be regarded as building blocks.⁵⁴ And it is true that the travaux préparatoires or negotiating history and precedents regarding those Agreements have been useful in interpreting the TRIPS Agreement.⁵⁵

Third, there is a need for comprehensive public participation conducted within various regions and IP regimes. This will

⁴⁷ TRIPS Agreement, art 66 (2). 'Where the acquisition of an intellectual property right is subject to the right being granted or registered, Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the *granting* or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.'

⁴⁸ Carlos Correa, 'Can the TRIPS Agreement foster technology transfer for developing countries?' in Keith Maskus and Jerome Reichman (eds) *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime*, (Cambridge University Press, New York, 2005); Carlos Correa, 'Reviewing the TRIPS Agreement: Fostering the Transfer of Technology to Developing Countries' <<http://www.twinside.org.sg/title/foster.htm>> accessed 4 August 2017.

⁴⁹ *Compendium of International Arrangements on Transfer of Technology: Selected Instruments* (UNCTAD/ITE/IPC/Misc.5, UNCTAD, 2001).

⁵⁰ See Chapters 22, 23, 24, 25, 26 & 27 of Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Transferring Technology for Sustainable Development* (Sihanya Mentoring and Innovative Lawyering, Nairobi & Siaya, 2016).

⁵¹ On utility model see Chapter 6 of Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Transferring Technology for Sustainable Development* (Sihanya Mentoring and Innovative Lawyering, Nairobi & Siaya, 2016).

⁵² See Ouma M, & Sihanya B, 'Chapter 4 – Kenya' in Armstrong, de Beer, Kawooya, Schonwetter (eds.), *Access to Knowledge in Africa* (2010).

⁵³ Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Transferring Technology for Sustainable Development*, (Sihanya Mentoring and Innovative Lawyering, Nairobi & Siaya, 2016).

⁵⁴ *ibid.*

⁵⁵ See Gervais, *The TRIPS Agreement, Drafting History and Analysis, op. cit.* Hannu Wager, the Secretary to the TRIPS Council expressed similar views in answer to the present author's comment on the 'patchwork' at the WIPO/WTO colloquium for IP teachers in 2005. He

help develop laws that best govern the specific areas of interest to relevant member states. There have been strong arguments that TRIPS was conceived and promulgated without sufficient involvement and participation by African countries. Some have argued that most of the provisions or clauses of TRIPS were enacted at the behest of many Western transnational corporations (TNCs) and interest groups. The conspiracy theory about the promulgation of WTO is usually supported, for example, by the following clauses which were influenced by the named parties:

- (a) the patent clauses largely by Western pharmaceutical transnational corporations (TNCs);
- (b) copyright clauses especially by Hollywood (entertainment industry) and Silicon Valley (software industries including Microsoft in particular); and
- (c) geographical indication (by the French and like-minded states).

Fourth, it has also been argued that Africa and other developing countries had very limited knowledge, skill, or aptitude, as well as human resources and financial capacity to effectively participate in negotiating TRIPS.⁵⁶ For instance, some countries had only about one to four representatives in Geneva. Some representatives participated in negotiations and attended most of the meetings to address the various issues. Agreements under discussions included TRIPS, General Agreement on Trade and Services (GATS), GATT, Sanitary and Phytosanitary Standards (SPS) and Technical Barriers to Trade (TBT). This is partly the reason why there were problems in Seattle, Cancun, Doha and Geneva trade negotiations. The representatives from the developing countries had not sufficiently participated in the previous negotiations, since at times numerous negotiations would be

going on at the same time.⁵⁷ Kenya and other African countries should ensure that they send well trained, informed and educated representatives to represent them in such negotiations. These representatives will be able to understand and negotiate from a well-informed position on the needs of their countries and also settle for the best agreements favouring their countries.

The Doha Round of negotiations recognised the difficulty the developing countries face in meeting these standards. As a result, the Doha Declaration on the TRIPS Agreement and Public Health allowed LDCs up to 2016 to meet patent related standards in pharmaceuticals. Remarkably, some countries argued in the context of the Seattle, Doha and Cancun rounds of the WTO that instead of focusing on reviewing the implementation of TRIPS, the WTO ought to focus on reviewing the terms and clauses of TRIPS itself. This is partly because TRIPS contains contested standards. And Article 27(3) on patentability of life forms was cognizant of this fact and provided that the 'provisions of this sub-paragraph shall be reviewed four years after the date of entry into force of the WTO Agreement.'⁵⁸

It is thus important that the clauses themselves be reviewed. Patentability of life forms under Article 27(3), parallel importation under Article 6 and compulsory licensing under Article 31 have been particularly controversial. Article 31 was reviewed and amended at the Hong Kong Ministerial conference (2005).⁵⁹ Reviewing the terms of TRIPS means that the relevant clause or provision is reviewed to be retained or changed on its own merits or individual terms. The US generally opposes review of clauses; it prefers to focus on how countries have implemented TRIPS rather than its terms. This has been a problem, especially since the 1999 Ministerial conference in Seattle (and even before).

was a speaker. See also UNCTAD/ICTSD, *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement*, (2004) *op. cit.*, at 388ff.

⁵⁶ Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Transferring Technology for Sustainable Development*, (Sihanya Mentoring and Innovative Lawyering, Nairobi & Siaya, 2016).

⁵⁷ *ibid.*

⁵⁸ Vanessa B. Kerry & Kelley Lee, 'TRIPS, the Doha Declaration and Paragraph 6 Decision: What are the remaining steps for protecting access to medicines?' (2007)

<<http://www.globalizationandhealth.com/content/3/1/3>> accessed 7 December 2011; Cf. The WTO Hong Kong Conference in Perspective <<http://www.sudanvisiondaily.com/modules.php?name=News&file=print&sid=20513>> accessed 7 December 2011.

⁵⁹ Vanessa B. Kerry & Kelley Lee, 'TRIPS, the Doha declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?' (2007) <<http://www.globalizationandhealth.com/content/3/1/3>> accessed 7 December 2011; Cf. The WTO Hong Kong Conference in Perspective <<http://www.sudanvisiondaily.com/modules.php?name=News&file=print&sid=20513>> accessed 7 December 2011.

Clearly, there is a need to integrate the discourse, scholarship, business, practice, and activism regarding IP, innovation, technology transfer and licensing.

6. CONCEPTUALISING AND CONTEXTUALISING TECHNOLOGY TRANSFER IN KENYA AND AFRICA

ToT provides a practical and dynamic context for the exploitation of IP. Yet some of the technology may also not be protected by IP, or may be in the public domain.⁶⁰ There are deep debates revolving around North-South,⁶¹ intra-South, and even South-North technology transfer.⁶² This discourse has been concerned with regulating technology transfer transactions and has even sought to deal with regulating the conduct of transnational corporations (TNCs).

Technology transfer brings to the forefront a question on trade, business, commerce and their efficient and equitable regulation. It links IP protection, promotion and commercialisation and is thus a major point of convergence among the following organisations: WTO, WIPO, ARIPO, East African Community (EAC), Common Market for Eastern and Southern Africa (COMESA), Southern African Development Community (SADC), and Economic Community for West African States (ECOWAS)⁶³ and Africa Continental Free Trade Area (AfCTA), among others. Equally important are the African national IP, innovation and trade systems or regimes.⁶⁴

The nature of the technology and the relevant IP often influence the form of technology transfer adopted by the parties. Some of the most commonly used forms of technology transfer include contractual licensing, franchising,

joint venture, and foreign direct investment. But these are general typologies, which in turn, consist of numerous forms of technology transfer. In contractual licensing, a premium is placed on the consent of the parties and on market operations, while compulsory licensing is largely involuntary and state controlled. Types of technology transfer are discussed below.

A. Nomenclature on technology transfer in Kenya and Africa

Africa's share in international trade is limited to about 2%,⁶⁵ and it is even much less in IP embodied goods, services and works.⁶⁶

There are various types of technology transfer. These include licencing, assignment, securitisation, venture capital, joint venture (JV), strategic alliance (SA), special purpose vehicle (SPV), business incubation, franchising, and commercialisation by business corporations, universities and research and development (R&D) institutions. Remarkably, the military-industry complex is not common in Kenya and Africa. The various types are discussed below.

(i) Licensing

A license is permission to do something that would otherwise be unlawful.⁶⁷ It takes two broad forms which are voluntary (contractual or consensual licensing) and involuntary or compulsory licensing. In contractual licensing, the licensor and licensee agree to the terms of the license,⁶⁸ while compulsory licensing or government use occurs when a Government agency such as Kenya's Industrial Property Tribunal (IPT) authorizes a third party to exploit the license.⁶⁹

⁶⁰ Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Transferring Technology for Sustainable Development*, op. cit.

⁶¹ Most of the debates on ToT assume that the northern corporations and states are the suppliers of technology while southern states, corporations and other organisations and people are generally the acquirers.

⁶² Most of the North-South technology transfer relate to TK, TCE, GI, and even brain drain where nurses, doctors, and other skilled workers migrate to the North. This is under-researched.

⁶³ Economic Community for West African States.

⁶⁴ These regional economic regimes are increasing the need to integrate IP, innovation, technology transfer and anti-counterfeiting. They have registered mixed results.

⁶⁵ Evita Schmieg, 'Africa's Position in Global Trade, Free Trade Agreements, WTO and Regional Integration' (2017) <https://www.swp-berlin.org/fileadmin/contents/products/projekt_papiere/Africas_Position_in_Global_Trade.pdf> accessed 6 April 2018.

⁶⁶ Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Cases and Materials* (Sihanya Mentoring and Innovative Lawyering, Nairobi & Siaya, forthcoming 2020).

⁶⁷ This definition is mainly associated with general English usage and real property or land and related transactions. See Paul Goldstein, *International Copyright: Principles, Laws and Practice*, (OUP, New York, 2001): 'License' has a different or more advanced meaning in IP, especially copyright. See Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Transferring Technology for Sustainable Development* (Innovative Lawyering and Sihanya Mentoring, 2016), Chapters 8 and 9; Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Cases and Materials* (Sihanya Mentoring and Innovative Lawyering, Nairobi & Siaya, forthcoming 2020).

⁶⁸ See Kenyan Copyright Act, 2001 (as amended), s 33.

⁶⁹ Copyright and patent maybe subject to compulsory license. A patent may be the subject of Government use under Industrial

Licensing can also be conceptualized or defined in terms of whether the licensee is sole, exclusive or non-exclusive. Sole licensing arises when there is only one licensee. The sole licence may be oral or evidenced in writing,⁷⁰ and the licensor may even compete with the licensee.⁷¹ Exclusive licensing occurs when no one may compete with the licensee; not even the licensor. Part I of the Nigerian Copyright Act deals extensively with licences and assignments. It provides for a guideline on the requirements and the procedure of exclusive copyright licenses.⁷²

An exclusive license must be in writing as was held in the Nigerian case *Adenuga v. Ilesanmi*.⁷³ In this case, the appellants submitted a book manuscript to the respondents, which the respondents published. The appellants, on realising the book had been published, went to court seeking damages. In court, the respondents claimed they had an exclusive license to publish the book. The court held an exclusive license must be in writing and signed by the owner or author of copyright.⁷⁴

An assignment is often similar to an exclusive license. Section 33(3) of the Kenyan Copyright Act states:

No assignment of copyright and no exclusive licence to do an act the doing of which is controlled by copyright shall have effect unless it is in writing signed by or on behalf of the assignor, or by or on behalf of the licensor, as the case may be and the written assignment of copyright shall be accompanied by a letter of verification from the Board⁷⁵ in the event of an assignment of copyright works from outside Kenya.

Section 22 of the South African Copyright Act 1978 makes provisions for the exclusive licensing of copyright. It provides for the conditions to be fulfilled and the requirements for the licensing of copyright.⁷⁶ Non-exclusive licensing involves more than one licensee. Licensees may compete with each other and the licensor. This kind of licensing mostly arises from voluntary licensing where parties agree to accommodate competition amongst themselves.

There are also sub-licensees and bare licensees in IP and innovation.⁷⁷ A sub-license may arise in any of the foregoing scenarios provided the license agreement permitted a sub-license expressly or by conduct. A licensee in this regard cannot sue in his or her own name. The power to sue remains with the licensor.

A bare license is a situation where the interest is limited to a non-proprietary interest. A ticket to watch a movie is limited to watching; not recording. Access to a lecturer's teaching notes and materials limits the student to reading and citing them appropriately. It does not include the student reproducing or adapting the materials for publication, distribution or communication to third parties. A bare license embodies the fewest bundle of rights or privileges very far from IP ownership, an exclusive license or an assignment, which embody the highest bundle of rights.

(ii) Assignment of IP Rights, Innovation and Technology Transfer in Kenya and Africa

An assignment is an agreement whereby the assignee replaces the assignor for the relevant intents and purposes with respect to all or certain rights. The assignment should

Property Act 2001 (Kenya), s 80. Trade Mark should not be compulsorily licensed under TRIPS Agreement, art 37(2).

⁷⁰ Cf Hodgin's analysis of the implications of oral contracts and the argument for written contracts in East Africa. R. W. Hodgin, *Law of Contract in East Africa* (East African Literature Bureau, Nairobi, 1975).

⁷¹ Kenyan Copyright Act, s 33 & Industrial Property Act 2001 (Kenya), s 5.

⁷² Nigeria Copyright Act, Part I Chapter C28 2004.

⁷³ *Adenuga v. Ilesanmi* [1991] 5 N.W.L.R 82.

⁷⁴ Charles Chudi, *Intellectual Property and Law in Nigeria*, (Malthouse Press Limited, Lagos, 2016).

⁷⁵ The Kenyan Copyright Board (KECOBO) is established by s 3 of the Kenyan Copyright Act, 2012. Its mandate includes to direct, coordinate and oversee the implementation of laws and international treaties and conventions to which Kenya is a party and which relate to copyright and other rights recognised by the Act and ensure the

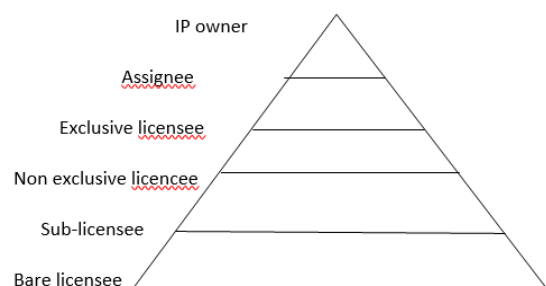
observance thereof; (b) license and supervise the activities of collective management societies as provided for under this Act; (c) devise promotion, introduction and training programs on copyright and related rights, to which end it may co-ordinate its work with national or international organisations concerned with the same subject matter; (d) organise the legislation on copyright and related rights and propose other arrangements that will ensure its constant improvement and continuing effectiveness; (e) enlighten and inform the public on matters relating to copyright and related rights; (f) maintain an effective data bank on authors and their works; and (g) administer all matters of copyright and related rights in Kenya as provided for under this Act and to deal with ancillary matters connected with its functions under this Act.

⁷⁶ South African Copyright Act 1978, s 22.

⁷⁷ Desforges Charles, *The Commercial Exploitation of Intellectual Property Rights by Licensing*, (Kaplan Hawksmere Publishers, London, 2001).

specify at least three matters: the scope of the rights assigned (the conceptual market); the specific geographical market; and the specific duration.

Figure 1: Intellectual Property Pyramid



Source: Developed from Sihanya *IP and Innovation Law in Kenya and Africa* Vol. 1 & 2 (2016 and forthcoming 2020).⁷⁸

(iii) Other Forms of Commercialisation of IP, Innovation and Technology Transfer in Kenya and Africa

While assignments and licences are the main and most common ways of commercialising IP, there are other various forms of commercialisation. These forms include securitisation, venture capital, joint ventures (JV), strategic alliances (SA), special purpose vehicles (SPV), business incubation, franchising, and commercialisation by universities and research institutions, which are discussed below.

(a) Securitisation of IP, Innovation and Technology Transfer

Securitisation has been regarded as a specific aspect of commercializing IP or innovation. It is the process of consolidating expected future payments, such as royalties, and selling them in the form of securities or collateral including shares, stocks or bonds.⁷⁹ The securities issued can

be debt instruments, equity instruments, or a combination of both.⁸⁰

Securitisation of IP is therefore the conversion of an IP asset into a marketable security or collateral. Securitisation is possible for future royalty payments, for example, from licensing a patent, trademark or trade secret, or from copyrightable materials such as books and other literary and artistic works, musical compositions or recording rights of a musician.⁸¹

An example of securitisation was the matter involving the royalty payments of rock musician David Bowie in the USA.⁸² In 1997 the singer introduced an innovative form of financing when he converted his future royalties from his record sales into securities in a private bond for \$55 million.

In Kenya, the fight for the copyright and related royalties of the legendary band Les Wanyika was taken to court in *Sijali Salum Zuwa & 4 Others v. Pamela Akinyi Atieno*.⁸³ Upon the death of Omar Shaban Salim, co-founder of the band, his widow, Ms. Pamela Akinyi, received letters of administration over the estate of Omar Shaban Salim on the basis of which she claimed all the rights under copyright relating to the forty eight (48) musical works of Les Wanyika.⁸⁴ The court had to determine whether the deceased was the exclusive composer and owner of the musical works, or whether the works were the 'joint effort'⁸⁵ of the Les Wanyika band, whose members included the applicants.⁸⁶ The matter is still in court awaiting a ruling.

Similarly, the royalties of the founder of the Maroon Commandos Mr Habel Kifoto have also left the family in a tussle over the control of his music royalties.⁸⁷ A similar battle

⁷⁸ Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Transferring technology for Sustainable Development*, 225. See also Ben Sihanya, *Intellectual Property Innovation and Technology Transfer Law in Kenya and Africa: Cases and Materials*, (Sihanya Mentoring and Innovative Lawyering, Nairobi & Siaya, forthcoming 2020).

⁷⁹ John M. Gabala Jr., 'Intellectual Alchemy: Securitization of Intellectual Property as an Innovative Form of Alternative Financing' (2004) The John Marshall Law School, <<http://repository.jmls.edu/cgi/viewcontent.cgi?article=1054&context=ripl>> accessed on 22 April 2015.

⁸⁰ The Kenyan Capital Markets Act, Cap 485A.

⁸¹ Ben Sihanya, *Constructing Copyright and Creativity in Kenya: Cultural Politics and the Political Economy of Transnational Intellectual Property* (Dissertation for the Juridical Science Doctorate (JSD) submitted to Stanford Law School, Stanford, CA, USA, 2003).

⁸² WIPO, 'The securitization of Intellectual Property Assets - A new trend' <http://www.wipo.int/sme/en/ip_business/finance/securitization.htm> accessed on 22 April 15.

⁸³ *Sijali Salum Zuwa & 4 Others v. Pamela Akinyi Atieno* [2016] eKLR.

⁸⁴ Les Wanyika was a band consisting of Kenyan and Tanzanian artists formed in 1978. See <<http://www.allmusic.com/artist/les-wanyika-mn0000250282>> accessed 20 January 2017.

⁸⁵ Copyright Act 2001, s 23 places some premium on labour and effort. The entry point and greater emphasis in copyright should be 'skill and judgment,' See Ben Sihanya, *IP and Innovation Law in Kenya and Africa*, (2016) *op. cit.*, 185-225.

⁸⁶ *Sijali Salum Zuwa & 4 Others v. Pamela Akinyi Atieno* [2016] eKLR, *ibid* at para 4.

⁸⁷ Abiud Ochieng, 'Musicians' Children Fight for Royalties' (*Daily Nation*, Nairobi, 29 January 2016)

was the cause of the breakup of the Franco led TPOK Jazz after his death in the early 1990s.⁸⁸ Luambo Luanzo Makiadi (Franco) was a legendary lingala (or rhumba) musician from the Democratic Republic of Congo (DRC). He left a huge copyright estate.⁸⁹

Remarkably, John M. Gabala, in 'Intellectual Alchemy,' suggests that holders of copyright can also benefit from IP securitization. He notes that in securitisation the artist does not sell their property rights.⁹⁰ Securitisation of IP in this way allows the royalty recipient to retain control over the assets (as collateral), since after the bonds mature the rights go back to the artist who is free to use them as he wishes.

The tussle between the Music Copyright Society of Kenya (MCSK),⁹¹ Safaricom Limited⁹² and majority of the Kenyan artist is an illustration of the importance of securitization of IP. The MCSK has defaulted in making payments to the artists hence the 2016 stalemate.⁹³ A section of Kenyan musicians have filed a lawsuit and also made demands to KECOBO accusing MCSK of performing its functions in a manner contrary to the law. One of their grievances was the failure by MCSK to implement a joint licensing, collection and distribution of royalties as required by the law.

Securitisation of an IP right, and especially securitisation of copyright, is complex because of valuation challenges regarding the intangible properties of the asset. Another problem is the issue of Internet and online or mobile music

piracy in this digital era that dilutes the 'royalties' of satisfactory candidates for suitable financing.⁹⁴

Copyright royalty or related assets may be used as a form of alternative financing or collateral where there is an integrated, equitable, and effective institutional and legislative framework. In May 2018, the family division of the Kenyan High Court asked the Legislature to create laws to guide the inheritance of an individual's online assets upon their death. This law, if enacted, will help bridge the gap that exists regarding definition of an individual's assets and their scope. It will also provide for their management, assessment, privacy, transfer, disposal, and use, including as security for loans to enhance incubation.⁹⁵

(b) Venture Capital, Joint Venture, Strategic Alliance and Special Purpose Vehicle in Intellectual Property and Transfer of Technology

These are agreements between or among innovators and entrepreneurs. They complement each other in terms of money, technology or know-how, human resources, or distribution network. This may be done by way of a merger or through a strategic allegiance (SA) or a special purpose vehicle (SPV) between standalone enterprises.

An illustration is the joint venture between Kenya Airways, Royal Dutch Airlines and Martin Air, which established Ken-Cargo.⁹⁶ Other examples include the 4G network venture between the Government of Kenya and mobile network operators;⁹⁷ and Mpesa (a mobile money transfer platform),

<<http://www.nation.co.ke/news/Musician-children-fight-for-royalties/1056-3053358-tyve07z/index.html>> accessed 10 January 2018.

⁸⁸ Amos Ngaira, 'The Rise and Fall of TP OK Jazz' (*Daily Nation*, (Nairobi, 2012) <<http://www.nation.co.ke/lifestyle/DN2/957860-1416052-jj1i6wz/index.html>> accessed 26 September 2017.

⁸⁹ *ibid.*

⁹⁰ John M. and Gabala Jr., 'Intellectual Alchemy: Securitization of intellectual property as an innovative form of alternative financing' (2003) 3 *J. Marshall Rev. Intell. Prop. L.* 3.

⁹¹ The Music Copyright Society of Kenya is a copyright collection society in Kenya tasked with the responsibility of collecting royalties on behalf of authors, composers, arrangers and publishers of music. It gets its mandate from Kenyan Copyright Act 2001, s 48(4).

⁹² Safaricom limited is a mobile network operator in Kenya registered under section 53 of the Kenyan Companies Act 2015.

⁹³ Abiud Ochieng 'Kenyan musicians sue copyright bodies over royalties' (*Daily Nation*, Nairobi, 31 July 2015) <<http://www.nation.co.ke/news/Kenyan-musicians-sue-copyright-royalties/1056-2815114-20aih6z/index.html>> accessed 10 January

2017. See also *Irene Mutisya & Anor v. Music Copyright Society of Kenya & Anor* Civil Case No. 262 of 2015; *Xpedia & 4 Others v. Attorney-General & 4 Others* Petition No. 317 of 2015; and *John Boniface Maina v. Safaricom Ltd & 4 Others*, High Court at Nairobi, Civil Suit 808 of 2010.

⁹⁴ 'Intellectual Property on the Internet: A Survey of Issues' (World Intellectual Property Organisation, 2002).

⁹⁵ See Elvis Ondieki, 'Family Court wants MPs to Create Online Property Inheritance Laws' (*Sunday Nation*, Nairobi, 17 June 2018).

⁹⁶ KenCargo International Limited was until 2004 based in Kenya. KQ held 60 per cent, Martinair Holland held 20 per cent, while KLM held 20 per cent. See Daniel Wesangula, 'Company affiliated to Raila Odinga named in questionable winding up of KQ's profitable arm' (*Standard Digital*, Nairobi, 2016) <<http://www.standardmedia.co.ke/article/2000218116/company-affiliated-to-raila-odinga-named-in-questionable-winding-up-of-kq-s-profitable-cargo-arm>> accessed 10 February 2016.

⁹⁷ These operators included Safaricom, Airtel, Orange, MTN Business, Liquid Telecoms and Essar Kenya. See 'Safaricom threatens to walk out of 4G joint venture' (*Business Daily*, Nairobi, 2016)

a joint venture (JV) between Safaricom and Vodafone.⁹⁸ Other cases include those between African Governments and relevant companies.

Relatedly, there are numerous JV's in infrastructure development in Kenya and Africa. In 1996, the Governments of South Africa and Mozambique signed a 30 year concession with private companies to help build and operate the N4 toll road from Witbank, South Africa to Maputo, Mozambique. The companies included the Rand Merchant Asset Management, the Standard Bank and the Development Bank of South Africa.⁹⁹

Kenyan company, competition and consumer protection law are not integrated and have dubious provisions on strategic allegiances, joint ventures, and mergers and acquisitions. Hence the debate that these laws be reviewed to integrate IP, innovation, unfair competition and ToT.¹⁰⁰ Remarkably, the Kenyan Competition Act was a revision of the Restrictive Trade Practices, Monopolies, Price Control Act, 1988. Most companies enter into strategic allegiances to circumvent the provision on mergers and acquisitions (M&A). For example, companies enter into such ventures or alliances¹⁰¹ for purposes of protecting their investments or innovations from political or economic risk. Governments may be interested in production or distribution or simply rent seeking or primitive accumulation.

<https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&uact=8&ved=0ahUKEwj55_z1ovPPAhWDMBoKHRi7AdYQFggiMAE&url=http%3A%2F%2Fwww.businessdailyafrica.com%2FCorporate-News%2FSafaricom-threatens-to-walk-out-of-4G-joint-venture-%2F539550-1365850-view-printVersion-5b42hh%2Findex.html&usg=AFQjCNHfkbtVPqo--vf7o7DjWCg8pGikA&sig2=MDPYhqtQTklFQAw0Him4jw> accessed 24 October 2016.

⁹⁸ Irene Petrick & Suwan Juntiwarakij, 'The Rise of the Rest: Hotbeds of innovation in emerging markets' (2011) 54(4) *Research-Technology Management*. See Robert Osei-Kyei & Albert Chan, 'Developing transport infrastructure in Sub-Saharan Africa through public-private partnerships: Policy practice and implications' (2016) 36 (2) *Transport Reviews* 170-186.

⁹⁹ Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa*, Vol. 1 and 2 (Sihanya Mentoring and Innovative Lawyering, Nairobi & Siaya, 2016; forthcoming 2020).

¹⁰⁰ *ibid.*

¹⁰¹ Kenya's Competition Act, 2010.

¹⁰² Ben Sihanya, 'Intellectual property and innovation in Kenya: Legal and regulatory issues in business incubation' in Prof Bernard Aduda (ed) *Science and Technology Park Development for Sustainable Industrial Growth*, (Proceedings of the National Workshop in

(c) Business Incubation, IP and Innovation

Business incubation is an economic development facility that may integrate (any combination of) advice, support services, business facilitation, and real estate development intended to nurture innovation and businesses. Business incubators provide physical space where new businesses can begin.¹⁰² There are also shared facilities and the incubators offer support services and relevant institutional linkages to new businesses.¹⁰³ Franchising performs a similar role in the commercialisation of IP and innovation.

(d) Franchising IP and Innovation

A franchise is a form of IP transaction, licence or technology transfer whereby the franchisor authorises the franchisee to use the franchisor's copyright or trademark in exchange for royalties and related consideration.¹⁰⁴ Some of the main franchises in East Africa are Kenya's Uchumi Supermarket and Nakumatt Supermarket,¹⁰⁵ as well as the Kengeles restaurant. Leading universities like the University of Nairobi, Makerere University and University of Dar Es Salaam also franchise some of their programmes, services or products. Other popular franchises integrated into the Kenyan and African economies include Steers, Nandos, Kenchick, Oilibya, Mr Price Home, and Deacons.

The two main merits of franchising are, first, the business relationship is already established by the franchisor for the

Commemoration of the Scientific Revival Day of Africa, June 2004, Kenya National Academy of Sciences (KNAS), Nairobi, 2004) at 41-58; Ben Sihanya 'Intellectual property for innovation and industrialization in Kenya,' (2007) in Proceedings of 2006 JKUAT Scientific, Technological and Industrialization Conference, *Harnessing Scientific and Technological Synergies for Innovation and Industrialization*, Jomo Kenyatta University of Agriculture and Technology, Nairobi, October 26-27, 2006 (published 2007), at 38-58. See also Ben Sihanya, *Cases and Materials: Intellectual Property and Innovation Law in Kenya and Africa* (IPILKA 2), (Sihanya Mentoring and Innovative Lawyering, Nairobi & Siaya, forthcoming 2020).

¹⁰³ In this sense, business incubators are related to the concept that undergirds the Kenya Industrial Estates (KIE), and the Export Processing Zones (EPZs).

¹⁰⁴ Ben Sihanya, 'Understanding Copyright' (2015) *Utafiti News* a publication of the Office of the Deputy Vice-Chancellor (Research Production and Extension), University of Nairobi (March 2015). See also Sihanya, 'Introduction to Copyright' (*Utafiti News*, University of Nairobi, July 2014).

¹⁰⁵ Uchumi and Nakumatt supermarket have faced serious financial, regulatory, tax and political challenges including competition from the politically connected Tusksys and Naivas.

benefit of the franchisee. In all likelihood, relationships with suppliers (and perhaps distributors) will already be in place and easier to manage.¹⁰⁶ The advantages of already established relationships with advertisers and marketing teams may also benefit the new business start-up. Second, investors are likely to secure greater benefits and are far more willing to invest in a business with an established network, secure brand and effective support structure.¹⁰⁷

The three main disadvantages are, first, the fact that the franchisee has no (or very limited) control of the business or how it is run. (The rules of the business are already established as part of the franchise agreement.) Second, there is a risk that others might damage the reputation of the business as a franchisee relies largely on the business's brand to bring customers. Third, when the franchise relationship ends (prematurely), the franchisee, licensee or investor and the Kenyan and African consumers lose out while the franchisor benefits from long-term brand recognition among others.

7. SUMMARY OF FINDINGS, CONCLUSION AND RECOMMENDATIONS

The main objective of this essay and discussion was to analyse IP, innovation, ToT, and licensing in Kenya and the relevant African states in respect to the WTO TRIPS Agreement. The overarching argument is that Kenya and Africa have a lot of potential for, and should, integrate innovation, technology development, and the protection and promotion of IP intensive goods, services, and works. Most developing countries view technology transfer as part of the bargain in which they agreed to protect IP as pointed out by Antony Taubman, Hannu Wager and Jayashree Watal.¹⁰⁸ The TRIPS agreement includes various provisions on this.¹⁰⁹

TRIPS generally does not account for IP systems which are important to Kenya and other developing countries, such as

folklore, traditional knowledge (TK), Traditional Cultural Expressions (TCE) and utility model. These are not dealt with seriously, if at all, in TRIPS, yet they are important in African countries.¹¹⁰ Remarkably, TK, TCE and GR are now being discussed at WTO, WIPO, UNCTAD and UNESCO. There is, therefore, the need to address IP systems important to Kenya and African countries. This can be done by Kenya and other African countries revising or including these neglected concepts in their national legislations. By revising their national legislations to include these principles not discussed by WTO TRIPS, Kenya and other African countries will have, to some degree, addressed the issue of use of western standards and have focused on standards relative to their scenarios.

From these discussions we can see that licensing plays a crucial role in the protection and use of IP, Innovation and ToT. Kenya and other African countries should therefore lay emphasis on sensitizing their citizenry on the importance of licensing, assignments, and JVs in the securitization and commercialisation of IP, innovation and ToT. This can be done by reviewing existing IP legislation. Key institutions such as the Kenya Copyright Board (KECOBO), the Kenya Industrial Property Institute (KIPI) and the Anti-Counterfeit Authority (ACA), should be more proactive in promoting these IP doctrines by offering relevant information and training to IP owners, managers, and the general public. Such measures will help integrate IP, innovation, technology transfer and licensing for sustainable development in Kenya and Africa.

¹⁰⁶ Dominic Omondi, 'Why 400, 000 SMEs are Dying Annually' (*Standard Newspaper*, Nairobi, 30 October 2016).

¹⁰⁷ Aktalay Banu, *Intellectual Property Management Strategy in New Technology-Based Start-Up Companies* (Doctoral Dissertation, Middle East Technical University, 2004). See also 'Advantages and Disadvantages of a franchise' (The Company Warehouse, 2010) <<https://www.thecompanywarehouse.co.uk/blog/2010/10/04/advantages-and-disadvantages-of-a-franchise/>> accessed 24 October 2016.

antages-and-disadvantages-of-a-franchise/> accessed 24 October 2016.

¹⁰⁸ Antony Taubman, Hannu Wager and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2012).

¹⁰⁹ *ibid.*

¹¹⁰ On utility model see Chapter 6 of Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Transferring Technology for Sustainable Development*, (2016). *ibid.*

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REGULATION OF TECHNOLOGY TRANSFER AGREEMENTS IN ETHIOPIA IN LIGHT OF THE WTO FRAMEWORK

Biruk Haile*

ABSTRACT

Accessing technology from developed countries requires accessing technological information, understanding it, adapting it to local realities and improving it. The existing WTO normative frameworks focus on diffusion of technical information from developed countries leaving host countries to take their own measures domestically to increase absorptive capacities. Art. 66.2 of the TRIPS Agreement is not particularly designed to increase absorptive capacities of least developed countries (LDCs). One major channel for technology transfer (TT) is through technology transfer agreements. Regulating TT agreements becomes imperative in view of restrictive and burdensome provisions dictated by technology suppliers. The prevailing international legal framework allows countries to adopt either ex post or ex ante approaches in regulating TT agreements. Ethiopia maintains a formality-based system of registration for investment related TT agreements and there is no system of registration for non-investment related TT agreements. The fact that non-investment related TT agreements are entirely unregistered goes contrary to various laws and policies including the national science, technology and innovation policy.

Key Words: Technology transfer, developing countries, regulation, restrictive agreements, new international economic order, globalization, North, South.

1. INTRODUCTION

It is said that one of the fundamental factors that determines a country's economic performance is its

technological prowess.¹ No country can industrialize and provide for its economic needs without technology.² Technology helps a country to complement or acquire industrial base. This makes access to technology a topic of paramount significance to developing countries in their attempt to extricate themselves from complicated economic and social problems. A given economy may access technology by innovating and diffusing it or by receiving technologies produced elsewhere, especially in developed economies.

Current literature on the subject shows that most technology is in the hands of developed economies that have the resources to invest in technology creation. Thus, the main focus of development literature for developing countries is towards ensuring diffusion of technologies created in such developed economies to developing economies. This requires defining international economic relationships in a manner that facilitates technology flow from North to South. Such transfer may take voluntary channels like trade, investment, licensing, franchising etc.; it may also take the form of involuntary channels like imitation. This research examines the suitability of the international and national regulatory framework in ensuring effective transfer of technology from developed countries to developing countries.

Understanding Technology Transfer

Technology transfer (TT) is perceived differently in different economies. In the North or developed economies, TT is about setting up market infrastructure to commercialize technologies to consumers who pay for access granted to them; whereas, in the South or developing economies, TT is about the diffusion of technology (as a matter of obligation) from North to South more on state-to-state terms.³ As a result,

* Biruk Haile, LL.B, LL.M, PhD has over 15 years of teaching and research experience in various higher learning institutions in Ethiopia. He is currently a full-time academic staff at the rank of assistant professor at the School of Law of Addis Ababa University, Ethiopia. His field of specialization and research interest is intellectual property. He can be contacted at biruk.haile@aau.edu.et

¹ Kevin E. Davis, 'Regulation of technology transfer to developing countries: the relevance of institutional capacity', 27 law and policy 6 (2005), p. 7

² Cezar T. F. Hilado, 'The Legal and administrative regulation of transfer of technology: the Philippine Setting', 51 Phil L. J, 69, 69 (1976)

³ Theodore Harper, 'Understanding technology transfer', 10 Whittier L. Review, 161, 161-162 (1988)

developed countries focus on strong intellectual property (IP) protection for technology owners and rules on technology export. For the developing world, TT is about affordable and easy acquisition of technologies from the North. Thus, the prevailing IP regime can be taken as retarding nonmarket based TT, especially through imitation and reverse engineering and encouraging market based transactions.

Technology is a result of huge personal and material investment by technology owners (in the North) and it is seen by corporate executives as the pride of their corporation and the biggest business asset; consequently private owners of such valuable asset will impart it only for profit.⁴ This also requires that the technology importing countries ensure certain and stable rate of return (eg. in terms of stable tax laws), stable exchange rates, absence of restriction on foreign exchange, transfer, and repatriation of funds. In addition, technology may be proprietary or non-proprietary and in the case of the former, it is important that the technology importing country maintains an appropriate property regime.

In addition to direct profit from the transaction, other benefits technology transferring corporations expect include assurance of market position in the technology recipient country/region; technical feedback/access to improvements to the transferred technology; sales support to penetrate market for the technology and to develop information and sell other products; and extension of manufacturing capacity by reducing cost of manufacturing.⁵

On the part of the technology recipient countries, the main areas of concern that warrant regulation of TT agreements include export restrictions on the products made using the technology, the price of technology,

packaging (i.e., linking TT to components, spare parts, and services) etc.

TT has various cognitive dimensions. Conceptually TT is understood as transfer of technological knowledge including acquisition of information concerning technology, transfer of capacity to assimilate, implement and develop technology.⁶ Thus, TT requires that the recipient should not only have access to technological information but also should (acquire capacity to) learn how to use the technology, adapt/assimilate it to local conditions and absorb (i.e., subsequent improvements/progression). This enables recipient to address local needs using local capabilities and opportunities.

Japan is a country well known in literature for its direct purchase of technology from abroad. But it is said that for each dollar it spent for technology purchase, it spent seven dollars for local research and development for local adaptation and improvement.⁷ In addition, the experience of Asian countries shows that local conditions like political will, high level of education and enlightenment, culture of work discipline and imaginativeness are important determinants of technology transfer. This shows TT cannot take place without deliberate regulatory and supervision policy.

TT can take the form of an economic operation itself or it may depend on operations that exceed it.⁸ When TT is dependent on other economic transactions like FDI, international trade, construction and supply of infrastructure, etc., it is a by-product or joint product and the importance and quality of TT depends on primary economic operations.⁹ The locus of decision making as to the modes of learning and the resources dedicated for TT is in foreign (technology exporting) country and scholars argue that there is risk of suboptimal decision making as the short term focus is drawing profit from the direct

⁴Danis M. Neill, Regulation of Technology Transfer, 1 Pub. L. Forum, 125, 126 (1981)

⁵Ibid, 126-127

⁶Dominique Foray, Technology transfer I the TRIPS age: the need for new types of partnerships between least developed and most

advanced economies, (ICTCID), (Issue paper No 3), (may 2009), p. 4

⁷Hilado, (n2) 75

⁸Foray, (n6) 4

⁹Ibid

economic transactions.¹⁰In addition, the model of TT does not ensure long term technological independence of the recipient and effective technology transfer may not ultimately take place.

On the other hand, when TT is the main economic operation itself, it takes the form of market mechanisms like TT agreements, licensing, franchising, joint ventures and non-market mechanisms like imitation and movement of people. Here TT is the prime motivation and its success is not predicated upon other economic operations. Moreover, technology importers have the opportunity to participate in various decisions pertaining to TT but the incentives do not depend on other economic transactions. Importing countries shall make such transaction attractive on their own merit to the technology supplier.

We cannot commend one mode of transfer over another and LDCs like Ethiopia should acquire capacity and design regulatory frameworks to benefit from various levels of TT that affect local productivity in various ways. Many scholars argue that TT in both models is important for LDCs and they should make available sufficient incentives. However, the challenge is that LDCs' participation in international trade and flow of FDI is low (i.e., limited exposure to foreign technology) and the incentive for TT as independent economic transaction is poor as local absorptive capacity is low.¹¹ This requires additional incentives (other than market incentives, if any) especially to enhance local absorptive capacity and design policy framework to attract foreign investment and enhance international trade.

Models of TT Regulation

When technology transfer takes place from developed countries to developing countries, obviously there is a need to regulate TT agreements to deal with burdensome

terms and conditions due to unequal bargain power on the part of the recipient. Some of the undesirable terms and conditions that such regulations aim to prevent include inappropriateness of the technology to local conditions, disproportionately high (royalty) payment by the transferee, restrictive business practices imposed on transferees, requirements for extensive use of expatriate staff, . There are two competing approaches to regulate TT agreements as discussed below.

2. THE NEW INTERNATIONAL ECONOMIC ORDER AND REGULATION OF TT

Following the vocal assertion of the developing world for reform in international economic relationship in a manner supportive of their economic realities (especially to increase flow of technology to the developing world), the United Nations (UN) came up with various resolutions in support of the so called New International Economic Order (NIEO). These are the UN Declaration on the Establishment of New Economic Order (1974a) and the UN Program of Action on the Establishment of New International Economic Order (1974b).¹² This followed from domestic and collaborative measures by developed states and restrictive business practices by their multinational companies to restrict availability to and competitiveness of developing world.

Following these declarations certain reforms were taken in domestic laws and at international level. One notable international measure related to TT is the Draft International Code of Conduct on Transfer of Technology developed by United Nations Conference on Trade and Development (UNCTAD) in 1985. The genesis of the code is said to be Decision 24 of the Cartagena Agreement by Andean Group Countries ¹³that recommended establishment of a national agency to supervise technology transfer agreements.¹⁴

¹⁰Ibid, p. 5

¹¹ Foray, (n6) 7

¹² Davis, (n1) p.7

¹³Andean Group Countries are Bolivia, Colombia, Ecuador, Peru and Venezuela

¹⁴Paul Kuruk, Controls on technology transfer: An Analysis of the Southern response to Northern technology protectionism, 13 Md. J. Int'l Law, 301, 312 (1989)

This instrument regulates both public and private aspects of TT agreements. In both cases the code tries to rectify unequal bargaining power between technology supplier and recipient. One notable provision affecting private aspect is Chapter 5.1 which encourages the parties to be responsive to the economic and social development objectives of respective countries of the parties and particularly of the technology acquiring country. In addition, Chapter 5.2 of the code again encourages parties to take in to account requests to include provisions requiring locally available resources and for unpackaging of information concerning various elements of technology to be transferred. Furthermore, Chapter 5.3 of the code requires parties to negotiate in good faith and requires the price or consideration charged for technology to be fair and reasonable and clearly indicated; the same provision requires the potential supplier party to disclose health, safety, and environmental risks associated with the use of technology and pending challenges to the validity of the rights to be transferred.

When we come to the public aspects of the code, it concedes huge discretion to state parties to regulate TT agreements in support of the weaker recipient party. Art.3.4 permits the establishment of national administrative agencies empowered to evaluate and aid in the negotiation of TT agreements with wide authority to review such agreements prior to their finalization. It also lists, under Chapter 4, the following restrictive business practices that may be prohibited in the TT agreement:

- Requiring the transferee to transfer improvements exclusively to the transferor (grant-back provisions) (4.1);
- Restricting the transferee's ability to challenge the validity of intellectual property claimed on the technology supplied (4.2);
- Unnecessarily restricting the freedom of acquiring party to enter in to sales, representation, manufacturing relating to similar or competing technologies or products (4.3)
- (Unreasonably) restricting the transferee's ability to engage in research and development to absorb and adapt to local conditions or to innovate new products, processes or equipment (4.4);
- (Unreasonably) requiring the transferee to use personnel, goods or services specified by the transferor(4.5);
- (unjustifiably) regulating the prices charged by the transferee for products produced using the technology supplied (4.6);
- (unreasonable) restrictions on adaptation or innovation of imported technology or restrictions that require transferee to introduce unwanted or unnecessary designs or specifications; (4.7)
- Exclusive sales or representation requirements in favor of the supplying party (4.8)
- Tying arrangements that impose duty to accept unwanted additional technologies, future inventions, goods, and services (4.9);
- Restricting exports (4.10); and
- Patent pool or cross licensing arrangements among technology suppliers (4.11);
- (unreasonable) restrictions on publicity or advertisement by acquiring party (4.12);
- Requiring transferee to pay after expiration of industrial property (4.13)
- Imposing obligation on the transferee after expiration of arrangement (4.14)

These are very important safeguards for developing countries in regulating TT agreements to prevent abuse and facilitate transfer of technology. However, the Code could not be adopted due to ambivalence of the developed world that is inclined to tolerate abusive arrangements to the extent that they do not entail anticompetitive effects.

The Globalization Model

The extensive regulation of terms of the TT agreements is said to be the reason why the NIEO model has not been adopted as a Treaty. The developed countries are said to have raised several objections to this model and opted for

a liberal model for the following reasons: the main developed country object to outright prohibition of restrictive business practices unless it entails unreasonable adverse effect on competition; application of same standard for TT agreements between commonly owned enterprises; and restriction on choice by parties of applicable law and court with jurisdiction as well as settlement by arbitration in the event of dispute.¹⁵The developed world seeks liberal treatment of TT agreements subject only on rules on competition as enshrined in various international agreements including the TRIPS Agreement. This globalization model embraced by developed countries is said to be particularly objected to non-competition related form of TT.

The NIEO model relies on scrutiny of TT agreements prior to conclusion (prior or at the time of contract) (ex ante) than the globalization model that uses competition law as instrument relying on later complaints (ex post) to enforce TT contract enforcement.¹⁶ When a system is predicated on predictability, ex ante regulation is preferable for it informs actors in advance.¹⁷ However, ex ante regulation is unattractive to countries with limited institutional capacity to administer such contracts.¹⁸ In addition, such compliance cost places smaller firms in developing countries at competitive disadvantage as such costs are fixed rather than variable.¹⁹ Thus, ex post regulation has two cost benefits especially to developing countries: savings in administrative expenses and compliance costs. Ex post approach deals with only a limited number of transactions suspected/reported to be non-compliant and is resource effective. But if the harm the transactions cause is not effectively dealt with for various reasons, ex post regulations entail irreparable loss to the economy. This is particularly the case in LDCs where the competition regime is ineffective. Secondly, the ex ante regulation does not give legislatures opportunity

for informed regulation to evaluate effects of a given practice.

As far as institutional aspect is concerned, the conventional developing country perspective is to authorize a specialized government agency 'to screen and regulate' terms of (international) Transfer of Technology agreements.²⁰

3. REGULATION OF TECHNOLOGY TRANSFER UNDER THE TRIPS AGREEMENT: PRIVATE AND PUBLIC ASPECTS:

Public Aspects

Paragraphs 5 and 6 of the preamble of TRIPS Agreement make mention of technology without any policy guidance on regulation of TT agreements. Similarly, the need for transfer and dissemination of technology is mentioned in Arts. 7 & 8 of the Agreement, again with no prescription of both public and private regulatory issues.

Art. 66.2 provides that 'developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to LDC Members in order to enable them to create a sound and viable technological base.' This provision focuses on measures by home countries of companies operating in LDCs and does not regulate measures by host LDCs. This provision is ill formulated in that it does not specifically impose obligation to enhance local absorptive capacity. A developed country may report to have sold or made available a technology or equipment to LDCs without being required to establish that measures have been taken to ensure that the recipient nation has actually understood how the technology works and has acquired capacity to adapt it to local reality. In such scenario, experts from the exporting country may be sent to operate the equipment for a certain period and the recipient may no longer be able to benefit from the technology once the experts have left or the equipment stops working. Thus, it is imperative that

¹⁵ Davis, (N.1) 12

¹⁶ Ibid, p. 23

¹⁷ Ibid

¹⁸ Ibid, p. 24

¹⁹ Ibid

²⁰ Ibid, p. 9

the obligation of the developed countries is defined in terms of the obligation both to impart the technological information and to improve local absorptive capacity.

The main impediments to this provision have been private ownership of technologies and host country measures or realities affecting TT. The TRIPS Council, following the Doha Declaration, came up with the 19 February, 2003 implementation decision. The decision requires annual reports and detailed reports every three year from developed countries on their implementation of this obligation.²¹

Home country measures taken to implement this obligation includes financing of TT, TT through FDI, matchmaking and provision of information on technologies, promoting public-private partnership, access to venture capital and TT, international alliances and transfer of technology, and measures to improve host country absorptive and technological capacity.²² Evaluation of the TRIPS implementation reports reveals that most of the private technology transfer initiatives follow business motive and LDCs, though target beneficiaries under the Art. 66.2, could not take advantage of the home country measures due to lack of absorptive capacities and resources.

Regulation of TT is also affected by legal regimes on investment. In this regard, Art. 2 of the Agreement of Trade Related Investment Measures (TRIMS) provides principle of national treatment. Thus, restrictions of investment that are inconsistent with the national treatment principle are not acceptable. For instance, imposing obligations on foreign firms to transfer technology will be inconsistent with the TRIMS. Such prohibited so-called local content requirements include the requirements on:²³

- purchase or use by enterprise of products of domestic origin from any domestic source;

- purchase or use of imported products be limited to an amount related to the volume or value of local products it exports;
- the importation by enterprise of products used in or related to its local production;
- importation by enterprise of products by restricting access to foreign exchange;
- the exportation or sale for exports by enterprise of products.

The TRIMS seems to be concerned more with prohibition of local content requirement than burdensome terms in TT agreements.

Bilateral investment agreements (BITs) (especially those negotiated by USA and Canada) exceed TRIMS and, in addition to prohibition on local content requirement, also prohibit requirements to transfer technology to local firms or to conduct a specified amount of research and development locally.²⁴ These prohibitions on requirements of local content easily spread to BITs that do not have such requirement on account of Most Favored Nation provisions. Such prohibition takes away the ability of state to use local content requirement to bring technology transfer or local innovation.

Private Aspects

Neither the Paris Convention nor the TRIPS Agreement regulates registration of technology transfer agreements. Art. 40 of the TRIPS Agreement allows members to regulate certain licensing conditions and practices which are very relevant to TT agreements. Moreover, Art. 31 (K) is interpreted as giving members the flexibility to regulate behavior of IP owners relating to TT agreements. In general the TRIPS allows member states to regulate TT agreements but only with a view to preserving competition. Furthermore, scholars who argue that the TRIPS follows a liberal model based on competition, as

²¹ WTO Council for TRIPS, Implementation of Art. 66.2 of the TRIPS Agreement, Decision of the Council for TRIPS of 19 February 2003, Art. 1

²² UNCTAD series on technology transfer and development: Facilitating transfer of technologies to developing countries –a survey of home country measures, (2004), PP. 5-11

²³ Agreement on Trade Related Investment Measures (Annex (1))

²⁴ Davis, (N.1) 15

opposed to the NIEO model, point to Art. 27.1. This provision is opposed to invalidation of patent on account of non-working and, even though it is controversial, there are scholars who further argue that same provision prohibits compulsory license for non-working locally.

In general, we can argue that the private and public aspects of the TRIPS regulation is not directly opposed to the NIEO model of regulation of TT agreements that relies on ex ante approval. However, it can also be argued that the prevailing multilateral framework is biased in favor of regulating TT agreements through the lenses of competition law than a system of ex ante evaluation, approval and registration.

4. REGULATORY FRAMEWORK FOR TECHNOLOGY TRANSFER IN ETHIOPIA

The Ethiopian economy is one of the fastest growing economies in Africa and the country aims at becoming a middle-income country by 2025.²⁵ There is a flurry of investment and TT activities. To mention just a few, the Ethiopian Airlines is acquiring state of the art aircrafts and undertaking a number of activities in partnership with foreign firms to benefit from new technologies; the country has embarked on building the largest hydro power generating dam in Africa; light municipal and cross country train services are under construction; multinational food chains like Pizza Hut and well known hotel managements have started entering the Ethiopian market; commercial agriculture is underway. Technology transfer is an important ingredient of such activities. In some cases TT agreements are entered for technologies like plant varieties not protected in Ethiopia even for longer period than duration of IP protection. It is also not difficult to anticipate restrictive or burdensome practices in many of those arrangements.

The current Science and Innovation Policy of the Country has, as its mission “creation of a technology transfer framework that enables the building of national capabilities in technological learning, adaptation, and utilization.”²⁶ One important strategy embraced in the policy to realize the objective of TT is through importation of effective and appropriate technologies. However, there has been a lack of clear regulatory framework relating to TT agreements.

The Period from 1993-2003

During the period 1974-1991 Ethiopia had relatively not been open for foreign investment and the private sector commercial transactions were discouraged with the dominant socialist ideology. In 1991 the country arguably reversed the ideology and embraced market-based economy. Following the new market inclination, it issued Encouragement, Expansion and Coordination of Investment Proclamation No 15/1992 to encourage domestic and foreign investment. It also issued Council of Ministers Regulation No 121/1993 (pursuant to Art. 23 (4) of the proclamation) to regulate technology transfer agreements.²⁷ The regulation was applicable to TT agreements between natural persons at least one of which is resident, domiciled in or is national of Ethiopia; a domestic private or public enterprise and a foreign enterprise; a foreign owned enterprise and a domestic private or public enterprise; and a parent company abroad and its branch or subsidiary in Ethiopia²⁸. The regulation introduced a system of advisory, evaluation, approval and registration of TT agreements by the Ethiopian investment Agency (EIA) and TT agreements not so registered are declared to have no legal effect.²⁹

The grounds for evaluation are: description of the technology transferred; ownership and validity of industrial property transferred and third party claims;

²⁵ Federal Democratic Republic of Ethiopia, The Second Growth and Transformation plan, (2015/16-2019/20)

²⁶ FDRE Science, Technology and Innovation Policy, (2012)

²⁷ Transfer of Technology Council of Ministers Regulation No 121/1993

²⁸ Transitional Government of Ethiopia Transfer of Technology Council of Ministers Regulation No 121/1993, Negarit Gazeta, Art. 3

²⁹ Ibid, Arts.7-25

suitability of the technology for use; termination of confidentiality clause; performance guarantee; technical service; training of personnel; provision of accessories, components and spare parts when the technology supplier is the sole or major supplier of same; quality standards (in case of use by recipient of supplier's trademarks, trade names, and similar identification of good will); and use of local resources and local personnel; and evaluation of payment obligations.³⁰

Similarly, the regulation requires the EIA to refuse registration: when the agreement imposes restriction on research, development adaptation and modification by recipient; when the technology is obsolete and/or unsuitable or available in Ethiopia; when the supplier directly or indirectly controls or intervenes in the management of the recipient; when there is obligation to transfer or use industrial property rights or improvements obtained by technology recipient with or without compensation; if the agreement is fixed for an unduly long period; if there is undue restriction on use of complementary technologies; if there are tie-in clauses to obtain equipment, spare parts, tools, or raw materials exclusively, from supplier; when production volume is limited or sale or resale price is imposed on national production or exports; when there is undue restriction on personnel supply; when there is undue requirement on recipient to conclude exclusive sales or representation contracts; when there is undue and onerous obligation for quality control; when there is unreasonable restriction or prohibition on export of goods and services by the recipient; when there is obligation to sell goods to exclusive client; when the payment is unjustified for national economy or receiving party; and when the technology is contrary to national order or priority.³¹

The idea behind the regulation is protection of the weaker party, i.e., technology recipient, owing to information asymmetry and lower bargaining power. The effect of

non-registered TT agreement is that it is not enforceable by courts of law.³²

The regulation was expressly repealed by Art. 5 of Investment (Amendment) Proclamation No 373/2003. This means the system of detailed ex ante evaluation and registration of investment related TT agreements addressed above is set aside. However, there are other proclamations issued later like the Mining Proclamation No 678/2010 (Art. 43) that refers to the TOT Regulation No. 121/1993 or registration of TT Agreements. Therefore, we may say that the regulation is partly revived in case of such instruments.

On the other hand, Art. 15 of the current investment proclamation No. 1180/2020³³ reinstalls system of registration and tries to regulate formal aspects of TT. Sub-article (1) provides any investor concluding technology transfer agreement in relation to his investment shall have the agreement registered with the (investment) Commission. We can see that this provision is applicable only to TT agreements in investment context and is not applicable to other TT agreements.³⁴ TT agreements concluded by parties not related to any investment transactions do not qualify for registration.

The provision does not provide substantive requirements against which the Agency has to evaluate the agreement before registration. It also removed detailed formality requirements provided under the repealed proclamation. Art. 21 (2) of the repealed proclamation requires the following for application for registration of TT agreements to fulfill: application form signed by recipient of technology; photocopy of authenticated agreement between the technology recipient and provider; photocopy of valid business license or investment permit of the recipient; and certificate of registration or business license of the technology provider. In addition, Art. 21(3) of the repealed proclamation requires the Agency to issue a registration certificate to the applicant investor upon receipt of complete application as per sub-article (2). These are important details left out under the new proclamation probably for regulations that may be issued

³⁰ Ibid , Arts.10- 22

³¹ToT Regulation (n28), Art. 23

³²Ibid, Art.24

³³ The proclamation repealed and replaced Proc. No. 769/2012

³⁴ 'Investment' is defined under Art. 2(1) of the new proclamation as expenditure of capital in cash, in kind or in both by an investor to establish a new enterprise, or to acquire, in whole or in part, or to expand or upgrade an existing enterprise.

pursuant to Art. 55. In any case both the new and repealed investment proclamations do not provide substantive criteria for the Commission to scrutinize terms of TT agreements in support of technology recipient and this is significant disregard of important policy considerations.

When we come to effect of registration of TT agreements, Art. 15 (2) of the new proclamation provides a technology transfer agreement that is not registered in accordance with sub-article (1) shall not have legal recognition with the Commission. This is important improvement from Art. 21 (4) of the repealed proclamation which states that TT agreements not registered with the Agency in accordance with the preceding formality requirements shall have no legal effect. Hence, under the new proclamation non-registration of investment related TT agreements does not render them effectless in the eyes of the law and they will be treated in equal footing with non-investment-related TT agreements. That is, unregistered TT agreements will be binding between parties but do not benefit from, among others, privilege of remittance of foreign currency available for registered agreements.

Sub-art. (3) of Art. 15 of the new proclamation requires the Commission to notify relevant federal executive organs and copy the National Bank of Ethiopia the registration of technology transfer agreement made in accordance with the same provision. This particularly because Art. 20 (c) of the new proclamation allows any foreign investor to remit (in convertible foreign currency) payments related to technology transfer agreements registered in accordance with Art. 15. One can question why the legislature guarantees remittance service to technology suppliers without ensuring that the technology and its terms of provision are in fact beneficial to the local economy. For instance, there is no point in

buying from abroad technologies available with local suppliers.

Failure to regulate terms of TT transfer agreements, investment related or otherwise, and absence of clear guidelines for remittance of royalty for non investment related TT agreements is serious gap a country like Ethiopia that desperately needs effective TT should rectify.

With the repeal of the TT regulation, Ethiopia seems to have been caught in between NIEO and globalization models to regulate TT agreements. It maintains a system of registration without substantive evaluation of the terms for investment related TT agreements. This (partial) move away from regulation to deregulation may partly be explained on account of maintaining consistency among different policies. That is, one may argue that the ex-ante model of regulation will only be successful if it is part of strict regulatory regime on FDI.³⁵ No doubt that the country maintains huge flexibility to attract foreign investment by providing lucrative incentives and tax and customs duties exemptions.³⁶ However, the regime has its own rigidities³⁷ and regulation of by-product transfer of technology does not necessarily contradict the policy behind the primary economic transactions.

The current approach does not have mechanism to implement policy direction embraced under the national Science, Technology and Innovation policy that requires transfer of only appropriate and effective technologies.

Examination of the experiences of many developing countries in Africa like Nigeria and Ghana shows that TT agreements are not registered when they contain provision which: transfers technologies freely available in the recipient country; permits technology exporter to unduly intervene in the administration of recipient; requires unnecessary quality controls; requires use of unnecessary package personnel and technologies;

³⁵See for example David Kremen, 'Anti-Trust and direct regulation of international transfer of technology transactions, A Comparison', 9 Md. J. Int'l Law and Trade 301, (1985)

³⁶ See Council of Ministers Regulation No. 270/2012, Arts. 5-15

³⁷See for example Ibid, Art. 3 (investment areas reserved for domestic investors), Investment Proc. 1180/2020 Arts. 6 (areas of investment reserved for the government or joint investment with the government)

imposes onerous obligation to transfer IP or improvements on the technology; requires royalty not commensurate to the technology; limits research and development; restricts sales, exportation, and use of complementary technology; unduly requires acquisition of inputs and personnel exclusively from supplier; imposes undue restrictions on volume of production and distributorship; prolongs duration of agreement beyond period of protection for the technology requires full payment for unexploited technology; requires submission to foreign jurisdiction and laws etc. In fact, countries like China have taken such deliberate measures dubbed at some quarters as 'forced transfer of technology' to ensure imparting and diffusion of foreign technology, for instance, by requiring foreign companies to operate in joint venture with local ones as condition to enter local market.³⁸

Most of the grounds of scrutiny above are also important socio-economic objectives in Ethiopia that TT agreements should not refute. Moreover, there are clear health, bio-safety, and environmental standards such agreements cannot disregard. The Commission cannot register anything parties agree. In addition, terms of non investment related TT agreements should not be entirely left to freedom of contract and provisions should be put in place to ensure that effective diffusion of appropriate technologies takes place and that such agreements are in tune with policy prescriptions and laws in diverse sectors.

Therefore, maintaining a system of prescreening through registration without clearly providing substantive grounds for evaluation is a paradox. Furthermore, if TT agreements in the mining sector are evaluated against detailed guidelines under Council of Ministers Regulation No. 121/1993, there is no reason why TT agreements in other sectors, investment-related or otherwise, should not be scrutinized ex ante against similar guidelines.

Ethiopia has a competition regime that prohibits anticompetitive trade practices that covers abuse of

market dominance; anticompetitive agreements, concerted agreements and decisions; and unfair competition.³⁹This can, among others, discipline such terms of TT agreements as tying arrangement (for basic inputs, spare parts and supplies after TT agreement), and export/import restrictions, and restrictions on competing local supplies. But this by no means justifies switching to ex post approaches. The inefficiencies of the competition regime means that there is a need for regulatory intervention at early stage than post facto analysis. The ex-ante registration and ex post competition regimes should complement each other.

5. TT AGREEMENTS UNDER ETHIOPIAN BILATERAL INVESTMENT AGREEMENTS

There were some (Latin American) countries in the past that required divestment of (existing foreign) investment and minority foreign shareholding in new investments with the aim to secure technologies thereby preventing decision making reflective of the corporate interest.⁴⁰This impedes the establishment of wholly-foreign owned subsidiaries in the developing world. The current Ethiopian law does not have such investment restriction; rather Ethiopia reserves a very long list of investment areas reserved for only domestic investors but this has nothing to do with regulation of TT. There are many wholly foreign owned subsidiaries in Ethiopia. The main focus at the moment is attracting more investment by reducing impediments and to strengthen the economy but in the future one may not rule out introduction of such requirement to facilitate TT.

Ethiopia has signed just over 30 bilateral investment agreements (BITs) with other countries to promote investment. The common provisions in the agreements related to TT regulation are national treatment and most favored nation treatment. Most of the agreements do not have provisions that directly regulate TT. However, certain BITS have provisions that can be seen as setting disciplines for domestic TT regulation. One such

³⁸ The legality of such measures is being examined within the WTO framework.

³⁹ See Trade competition and consumer protection Proclamation no. 813/2013, Arts. 5-8

⁴⁰ Neill, (N4) 132

agreement is the Ethio-Finland bilateral agreement. Art. 3(3) of the agreement prohibits the contracting parties from mandating or enforcing measures on investments by investors of the other contracting party concerning purchase of materials, means of production, operation, transport, marketing of its products, or similar orders having discriminatory effects.

In the Ethio-France bilateral agreement, Protocol on Art. 3 (fair and equitable treatment) regards as impediment to fair and equitable treatment any restriction on purchase or transport of raw materials or auxiliary materials and hindrances of sale or transport of products. This can be construed as a guarantee against local content requirement in the host country.

The Ethio-Germany, Ethio-Iran, and Ethio-Kuwait agreements prohibit arbitrary or discriminatory measures that impair the management, maintenance, use, enjoyment, acquisition or disposal of investments. Moreover, the Ethio-Kuwait agreement prohibits imposition on foreign investors that require or restrict the purchase of materials, energy, fuel, or means of production, transportation, or operation of any kind that restrict the marketing of its product inside or outside its territory, or any other measure that has discriminatory effect. It also prohibits additional performance requirements (after establishment) by host countries that may hinder or restrict their use, enjoyment, management, maintenance, expansion and other activities of the investment.

Similarly, there are economic partnership agreements and treaties (with investment provisions) that may be considered as impacting TT regulation. One Such instrument is the Interim Agreement establishing a framework for an Economic Partnership Agreement between Eastern and Southern Africa States (ESA) and the European Community (EC) (2012). Under Art. 17 it requires elimination of all prohibitions or restrictions in trade on the importation, exportation or sale for export between the parties. This can be understood as

prohibiting import or export restrictions in TT agreements.

6. CONCLUSION

The prevailing international law does not impose firm obligation to ensure diffusion of technology from North to South. In particular, the prevailing international norms seem to focus only on limited aspect of TT, i.e., imparting of technical information. In terms of regulating private TT agreements between parties, the existing international instruments seem to be biased against ex ante regulation.

Ethiopia does not provide adequate measures for technological diffusion. The experience of successful Asian countries reveals that for effective technology transfer to take place, measures taken by recipient countries are important determinants. Especially building local absorptive capacity through promotion of scientific education and strengthening disciplined work culture is important. These are scarce commodities in LDCs like Ethiopia where advanced scientific education is at its early stage and capital is limited to public spending. Ethiopia concedes huge incentives for investment-related TT through investment incentives and tax exemptions. However, TT models as independent economic transactions are given no such incentives.

When we come to regulation of TT agreements the Ethiopian law entirely leaves aside non-investment-related TT agreements. Even with respect to investment-related TT agreements, the country has moved away from regulation to deregulation. As a result, there is no mechanism to check terms burdensome TT agreements on the recipient. And this undermines important public policy considerations.

The TRIPS system concedes flexibility to member countries to craft either NIEO or globalization/liberal model of TT regulation. In 1993 Ethiopia introduced a system of ex ante registration and evaluation of investment-related TT agreements. However, in 2003 it switched to a formality-based system of regulation, except for mining-based TT agreements. Registration of

an agreement without authority to correct restrictive and burdensome clauses does not serve much purpose. Similarly, it is imperative to exercise oversight over non-investment related TT agreements. It is important that Ethiopia maintains a system of prior evaluation and registration for all TT agreements, investment related or not. The existing system of regulation on TT agreement is extremely fragmented and chaotic and is not compatible with various national policies, especially science, technology and innovation policy. This, ultimately, needs to be rectified.

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THE TEACHING OF INDIGENOUS KNOWLEDGE AS A TOOL FOR CURRICULUM TRANSFORMATION AND AFRICANISATION

Amos Saurombe*

ABSTRACT

The debate on teaching of indigenous knowledge and its associated benefits has been recognised for a long time. Not much has been said about how the teaching of IK in both theory and practice can be tailor made for any subject of scientific enquiry. At the same time, the debate on curriculum transformation and Africanisation has made it critical for scholars and students alike to seriously consider IK as a catalyst in education that can empower communities to participate in their educational development since it respects diversity and acknowledges the challenge of hegemony of Western Eurocentric forms of universal knowledge.¹ This paper comprises of a literature study focusing on the role the teaching of IK in transforming the education system in Africa, which in many respects is out of touch with the realities of respective communities. The paper also draws from the experience of the author, who teaches at one of the IKS Centres in South Africa. The paper concludes with a realisation that African Universities and the education sector as a whole must become a vehicle for improving the socio-economic and political landscape of its people.

Keywords: indigenous knowledge (IK), curriculum transformation, Africanisation, decolonization, Ubuntu, African knowledge systems

1. INTRODUCTION

Indigenous knowledge (IK) is a fast-growing field of inquiry at both national and international level. At the same time there

has been a robust debate on curriculum transformation and Africanisation. In South Africa, full degree programmes on IK at both undergraduate and postgraduate level are already being offered at different universities. In some cases, these courses are offered as electives in other programmes. Students from across all scientific enquiry areas are using IK courses to understand the context of their knowledge fields especially those that define their upbringing as African people. In true fashion for the call of transformation of the Africanisation of knowledge, students and academics are demanding a shift from Eurocentric knowledge systems. Most African academics and their students have started vigorously to question the definition of IK. This is the case notwithstanding the fact that this debate has been ongoing in the past and current academic discourse.

There is no universally acceptable definition of IK. The definition of IK is mostly influenced by context and in most cases; Eurocentric scholars seek to understand it as a cognitive system that is alien to them. According to Noyoo, the indigenous knowledge system (IKS) refers to the complex set of knowledge, skills and technologies existing and developed around specific conditions of population and communities indigenous to the particular geographic area.² IKS constitutes the knowledge that people in a given community have developed over time and continue to develop. This is contrary to the Eurocentric context where IK is interchangeably defined as traditional knowledge (TK) which suggests an unchanged old and static body of knowledge that has been passed from generation to generation. This is not how IK is perceived in the African context. The Eurocentric approach only targets knowledge, practices and techniques used by indigenous peoples, recording their local names, and cataloguing their reported

* Amos Saurombe (South Africa) LLB, LLM, LLD, Professor of Law, University of South Africa, South Africa. Graduated with a Master's Degree from UWC-SA and Amsterdam Law School. Doctoral degree in International Economic Law from the North West University, South Africa. Doctoral Research study and residency in Geneva was covered by the WTO- Doctoral Fellowship programme in 2010. Former Head of Graduate Studies, Research and Innovation at the University of South Africa. Adjunct Faculty of the Trade Policy Law Centre (TRAPCA) –Arusha Tanzania. Guest Lecturer at the University of Pretoria, NWU IKS Centre, University of Fort Hare and Africa University. Authored more than 30 papers in areas taught which are International Trade Law, Intellectual Property Law, Indigenous

Knowledge Systems, Biodiversity, and E-commerce. Presented as key-note and plenary at a number of International conferences and seminar dealing with intellectual property law. A member of the BRICS Academic Think Tank that deals with trade and intellectual property matters. A Y2 National Research Foundation rated Researcher and Members of Southern Africa Academy of Science (SAYAS).

¹ V Msila, 'Africanisation of Education and the Search for Relevance and Context' (2009) *Education Research and Review*, 315.

² N Noyoo, *Indigenous Knowledge Systems and Their Relevance for Sustainable Development* (2007) A Case of Southern Africa.

uses.³ The teaching of IK is thus biased through this cognitive process. African scholarship has now started to go deep into an enquiry that proves this bias. Beyond the pursuit of knowledge, many scholars are now seeking to ensure that the African voice is heard. The understanding that African challenges need to be viewed within the context of African solutions has become paramount.

Related to the above, Africanisation is now understood as a renewed focus on Africa and it entails salvaging what has been stripped from the continent.⁴ It is a process of restoring the original 'living or people's science' as per the earlier discussion. No one can deny that IK has been negatively affected by colonialism. Africanisation is a regeneration of that which was good and respected in African culture.⁵ The realisation that Africa and its people existed in contemporary peace and harmony before colonialism prompts the need to investigate how this was experienced. Colonialism was holistic and cross-cutting in nature. All aspects of life were affected with the most dangerous trend being that Africans were voluntarily and, in many cases, forced to abandon their entranced knowledge systems under the impression of it being labelled barbaric, backward and ungodly. IK was vilified. Ramose⁶ opines that for the colonial conqueror and successor in title thereto, the indigenous conquered peoples had neither an epistemology nor a philosophy worth including in any educational curriculum. For many decades, the African values have been marginalised by an education system in favour of Western values only.⁷ As early as the 18th century, the coloniser was intent on disposing the blacks of anything African.⁸ In South Africa, the 'Bantu education' system for black Africans had been a means of restricting the development of the learners by distorting school knowledge and ensuring control over the intellect of the learners and teachers.⁹ Africanisation is thus a viable proposition to

change this state of affairs. There is a call for a regeneration of that which was good and respected in African culture, as well as a rejection of sub-service to foreign masters and the assertion of the rights and interests of the African.¹⁰ Colonisation has caused multigenerational trauma.¹¹

Notwithstanding this, African knowledge systems have a rich heritage in that they have shaped and defined the way of life for African people for many centuries. It is because of the nature of the 'way of life' that IK refused to die and be erased from the face of the earth. IK is gradually being re-evaluated and it is considered an inspiring source of strategies for sustainable development.¹² African knowledge systems have the potential to contextualise any knowledge field to the environment it is offered. It presents a system that would meaningfully involve students in the discovery of their own environment.¹³ Thus, it was difficult to completely erase it from the face of the earth despite the best efforts of the colonial master. Post-independence, many African countries have battled to realise economic and social emancipation. In most cases, only a level of political independence exists. It is thus critical that in order to deliver true emancipation, Africans are called upon to tackle the colonial knowledge system. In linking it to higher education, it can be viewed as a call to adapt curricula and syllabi to ensure that teaching and learning is adapted to African realities and conditions. Thus, teaching of IK can be a viable tool in the decolonisation and Africanisation of the curriculum. Transforming education in Africa would be truly meaningful if Africans realise the importance of that which belongs to the continent.

Given the decontextualised state of curricula and Eurocentric nature of knowledge production and dissemination in South African higher education and Africa in general, the concept of 'Africanisation' is contemporary. This paper discusses the importance of integrating IK into the classroom while pointing

³ R Barsh, 'United Nations Seminar on Indigenous Peoples and State' (1989) 3 *Journal of International Law* 599.

⁴ M Letseka, 'African Philosophy and Educational Discourse,' (2000) *African Voices in Education*, 92.

⁵ GEF Urch, 'The Africanisation of the Curriculum in Kenya (1968) Ann Arbor: University of Michigan.

⁶ MB Ramose, 'In Search of an African Identity' (2004) 3 *South African Journal of Education* 138-160.

⁷ V Msila, (n 1) 312.

⁸ V Msila (n 1) 311.

⁹ P Kallaway, 'From Bantu Education to People's Education' (1988) Cape Town: University of Cape Town.

¹⁰ GEF Urch (n 5) 71.

¹¹ A Tamburro, 'Including Decolonization in Social Work Education and Praxis' (2013) *Journal of Indigenous Social Development* 1-16.

¹² JL Fernando, 'NGOs and the Production of Indigenous Knowledge under the Condition of Postmodernity' (2003) *Annals of the American Academy of Political and Social Science*, 590 (1), 54-72.

¹³ V Msila (n 1) 313.

at the contemporary debate of Africanisation of the curriculum. The use of insider perspectives on knowledge generation gives us the edge in developing relevant African curricula. According to Seepe¹⁴, a radical restructuring of education in Africa which makes education relevant to African challenges can hardly be complete without a serious consideration of IK. IK can become the true catalyst of modern pedagogy if seriously considered.

2. SHAPING THE RESEARCH QUESTION

The contemporary discourse that depicts IK as less scientific and backward is equally portrayed through inappropriate and irrelevant current curricula. The call for recognition of IK and its teaching is also supported by the desire for the Africanisation of higher education. Both these aspects can be understood as the adaptation of the subject matter, and teaching methods, geared to the physical and cultural realities of the African environment.

3. DEFINING INDIGENOUS KNOWLEDGE

A universally accepted definition of IK is hard to find. The definition given here is one that is supported by the context of this paper. IK is described as the knowledge systems developed by a community as opposed to the scientific knowledge that is generally referred to as 'modern' knowledge.¹⁵ Indigenous knowledge is the basis for local-level decision-making in many rural communities. IK constitutes the knowledge that people in a given community have developed over time and continue to develop. It has value not only for the culture in which it evolves, but also for scientists and planners striving to improve conditions in rural localities. Accordingly, IK is defined as a combination of knowledge systems consisting of technology, social, economic and philosophical learning. Indigenous communities themselves

believe that their IK is their constantly refined wisdom that has been passed on from their ancestors and the elders in their communities with a capability to survive for many centuries in the unique locations they identify as their homelands.

This knowledge is naturally passed down from one generation to another. In addition to this definition, Ellen and Harris¹⁶ conclude that IK is localised to a particular place and is generated by people living in those places. It is manifested through trial and error and deliberate experiment.¹⁷ IK is alive to evolution that stands the test of time. In its full realisation, IK is holistic, integrative, situated within the broader cultural traditions, and is empirical rather than hypothetical.¹⁸ This is also to say IK is a 'living science' or a peoples' science, it is not static but changes with the times. Linking the above explanation to Africanisation means IK is compatible with African knowledge systems that are now a big reference point of research in Southern Africa and beyond.

4. DEFINING AFRICANISATION

Africanisation is defined in relation to educational reform that brings African culture into formal schooling.¹⁹ Makgoba²⁰ defines Africanisation as a process of inclusion that stresses the importance of affirming African cultures and identities in the world community. He adds some characteristics that include it as a learning process and a way of life for Africans. In it there is no exclusivity but involves the incorporation, adaptation and integration of other cultures into and through African visions to provide the dynamism, evolution and flexibility so essential in the global village. Thus, African knowledge systems are not exclusively indigenous since they are able to incorporate other knowledge systems beyond the continent of Africa. By implication, it means that westernisation needed not to discard IK since the two can be

¹⁴ S Seepe, 'Editorial Notes' (2004) 18 South African Journal of Higher Education, 15.

¹⁵ LT Ajibade, 'A Methodology for the Collection and Evaluation of Farmers Indigenous Environmental Knowledge in Developing Countries' (2003) African Journal of Indigenous Knowledge Systems, 110.

¹⁶ RF Ellen & H Harris, 'H. Introduction' in R Ellen, P Parkes, and A Bicker (Eds.), *Indigenous Environmental Knowledge and its Transformations: Critical Anthropological Perspectives* (Amsterdam: Harwood, 2000), 33.

¹⁷ K Mehta, TR. Alter, LM. Semali, and A M Academ, *IK Connections: Bringing Indigenous Knowledge and Perspectives into the Classroom* (2013) <<http://jces.ua.edu/academik-connections-bringing-indigenous-knowledge-and-perspectives-into-the-classroom/>> accessed 18 July 2020.

¹⁸ *ibid* 73.

¹⁹ E Van Heerden, 'Cultural Diversity and Schooling' in EM Lemmer & DC Badenhorst (Eds), *Introduction to Education for South African Teachers* (Kenwyn: Juta, 1997).

²⁰ Makgoba, 'Makoko: 'The Makgoba Affair: A Reflection on Transformation,' (Florida: Vivli, 1996).

infused when this is good for the Africans.²¹ Ironically, African knowledge systems have also influenced the knowledge systems of other continents. For the past few decades, there has been a sudden rush by a number of Western pharmaceutical companies to invest in research and development programmes that seek to test the medicinal value of medicines that are used by indigenous communities.

Le Grange also supports this idea of co-existence of African knowledge systems and Western knowledge systems.²² Africanisation will in turn mean that this is not a process of getting rid of the already entrenched Western knowledge systems already being practiced in Africa. There is a need to instil a sense of security; if this happens, Africa could borrow from the West without fear that changes would destroy the African character.²³ This paper argues that Western knowledge systems need to adapt to the African context for them to prove valuable and functional in African communities. In addition, Western knowledge systems can learn a lot from their African counterparts. Mutwa²⁴ opines that in Western civilisation, people live in a world of separatism, where things, which ought to be seen as part of a greater whole, are separated. On the contrary and as exemplified in the African knowledge systems, education needs to reflect the unity between various factors of life.²⁵

Africanisation would also involve the indigenisation of African knowledge systems. This becomes a process of defining or interpreting African identity and culture. Ramose²⁶ expands this concept by identifying it as an African experience, which is a source for the construction of knowledge. Higgs²⁷ invokes the notion of 'ubuntu' and its attributes of humanity, human allegiances, and humanistic ideals. Ubuntu is widely defined as humanism and communalism.²⁸ This expounds why African

identity is part and parcel of a living knowledge system. This is why Mbingi²⁹ explains that 'ubuntu' literally means 'I am because you are' - one can only be a person through others. Relations among individuals in a community bring about the true humanity. Despite it being the major fabric of strength for the African people this attribute of 'ubuntu' became one of the weak links that was exploited by imperialism through easy acceptance of other people and their teachings.³⁰ According to Prinsloo³¹ the attributes of humanism involve alms-giving, sympathy, care, sensitivity to the needs of others, respect, consideration, patience and kindness. This aspect of humanism is considered more paramount than the desire to derive gain from inventions and discoveries that occur especially in the pharmaceutical industry. An African traditional healer is more inclined to treat the illness or disease of a fellow villager for free and even share the knowledge of the traditional medicine as opposed to a Western doctor whose mandate and confines of running a business will in most cases influence him to seek compensation for the services rendered. Waghid³² sees African influenced IK as having the potential to promote justice, courage and truthfulness in people. In linking this to intellectual property rights (IPRs) as defined through some of its theories, Parker³³ speaks of Africanised scholarship that ought to include the notion of 'critical activism' concerned with justice and human rights. This is also an attribute of 'ubuntu'. This needs to be part of each and every student's learning process that prepares them to function well in the society. An education system that prepares the well-equipped student to give back to the community where he or she comes from is fit for purpose. In addition, the utilitarian theory advocates that when lawmakers legislate in the field of IP, the result must be the maximisation of social welfare.

²¹ K Wirendi, 'Proegomena to African Philosophy of Education' (2004) South African Journal of Higher Education, 25.

²² L Le Grange, 'Western Science and Indigenous Knowledge: Competing Perspectives or Complementary Frameworks?' (2004) South African Journal of Higher Education, 85.

²³ GEF Urch (n 5) 17.

²⁴ CV Mutwa, 'Isilwane - The Animal' (1997) Cape Town, 1.

²⁵ V Msila (n 1) 313.

²⁶ Ramose (n 6) 158.

²⁷ P Higgs, 'African Philosophy and the Transformation of Educational Discourse in South Africa' (2003) African Journal of Education, 21.

²⁸ P Higgs & Van Wyk B, 'Lifelong Learning Revisited: An African Educational Discourse' (2007) 11 Education Change, 114.

²⁹ L Mbingi, 'In Search of the African Business Renaissance: An African Culture Perspective' (2000) Randburg: Knowledge Resources.

³⁰ L Mbingi (n 29)

³¹ ED Prinsloo, 'Ubuntu Culture and Participatory Management' in PH Cotzee & APJ Roux (Eds), *The African Philosophy Reader* (London: Routledge, 1997).

³² Y Waghid, 'African Philosophy of Education: Implications for Teaching and Learning' (2004) 18 South African Journal of Higher Education, 53.

³³ B Parker, 'Back on the Chain Gang: Some Difficulties in Developing a (South) African Philosophy of Education' (2003) 30 Journal of Education, 40.

There is therefore a need to strike a balance between encouraging invention or innovations and ensuring that social welfare is not relegated to backburner status.³⁴ I thus argue that IK needs protection by lawmakers as well as the Western judicial system that is prevalent in African countries. When this happens, it becomes evident that Africanisation is producing the desired results.

Louw³⁵ views Africanisation as a way of transcending individual identities, seeking commonality, as well as a way of recognising and embracing 'otherness'. IK has the opportunity to bring forth an inclusive approach to education.³⁶ These attributes have been the founding principles of African leaders like Julius Nyerere of Tanzania and Kwame Nkrumah of Ghana.³⁷ Their identity of the village or community as part of the family, extending it beyond the tribe is pertinent. This village-based ideology of the founding fathers of African emancipation produced remarkable results that led to the realisation of an African continent free from colonialism. This gives rise to communitarianism that is practiced when individuals consider themselves as communal beings and not isolated.³⁸ The aspect of commonality is critical in understanding the attributes of Africanisation of IP and how it should be taught so that students and practitioners alike are convinced of this important issue. Nyerere and Nkrumah embraced the idea of broad inclusivity as a virtue. This was not the genesis of the idea; the fact that this aspect was accepted in many parts of Africa is a clear indication that Africans were living this virtue. When students of IP study the subject in this context, they are in a better place to explain to communal stakeholders what IP protection means for their IK. The communal stakeholders' voices need to be heard and be considered as valuable contributions to the body of science.

In the above discussion we find a desire for the establishment of curricula that is all-inclusive. Many scholars have also argued for the need to give IK the same protection rendered to IP along the line of inclusivity. This is particularly important in catering for the protection of particular individual countries under sui generis models.³⁹ Nkoane⁴⁰ gives an interpretation of an Africanised educational system that maintains African awareness of the social order and rules by which culture evolves. Higgs and van Wyk⁴¹ call it an education within an African context that sheds light on how Africans learn and construct knowledge and focusing on the underlying beliefs and values that constitute education within an African context. In addition fostering the understanding of African consciousness while facilitating an educational system that would result in the production of knowledge, which is relevant, effective and empowering.

If African consciousness in our education system is ignored, collaboration and cooperation between universities and communities may quickly become strained, especially if the academic knowledge produced seems unrelated to, or out of touch with, the realities of peoples' local life. The African IK is based on ecological relationships in nature⁴². When people feel that their culture and beliefs are not respected, their interest in engaging with outside experts may diminish. We may end up with knowledge that is not applicable to the solving of real life challenges. Knowledge devoid of contextual considerations is not useful. Knowledge generated as well as educational purposes formulated, need to respond to the immediate environment of Africans.⁴³ At the North West University IKS Centre in South Africa, the majority of students undertake their research studies in the communities where they come from. In my experience of grading the work that comes because of this exercise, the participation of the

³⁴ L Ndlovu, 'Access to Medicine under the WTO TRIPS Agreement: A Comparative Study of select SADC Countries' (2014) Doctoral Thesis University of South Africa.

³⁵ W Louw, 'Africanisation: A Rich Environment for Active Learning on a Global Platform' (2010) 32 *Progressio* 32, 42.

³⁶ V Msila (n 1) 313.

³⁷ J Benjamin, 'Decolonizing Nationalism: Reading Nkrumah and Nyerere's Pan-African Epistemology' (2011) *Journal of Emerging Knowledge on Emerging Markets* Vol. 3 November 2011, 229-269

³⁸ K Gyekye, 'Person and Community in African Thought' in A.H. Coetzee & APJ Roux (Eds), *The African Philosophy Reader* (London Routledge, 1998).

³⁹ S K Verma, 'Protecting Traditional Knowledge: Is a Sui Generis System an Answer?' (2004) 7 *Journal of World Intellectual Property* 765, 800.

⁴⁰ MN Nkoane, 'The Africanisation of the University in Africa' (2006) 13 *Alternation*, 49.

⁴¹ P Higgs & B Van Wyk (n 25) 16.

⁴² V Msila (n 1) 20.

⁴³ V Msila (n 1) 313.

community in the study adds much value to the study. Africanisation of the curricula is specifically aimed at enabling students to use contextualised theories to enable them to engage in best-practice work. The decolonisation of the curriculum empowers students to develop their own understanding of the African context and to become able to deliver culturally sensitive knowledge. This entails a strong emphasis on challenging the status quo and the relevance of existing knowledge systems (Western theories) in the African context.

5. WHY AFRICANISATION

Africanisation can be applied in different contexts. For the purposes of this paper, it is now clear that Africanisation is being applied in the context of developing curricula that takes into cognisance the African setting where students find themselves in. It comes at the backdrop of a long-held view that some of the education being taught on the African continent is out of touch with the reality of the continent. In addition, part the Eurocentric aspects of the curriculum was purposely put in place to systematically exclude or replace African knowledge systems that were and are still relevant to the needs of the society where they exist. Africanisation of curricula implies that education and training as well as praxis be informed by the reality of the South African context, the viewpoints of the people of South Africa and their descriptions of what is needed to build a just society.⁴⁴ The term 'Africanisation', 'decolonisation' and 'contextualisation' are interrelated in this discussion.

This paper argue that, in order for Africanisation to take place, education and training on the African continent should be based on the realities of the African contexts in which our service beneficiaries are functioning. Therefore, we need to explore how we can ensure that we develop curricula that will empower students, include them in exploring solutions for societal problems, through participation, collaboration and cooperation and guide them to become effective facilitators of community development where beneficiaries participate

in decision-making processes that affect their lives. For decolonisation to be meaningfully effective, it requires that we actively engage with processes based on a desire to reclaim and revalue the African socio-economic heritage or culture. The present focus on decolonisation in academic discourses could be seen as a reflection on a need to, after so many decades of colonial rule, move beyond the colonised eras to an era where indigenous voices determine future praxis. It should be noted that, if we intend to decolonise and to acknowledge IKS (i.e. the African praxis and ways of doing, knowing and being), we must be informed by the African people and utilise this information when developing academic curricula and material with the aim to inform praxis. It requires a bottom-up approach where grassroots information is not only being acknowledged but also used to inform the development of a decolonised curricula. Colonisation has caused multigenerational trauma. The colonisation of the mind brought about a lack of self-worth based on not being heard, that lingers on after the end of colonialism. This challenge can be addressed when we start to not only to hear the perspectives, experiences and needs of the people but when we start to act on these expressions, showing that the viewpoints of those on grassroots level matter.

6. THE NEXUS BETWEEN IK AND AFRICANISATION

Emanating from the above discussion it is clear that there are a number of cross cutting issues that gives compelling connection between IK and Africanisation. These issues are as follows:

- Notion of commonalities
- Affirmation of one's culture, tradition and value systems
- Fostering an understanding of African consciousness and finding ways of blending Western and African methodologies

The use of IK is one way of understanding the term 'Africanisation', as it implies that an understanding of the African context and the socio-economic realities of the

⁴⁴ M van der Westhuizen, TG; J W. Beukes, 'Are we hearing the Voices? Africanisation as Part of Community Development,' (2017) *Herv. teol. stud.* vol.73 n.3 Pretoria

African people exists. Considering the diversity of the African context, Africanisation implies that we base our efforts to obtain new insights and to develop new praxis on the contextual realities of the beneficiaries of services within the specific African context. In addition, it requires that we utilise current knowledge bases which are often representing a Western perspective and explore how it relates to the African context. Even though there is a connection between IK and Africanisation a number of challenges that emanate from this exercise need to be discussed.

7. CHALLENGES

It would be a fallacy to state that IK alone will address social needs; however, the introduction of IK teaching in universities is just one factor that can address the challenges of relevance of the curriculum⁴⁵. Other challenges that arises out of the IK and Africanisation debate need consideration. Greenstein⁴⁶ has long argued that Africanisation poses the greatest challenge for the renewal of education in general and curriculum policies in particular. This may be true if one considers that until the processes of knowledge production and dissemination are consistent with the contexts and cultural orientation of the people at universities present, the transformation of higher education institutions remains incomplete. Students at African universities most of the time face a cultural shock when they enter the modern university. Majority of them come from rural areas. The culture shock forces them to abandon their cultural orientation. In most cases, they then consciously or sub-consciously reject their rich history and replace it with a contemporary culture that does not favour IK.

Entering into a formal education system like the contemporary university must not be seen as a way to unseat

or compete with existing IK pedagogies and methods. This process should rather be embraced as the process of integrating new perspectives and epistemologies. It must be shaped by the desire to unify or get a common ground. The way we view and understand the world around us is uniquely shaped by attitudes, values, and beliefs acquired over the course of our lives.⁴⁷ Every situation we encounter, every experience we have, directly contributes to our epistemology: the manner in which we come to know what we know.⁴⁸ Thus, when students enter the university classroom, it should not be a case of them being told to discard the knowledge they already possess. This is possible if one considers that cultures tend to be permeable and are constantly influenced by other cultures.⁴⁹ IK pedagogies present a system that would meaningfully involve learners in the discovery of their own environment and is bound to support lifelong learning.⁵⁰ Matos⁵¹ argues that a major 'disease' of education and research in Africa is the systematic attempt to dismiss the intrinsic value of African culture, language, customs and practices from the curricula. On the contrary, conservation of IK for and by the local peoples could have positive implications for protecting their IP from predations by outsiders.⁵² Intellectual engagement must not lead to marginalisation of IK. Education about how to incorporate indigenous perspectives in the study of science at all academic levels is lagging in some disciplines, and virtually absent in others.⁵³

8. HOW THIS CAN BE DONE

There is no need to argue the use of science to solve local problems in many disciplines including medicine, engineering, food science, and agriculture. According to Seepe⁵⁴, the utilisation of IK technology and African

⁴⁵ V Msila (n 1) 314.

⁴⁶ R Greenstein, 'Education, Identity and Curriculum Policies in the New South Africa' in P. Kallaway, A., Fataar & G. Donn (Eds.) *Education After Apartheid: South African Education in Transition* (Rondebosch: University of Cape Town, 2007).

⁴⁷ K Mehta, TR. Alter, LM. Semali, and A M Academ, 'IK Connections: Bringing Indigenous Knowledge and Perspectives into the Classroom' <<http://jces.ua.edu/academik-connections-bringing-indigenous-knowledge-and-perspectives-into-the-classroom/>> accessed 05 June 2018.

⁴⁸ *ibid.*

⁴⁹ L Le Grange (n 20) 19.

⁵⁰ V Msila (n 1) 313.

⁵¹ Matos N, 'The Nature of Learning, Teaching and Research in Higher Education in Africa' in P. Higgs, N.C.G. Mda, P. Vakalisa, T.V. Mda & N.T. Assie-Lumumba (Eds.), *African Voices in Education* (Cape Town: Juta, 2000), 12-38.

⁵² F Indígena (FSI) and B Kothari, 'Rights to the Benefits of Research: Compensating Indigenous Peoples for their Intellectual Contribution' (1997) *Human Organization*: Summer, Vol. 56, No. 2, 127-137 <<https://doi.org/10.17730/humo.56.2.j63678502x782100>> accessed 01 June 2018

⁵³ Mehta, et al (n 43) 73.

⁵⁴ S Seepe (n 14) 17.

knowledge systems is the key to unlocking the door that has prevented the masses from accessing mathematics, science and engineering. In many African communities, students who have left college and university find themselves unemployed. One needs to ask, how can this be when the communities they come from need assistance? In South Africa, some have often argued that the reason why there are so many unemployed university graduates has to do with them having studied the wrong qualifications.⁵⁵ In this discussion, one needs to ask, 'what is a wrong qualification?' The decision to study a particular discipline needs to be informed by many rationales, one of it being career prospects as well as the needs of a learner's community. When the learner's community and background are taken into consideration, learning is more likely to be effective.⁵⁶ As discussed earlier, the use of IK in teaching can thus link the need to solve these problems and the formulation of prospective solutions. Collaboration and cooperation between universities and communities is the key. However, if this is not done properly and if the academic knowledge produced seems unrelated to, or out of touch with, the realities of peoples' local life, the challenges will remain.

Teaching of IK emphasises contextual considerations and in that way the interpretation and utilisation of data will produce the desired results. With the utilisation of IK, how data are interpreted and utilised will change. IK teaches that in approaching community development and engagement projects, it is imperative that we consider the cultural context of our work, as well as the knowledge that is produced within that context. Indigenous knowledge is uniquely valuable, as it provides insights and information that directly reflect the opinions, values, and attitudes of the local people engaged in a community development initiative.⁵⁷ The discussion now moves to my personal experiences of teaching IK and how it has shaped the way I share knowledge with students and other academics.

My teaching of the subject of IP at the IKS Centre at the North West University in South Africa has been a fulfilling

experience in both the realisation of the need for the reconstruction of the pre-colonial past and as an orientation to the problems of society and social change. All the students at the IKS Centre are required to come up with a project that involves the community in terms of how IK is practiced in the communities. It is interesting to note that most of the students select to do a study of the rural communities where they come from. This is a pertinent observation that speaks of students' capability to apply the knowledge gained in solving real life challenges of their communities while they obtain a qualification at the university through the IKS Centre. The IKS Centre is at the forefront of addressing both academic and societal challenges and extending the university's knowledge and expertise to solve problems affecting communities by utilising the IK that resides within those communities. A number of students have chosen topics that range from examination of nutritional value of indigenous foods, indigenous medicines, IK methods of farming, weather patterns prediction and preservation of natural resources like water in the rivers and the forest trees. Other students also chose topics that address traditional methods of dispute resolution and traditional games that enhance learning skills (communication and numeracy skills). Some of the student's work is of such good quality that they are encouraged to continue with the studies at postgraduate level. At Postgraduate level, students will end up enrolling for the Master's and Doctoral programmes. The IKS Centre has even attracted students from the whole Southern African region. This shows how import IK has become not just for South Africa but for the whole continent of Africa.

This enterprise has been successful due to a number of reasons. I will mention a few here. Firstly, the IKS Centre makes sure that the curriculum is inclusive of indigenous social and cultural history and informed by the full scope of ideas and events that have shaped and continue to shape human growth and development. Students are able to relate to their upbringing and surroundings in this process of learning. Secondly; students, communities and academic

⁵⁵ Z Bongani, 'Graduates and their Unemployment Dilemma' Mail & Guardian <<https://mg.co.za/article/2019-08-07-graduates-and-their-unemployment-dilemma/>> accessed 18 July 2020

⁵⁶ U Bude, 'Primary Schools, Local Community and Development on Africa' (1985) 8 Baden-Baden: Nomos Verlagse-sellschaft.

⁵⁷ Mehta, *et al* (n 43) 73.

institutions are able to learn from indigenous knowledge innovations. For this reason, a number of ground-breaking projects have been produced through IK innovations. Thirdly, the classroom has become an open marketplace of diverse ideas and practical discussions aimed at real solutions. The University has gone on to initiate successful community engagement projects with the communities of the study area. As part of the learning process, students are required to present their work to fellow classmates in a formal setting where they critique each other while being guided by their teachers. In some instances, community members form part of these discussion sessions. This experience illustrates why IK matters in community engagement and scholarship. In this experience, there is a growing recognition of the importance of integrating IK into the curricula. The socially and relevant theses of IK is that we are able to effectively educate students for the globalised world.⁵⁸

9. CONCLUSION

A growing number of African intellectuals have acknowledged that the time for the recognition of IK in schools is long overdue.⁵⁹ The founding father of African independence from colonial rule, Nkwame Nkrumah (1956) emphasised the need for real African universities, bearing in mind that once it has been planted in the African soil, it must take root amidst African traditions and cultures.⁶⁰ For the African university to be truly useful to Africa and the world it has to be grounded in African communities and cultures.⁶¹ Future research should investigate further, the role of internationalisation in Africanisation and IK. African higher education institutions are increasingly becoming defined by internationalisation, further putting to the periphery the desire to Africanise. This trend should be resisted and IK should be placed at the forefront of this exercise. There is a need to approach research, teaching, and outreach in a discipline that incorporates knowledge generated in the local context. IK

needs to be embraced as a means of enhancing our discussion concerning the challenges that face local and global communities. African knowledge systems can be tapped as a foundational resource for the social-educational transformation of the African continent, and how IK can be politically and economically liberating.⁶² In the end, introducing IK as a tool of Africanisation assists students to engage in and to facilitate processes where local indigenous knowledge is linked and blended with existing academic knowledge. Additionally, in the multicultural African context, the link between different indigenous praxis and knowledge should be explored. The latter is aimed at discovering what ‘...we have in common with other African indigenous praxis and knowledge, and indeed with all other people of the globe, especially those with deep rooted indigenous foundations’.⁶³ Ultimately, The Africanisation of our knowledge and skills serves as a stimulus to construct transformation towards a decolonised society.

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⁵⁸ M Battiste & J Henderson, *Protecting Indigenous Knowledge and Heritage* (Saskatoon, SK: Purich Publishing Ltd, 2000).

⁵⁹ V Msila (n 1) 310.

⁶⁰ J Benjamin (n 37).

⁶¹ M Makgoba & S Seepe ‘Knowledge and Identity: An African Vision of Higher Education Transformation’ in S. Seepe (Ed.), *Towards an African Identity of Higher Education* (Pretoria: Vista University, 2004) 1-44.

⁶² P Higgs P & B Van Wyk (n 26) 8.

⁶³ JA Hammersmith, *Converging Indigenous and Western Knowledge Systems: Implications for Tertiary Education* (Doctor of Education Thesis: University of South Africa, 2007) <<https://core.ac.uk/download/pdf/43165783.pdf/>> accessed 18 July 2020.

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SCHOLARSHIP AND TEACHING OF INTELLECTUAL PROPERTY AND INNOVATION IN KENYA AND AFRICA: CURRICULUM CONTENT, METHODOLOGY AND REFORMS

Ben Sihanya*

ABSTRACT

I advance a three-pronged argument in this essay. First, scholarship and teaching of intellectual property (IP) need to be reconceptualized to cover IP, innovation, transfer of technology (ToT) and licensing as well as topics that are relevant to Kenya's and Africa's sustainable development including socio-economic, cultural and political development. Second, IP scholarship and teaching in Kenyan and African universities should be inter-disciplinary and inter-sectoral and should also be integrated with sub-national (or county), national, sub-regional and Africa-wide frameworks on research, science, technology, and innovation (RSTI). Third, there is need to reform the objectives, agenda and curricula on university scholarship and teaching so that IP, innovation, ToT and licensing law should be offered in all universities. Moreover, they should be offered to non-law students and staff leading to awareness or sensitization at certificate, diploma as well degree, master's and PhD qualifications.

1. BACKGROUND TO SCHOLARSHIP AND TEACHING OF INTELLECTUAL PROPERTY AND INNOVATION IN KENYA AND AFRICA

Scholarship and teaching of intellectual property (IP) need to be reconceptualized to cover IP, innovation, transfer of technology (ToT) and licensing as well as topics that are relevant to Kenya's and Africa's sustainable development including socio-economic, cultural and political development. This is because IP is an interdisciplinary field as it covers all sectors of the economy including the legal, business, medical, agricultural, industrial, and education fields. IP scholarship and teaching in Kenyan and African universities should be inter-disciplinary and inter-sectoral and should also be integrated with sub-national (or county), national, sub-regional and Africa-wide frameworks on research, science, technology, and innovation (RSTI). The arts, humanities and social sciences are sites of innovation or creativity as well as contributors to the analysis, debates, prescription, and reform of innovation policies. There are important interdisciplinary

contributions in literature, sociology, anthropology, cultural studies, political science, history and economics.

IP has become an increasingly important generator of economic, social and cultural growth and development.¹ This has led to the need for a clear understanding of IP and the enhancing IP scholarship, teaching and education in order to meet the growing need for informed and effective personnel trained in the field.² For these reasons, there is need to reform the objectives, agenda and curricula on university scholarship and teaching of IP, innovation, ToT and licensing.

This study focuses on the role that various Kenyan and African institutions have taken in enhancing scholarship and teaching of IP.

2. METHODOLOGY ON IP, INNOVATION AND TECHNOLOGY TRANSFER SCHOLARSHIP, RESEARCH AND TEACHING IN AFRICA

"Scholarship" has been conceptualized in various ways. Some have focused on the "product" of scholarly, professional, and creative work in conceptual scholarship while others have focused on the "process." In this essay we focus on IP scholarship as the creation, development and maintenance of the intellectual architecture of IP subjects and disciplines in forms such as journal articles, books, monographs, encyclopedia, dictionaries, catalogues and contributions to major research databases.³

IP scholarship in Kenya and Africa is supported by universities, colleges, research institutes or centers, libraries, archives, publishers and scholarly consortia or communities.⁴ These are mainly institutions that promote learning and education. These institutions give scholars and students the freedom to conduct research and to express their ideas in their works. Scholars and students are therefore able to publish their work and make it available to others.

With the development of IP and its fast-rising popularity, various scholars have taken up the mantle to research and develop African IP literature through books and articles. While this is a positive step in the promotion of IP scholarship, research and learning in Africa, there is still a lot more that is needed to be done.

Most of the IP scholarship in Africa is based on the review of Constitutions, and national and international laws and policies and most of the literature on IP is by western

* Ben Sihanya, 'Intellectual Property and Innovation Audit, Valuation, and Commercialisation in Kenya' (2018) A paper presented at the University of Nairobi 2018 Innovation Research Symposium. Cf. Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Cases and Materials* (Sihanya Mentoring and Innovative Lawyering, Nairobi & Siaya, forthcoming 2018).

¹ Yo Takagi, Larry Allman, and Mpazi A. Sinjela, *Teaching of Intellectual Property* (Cambridge University Press, Cambridge, New York, 2011).

² *ibid.*

³ Ben Sihanya, 'Reflections on Open Scholarship Modalities and the Copyright Environment in Kenya' in Jeremy De Beer, Chris Armstrong, Chidi Oguamanam & Tobias Schonwetter *Innovation & Intellectual Property: Collaborative Dynamics in Africa* (UCT Press, Cape Town, 2014).

⁴ *ibid.*

scholars from the US and UK. There is need for African scholars to develop literature relevant and authentic to the African situations. This will help develop an IP curriculum that is relevant to African students. This will reduce the over reliance on western materials in IP teaching and scholarship in Africa.

For all these to be achieved there is need for cooperation among universities and institutions of higher learning and their respective governments. Without governmental support, it is very hard for these institutions to singlehandedly tackle all these challenges. It is for this reason that RSTI institutes are important. Their main aim is to ensure they support and promote RSTI in all sectors of the economy while also involving public and private institutions in key discussions and decisions involving RSTI. Governmental support and corporation are therefore key in ensuring that IP teaching and training is conducted at a national strategic perspective in order to facilitate national debate and policy formulation. This will in turn lead to the establishment of institutional bases such as IP research centres and promote more effective mechanisms on the collection and dissemination of current and relevant documentation of IP education and research.

3. RESEARCH SCIENCE TECHNOLOGY AND INNOVATION INSTITUTES IN KENYA AND AFRICA

IP scholarship and teaching in Kenya and Africa in universities are key in securing sustainable development, including socio-economic, cultural and political development. Thus, IP scholarship and teaching should be inter-disciplinary and inter-sectoral and should also be integrated with sub-national (or county), national, sub-regional and Africa-wide frameworks on research, science, technology, and innovation (RSTI). And have sciences including the arts, humanities and social sciences.

3.1 Legal and Policy Framework on Research Science Technology and Innovation Institutes in Kenya and Africa

RSTI institutes or organisations are part of the society and general framework or architecture on the research scholarship, research, training and teaching of IP, innovation and ToT. RSTI plays a crucial role in socio-

economic growth and development, (global) competitiveness, and meaningful employment creation while playing as a key component of social integration, sustainable development and poverty eradication based on equity, freedom, justice, governance, peace and prosperity.⁵ In Kenya and other African countries, RSTIs are recognized as essential and key components to strengthened governance and management at sectoral and institutional levels and further to ensure financial sustainability.⁶

RSTI in Kenya is provided for by the Science, Technology and Innovation Act No 28 of 2013.⁷ The Act aims to facilitate the promotion, co-ordination, and regulation of the progress of research, science, technology and innovation.⁸ The Act establishes three key institutions that play a critical role in the coordination of important projects and tasks in all sector ministries, universities and research institutes and centres with respect to RSTI.⁹ These are the National Commission for Science, Technology and Innovation (NACOSTI), the Kenya National Innovation Agency (KENIA) and the National Research Fund (NRF).¹⁰

3.2 Institutional Framework on Research, Science, Technology and Innovation Institutes in Kenya and Africa

Research, science, technology and innovation (RSTI) institutes play an important role in Kenya and Africa in promoting research and development (R&D). the main mandate of RSTI institutes is usually to carry out research, coordinate and cooperate with other research organisations and institutions of higher learning on relevant matters of research and training.

3.2.1 National Commission for Science, Technology and Innovation (NACOSTI)

The National Commission for science, technology and innovation (NACOSTI) is established by section 3 of the Science, Technology and Innovation Act No 28 of 2013 (STI Act), which repealed the Science and Technology Act Cap 250,¹¹ as a body corporate. NACOSTI's main mandate is establishing RSTI offices in every county,¹² communicating research and development (R&D) issues to the National Government, promoting RSTI in all

⁵ See Republic of Kenya, 'A Policy Framework for Science, Technology and Innovation' (2012) Ministry of Higher Education Science and Technology Sessional Paper < https://www.strathmore.edu/wp-content/uploads/2016/10/sti_final_policy_draft-1.pdf> accessed 18 June 2018.

⁶ See Kenya's Vision 2030 and Millennium Development Goals.

⁷ Kenya's Science, Technology and Innovation Act No 28 of 2013

⁸ Preamble of Kenya's Science, Technology and Innovation Act No 28 of 2013

⁹ Republic of Kenya, 'A Policy Framework for Science, Technology and Innovation' (2012) Ministry of Higher Education

Science and Technology Sessional Paper < https://www.strathmore.edu/wp-content/uploads/2016/10/sti_final_policy_draft-1.pdf> accessed 18 June 2018.

¹⁰ Kenya's Science, Technology and Innovation Act No 28 of 2013.

¹¹ National Commission for Science, Technology, and Innovation website < <https://www.nacosti.go.ke/about-us/history>> accessed 18 June 2018.

¹² There are 47 counties in Kenya under the First Schedule of the Constitution 2010. See the Kenyan County Government Act 2012.

counties, forming partnerships with local industries and institutions of learning, among others.¹³

3.2.2 Kenya National Innovation Agency (KENIA)

The Kenya National Innovation Agency (KENIA) is a body corporate established by section 28 of the STI Act under the Ministry of Education.¹⁴ Its core mandate is to develop and manage Kenya's National Innovation System as well as the co-ordination, promotion and regulation of the national innovation ecosystem.

3.2.3 National Research Fund (NRF)

Section 32 of the STI Act establishes the NRF. The main purpose of this research endowment fund is to support the advancement of scientific research, inventions, and innovations and to build capacity in the RSTI sector for national development.¹⁵ The fund is supposed to target multi-institutional and multi-disciplinary research from public and private institutions in Kenya.¹⁶

3.2.4 Consolidated Research and Development Institutions

The Kenyan Science and Technology Act, Cap 250 (now repealed) had established six (6) R&D institutes.¹⁷ It was replaced by the STI Act. These R&D institutes were retained under the STI Act to continue to operate as they had been accredited under the Science and Technology Act, Cap 250.¹⁸ The purpose of these institutions is to promote RSTI in Kenya. These institutions include the Kenya Industrial Research and Development Institute (KIRDI), the Kenya Agricultural Research Institute (KARI), the Kenya Forest Research Institute (KEFRI), the Kenya Medical Research Institute (KEMRI), and the Kenya Trypanosomiasis Research institute (KETRI). Some of these have been merged and others have been restructured.¹⁹

3.2.4.1 The Kenya Industrial Research and Development Institute (KIRDI)

The Kenya Industrial Research and Development Institute (KIRDI) is a state corporation under the Ministry of Industry, Trade and Cooperatives²⁰ and is mandated to

undertake multidisciplinary R&D in industrial and allied technologies including: mechanical, electrical & electronics, chemical, ceramics and building materials, food, leather, textile, ICT, environment and energy.²¹ The technologies developed are to be transferred to Micro, Small and Medium Enterprises (MSMEs) and large industries to enhance their competitiveness and productivity.²²

3.2.4.2 Kenya Agricultural and Livestock Research Organisation (KALRO)

The Kenya Agricultural and Livestock Research Organisation (KALRO) emerged from the merger of KARI and other research institutions. It is a government organisation mandated with the task and duty of conducting research into, among others, crop and livestock production and marketing.²³ KARI was established by the now repealed the Kenyan Science and Technology Act, Cap 250. KARI accounted for more than half of the total research and development (R&D) expenditure in Kenya and was responsible for research on crops (except research on coffee, tea and sugarcane), livestock, and land and water resources. It has a network of national commodity and factor research centres responsible for generating knowledge and technology, and also regional centres responsible for applied and adaptive research in respective regions.²⁴

In 2013, KARI merged with Coffee Research Foundation (CRF), Tea Research Foundation of Kenya (TRF) and Kenya Sugar Research Foundation (KESREF) to form KALRO.²⁵ KALRO was established through the establishment of the Kenya Agricultural and Livestock Research Act No. 17 of 2013. The reorganization of KARI was so as to lead to higher efficiency in the delivery of services necessary to propel the advancement of the agricultural sector and national economy in general.²⁶

3.2.4.3 The Kenya Forest Research Institute (KEFRI)

The Kenya Forest Research Institute (KEFRI) is a state corporation provided for under the Science Technology

¹³ *ibid.*

¹⁴ Republic of Kenya, *Organization of the Government of the Republic of Kenya* Executive Order No. 1 of 2018.

¹⁵ Section 32 of Kenya's Science, Technology and Innovation Act No 28 of 2013. Cf. National Research Fund website <<http://researchfund.go.ke/background/>> accessed 18 June 2018.

¹⁶ *ibid.*

¹⁷ Fourth Schedule of the (now repealed) Kenyan Science and Technology Act, Cap 250.

¹⁸ Section 53 of the Kenyan Science Technology and Innovation Act, No. 28 of 2013.

²⁰ Republic of Kenya, *Organization of the Government of the Republic of Kenya* Executive Order No. 1 of 2018.

²¹ Fourth Schedule of the Kenyan Science Technology and Innovation Act No. 28 of 2013. Cf. Kenya Industrial Research and

Development Institute website < <https://www.kirdi.go.ke/>> accessed 29 June 2018.

²² *ibid.*

²³ Maureen Kiruka, Julius Okello, Violet Kirigua & Festus Murithi (eds), 'The role of the Kenya Agricultural Research Institute (KARI) in the attainment of household food security in Kenya: A policy and organizational review' (2012) <https://www.researchgate.net/publication/257788782_The_role_of_the_Kenya_Agricultural_Research_Institute_KARI_in_the_attainment_of_household_food_security_in_Kenya_A_policy_and_organizational_review> accessed 29 June 2018.

²⁴ *ibid.*

²⁵ KALRO, Kenya Agricultural and Livestock Research Organisation Strategic Plan 2017-2021' (2017) <<http://www.kalro.org/sites/default/files/strategic-Plan-KALRO-2017-2021.pdf>> accessed 30 June 2018.

²⁶ *ibid.*

and Innovation Act, No. 28 of 2013.²⁷ It is mandated to undertake research in forestry and allied natural resources.²⁸ KEFRI conducts research and development activities under five thematic areas namely: Forest productivity and Improvement; biodiversity and environment management; forest products development; social-economics, policy and governance and technical support services.²⁹

3.2.4.4 The Kenya Marine and Fisheries Research Institute (KMFRI)

Kenya Marine and Fisheries Research Institute (KMFRI) is a State Corporation that was established by the Science and Technology Act, Cap 250 that was repealed by the STI Act. The STI Act recognizes KMFRI as a national research institution under section 56, fourth schedule.³⁰ KMFRI's mandate is to undertake research in marine and freshwater fisheries, aquaculture, environmental and ecological studies, and marine research including chemical and physical oceanography.³¹ This is in order to provide scientific data and information for sustainable exploitation, management and conservation of Kenya's fisheries and other aquatic resources, and contribute to national strategies of food security, poverty alleviation, clean environment and creation of employment as provided for under Kenya's Vision 2030.³²

3.2.4.5 Kenya Medical Research Institute (KEMRI)

Kenya Medical Research Institute (KEMRI) is a State Corporation established through the Science and Technology Act Cap 250, which has since been amended to Science, Technology and Innovation Act 2013.³³ KEMRI's main mandate is; first, to carry out research in human health. Second, cooperate with other research organizations and institutions of higher learning on matters of relevant research and training. Third, liaise with other relevant bodies within and outside Kenya carrying out research and related activities. Fourth,

disseminate and translate research findings for evidence-based policy formulation and implementation. Fifth, cooperate with the Ministry of Health, the NACOSTI and the Medical Sciences Advisory Research Committee on matters pertaining to research policies and priorities.³⁴

3.2.4.6 Kenya Trypanosomiasis Research Institute (KETRI)

The Kenya Trypanosomiasis Research Institute (KETRI) is a research institution established under the section 53 and fourth schedule of the Kenya Science Technology and Innovation Act No 28 of 2013.³⁵ KETRI's main mandate was to carry out research and develop technologies for effective control of trypanosomiasis including collection and preservation of trypanosomiasis stabilities.³⁶ KETRI was later merged with KARI after the recognition by the government that there was need to further strengthen its agricultural research system to create an institutional framework to effectively manage, reorganize and consolidate agricultural research in Kenya.³⁷ KARI would later merge with Coffee Research Foundation (CRF), Tea Research Foundation of Kenya (TRF) and Kenya Sugar Research Foundation (KESREF) to form KALRO in 2013.³⁸

4. INTELLECTUAL PROPERTY MANAGEMENT OFFICES, TECHNOLOGY TRANSFER OFFICES AND INCUBATORS

Intellectual Property Management Offices (IPMOs), technology transfer offices (TTOs) and incubators play an important role in IP teaching and scholarship in Kenya and Africa. This is because they promote IP and innovation by funding R&D of individuals, public and private institutions.³⁹ They play an important role in connecting research institutions which are typically focused on basic research with the industry sector which is focused on development and commercialization.⁴⁰

²⁷ Fourth Schedule of the Science Technology and Innovation Act, No. 28 of 2013.

²⁸ Kenya Forestry Research Institute website < <https://www.kefri.org/> > accessed 29 June 2018.

²⁹ *ibid.*

³⁰ Fourth Schedule of the Science Technology and Innovation Act, No. 28 of 2013.

³¹ *ibid.* Kenya Marine and Fisheries Research Institute website < <http://www.kmfri.co.ke/> > accessed 29 June 2018.

³² Republic of Kenya, *Kenya Vision 2030: A Globally Competitive and Prosperous Kenya* (Government Printer Press, Nairobi, 2007).

³³ Section 53 and Fourth Schedule of the Science Technology and Innovation Act, No. 28 of 2013.

³⁴ Caroline Githinji, 'KEMRI Research Review Process' (2014) < https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=10&cad=rja&uact=8&ved=0ahUKEwjArq7RsPjbAhURGe wKHVPFCmsQFgSATAJ&url=https%3A%2F%2Fbioethics.medicin e.iu.edu%2Findex.php%2Fdownload_file%2Fview%2F312%2F41 4%2F&usg=AOvVaw0k8tYS-P6Xa5A_51-Eb-IU > accessed 29 June 2018. Cf. Kenya Medical Research Institute website <

<https://www.kemri.org/index.php/features-intro/background> > accessed 29 June 2018.

³⁵ Section 53 and Fourth Schedule of the Science Technology and Innovation Act, No. 28 of 2013.

³⁶ Grace Murilla, Joanna Auma, & Johnson Ouma (ed), 'Kenya Trypanosomiasis Research Institute Cyrobank for Human and Animal Trypanosome Isolates to Support Research: Opportunities and Challenges' (2014) PLOS Vol. 8, Issue 5 < <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.874.7019&rep=rep1&type=pdf> > accessed 29 June 2018.

³⁷ KALRO, Kenya Agricultural and Livestock Research Organisation Strategic Plan 2017-2021' (2017) < <http://www.kalro.org/sites/default/files/strategic-Plan-KALRO-2017-2021.pdf> > accessed 30 June 2018.

³⁸ *ibid.*

³⁹ Ben Sihanya, Intellectual Property and Innovation Law in Kenya and Africa: Cases and Materials (Sihanya Mentoring & Innovative Lawyering, forthcoming 2018).

⁴⁰ *ibid.* Cf. Graff G, Heiman A, & Zilberman D (eds), 'University Research and Offices of Technology Transfer' (2002) *California Management Review*, 45(1): 88-115.

Some IPMOs, TTOs and incubators have the necessary funds, facilities and connections that individual innovators or researchers do not possess and thus limiting them in their research. By partnering with these IPMOs, TTOs and Incubators, researchers and innovators have access to a wide range of information and materials crucial to their research which enables them to make progress that they would have otherwise been unable to without the help of these offices.

In Kenya the University of Nairobi has established an IPMO whose role includes protecting the IP rights of the University of Nairobi, its innovators, inventors, breeders, research sponsors and the public.⁴¹ It also has the mandate to eliminate the infringement, improper exploitation, and abuse of the IP assets belonging to the University of Nairobi or others, promote creativity and innovation, ensure fair and equitable distribution of all benefits accruing from all innovations, inventions and breeding activities and to promote linkages with industry and stimulate research through developing and utilizing novel works for commercialization.⁴²

The University of Nairobi also has an incubation policy governed by the office of the Deputy Vice Chancellor (DVC) Research, Production and extension (RPE).⁴³ The main goal of the incubation policy is to nurture new enterprises that have innovative products and services for local, regional and global markets and develop them into sustainable and competitive businesses that contribute to the realization of Kenya's Vision 2030.⁴⁴

5. THE ROLE OF UNIVERSITIES IN SCIENTIFIC AND TECHNOLOGICAL INNOVATION IN KENYA AND AFRICA

There is need to reform the curriculum on university scholarship and teaching of IP, innovation, ToT and

licensing in Kenya and Africa. The legal aspects of IP and related concepts should be offered in all universities. In developed countries such as the US, UK, Germany and Japan, universities and the science-based industries grew up together. In various fields like chemistry, biochemistry, physics, engineering and electrical science, academic research and teaching played a major role in the growth of these industries in USA and Europe.⁴⁵ This system needs to be adapted in Kenya and Africa. Universities ought to be a source of technical human resource for industry. They should generate and nurture new ideas about product and process innovation. Closer linkages between industries and institutions of higher learning need to be developed.⁴⁶ Industries involved in a particular field need to be consulted on curriculum development at all levels.

Education and training institutions should integrate research, and also develop institutional policies on R&D, innovation and IP. Currently, a few companies, as well as the University of Nairobi, Moi and JKUAT have developed IP policies. These should be bolstered through appropriate linkages with industry and the public sector to help develop relevant skills, knowledge, attitudes, values, and innovation (SKAVI) for sustainable livelihoods.

Universities have historically focused on teaching and academic research.⁴⁷ Furthermore, new universities merely copy paste(d) the programmes, curricula and syllabi of their predecessors. Thus, many Kenyan universities have merely copied the programmes, curricula and syllabi of the University of Nairobi (UoN),⁴⁸ the oldest and largest in Kenya. Some had a lot of promise and had the opportunity to focus on niche fields. Five examples. First, Moi University (ICT and technology or

⁴¹ University of Nairobi, 'Role of IPMO in Promoting Research at the University of Nairobi' (2014) <http://erepository.uonbi.ac.ke/bitstream/handle/11295/78385/UON_Role%20of%20intellectual%20property%20management%20office%20in%20promoting%20research%20at%20the%20University%20of%20Nairobi.pdf?sequence=1&isAllowed=y> accessed 18 June 2018. Cf Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Transferring Technology for Sustainable Development* (IL&SM, 2016).

⁴² *ibid.*

⁴³ University of Nairobi, 'Incubation Policy' (2015) <<http://dvcrpe.uonbi.ac.ke/sites/default/files/centraladmin/dvcrpe/Incubation%20Policy.pdf>> accessed 29 June 2018.

⁴⁵ Richard Nelson, 'What is commercial and what is public about technology, and what should be?' in Rosenberg *et al.* (eds), *Technology and the Wealth of Nations*, *op. cit.* Cf. Nathan Rosenberg, 'Scientific instrumentation and university research' in *Exploring the Black Box: Technology, Economics and History* (Cambridge University Press, New York, 1994) Chapter 13.

⁴⁶ This point has been emphasized in Sessional Paper No. 1 of 2005, *op. cit.*

⁴⁷ According to the Kenyan Commission of University Education website, <<http://www.cue.or.ke/index.php/accredited-campuses-of->

[universities-in-kenya](#)> accessed 4 October 2017, there are currently thirty (30) public chartered universities, five (5) public university constituent colleges, eighteen (18) private chartered universities, five (5) private university constituent colleges and thirteen (13) institutions with letters of interim authority. According to Times Higher Education the fifteen (15) leading universities in Africa are University of Cape Town (South Africa), University of the Witwatersrand (South Africa), Makerere University (Uganda), Stellenbosch University (South Africa), University of Kwazulu-Natal (South Africa), American University (Egypt), Uganda of Ghana (Ghana), University of Johannesburg (South Africa), University of Pretoria (South Africa), Sohag University (Egypt), Suez Canal University (Egypt), University of the Western Cape (South Africa), Ain Shams University (Egypt), Alexandria University (Egypt), Cairo University (Egypt), University of Ibadan (Nigeria), Mansoura University (Egypt), University of Marrakech Cadi Ayyad (Morocco), Mohammed V University of Rabat (Morocco), University of Monastir (Tunisia), University of Nairobi (Kenya), University of South Africa (South Africa), South Valley University (Egypt) and University of Tlemcen (Algeria).

⁴⁸ John Odhiambo, 'Advancing the quality of higher education through internalization' (2005) <http://www.ifc.org/wps/wcm/connect/480037804970c1a69fcedf336b93d75f/Internationalization+Kenya_JohnOdhiambo_Paper.pdf?MOD=AJPERES> accessed 4 October 2017.

information technology generally);⁴⁹ secondly, Kenyatta University (education, literature and cultural studies).⁵⁰ Thirdly, Egerton University (agriculture);⁵¹ fourthly Jomo Kenyatta University of Agriculture and Technology (JKUAT) (agriculture and technology).⁵² Last, and fifthly, Strathmore University (accounting and business; ICT).⁵³

Some universities are now engaged in commercialising the research findings. Some Kenyan public and private universities play a leading role in advancing the frontiers of science, technology, innovation and cultural creativity. There is a need to establish and strengthen innovation, transfer of technology and structures for IP administration in Kenyan universities to coordinate the development, commercialization and dissemination of innovation within academia, industry and public spaces.⁵⁴

Universities play a major role in R&D. Their role and mandate in national development is increasingly becoming important. The primary and traditional role of universities was to transmit SKAVI, especially through education, training, research, innovation and mentoring (ETRIM). Over the years, the importance of research and dissemination of research findings or outreach in the Kenyan and African society has been underscored. Through research, and the research results or findings, universities are expected to contribute to the improvement of the quality of life and to social and technological change.

The University of Nairobi has embarked on a business incubation project and related projects with the National Government agencies and private corporations as well as state departments to help in the development, dissemination and utilization of science, technology and innovation (STI).⁵⁵ There are concerns regarding application, commercialization and efficient utilization of

STI that has been or is being developed. There are also concerns that innovations and creativity in the arts, humanities and social sciences should be encouraged and nurtured. These should get appropriate support even as the relevant agencies also improve support for patentable technologies, inventions and innovations.⁵⁶

In the medium to long term, this calls for institutional (re)design in at least three ways. First, universities should enhance the orientation of their programmes to ensure they are practical and income-orientated. They should enrich or move beyond the privately sponsored Module II or the direct paying student model that began in the late 1990s.⁵⁷ While this model has provided opportunity to thousands of students and earned universities a lot of money, it has its weaknesses. These include focus on teaching or training using already generated knowledge, some of which is dated. This has a detrimental impact of the quality of education.

There is also general complacency among some university managers whereby teaching or training units focus on mere clerical and accounting work involving collecting student fees rather than pro-active R&D activities such as cutting-edge research or job focused post graduate training based on a needs assessment of the academy, the national and county government, industries and civil society organizations.⁵⁸

Secondly, some scholars, like the Kenya School of Government's Prof Calestous Juma, have suggested that the relevant Government Ministries, Departments, and Agencies (MDAs) be converted into universities.⁵⁹ What are the implications of this? Author's views? The third model is probably more focused centres and institutes.⁶⁰ What is the third model??

⁵⁴ See Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa* (op. cit.), at 623.

⁵⁵ A challenge is that universities develop appropriate programs with the relevant agencies of the National Government and the relevant 47 County Governments.

⁵⁶ There is a running debate in which some Kenya government officials express preference for science, technology, engineering, and mathematics (STEM) or science, technology or innovation (STI) in comparison to the arts, humanities and social sciences. Deputy President William Ruto expressed such sentiments while serving as Minister for Higher Education in the Grand Coalition Government. He has not retracted. Cf. BA. Ogot, 'Rereading the history and historiography of epistemic domination and resistance in Africa' (2009) 52.01 *African Studies Review* 1-22.

⁵⁷ My argument is that all students who qualify for university or college education and training should be given adequate concessionary and long-term loans. They should pursue degrees or diploma and even doctoral programmes. And university staff should be compensated and remunerated appropriately including in terms of salaries, allowances and research grants, rather than the basis of participation module II where the

payment to staff has always delayed, declined and even collapsed in most universities anyway. Cf. Duncan Omanga, 'The crisis in our universities starts from sub-standard teaching in lecture rooms' *Daily Nation* Newspaper (Nairobi, 2015) <<http://www.nation.co.ke/oped/opinion/Universities-Teaching-Lectures-Crisis/440808-2760372-3ktafhz/index.html>> accessed 4 October 2017. Also see Duncan Omanga, 'Kenya stands to gain most when lecturers are well remunerated' *Standard Digital* newspaper (Nairobi 2017) <<https://www.standardmedia.co.ke/article/2001231373/kenya-stands-to-gain-most-when-lecturers-are-well-remunerated>> accessed 16 November 2017.

⁵⁸ See appropriate teaching and training programs have been discussed under the auspices of University of Nairobi Enterprise Services (UNES).

⁵⁹ Calestous Juma, 'African universities are lagging behind as the world moves on' *Daily Nation* (Nairobi, 2016) <<http://www.nation.co.ke/lifestyle/weekend/African-universities-are-lagging-behind-as-the-world-moves-on/1220-3358812-r1sgl7z/>> accessed 13 November 2016.

Some are owned by fully affiliated, loosely affiliated to, managed or independent of universities. This is a major source of inspiration behind Sihanya Mentoring (SM) and Innovative Lawyering (IL). Also see Bitange Ndemo, 'Our education through my eyes' *Daily Nation* newspaper (Nairobi, 2014) <<http://www.nation.co.ke/oped/blogs/dot9/Our-Education->

6. TEACHING IP AND INNOVATION IN KENYA & AFRICA

For a long time, IP has been the exclusive domain of a small number of specialist lawyers, who had generally acquired their expertise from working in IP based companies or representing clients with IP related problems.⁶¹ However, with the rapid acceleration of globalization of a world economy, IP has become recognized as a trade issue. This increasing prominence of IP on the national and international scenes has led to a significant impact on how IP is taught and the content that is taught.⁶²

The importance of IP in the modern world goes beyond just the protection of creations of the mind as it also affects all aspects of economic and cultural life. As a result, IP education at university level is increasingly becoming popular.⁶³ There are four (4) types of IP courses taught at university level. First, survey courses. These are basic and broadly focused courses which are intended to give an overview of the various fields of IP. Secondly, specialized courses are taught. These focus in-depth on a single or particular field of IP. Thirdly, advanced seminars. These seminars are designed for students who have taken a specialized course in a particular field e.g. copyright, patents, trademarks etc. Fourth, practice courses. These courses focus on the actual steps that IP attorneys would take to obtain and enforce IP rights.⁶⁴

Leading Kenyan and African universities and training institutions have adapted to providing courses either at the undergraduate level, LLM level and doctoral level. In Kenya, IP is offered as a course unit at the University of Nairobi, which is the leading University.⁶⁵ Other institutions that offer IP as a course unit are Strathmore University,⁶⁶ JKUAT,⁶⁷ KU,⁶⁸ and MKU.⁶⁹ At the University of Nairobi, IP is taught as a compulsory course unit at LLB 4 level. This is usually during a candidate's fourth (final) year and second semester.⁷⁰ The course gives the

candidates an overview of the various fields of IP law, with specific evidence and legal analysis of the core doctrines of IP, innovation, ToT, and licensing. This is to interest students in IP and those who might decide to specialize in IP in practice in advanced research, scholarship or teaching.⁷¹

Leading African universities such as the University of Cape Town (UCT), Pretoria University, the University of South Africa (UNISA), Africa University, the University of Witwatersrand, the University of Botswana, the University of Dar Es Salaam, Makerere University, Open University of Tanzania, and the University of Lagos among others have also introduced IP in their curricula. At the University of Botswana, IP is divided into two course units i.e. Intellectual Property I and Intellectual Property II.⁷² At the University of Cape Town (UCT), IP is taught at a more advanced level of LLM as Intellectual Property Law, Development and Innovation.⁷³

The Africa University in particular, has partnered with WIPO and ARIPO to offer a Masters in Intellectual Property (MIP) Programme that offers the training of trainers in IP.⁷⁴ The main objectives of the programme are to create IP expertise in Africa, support IP teaching in institutions of higher learning and promote IP systems in Africa.⁷⁵ The programme was established in 2008 and has had nine (9) editions. The MIP programme has attracted 315 participants with 256 graduating with a Masters in IP.⁷⁶ ARIPO is also launching an MIP course in collaboration with the Nkwame Nkrumah University of Science and Technology, Ghana scheduled to start in August 2018 and also the University of Dar es Salaam, Tanzania in May 2019.⁷⁷

The incorporation of IP in the curricula has also played a huge role in the development of IP policies in these institutions. As such IP benefits students from a wide

through-my-eyes/1959700-2161438-goodo1z/index.html
accessed 26 September 2017.

⁶¹ Yo Takagi, Larry Allman, and Mpazi A. Sinjela, *Teaching of Intellectual Property* (op. cit., 2011).

⁶² *ibid.*

⁶³ WIPO, *WIPO Intellectual Property Hand Book: Policy, Law and Use* (2004) WIPO Publication No 489(E), Geneva.

⁶⁴ *ibid.*

⁶⁵ University of Nairobi website
<<http://www.uonbi.ac.ke/>> accessed 4 April 2018.

⁶⁶ Strathmore University website
<<https://www.strathmore.edu/>> accessed 4 April 2018.

⁶⁷ Jomo Kenyatta University of Agriculture and Technology website <<http://www.jkuat.ac.ke/>> accessed 4 April 2018.

⁶⁸ Kenyatta University website
<<http://www.ku.ac.ke/>> accessed 4 April 2018.

⁶⁹ Mount Kenya University website
<<http://www.mku.ac.ke/>> accessed 4 April 2018.

⁷¹ The present author has taught IP since 1997, with a 3 year break as a JSD (PhD) student in IP at Stanford University Law School (2000-03).

⁷² Email correspondence of April 5, 2018 between Prof Ben Sihanya and Dr Jimcall Pfumorodze.

⁷³ Email correspondence of April 1, 2018 between Prof Caroline Ncube and Prof Ben Sihanya

⁷⁴ Africa University website
<<http://www.africau.edu/admissionrequirements.html>>
accessed 4 April 2018.

⁷⁵ *ibid.*

⁷⁶ Fernando Dos Santos, 'The role of Regional IP Organizations in Shaping IP Substance and Teaching in Africa-The Case of ARIPO' (2018) Presentation at the WIPO-WTO Colloquium for Intellectual Property Teachers and Researchers in Africa, held on 9 April 2018 to 12 April 2018, Pretoria, South Africa. Cf. Barthelemy Nyasse, 'IP Teaching Methodology and Syllabi: African Experiences' (2018) Presentation at the WIPO-WTO Colloquium for Intellectual Property Teachers and Researchers in Africa, held on 9 April 2018 to 12 April 2018, Pretoria, South Africa.

⁷⁷ *ibid.*

range of disciplines such as law, business, fine arts, engineering, sciences, and journalism.

7. SUMMARY OF FINDINGS, CONCLUSION AND RECOMMENDATIONS

The main objective of this essay was to analyse scholarship and teaching of IP, innovation, technology transfer and licensing in Kenya and Africa. The overarching argument was that scholarship and teaching of intellectual property (IP) needs to be reconceptualized to cover IP, innovation, ToT and licensing as well as line topics that are relevant to Kenya's and Africa's sustainable development including socio-economic, cultural and political development. This is because IP is an interdisciplinary field as it covers all sectors of the economy including the legal, business, medical, agricultural, industrial, and education fields.⁷⁸ It therefore benefits not only legal students and professionals but also other professions. From the discussions above, it is clear that IP scholarship, teaching and training is very important and should be given considerable priority in universities and training institutions. IP scholarship and teaching in Kenyan and African universities should therefore be inter-disciplinary and inter-sectoral and should also be integrated with sub-national (or county), national, sub-regional and Africa-wide frameworks on RSTI.

Remarkably, most Kenyan and African universities focus on teaching for the diploma and degree qualifications. Thus, most human, financial, technical and infrastructural resources are dedicated to the first-degree culture. There is limited basic and applied research in RSTI, as well as in the arts, humanities and social sciences. Most of the research is based on the motivation of individual scholars, their interests in promotion or career advancement or in the context of research funded by foundations and institutions outside Kenya and Africa. While various leading universities and institutions in Kenya and Africa have adopted IP teaching and training in their curricula, there is still a lot that needs to be done. The teaching curricula and methodology is inadequate. A three-pronged methodology and appraisal is necessary to address the major challenges.⁷⁹

First, there is need to keep up with the dynamic and rapid changes taking place in IP, innovation and technology transfer. Each day new developments are being made in the IP world. Therefore, IP teachers and scholars need to keep updating and reviewing their teaching materials so as not to be left behind. Reviewing and updating of the IP curricula is very important as it ensures that the IP

students and trainees are up to speed with the developments that are taking place in the IP world. A majority of institutions in Kenya borrow their curricula from institutions that have been offering IP for a long time such as the University of Nairobi and may not use the curricula or syllabi that these institutions have revised. They therefore do not have their own authentic IP curricula and thus updating the borrowed curricula also poses a challenge as they do not have the relevant materials to refer to.

Secondly, teaching that address emerging IP issues from an African perspective are inadequate. For IP teaching and training to be effective, the materials used must be appropriate and up to date. There is therefore the need to invest in locally written and up to date materials on IP issues and matters in order to provide the best training for IP students. In Kenya and other African countries, IP teachers and scholars mostly rely on IP material written and prepared by foreign scholars from the US and Europe. The lack of IP materials by African authors poses a huge challenge and concern as the emerging IP issues discussed by authors from developed countries are not necessarily the challenges that Kenya and other African countries are facing. Some authoritative journal articles and books are emerging on Kenya and Africa IP.⁸⁰

Thirdly, the objectives, agendas and curricula on IP, innovation, and ToT should be reviewed to make them suitable for an interdisciplinary approach in which IP scholarship and teaching are conducted the light of its increasing role in fields such as business, commerce, science, medicine and engineering.⁸¹ There is therefore the need to develop inter-disciplinary objective, agenda and curricula on IP. The establishment of IPMOs, TTOs and incubators in public and private institutions, and not just in law schools is crucial. This will enable students from all fields to access the necessary IP knowledge and knowhow to all disciplines and including law.

To recap: The methodology in the scholarship and teaching of IP, Innovation, ToT, and licensing in universities should be enriched through interdisciplinary research, teaching and collaboration among students and scholars of law, health, agriculture, engineering architecture, business, education, communication, sociology, political sciences, (cultural) history, cultural politics and literature.

⁷⁸ Sihanya, 'Intellectual Property and Innovation Audit, Valuation, and Commercialisation in Kenya' (forthcoming 2018).

⁷⁹ Yo Takagi, Larry Allman, and Mpazi A. Sinjela, *Teaching of Intellectual Property* (op. cit., 2011).

⁸⁰ See *Intellectual Property and Innovation law in Kenya and Africa: Transferring Technology for Sustainable Development*; See also Ben Sihanya, *Intellectual Property and Innovation law in Kenya and Africa: Cases and Materials* (2018) and the books and articles cited therein.

⁸¹ *ibid.*

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AFRICAN CONTINENTAL FREE TRADE AREA AGREEMENT: THE ENVISAGED PHASE II-INTELLECTUAL PROPERTY ASPECT

Sheila Mavis Nyatlo*

ABSTRACT

Economic growth based on innovation and trade agreements facilitate transfer of technology between countries. The World Trade Organization (WTO) enables members to enter into regional trade agreement granting more favorable trade conditions to its fellow signatories than it does to other parties and provide the legal basis for preferential trade agreements between developing countries. To exploit these regional trade opportunities, the African Union (AU) undertook to establish the African Continental Free Trade Area Agreement (AfCFTA) and to bring coherence to the regional intellectual property (IP) cooperation. The inclusion of IP in trade agreements provide an opportunity to set common rules on IP protection and a common approach to the use of flexibilities offered through WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. A strategic approach to IP policy at a continental level has the potential to provide a basis for pooling resources among African countries and regional economic communities (RECs), thus building substantial capacities required for IP. Furthermore, it has the ability to strengthen a common approach to negotiating IP trade and investment agreements with external partners.

Through this regional IP co-operation framework, the AU embraces IP as a tool for public policy to promote economic,

social and cultural progress by stimulating creative work and technological innovation. A well-functioning IP regime provides incentives for development and innovation leading to economic competitiveness, technological diffusion and economic growth as a spin off.

Key words: trade agreements, intellectual property, transfer of technology, WIPO, WTO, ARIPO, PAIPO

1. INTRODUCTION

The IP system is deemed a tool for public policy to promote economic, social and cultural progress by stimulating creative work and technological innovation.¹ The term intellectual property refers broadly to the creations of the human mind. Intellectual property rights (IPRs) safeguard the interest of creators by awarding property rights to them, mostly the freedom to operate for their creations. IPRs are largely protected by granting statutory expression to the moral and economic rights for creations to IP creators. IPRs aim to promote creativity through the reward, dissemination and application of creations.²

A well-functioning IP regime should facilitate direct and indirect transfer of technology (TT) through FDI trade and licensing.³ Furthermore, a well-functioning IP regime provides incentives for development and innovation leading to economic competitiveness and technological diffusion for an economic growth spin off. Developed countries recognize IP rights as a critical component of FDI and TT; they ensure that maximum IP benefits are derived from trade

* **Dr Mavis Nyatlo** is currently employed as a Senior Researcher for Intellectual Property Management at the University of South Africa under the South African Research Chair initiative for Law Society and Technology. Her current responsibilities include supervision and mentoring of postgraduate students, teaching of intellectual property management modules, development of intellectual property management teaching material. She has previously worked as a Director within the National Intellectual Property Management Office of the Department of Science and Technology for the implementation of the Intellectual Property Rights from Publicly Funded Research and Development Act, no.51 of 2008. Other work experience includes working as a Deputy Director for Technical Skills within the Department of Science and Technology. Being an Assistant Director for Innovation and Technology within the Department of Trade and Industry. Working as a Medical Technologist within the following disciplines: Immunology, Human Genetics and Medical Microbiology). She holds a PhD in Management of Technology and Innovation (Da Vinci Institute of Innovation and Technology Management); MSc Technology

Management (University of Pretoria); BSc Hons Technology Management (University of Pretoria); BTech in Biomedical Technology (Technikon Pretoria); National Diploma Biomedical Technology (Technikon Northern Transvaal). Her current studies include LLB at the University of South Africa. She has also completed certificate courses through the World Intellectual Property Organization: Patent Search Strategies, Advanced Course on Patents, Patent Co-operation Treaty, and Advanced Courses on Trademarks, Industrial Designs and Geographical Indicators. She has also participated in an Advanced Training on Intellectual Property for Government Officials with WIPO and WTO.

¹ Jayashree Watal and Antony Taubman (eds), *'The Making of TRIPS Agreement, Personal insights from Uruguay Round Negotiations'* (WTO 2015) 2.

² Karky R, 'Intellectual Property Rights and Foreign Direct Investment Agreements' in: Perry M. (eds) *Global Governance of Intellectual Property in the 21st Century* (Springer, Cham, 2016) 209-223.

³ Watal (n 1).

agreements; contrarily; developing countries and least developed countries (LDCs); are not yet in a position to fully utilize possible opportunities brought about by the IP regime as a result of a series of challenges.⁴ When negotiating trade agreements, developing countries only accept inclusion of IP rights as a bargain providing an opportunity for improved market access for its textiles and agricultural goods.⁵ Developing countries are thus struggling to generate value from IP due to their tangible asset economic focus being based on raw material and manufacturing capabilities.⁶

The African Union (AU) recognized the opportunities afforded through trade agreements for the African continent to enable the movement of goods and services, eradicate trade barriers, tariffs and quotas. In its effort to boost intra-African trade the AU proposed the African Continental Free Trade Area Agreement (AfCFTA) for its member states. However, some issues such as IPRs go beyond elimination of trade barriers and have implications on domestic policies. The implications influence technological development, national economy and the society.

The World Trade Organization (WTO) regimes, such as Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, control trade-related IPRs.⁷ Through the TRIPS Agreement, the WTO enables members to enter into regional trade agreements (RTAs) granting more favorable trade conditions to its fellow signatories than it does to other

parties and to provide the legal basis for preferential trade agreements (PTAs) between developing countries and LDCs. Trade agreements facilitate innovation, economic growth and TT between countries.⁸ This paper focuses on the IP aspects envisaged in the AfCFTA.

2. THE ROLE OF WIPO & THE WTO

World Intellectual Property Organization (WIPO) promotes the protection of IP throughout the world through administering 15 IP treaties in 24 regimes. These regimes are categorized in three tiers – the first tier is comprised of 15 treaties⁹ that define internationally agreed basic standards of IP protection in each country. The second tier is comprised of five treaties¹⁰ that are termed global protection treaties. They ensure that one international registration or filing have effect in any of the signatory states. IP applications are simplified and costs reduced through the WIPO application system. The third tier is comprised of four ‘classification treaties’¹¹ that organize information on inventions, trademarks and industrial designs into indexed, manageable structures, to simplify retrieval.¹²

Whilst WIPO ensures administrative co-operation through treaties; WTO administers the TRIPS Agreement. The TRIPS Agreement set a global and uniform set of IPR regulation for recognizing IP as a trade issue.¹³ TRIPS was aimed at:

Reducing impediments to international trade. Focusing on the need to promote effective and adequate protection of

⁴ *ibid* 2.

⁵ Manfred Elsig and Jenny Surbeck, ‘Intellectual Property Rights and Preferential Trade Agreements: Data, Concepts and Research Avenues’ (European Consortium for Political Research General Conference, Prague, 07-10 September 2016).

⁶ Raymundo Valdés and Maegan McCann, ‘Intellectual Property Provisions in Regional Trade Agreements: Revision and Update (WTO Staff Working Paper, ERSD 2014-14).

⁷ Shik-Lee Yong, ‘The United States-Korea Free Trade Agreement’ in Lester S Mercurio B and Bartels L (eds), *Bilateral and Regional Trade Agreements: Case Studies* (Cambridge University Press 2016) 22-23.

⁸ Valdés (n 6).

⁹ Paris Convention for the Protection of Industrial Property (1883); Berne Convention for the Protection of Literary and Artistic Works (1886); Madrid Agreement for the Repression of False or Deceptive Indications of Sources of Goods (1891); Buenos Aires Convention (1910); Universal Copyrights Convention (1952); Rome Convention for the Protection of Performers, Producers of Phonographs, and Broadcasting Organizations (1961); United Nations Convention Establishing the WIPO (1967); Convention for the Protection of Producers of Phonograms against Unauthorized Duplication of their Phonograms (1971); Brussels Convention (1974); Nairobi Treaty on the Protection of the Olympic Symbol (1981); Film Register Treaty

(1989); Treaty on Intellectual Property in respect of Integrated Circuit (1989); Trademark Law Treaty (1994); WIPO Copyright Treaty WIPO Performances and Phonograms Treaty (1996).

¹⁰ Hague Agreements (1934, 1964) Lisbon Agreement for the Protection of Appellations of Origin and their International Registration (1958); Patent Cooperation Treaty (1970); Budapest Treaty on the International Recognition of Deposit of Microorganisms for the Purposes of Patent Procedures (1977); Madrid Agreement concerning the International Registration of Marks (1891); and the Protocol relating to that Agreement (1989).

¹¹ Nice Agreement concerning the International Classification of Goods and Services for the purpose of the Registration of Marks (1957); Locarno Agreements and establishing an International Classification for Industrial Designs (1968); Vienna Agreements establishing an International Classification of the Figurative Elements Marks (1973); Strasbourg Agreement concerning the International Patent Classification (1979).

¹² Economic Commission for Africa, African Union and African Development Bank Group, ‘Assessing Regional Integration in Africa (ARIA) VII: Innovation, Competitiveness and Regional Integration’ (ECA 2016) 64.

¹³ Elsig (n 5).

intellectual property rights. Ensuring that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade, to develop a multilateral framework of rules and disciplines dealing with international trade in counterfeit goods.¹⁴

3. THE TRIPS AGREEMENT

The TRIPS Agreement sets the minimum benchmark for IP protection in the territories of WTO Members. TRIPS incorporates some of the main international WIPO agreements that already existed prior to WTO's establishment. The TRIPS Agreement complements the WIPO treaties and conventions, and covers additional areas of IP and introduces higher standards of protection than that which are provided for under the two WIPO treaties.^{15,16} Even though not all countries are party to all WIPO-administered treaties, by virtue of the TRIPS Agreement, WTO member states are bound by core WIPO treaties.¹⁷

African countries as a developing continent formed the AU; made up of 55 members, 33 of which are classified as Least Developed Countries (LDCs). LDCs are low income countries with structural limitations to sustainable development.¹⁸ 53 African countries are WIPO Member states. In terms of the WTO, 43 of the African countries are WTO member states; 29 of which are LDCs.¹⁹

TRIPS Agreement established minimum standards of IP protection and requirements to which member countries must subscribe, as well as rules for administration of enforcement of IPRs. The TRIPS Agreement also provides for the application of the WTO dispute settlement mechanism to resolve disputes between members concerning its compliance.²⁰ It is termed:

A far-reaching international treaty on IP to date covering a wide sweep of substantive subject matter as well as administration and enforcement of IP and settlement of disputes between trading partners over IP.²¹

WTO members, apart from LDCs, are obliged to implement TRIPS minimum standards. Members are left free to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice²². This had fundamental implications for the policy space available to developing countries in designing their national IP rules and policies. It is indicated that the TRIPS Agreement's general standards of IP protection benefit certain industrial sectors where companies from developed countries are dominant.²³ The minimum standards of IP rights regulation that the TRIPS Agreement promoted brought about varying implementation strategies. In this context big businesses had a competitive edge over small businesses due to the advantage for the economies of scale and the ability to handle the overhead costs of litigation and compliance. Similarly, developed countries will have an advantage over developing and LDCs as well.²⁴ Developing countries have been unable to bear significant costs for adopting TRIPS provisions. The provisions come with the need to ensure judicial and institutional infrastructure to educate, implement, manage and enforce IPR provisions.²⁵

It is deemed that the current role of the WTO in developing the international IP trade system is minimal despite its major role in enhancing the global standards for IP protection. The WTO Council is seen to be paralysed by basic disagreements on the role of the socio-economic development aspect of TRIPS.²⁶ It is submitted that even though IPRs offer incentives

¹⁴ Watal (n 1) 6.

¹⁵ These include the Paris Convention and the Berne Convention for the Protection of Literary and Artistic Works.

¹⁶ Valdés (n 6).

¹⁷ Economic Commission for Africa (n 12) 66.

¹⁸ United Nations 'Economic Analysis and Policy Division: Least Developed Countries' What does the Adoption of the African Continental Free Trade Agreement signify? 29 March 2018 available at <<https://www.un.org/development/desa/dpad/least-developed-country-category.html>> accessed 26 May 2018.

¹⁹ Economic Commission for Africa (n 12) 67.

²⁰ Watal (n 1) 6.

²¹ *ibid* 16.

²² WTO Overview: The TRIPS Agreement <https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm> accessed 10 June 2020

²³ Economic Commission for Africa (n 12) 77.

²⁴ *ibid* 45, 50.

²⁵ Narayanan G Badri and Sangeeta Khorana, 'Meta-Regional Trade Agreements: Costly distraction for Developing Countries' (*Economic Structures*, 2017) 6: 29 <<https://0-doi-org.oasis.unisa.ac.za/10.1186/s40008-017-0090-y>> accessed 26 June 2018.

²⁶ Carlos Correa, 'The Role of the World Trade Organization in the Intellectual Property System' in Christopher Geiger and Xavier Seuba (eds), *Rethinking International Intellectual Property Law: What*

to innovate, the difficulty in their application is that they work in certain contexts. The requirements for IP rights and the enhancement of innovation is the existence of conditions such as skills, information, capital and market prospects.²⁷

A large market with sufficient capital, qualified personnel, and innovation-oriented entrepreneurs is necessary for an effective IP regime. African countries are struggling with these conditions. In some instances, even if these conditions are met, IP rights may not promote innovation. An example is that pharmaceutical patent protection that has been unable to increase research and development (R&D), FDI and domestic investment in developing countries as right holders import or export final products rather than invest in local production.²⁸

IP is one of the essential determinants of inward FDI, as stated the existence of a sound IP regime attracts FDI and encourages TT as an important consideration of foreign investors. TRIPS article 7 sets out:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.²⁹

4. INTELLECTUAL PROPERTY AND TRADE AGREEMENTS

Trade agreements are formulated with the objective of economic development. The inclusion of IP in trade agreements promotes innovation and leads to economic growth. The TRIPS Agreement being an instrument to facilitate economic growth and development through the

administration of IPRs has been criticised for failing to take into account the different levels of capacity for innovation and the interests of developing and LDCs.³⁰ The different levels of innovation capacity has made it difficult for the developing and least developed countries to grow their economies under the indicated prescribed minimum TRIPS standards.³¹ WTO however, enables member states to enter into RTAs granting more favorable trade conditions to its fellow signatories than it does to other parties and it also provides the legal basis for preferential agreements between developing countries. WTO member states have actively engaged in the formation of RTAs as evident in international trade policy through the rapid increase in the number of RTAs.³² The economic impact of RTAs with IP provisions relates to the estimation of the costs and benefits of adopting common policies and regulations among countries at different stages of economic development.³³

Developing countries may be pressured into adopting common rules when entering into RTAs which are inappropriate for their level of development, or rules that are used to protect the vested interests of certain groups.³⁴ Despite the emergence of RTAs very few have been registered purely between developing countries. The following figures show number of trade agreements regulating IP and their distribution between developed and developing countries.³⁵

Institutional Environment for the Development and Enforcement of IP Law? (CEIPI ICTSD 2015) 41.

²⁷ Economic Commission for Africa (n 12) 61.

²⁸ *ibid* 68.

²⁹ Karky R, 'Intellectual Property Rights and Foreign Direct Investment Agreements' in Perry M (eds), *Global Governance of Intellectual Property in the 21st Century* (Springer Cham 2016) 209-223.

³⁰ Christopher Geiger, 'Multilateralism vs Pluralism in international IP Law: lessons to be Learned from the Failure of the Anti-Counterfeiting Trade Agreement' in Christopher Geiger and Xavier Seuba (eds), *Rethinking International Intellectual Property Law: What Institutional Environment for the Development and Enforcement of IP Law?* (CEIPI ICTSD 2015) 45.

³¹ Valdés (n 6).

³² Xavier Seuba, 'Substantive and Jurisdictional Challenges Arising from Bilateralism in Christopher Geiger and Xavier Seuba (eds), *Intellectual Property' in Rethinking International Intellectual Property Law: What Institutional Environment for the Development and Enforcement of IP Law?* (CEIPI-ICTSD, 2015) 57.

³³ Valdés (n 6).

³⁴ *ibid*.

³⁵ Seuba, Xavier, 'Intellectual Property in Preferential Trade Agreements: What Treaties, What Content?' (2015) *The Journal of World Intellectual Property* 240.

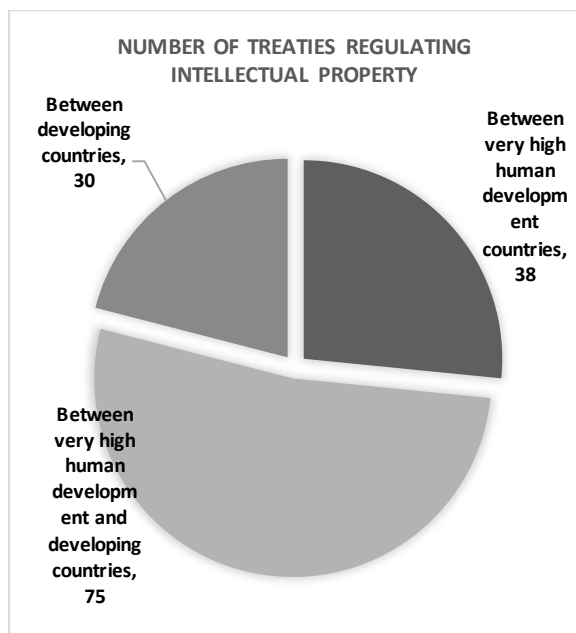


Figure 1: Number of Preferential Trade Agreements regulating IP registered at the WTO

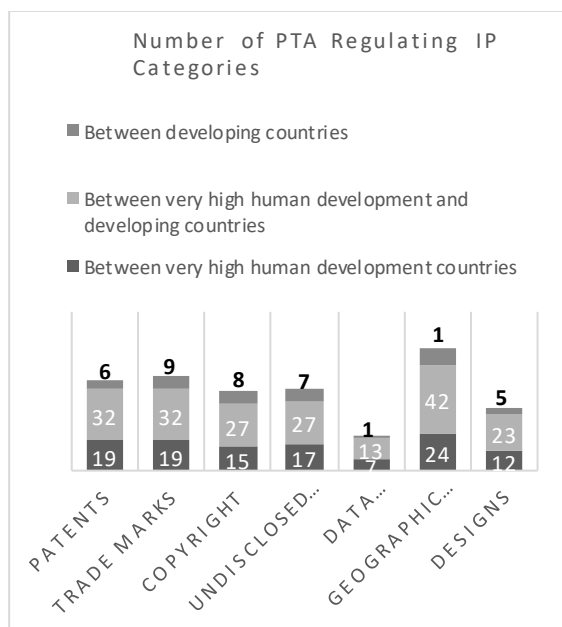


Figure 2: Number of Preferential Trade Agreements regulating IP categories

The number of trade agreements entered into between developed and developing countries is strikingly high, and there are very few agreements between developing countries.

To fully exploit the regional trade opportunity, the AU in its 2063 Agenda³⁶ undertook two initiatives that could help bring coherence to the regional IP cooperation. The initiatives are the Continental Free Trade Area Agreement and efforts to establish a Pan-African Intellectual Property Organization (PAIPO), with its headquarters in Tunisia. South Africa’s Trade and Industry Minister commented that ‘a Continental Free Trade Area agreement on IP would provide an opportunity to set common rules on IP protection and use of flexibilities in the global IP regimes, based on a common approach.’³⁷ However, taking into the differentiated development levels, different levels of industrial developments and different IP policies, it would be advisable rather to have some level of harmonization of IP regimes across the continent.

It is submitted that IPRs confer an incentive to innovate, however in countries where dominance is based on incremental innovation as a result of scarcity of required conditions to enable innovation such as weak scientific and technological infrastructure as well as skills, information, capital, market³⁸ enforcement of common rules on IP protection is likely to perpetuate the currently existing inequalities as technology exporting countries are likely to benefit more than technology importing least developed countries.

5. AFRICAN CONTINENTAL FREE TRADE AREA AGREEMENT

The AU member states met in Kigali, Rwanda on 21 March 2018 to deliberate on the signing of the new African Continental Free Trade Area Agreement (AfCFTA). The AfCFTA is one of the key deliverables in the AU’s first 10-year implementation plan of Agenda 2063 (2014 to 2023). The

³⁶ ‘Assessing Regional Integration in Africa (ARIA) VIII: Bringing the Continental Free Trade Area About’ (Economic Commission for Africa, African Union and African Development Bank Group, 2017) xi.

³⁷ Department of Trade and Industry, ‘Minister Rob Davies on the Outcomes of the African Continental Free Trade Area’ (4-Traders, News: Companies, 27 March 2018) <http://www.4-

traders.com/news/Minister-Rob-Davies-On-Outcomes-of-the-African-Continent-Free-Trade-Area--26235110/> accessed 07 April 2018.

³⁸ Carlos Correa, ‘Intellectual Property in LDCs: Strategies for Enhancing Technology Transfer and Dissemination’ (UNCTAD The Least Developed Countries Report 2007) 7

agreement is envisaged to enter into force once 22 member states have ratified it.³⁹

A. OBJECTIVES OF THE AFRICAN CONTINENTAL FREE TRADE AREA AGREEMENT

The key objective of the AfCFTA is to boost intra-African trade by forging a single continental legal regime for all relevant trade disciplines. This will include lower tariffs, simplified rules of origin and customs procedures and regulations for trade in services. In addition to that, AfCFTA's objective is to create a single continental market for goods and services, with free movement of business persons and investments, to pave the way for accelerating the establishment of the Customs Unions; to enhance competitiveness at the industry and enterprise level through exploiting opportunities for production, continental market access and better resource allocation.⁴⁰

The first phase of the AfCFTA includes a package of legal instruments such as a founding agreement, protocols on trade in goods and services, and annexures on trade-related rules and procedures, as well as a dispute settlement mechanism.⁴¹ The focus of the second phase of AfCFTA will be protocols on investment, competition and IP.⁴² The African Continental Free Trade Area (AfCFTA) seeks to ensure African integration and unity. It provides an opportunity to advance a continental approach to a balanced IP rights system that responds to the aspirations contained in Agenda 2063.⁴³ It promises a new trade order with an intention is to liberate Africa from the shackles of underdevelopment ...⁴⁴ AfCFTA, then, aims to support African-led development and industrialization.⁴⁵ Lessons should be drawn from the South-South co-operation that African countries turned to. Although theoretically focused on Brazil, Russia, India, China, and South Africa (BRICS), in practice, China dominated this

South-South partnership. The outcome of the co-operation resulted in infrastructure investment with China through its Belt and Roads Initiative raising major socio-ecological questions such as employment structures that prioritize Chinese and undervalue African labor. Furthermore, it is submitted that these infrastructure projects are usually bartered with African resources, generate crippling debt and related debt crises, involve the physical loss of land, and cause economic dislocations related to the increase in land values. The Chinese co-operation has also brought about the destruction of African textile manufacturing and locally produced goods and services as they are unable to compete with the imported Chinese goods in Africa.⁴⁶ The implementation of the first phase is likely to have challenges because as transaction costs decline, transnational corporations (TNCs) will gain larger markets and increased opportunities for land speculation. TNCs will become even more powerful as they purchase more African land and resources.⁴⁷ Furthermore it is submitted that AfCFTA has failed to take seriously the problem of inequality in Africa, which is even more pressing than barriers to productivity and trade. Instead of developing a framework to overcome this problem, the currently envisioned trade system will increase inequality and thereby cause social, economic, and environmental damage.⁴⁸

The IP aspect of the AfCFTA Agreement is expected to provide an opportunity to set common rules on IP protection and use of flexibilities in the global IP regimes, based on a common approach.⁴⁹ It would also provide a framework for sub regional cooperation, building on integration already achieved in the regional economic communities such as the Tripartite Free Trade Area (TFTA) between Common Market for Eastern Southern Africa (COMESA),⁵⁰ Eastern African

³⁹ What does the Adoption of the African Continental Free Trade Agreement signify? (tralac, 29 March 2018) <<https://www.tralac.org/discussions/article/12893-what-does-the-adoption-of-the-african-continental-free-trade-agreement-signify.html>> accessed 20 May 2018.

⁴⁰ Continental Free Trade Area <<https://au.int/en/ti/cfta/about>> accessed 20 June 2018.

⁴¹ Economic Commission for Africa (n 35) 56.

⁴² Department of Trade and Industry (n 36).

⁴³ 'Assessing Regional Integration in Africa (ARIA) IX: Assessing Regional Integration in Africa' (Economic Commission for Africa, African Union and African Development Bank Group, 2019) 154

⁴⁴ Franklin Obeng-Odoom, 'The African Continental Free Trade Area' (January, 2020) *American Journal of Economics and Sociology* Vol. 79 No. 1, 167.

⁴⁵ *ibid* 180.

⁴⁶ *ibid* 174.

⁴⁷ *ibid* 186.

⁴⁸ *ibid* 192.

⁴⁹ Economic Commission for Africa (n 35) 145.

⁵⁰ COMESA is a free trade area agreement formed in 1994 by 19 member states namely: Democratic Republic of Congo, Burundi, Union of the Comoros, Republic of Djibouti, Egypt, Eritrea, Ethiopia, Kenya, Madagascar, Malawi, Mauritius, Rwanda, Seychelles, Sudan,

Community (EAC)⁵¹ and the Southern African Development Community (SADC).⁵² The AfCFTA builds on the notion that the three RECs are committed to cooperating on IP policy under the TFTA.⁵³

In promoting policy coherence and based on a common approach; IP rights protocol in the AfCFTA are expected to provide an opportunity to establish common rules on IP protection and the use of flexibilities in the global IP regimes. It would also provide a framework for sub-regional cooperation and promote further cooperation at the continental level. The objective of promoting policy coherence should help Africa address the relationship between IP rights and other socioeconomic objectives, including innovation, environmental protection and traditional knowledge.⁵⁴ However, the flexibilities provided by TRIPS Agreement have to be carefully considered as it does not exempt regional preferential trade agreements established after it had come into force (such as the AfCFTA) from providing better treatment to the nationals of the members of those agreements. In other words, agreements made by countries in the context of the AfCFTA, for example, must be extended to nationals of all WTO member States.⁵⁵ This has the ability to favour technology exporting countries and increase inequality.

B. IP DIMENSION OF THE AfCFTA

The competition policy and IP rights disciplines of the AfCFTA Agreement are expected to be launched after the conclusion of the negotiations on goods and services.⁵⁶ A strategic approach to IP policy at continental level has the potential to

provide a basis for pooling resources among African countries and RECs to build the heavy capacities required for ensuring IP protection. This could also strengthen a common approach to negotiating IP trade and investment agreements with external partners.⁵⁷

C. CHALLENGES AND OPPORTUNITIES

As detailed in the United Nations Economic Commission for Africa (UNECA) 2016 report 'Assessing Regional Integration in Africa (ARIA VII, 2016)' one of the key challenges facing the African continent is the fragmented IP regulatory framework.⁵⁸ There are currently two sub-regional IP organizations; the African Regional Intellectual Property Organization (ARIPO) and the Organisation Africaine de la Propriete Intellectuelle (OAPI). ARIPO focuses on 19 English speaking African countries⁵⁹ whilst OAPI's focus is on the 17 French speaking African⁶⁰ countries. There are however 19 AU member countries that neither belong to neither ARIPO nor OAPI, including regional powerhouses such as Egypt, Nigeria and South Africa. In addition to that, ARIPO member states have different IP frameworks, while OAPI member states subscribe to a unified IP legal system framework for negotiating bilateral trade and investment agreements.⁶¹ The two IP organizations are independent from RECs and disengaged from the regional integration agenda leading to: (i) Policy and Institutional incoherence; (ii) Focus on the grant of patent rights at the exclusion of giving significant guidance to exercise of rights; (iii) Harmonization effort sometimes reducing policy space available to member states (iv) Lack of IP co-operation.⁶²

Swaziland, Uganda, Zambia and Zimbabwe. <<http://www.comesa.int/comesa-members-states/>> accessed 07 April 2018.

⁵¹ EAC is a regional intergovernmental organisation of six partner states: Burundi, Kenya, Rwanda, South Sudan, Tanzania and Uganda <https://www.eac.int/overview_of_eac7> accessed 07 April 2018.

⁵² SADC is a regional intergovernmental organisation comprised of 15 partner states: Angola, Botswana, Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe <<https://www.sadc.int/member-states/>>.

⁵³ Caroline Ncube, Tobias Schonwetter, Jeremy de Beer and Chidi Oguamanam, 'Intellectual Property Rights and Innovation: Assessing Regional Integration in Africa (ARIA VIII)' (2017) Open AIR Working Paper 5.

⁵⁴ Economic Commission for Africa IX (2019) 125.

⁵⁵ *ibid* 105.

⁵⁶ Economic Commission for Africa (n 35) 145.

⁵⁷ Department of Trade and Industry (n 35).

⁵⁸ Ncube, *et al* (n 53).

⁵⁹ Economic Commission for Africa (n 35) 72.

⁶⁰ African Regional Patent Office member states <www.aripo.org/resources/member-states> accessed 20 May 2018. Currently 19 states are members to the Lusaka Agreement and therefore members of ARIPO. These are Botswana, The Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Liberia, Rwanda, São Tomé and Príncipe, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

⁶¹ OAPI member states <www.oapi.int/> accessed 20 May 2018. Currently 17 member states that are members thereto: Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Côte d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Union of the Comoros and Togo.

⁶² Economic Commission for Africa (n 12)

⁶³ *ibid* 72.

The AU proposed the establishment of PAIPO as a chance for a coherent approach to IP policy co-operation as well as to deal with deficiencies left by ARIPO and OAPI.⁶³

Another identified challenge is multiple IP related initiatives being led, or planned, by RECs brought about by the independent disengagement of ARIPO and OAPI from regional integration efforts.⁶⁴ These initiatives do not include existing or proposed regional IP organizations.⁶⁵ The promotion of regional integration is proposed. It is stated that regional exhaustion regimes for IP rights can help to promote regional trade and value chain integration and reduce discrimination between State Parties.⁶⁶

Developing countries and LDCs are IP consumers and importers of IP not producers and exporters.⁶⁷ It is submitted that whatever framework is considered should reflect the fact that innovation in the context of Africa is different from elsewhere in the world. Innovation occurs mainly in the informal sector and not heavily reliant on predictable means of knowledge authority and appropriation.⁶⁸

Trade agreements in developing countries should reflect the innovation context through the support of traditional knowledge-based innovations in two ways: first, for the benefit of local indigenous communities that hold and are dependent on such knowledge; second, for the promotion and capability building initiatives to utilize traditional knowledge (TK) as a source of modern innovation for growth in a way that empowers TK holders. In both perspectives, connections need to be made between development, public health, industrial, trade and IP related policies and institutions. Appropriate institutions for managing interactions among TK holders and the diversity of TK users should be implemented to deal with uncertainties that surround knowledge sharing.⁶⁹

D. KEY CONSIDERATIONS FOR IP IN AfCFTA

A functional IP governance framework includes institutional frameworks, policies, strategies, laws and regulations as well as IP administration and adjudication mechanisms to integrate and enforce rights agreed upon. It is costly for developing countries or LDCs to implement all these mechanisms. It is thus imperative for the AfCFTA IP agreement to highlight flexibility, the importance of a transition period, and the safeguarding of policy space to create limitations and exceptions that suit countries at various stages of economic development.⁷⁰

In addition to maximizing the utilisation of flexibilities where applicable⁷¹ other general IP provisions as key points for consideration:⁷²

- a. Adoption of a regional IP exhaustion regime in order to prevent fragmentation of the market.
- b. Enforced ratification of the Protocol amending the TRIPS Agreement, 2005 to benefit from the facilitation of production and exportation of pharmaceuticals for a regional trade agreement in which 50 per cent or more of its members are least developed countries. (The AfCFTA will also qualify under the Protocol).
- c. Adoption of a tripartite regional policy on IP rights and public health based on the East African Community Regional IP Policy on the Utilization of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National IP Legislation.
- d. Endorsement of the Nairobi Statement on Investment in Access to Medicines or adoption of a similar commitment.
- e. Adoption of an in-built agenda to develop a plant breeders' rights regime tailored to the interests of the region, based on the needs of the local seed industry and publicly funded agricultural research centres.
- f. Enforced ratification of the Marrakesh Treaty to Facilitate Access to Published Works for Persons who are Blind, Visually Impaired or Otherwise Print Disabled.

⁶³ *ibid* (n 12) 149.

⁶⁴ *ibid* 149.

⁶⁵ *ibid* 149.

⁶⁶ Economic Commission for Africa IX (2019) 150.

⁶⁷ Badri (n 24).

⁶⁸ Kraemer-Mbula E and Wunsch-Vincent S (eds), *The Informal Economy in Developing Countries: Hidden Engine of Innovation* (Cambridge University Press, UK 2016) 150.

⁶⁹ Economic Commission for Africa (n 35) 16.

⁷⁰ *ibid* 16.

⁷¹ Watal (n 1) 23.

⁷² Economic Commission for Africa IX (2019) 108-109.

- g. Adoption of mandatory disclosure requirements in patent laws and in plant variety protection laws, except for partner States that are members of the 1991 UPOV Convention.
- h. Consideration of the adoption of a tripartite agreement which ascertains that measures in accordance with the WHO Framework Convention on Tobacco Control do not constitute an expropriation of IP assets or an infringement of IP rights.
- i. Adoption of measures for cooperation on patent examination, including for the sharing of patent examination results.

E. PROVISIONS RELATED TO SPECIFIC IP CATEGORIES⁷³

The eighth United Nations Economic Commission for Africa (UNECA) report on 'Assessing Regional Integration in Africa'⁷⁴ suggests that the specific IP categories are to be handled as follows in the AfCFTA:

Copyright – Balanced, sound and coherent domestic frameworks that are practically relevant, context appropriate and responsive to digital technologies encourage innovation and creativity. Inclusion of express provisions, to cater to disabled persons; temporary copies; parallel importation; orphan works and text; and data mining is imperative with regard to exceptions and limitations. In addition, maximum use of flexibilities under copyright to facilitate access to creative works is very critical.⁷⁵

Patents - A more robust approach to using existing flexibilities and more aggressively leveraging policy space is required. The continent needs better patents that are granted according to patent law that adequately address its socio-economic needs for example access to medicines. Despite Africa's requirement for improvement in IP ranking in relation to numbers of patents granted per resident; the agreement should not simply seek to secure the grant of patents for the sake of improving Africa's position in ranking systems. It should ensure the consideration of innovation in the context of Africa and support for traditional knowledge-based

innovations. Patent office capacity and processes are to be strengthened for credible and effective patent examination.⁷⁶

Trademarks – Communal trademarks strategies are underutilized in Africa and they are better suited for the development vision of African producers into marketable inventions. The AfCFTA negotiations afford a platform to promote IP policies tailored to achieving some form of sui generis framework for the protection of the less conventional trademarks at the national level.⁷⁷

Traditional knowledge – As a key strength for Africa, the AfCFTA needs to recognize the progress made for global recognition and protection of TK and its expression in major areas innovation and knowledge, including in medicine, agriculture, biotechnology and food.⁷⁸

The seventh United Nations Economic Commission for Africa (UNECA) report on "Assessing Regional Integration in Africa" outlines four areas that are imperative in relation to integrating IP issues into national development policies to improve the prospects of socio-economic development. These areas are – Agriculture, Manufacturing, Public Health and Access to Knowledge.

Agriculture – 'the agricultural sector is of huge importance to most African countries as a source of livelihood, income and employment. Around 53% of Africa's agricultural producers are comprised of smallholder farmers who requires integration into larger value chains, through promotion and access to market as well as export opportunities.⁷⁹

When designing an IP system, policy makers must consider the sector's characteristics, possible changes from growing liberalization of agricultural trade, the inputs in sustainable productions, and food security—including the structure of the seed supply system. A system that strikes a balance between plant breeders' rights and the ability for farmers to save and exchange seeds should be devised.'⁸⁰

Manufacturing - National IP policy should reflect the country's industrial development stage. IP should enable and

⁷³ Economic Commission for Africa (n 35) 152.

⁷⁴ *ibid* 135.

⁷⁵ *ibid* 151.

⁷⁶ *ibid* 151.

⁷⁷ *ibid* 151.

⁷⁸ *ibid* 152.

⁷⁹ Economic Commission for Africa (n 35) 4.

⁸⁰ Economic Commission for Africa (n 12).

promote local innovation, there should be access for absorption and diffusion of acquired technologies. Available flexibilities should be used to promote technology diffusion and allow reverse engineering, a strict criterion to assess patentability should be explored.

Public Health – The IP system must not constrain access to affordable generic medicines and health technologies. Flexibilities such as compulsory licensing should enable the production and establishment of generic medicine industries. It is imperative for IP rights holder to invest in local R&D and locally produced generics for the local market. Administrators may wish to adopt a clear approach in which trade and IP policies are formulated in a manner that preserves developing countries' ability to provide long term, affordable and sustainable access to medicines.⁸¹

Access to Knowledge - Maximum use of flexibilities under copyright to facilitate access to creative works, scientific and factual data and to enable R&D projects. There is a crucial need for exceptions for education in copyright laws to balance IP protection, access to works and to promote access to knowledge.⁸²

Competition policy and law have the ability to complement IP and trade rules to increase access to and reduction in the IP rights cost in respect of protected knowledge and technology. It was also stated that the complex issue of the intersection between IP rights and human rights, which formed a challenge for some international trade agreements, should not be ignored in the AfCFTA negotiations.⁸³ TRIPS flexibilities should be used in the AfCFTA to safeguard and address developmental needs.

An IP rights protocol for the AfCFTA is necessary for the following reasons:⁸⁴

- a. To cover the trade aspects of IP rights that contribute to regional trade and value chain
- b. and certification marks.

- c. Facilitating the use of flexibilities under international integration.
- d. To avoid the differential treatment of the AfCFTA countries compared to countries outside Africa arising from participation in different multilateral and bilateral IP rights treaties.
- e. To provide for harmonized approaches to key IP issues of interest for Africa that are not adequately covered under multilateral treaties, including plant variety protection and the protection of genetic resources, traditional knowledge and cultural expressions.⁸⁵
- f. Enhancing the use of geographical indications, collective marks instruments for the protection of public health.
- g. Strengthening IP administration through exchange of experience and capacity- building and the creation of a continental database on IP registration.⁸⁶

6. CONCLUSION

Africa boasts a huge untapped trade potential as it boasts majority of developing and least developed countries that are still rich in natural resources. The AfCFTA provides a great opportunity for intra continental trade and investment. It is acknowledged that there are hurdles and challenges to be overcome as a result of different levels of industrial developments, institutional arrangements and IP legislative and regulatory landscape within the continent.

For the AfCFTA to be effective the key considerations as suggested by the UNCTAD seventh, eighth and ninth reports must be taken into consideration, in addition to certain procedural principles that need to be adhered to. The focus of the AfCFTA negotiations should be how best to integrate human rights issues with IP law and policy, especially regarding questions of access to educational materials and health care in Africa as well as consideration for traditional based innovations and innovations taking place in the informal sectors. The AfCFTA IP Protocol negotiations should consider exploring the stipulations of maximum instead of minimum standards in the area of user-focused flexibilities,

⁸¹ Badri (n 24).

⁸² Economic Commission for Africa (n 12).

⁸³ Economic Commission for Africa (n 35) 152.

⁸⁴ Economic Commission for Africa IX (2019) 125.

⁸⁵ *ibid.*

⁸⁶ Economic Commission for Africa IX (2019) 129.

such as exceptions and limitations. AfCFTA could be a platform used to negotiate IP trade and investment agreements with external partners. To fast track IP skills and capacity development, resources should be pooled to build the extensive capacity required for ensuring IP protection. Intellectual property rules should encourage country relevant innovation and to improve prospects of socio-economic development and not to just protect and promote IPRs and promote IP related rankings.⁸⁷

The fundamental priority is to ensure democratic legitimacy. This can be achieved by using open, transparent and inclusive consultative processes that facilitate public debate and engagement. Reporting on such processes, by publishing session notes and or videos, is also a key aspect of widening engagement. It permits those who were not able to participate in person to gain insight into proceedings so that they can provide feedback.⁸⁸

The acceptance and the effect of a treaty depends on its content, which must reflect a balance between rights, obligations and responsibilities. Intellectual property rights enforcement cannot be considered strictly from an economic perspective but has to incorporate social aspects as well. A degree of flexibility also allows countries to adopt measures according to their specific needs and circumstances. This will encourage better coherence and greater acceptance of the entire system.⁸⁹

Africa already boasts a number of networks and regional instruments such as RECs, COMESA, EAC, SADC and ECOWAS that have already developed capacity and have had successful trade negotiation experiences. Building upon the success of these instruments will ensure that implementation of AfCFTA does not unnecessarily re-invent wheels.

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⁸⁷ Correa (n 25) 29.

⁸⁸ Economic Commission for Africa (n 35).

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The IP DIMENSION OF BILATERAL AND REGIONAL TRADE AGREEMENTS IN AFRICA: IMPLICATIONS FOR TRADE AND DEVELOPMENT POLICY

Moses Nkomo*

ABSTRACT

Free Trade Agreements are gaining traction with the 'Africa Rising' mantra that has taken hold of the continent over the past couple of years. In March 2018, the African Union launched the Africa Continental Free Trade Area (AfCFTA)¹ in Kigali, Rwanda. Over a dozen Trade and Investment Framework Agreements have been signed between the United States of America and African countries and Regional Economic Communities.² So far, only Morocco has signed a Free Trade Agreement with the United States of America.³ The negotiations for the Free Trade Agreement between the US and the Southern Africa Customs Union have stalled over intellectual property provisions.⁴ The European Union has also entered into several Economic Partnership Agreements with countries and RECs in Africa within the framework of the Cotonou Agreement.⁵ Intellectual property plays a central role in the trade and development policy of developed countries. So important is intellectual property to the US trade policy that the 2002 Trade Act boldly states that, '[T]he principal negotiating objectives of the USA regarding trade-related intellectual property are ... (A) to further promote adequate and effective protection of intellectual property rights, including through ... ensuring that the provisions of any multilateral or bilateral trade agreement governing

intellectual property rights that is entered into by the USA reflect a standard of protection similar to that found in US law.'⁶ The question that arises in the context of bilateral and regional trade agreements in Africa is the effect of such agreements on the intellectual property, trade and development policy. What is the impact of the Free Trade Agreements on TRIPS flexibilities? This paper focuses on the impact of the US and EU Trade policies and approaches to the flexibilities developing countries fought so hard to secure in the TRIPS Agreement.⁷

Key words: Bilateral trade agreements, regional trade agreements, trade policy, development policy.

1. INTRODUCTION

With the 'Africa Rising' mantra gaining momentum over the past couple of years, there has been substantial interest in concluding bilateral and regional trade agreements with various countries and regional trade blocks from the United States and the European Union. African Countries and regional groupings have escalated their pursuit of Free Trade Agreements (FTAs) with local and international trading partners. The recently concluded Continental Free Trade Area (CFTA) and various regional initiatives bear testimony to the increasing appetite for FTAs on the continent.

While the Continental Free Trade Area is trending at the time of compiling this paper, and there are a handful of regional FTAs on the continent, this paper focuses on the intellectual property ramifications of FTAs with the United States and the European Union. This focus is informed by the aggressive

* **Moses Nkomo** is Intellectual Property Law Lecturer, University of Zimbabwe, Harare, Zimbabwe. A passionate, highly motivated intellectual property law advocate and thought leader, a chronic possibility thinker and avid student of strategy, Moses Nkomo has over sixteen years' experience as a registered practising IP attorney in Zimbabwe, over six years' experience as a consultant, lecturer and researcher of intellectual property law and policy. He has been a lecturer of Intellectual Property law at the University of Zimbabwe since 2007, also lectured Enforcement of Intellectual Property Rights for the WIPO funded Master's Degree in Intellectual Property Law at Africa University from 2011 to 2013, and is a regular resource person for IP locally, regionally and internationally. Currently he is the Senior Partner of Donsa-Nkomo & Mutangi Legal Practice, a commercial law firm with a special interest in intellectual property law and strategy. He is the founder of IPIQ Business Solutions (Private) Limited, a consultancy company which advocates for mainstreaming of intellectual property for sustainable competitive advantage at enterprise and national levels. Moses is a holder of a

Bachelor of Laws Honours Degree, a Master's Degree in Intellectual Property and an Executive Master's Degree in Business Administration and is working towards a Doctor of Laws degree in intellectual property.

¹ Agreement establishing the African Continental Free Trade Area (signed on 21 March 2018) [hereinafter AfCFTA]

² 'Countries and Regions – Africa' (*United States Trade Representative website*) <<https://ustr.gov/countries-regions/africa>>.

³ 'Morocco Free Trade Agreement' (*United States Trade Representative website*) <<https://ustr.gov/trade-agreements/free-trade-agreements/morocco-fta>>.

⁴ Sunday Times (Johannesburg, 19 September 2004)

⁵ Agreement between the European Union and African, Caribbean and Pacific (ACP) Countries 2000

⁶ Trade Act of 2002 (United States) s 2102

⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994) 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement] <https://www.wto.org/legal_e27-trips>

approach to enforcement of intellectual property rights by the US and the EU, especially regarding the flexibilities in the TRIPS Agreement as reflected in the 2018 Special 301 Report.⁸

This paper was conceived on the premise that the protection and enforcement of intellectual property rights must not impede legitimate socio-economic developmental goals for developing countries. It took a huge effort for developing countries to achieve the flexibilities currently enshrined in the TRIPS Agreement and these flexibilities must be jealously guarded from erosion through FTAs and Economic Partnership Agreements. It is this writer's conviction the trade and development policy of African countries must be informed by their domestic needs, dreams and aspirations and not be dictated by powerful developed countries. African countries must leverage the intellectual property system, and capitalize on the existing flexibilities in the intellectual property system to boost their industrial, technological and economic capacity. Lessons may be drawn from how Asian countries leveraged on technology transfer to build their industrial and technological capacities. There is therefore no room for TRIPS Plus intellectual property regimes which are invariably part of FTA baggage.

The noble objectives set out in the TRIPS Agreement to the effect that, '[T]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations,'⁹ have been progressively undermined by a rather aggressive approach to protection of intellectual property, especially by the USA.¹⁰

This paper covers an analysis of the USA and EU policy positions in Free Trade Agreements, reviews the intellectual property provisions of the USA – Morocco Free Trade

Agreement, draws lessons from other jurisdictions, highlights the main challenges African countries face in dealing with IP in Free Trade Agreements, and recommends possible approaches to mitigate the erosion of flexibilities through FTAs.

2. USA POLICY ON IP IN FREE TRADE AGREEMENTS

The USA has followed a consistent and unremitting policy of elevating intellectual property right (IPR) standards. It has done so through unilateral, bilateral, regional and multilateral action. First of all, it has raised the levels of protection domestically¹¹ and has kept on monitoring enforcement of IPRs internationally, through the Special 301 Report, by listing countries that do not meet US expectations for protecting and enforcing IPRs.¹² The Special 301 report is part of the Trade Act which orders the US Trade Representative to produce an annual report that is the first step to imposing trade sanctions on countries which systematically damage the interests of IPR holders in the US.¹³

It is the declared policy of the United States to increase intellectual property protection, and through FTAs and trade and investment framework agreements (TIFAs) through which it is seeking 'higher levels of intellectual property protection in a number of areas covered by the TRIPS Agreement.'¹⁴ For example, in December 2017, the United States concluded an Out-of-Cycle Review of Thailand and moved Thailand from the Priority Watch List to the Watch List.¹⁵ Engagement on IP protection and enforcement as part of the bilateral U.S.-Thailand Trade and Investment Framework Agreement yielded results on resolving US IP concerns across a range of issues, including enforcement, patents and pharmaceuticals, trademarks, and copyright.¹⁶ The US has at least 12 TIFAs in Africa, four of which are with Regional Economic Communities¹⁷ with several member states each.¹⁸

⁸ Special 301 Report (2018) USTR, 5

⁹ TRIPS Agreement, art 7

¹⁰ Special 301 Report (2018) USTR, 5

¹¹ Pedro Roffe, 'Bilateral Agreements and a TRIPS-plus World: The Chile-USA Free Trade Agreement TRIPS' (2004) Issues Papers (Quaker International Affairs Programme, Ottawa), 3 <[http://geneva.quino.info/pdf/Chile\(US\)final.pdf](http://geneva.quino.info/pdf/Chile(US)final.pdf)>.

¹² Special 301 Report (2018) USTR, 5

¹³ *ibid.*

¹⁴ Special 301 Report (2004) USTR, 2 <<http://www.ustr.gov>>.

¹⁵ Special 301 Report (2018) USTR, 10.

¹⁶ *ibid.*

¹⁷ <<https://ustr.gov/countries-regions/africa>>

¹⁸ *ibid.*

Under the Special 301 provisions, compliance with TRIPS does not amount to adequate and effective intellectual property protection. For example, in the 2018 Special 301 report, 'USTR identifies India on the Priority Watch List for lack of sufficient measurable improvements to its IP framework on longstanding and new challenges that have negatively affected U.S. right holders over the past year.'¹⁹ Seeking higher levels of protection beyond TRIPS and requiring developing countries to apply standards similar to the US suggests that the net effect of the FTAs is to curtail the use of legitimate flexibilities under the TRIPS Agreement, such as compulsory licensing.

The main areas of flexibility targeted by the United States FTA are patent protection and protection of undisclosed information.²⁰ On patent protection, there is an array of requirements including compensatory patent term extension, protection of plants and animals, curtailment of compulsory licensing, and others.²¹ For example, even before the completion of the TRIPS Agreement the USA concluded its bilateral agreement with Canada,²² in which IP is featured prominently. The USA had a particular concern about liberal Canadian policies in allowing compulsory licensing to support its pharmaceutical domestic generic industry.²³ Further, in the 2018 Special 301 Report, the USTR contends that, '[T]o maintain the integrity and predictability of IP systems, governments should use compulsory licenses only in extremely limited circumstances and after making every effort to obtain authorization from the patent owner on reasonable commercial terms and conditions.'²⁴ (emphasis added)

The requirement to restrict compulsory licenses to extremely limited circumstances is an affront to permissible flexibilities

under TRIPS, particularly Article 30. It is also inconsistent with the interpretation of Article 30 rendered by the WTO DSB in the Canada Generics case.²⁵

On May 18, 2017, President Donald Trump notified Congress of the Administration's intent to renegotiate North American Free Trade Agreement (NAFTA) in order to modernize and rebalance the Agreement.²⁶ On 17 July 2017 USTR publicly released a detailed summary of the objectives the Administration seeks to achieve through this renegotiation.²⁷ Through the renegotiation, the Administration has two principal objectives: first, to update the agreement with modern provisions representing the best text available. **This will bring NAFTA into the 21st century by adding improved provisions to protect intellectual property** and facilitate efficient cross-border trade, among other updates.²⁸

This reflects the level of seriousness with which the United States views intellectual property in the context of FTAs, and whenever it has opportunity, it pushes back any flexibilities which may be at the disposal of its trading partner. According to the USTR, Intellectual property (IP) infringement, including patent infringement, trademark counterfeiting, copyright piracy, and trade secret theft, causes significant financial losses for right holders and legitimate businesses around the world. IP infringement undermines US competitive advantages in innovation and creativity to the detriment of American businesses and workers.²⁹

The official negotiating objectives of the US with respect to IPRs are clearly enunciated in the Trade Act of 2002 as follows:

Section 2102

¹⁹ Special 301 Report (2018) USTR, 5.

²⁰ Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International, 2001).

²¹ Frederick M. Abbott, *IP Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law* (2006).

²² The Canada – US Free Trade Agreement (entered into force on 1 January 1989) 27 I.L.M. 281 (1988) <<http://wehner.tamu.edu/mgmt.www/nafta/fta/>>.

²³ Jerome H. Reichman, 'Managing the Challenge of a Globalized Intellectual Property Regime,' (2003) Paper prepared for the ICTSD–UNCTAD Dialogue.

²⁴ Special 301 Report (2018) USTR, 14.

²⁵ WTO, *Canada – Patent Protection of Pharmaceutical Products – Report of the Panel* (17 March 2000) WT/DS114/R.

²⁶ North American Free Trade Agreement, 32 I.L.M. 289 and 605 (1993) [hereinafter NAFTA] <<https://ustr.gov/trade-agreements/free-trade-agreements/north-american-free-trade-agreement-nafta>>.

²⁷ *ibid.*

²⁸ Annual Report II (2018) USTR, 2.

²⁹ Special 301 Report (2018) USTR, 11.

(4) Intellectual property. ...The principal negotiating objectives of the USA regarding trade-related intellectual property are...

(A) to further promote adequate and effective protection of intellectual property rights, including through –

(i) (I) ensuring accelerated and full implementation

of the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(15)), particularly with respect to meeting enforcement obligations under that agreement; and

(II) **ensuring that the provisions of any multilateral or bilateral trade agreement governing intellectual property rights that is entered into by the USA reflect a standard of protection similar to that found in US law;**

(ii) providing strong protection for new and emerging technologies and new methods of transmitting and distributing products embodying intellectual property;

(iii) preventing or eliminating discrimination with respect to matters affecting the availability, acquisition, scope, maintenance, use, and enforcement of intellectual property rights;

(iv) ensuring that standards of protection and enforcement keep pace with technological developments, and in particular ensuring that rightholders have the legal and technological means to control the use of their works through the Internet and other global communication media, and to prevent the unauthorized use of their works; and

(v) providing strong enforcement of intellectual property rights, including through accessible, expeditious, and effective civil, administrative, and criminal enforcement mechanisms;

(B) to secure fair, equitable, and non-discriminatory market access opportunities for US persons that rely upon intellectual property protection; and

(C) to respect the Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization at the Fourth Ministerial Conference at Doha, Qatar on November 14, 2001.³⁰

Through the mechanism of the Special 301 Report, the USTR pursues an aggressive policy to protect US creators, inventors and innovators. This has become more brazen with President Trump's America First mantra. In the 2018 Special 301 Report, the USTR states that:

The identification of the countries and IP-related market access barriers in this Report and of steps necessary to address those barriers are a critical component of the Administration's aggressive efforts to defend Americans from harmful IP-related trade barriers.³¹

3. EU POLICY ON IP IN ECONOMIC PARTNERSHIP AGREEMENTS

While not as blunt as that of the United States, the European Union policy on intellectual property is also fairly aggressive. The European Union is negotiating Economic Partnership Agreements with various African countries in terms of the Cotonou Agreement, which provides, among other things, the need 'to ensure an adequate and effective level of protection of intellectual, industrial and commercial property rights ... **in line with international standards.**'³²

New international standards are continuously being established with respect to areas covered by the TRIPS, including through FTAs and the international standards of IP protection which are the basis of the EPAs.³³

The attitude of the EU on TRIPS Flexibilities was exposed in the case of EC v Canada,³⁴ commonly known as the Canada Generics case. The dispute between the parties arose from the enactment in the Canadian Patent Amendment Act in

³⁰ Trade Act of 2002 (United States) s 2102

<http://www.tpa.gov/pl107_210.pdf>

³¹ Special 301 Report (2018) USTR, Executive Summary 5.

³² Cotonou Agreement, art 46.

³³ Lorand Bartels, 'The Trade and Development Policy of the European Union,' (2007) *The European Journal of International Law* Vol. 18 no. 4.

³⁴ WTO, *Canada – Patent Protection of Pharmaceutical Products – Report of the Panel* (17 March 2000) WT/DS114/R.

1993. The Amendment Act introduced two new exceptions to the rights of patent holders, namely the Regulatory Review exception and the stockpiling exception. The Act provided that 'it is not an infringement of a patent for any person to make, construct, use or sell a patented invention solely for uses reasonably related to the development and submission of information required under the law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.'

In the Canada Generics case, the EC managed to successfully argue for a very narrow interpretation of exceptions to patents rights set out in Articles 30 and 31 of the TRIPS Agreement. This was a push back on the flexibility given by the unambiguous language of Article 31 in particular.

4. THE GENERAL APPROACH OF DEVELOPED COUNTRIES TO IP IN FREE TRADE AGREEMENTS WITH DEVELOPING COUNTRIES

Pedro Roffe notes that, '[W]hile TRIPS introduces minimum standards of protection, albeit with some flexibility, recent trends suggest a more complex picture characterized as a TRIPS-plus phenomenon.'³⁵

The common TRIPS-plus features in bilateral and regional trade deals the United States has entered with developing countries include:

- Provisions establishing special 5-10 year monopoly protections for pharmaceutical test data required to demonstrate drug safety and efficacy and to authorize a drug for use ('data exclusivity'). Data exclusivity may effectively bar compulsory licensing or generic competition for drugs that are not patent protected.
- Measures prohibiting drug regulatory agencies from granting marketing approval to a generic version of a medicine if the product is covered by a patent ('linkage'). As even the Bush administration has acknowledged, such requirements have been subjected to repeated abuse in the United States,

unjustifiably delaying the introduction of generic competition.

- Patent extensions beyond the 20 years of monopoly protection mandated by the WTO.
- Restrictions on the ability of countries to undertake re-importation (also known as parallel importation).
- Obligations to extend patent protection to minor improvements in, or new uses of, older products.

It is clear that Free Trade Agreements pose a real risk to the flexibilities guaranteed by the TRIPS Agreement, but this research will seek to demonstrate that developing countries have room to cement, rather than surrender, their flexibilities when entering into Free Trade Agreements.

5. ANALYSIS OF USA-MORROCO FREE TRADE AGREEMENT

The FTA³⁶ is composed of 24 chapters dealing with broad aspects of trade, including general provisions establishing a free trade zone between the two countries, definitions, administrative aspects, settlement of disputes and specific chapters dealing with standards in areas such as market access, services, investment, telecommunications and intellectual property (IP). Chapter 15 deals with IP. It begins with general provisions, followed by 12 sections dealing, respectively, with general provisions, trademarks, domain names on the internet, geographical indications, copyright, related rights, obligations common to copyright and related rights, protection of encrypted program-carrying satellite signals, patents, measures related to certain regulated products, enforcement of IPRs and final provisions.

The FTA builds on the international architecture of IPRs. It establishes as a major principle that nothing in the Agreement derogates from the obligations and rights of the Parties by virtue of TRIPS or other multilateral IP agreements administered by the World Intellectual Property Organization (WIPO) (hereinafter referred to as the 'non-derogation principle'). It enshrines the national treatment principle of

³⁵ Pedro Roffe, 'Bilateral Agreements and a TRIPS-plus World: The Chile-USA Free Trade Agreement TRIPS' (2004) Issues Papers (Quaker International Affairs Programme, Ottawa), 3 <[http://geneva.quino.info/pdf/Chile\(US\)final.pdf](http://geneva.quino.info/pdf/Chile(US)final.pdf)>.

³⁶ US - Morocco Free Trade Agreement (Signed 15 June 2004, entered into force on 1 January 2006) [hereinafter US - Morocco FTA] <<https://ustr.gov/trade-agreements/free-trade-agreements>>.

non-discrimination between nationals of the two countries and, as a consequence of the most-favoured nation clause in TRIPS, the advantages, benefits, and privileges granted by the FTA are automatically accorded to the nationals of all other Members of the World Trade Organization (WTO).

In terms of Article 15.10 of the United States-Morocco Agreement, Morocco is required to grant data exclusivity way beyond the requirement in Article 39 TRIPS. While Article 39.3 of TRIPS envisages protection of test data submitted to governments to meet regulatory approval, Article 15.10 goes far beyond this requirement and introduces layers and layers of protection. Particularly important is the fact that the FTA requires data exclusivity applicable to all new medicines irrespective of whether they are patentable. The FTA introduces a mandatory five year period of exclusivity for test data. Article 39.3 only requires the application of unfair competition rules as opposed to exclusivity. This is calculated to prevent generic drug manufacturers from relying on test data submitted by originator companies.

The FTA does not provide for an exception to the data exclusivity where it is necessary for the protection of public health.

Article 15.10(3) of the FTA introduces the principle of patent term restoration to compensate for unreasonable curtailment of the effective patent term due to delays in the marketing approval process, as well as additional provisions requiring patent term extensions based on delay in granting of the patent. In addition to all the cumbersome requirements related to the protection of test data in its own right, the FTA goes even further to link the test data protection to the patent term with the effect that for new products which are also patented, no generic can be registered except with the consent of the patent owner during the term of the patent, including when the patent term is extended based on the delays in either granting the patent or marketing approval.

The FTA also seeks to define patentability criteria such as utility to conform to the United States standard. The FTA also

requires Morocco to provide mandatory patents for plants and animals, as well as to grant patents for new uses of known pharmaceutical products.³⁷ This makes the ever greening of patents relatively easy and delays the entry of generic medicines in the market with potentially catastrophic consequences.

The FTA also prohibits, or at the very least restricts, parallel importation. Article 15.9(4) provides that:

Each party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory.³⁸

Such provisions essentially allow the patent holders, through contract laws, to segment markets and maintain price discrimination.

6. LESSONS FROM THE USA-CHILE FTA NEGOTIATIONS

In the early 1990s, Chile and the United States America (USA) started discussions on the possibility of launching negotiations of a free trade agreement. For the USA, the negotiations with Chile represented an important opportunity to consolidate changes in the area of IP for which some industrial domestic groups were driving for reforms, namely in the area of new copyright disciplines in the digital environment and improved protection for pharmaceutical and agricultural chemical products. The US copyright industry, including entertainment and software, together with the pharmaceutical sectors from both countries, played a key role during the negotiations. The Chilean domestic pharmaceutical sector was also an important player. It met 90% of the public health sector needs, was the only one with installed capacity, and generated more than 6,000 jobs plus 50,000 related to sub-contracting and out-sourcing. Foreign pharmaceutical companies, on the other hand, were mere importers and distributors of products produced abroad. Understandably, the Chilean domestic pharmaceutical industry was particularly alert during the FTA negotiations

³⁷ US - Morocco FTA, art 15.9(2).

³⁸ US - Morocco FTA, art 15.9(4).

and expressed concerns from the outset about the introduction in the negotiations of issues such as:

- Increase of patent protection term;
- Reinstatement of pipeline protection for pharmaceutical products;
- Prohibition of parallel importation and exhaustion of patent rights;
- Restrictions on procedural issues (e.g., elimination of the opposition process);
- Enhancement of the protection of undisclosed information;
- Increasing fines in case of infringement;
- Linkage between sanitary permits and the granting of patents;
- Limitations for granting compulsory licenses; and,
- Scope of the reversal of the burden of proof in case of process patents.

The FTA IP Negotiating Group met for the first time in January 2001. Reportedly, Chile tried to avoid the inclusion of TRIPS-plus provisions from the very beginning particularly because it felt, as illustrated above, that it had intensively advanced in the implementation of TRIPS and in the signature of important international conventions in this field. However, for the USA, a trade agreement without higher standards of protection was not an option. From the outset, the USA indicated the areas considered to be of major concern in reaching an agreement on IP matters and these included:

- Better coordination between the health authorities and the Industrial Property Department to avoid granting marketing approval to pharmaceutical products similar to pharmaceuticals still under patents;
- A ban on the use of undisclosed information required to grant marketing approval of competing or similar pharmaceutical and agricultural chemical products;
- Implementation of an adequate system to protect undisclosed information under Article 39.3 of the TRIPS Agreement;
- Establishment of pipeline protection for pharmaceuticals products;
- The patenting of transgenic plants and animals;

- Limitations in the granting on compulsory licenses;
- Limitations to the denial of patent applications based upon certain grounds such as morality, prejudice to the environment, and diagnostic, therapeutic and surgical methods for human and animal treatments;
- Limitations on the use of parallel importation;
- Establishment of an effective mechanism to guarantee that all public agencies use only authorized computer programs;
- Clarification of the right of reproduction with respect to temporary reproductions;
- The non-recordal of trademark licenses for their validity;
- The increase in the level of enforcement for infringement of digital related products;
- Participation of governments in Internet Corporation for Assigned Names and Numbers (ICANN) and adoption of the Uniform Domain-Name Dispute-Resolution Policy (UDRP);
- The possibility of the right holder to recover profits perceived by the infringer of copyrighted products;
- The seizure of infringing goods and of material and implements by means of which such goods are produced; and,
- Establishment of criminal remedies to provide a deterrent to future infringements.

The final and decisive round of negotiations took place in December 2002, where over 90 Chilean and 140 US negotiators from different agencies worked for nine straight days to conclude the Agreement. On that occasion, most of the outstanding questions were overcome, including those in the Chapter on IP.

The foregoing example illustrates the need to have stakeholder buy-in and involvement in FTA negotiations. It also illustrates the need to have sufficient human resource capacity and expertise and the necessity of putting national developmental objectives at the centre of any trade and development policy. The example also shows that with sufficient will and expertise, it is possible to resist erosion of TRIPS Flexibilities through Free Trade Agreements. The sheer numbers of the negotiators involved is indicative of the level of seriousness of the parties involved. African countries are

usually represented by a few individuals at the negotiations and this disadvantages them.

7. THE AFRICAN CONUNDRUM

Who determines the IP and Trade & Development policies for Africa? Whose agenda is served by the IP and Trade & Development policies adopted in African countries? Do African countries sell their birthright for a bowl of stew? Is the Trade and Development policy of African Countries home grown or it is dictated by the West? Whose interests are served by the FTAs and EPAs African countries are stampeding to enter into? How sustainable are the Trade and Development policies pursued by African countries? Is IP an enabler or a disabler of trade and development in the context of FTAs and EPAs?

With the advent of the AfCFTA, the question of intellectual property and trade & development policy has become very topical. The Agreement Establishing AfCFTA provides for cooperation by State parties on investment, IPR and competition policy.³⁹ The Agreement further provides that, '[T]his Agreement shall cover trade in goods, trade in services, investment, intellectual property rights and competition policy.'⁴⁰ Article 7 provides that phase 2 of the negotiations shall cover IPRs, investment and competition policy. The agreement also provides that, '[T]he Protocols on Trade in Goods, Trade in Services, Investment, Intellectual Property Rights, Competition Policy, Rules and Procedures on the Settlement of Disputes and their associated Annexes and Appendices shall, upon adoption, form an integral part of this Agreement. The Protocols on Trade in Goods, Trade in Services, Investment, Intellectual Property Rights, Competition Policy, Rules and Procedures on the Settlement of Disputes and their associated Annexes and Appendices shall form part of the single undertaking, subject to entry into force.'⁴¹ This demonstrates that intellectual property is getting increasing prominence on the continent. However, given the general lack of technical capacity in Africa, there is a high possibility the intellectual property protocol will rely

heavily on US or EU technical assistance and will thus be inspired by US and EU standards of IP protection.

According to the USTR Special 301 Report for 2018, 'A top trade priority for the Administration is to use all possible sources of leverage to encourage other countries to open their markets to U.S. exports of goods and services, and provide adequate and effective protection and enforcement of U.S. intellectual property (IP) rights. **Toward this end, a key objective of the Administration's trade policy is ensuring that U.S. owners of IP have a full and fair opportunity to use and profit from their IP around the globe.**'⁴²

Intellectual property protection and enforcement are central to the American trade policy, as stated in the 2018 Special 301 Report: 'Fostering innovation and creativity is essential to U.S. economic growth, competitiveness, and an estimated 45 million American jobs that directly or indirectly rely on IP-intensive industries. USTR continues to work to protect American innovation and creativity in foreign markets with all the tools of U.S. trade policy, including through the annual Special 301 Report.'⁴³

This essentially means that in so far as African countries wish to tap into the sizeable American and European market, the IP and Trade & Development Policy is dictated by the bigger, more powerful trading partners. This explains why, despite investing so much to secure reasonable flexibilities in the TRIPS Agreement, there is a real risk that all these gains will be wiped away through Bilateral Free Trade Agreements. This is a classical illustration of the old adage that 'he who pays the piper calls the tune.' The lack of a deep understanding of the strategic importance of intellectual property for socio-economic development results in governments diving into FTAs without counting the cost.

8. THE PROBLEMS OF AFRICA

A. Lack of a coordinated and harmonised approach to intellectual property and trade & development policy is a major handicap on the continent. In most countries, IP is administered by the Ministry of Justice; Trade is administered

³⁹ AfCFTA, art 4.

⁴⁰ AfCFTA, art 6.

⁴¹ AfCFTA, art 8.

⁴² Special 301 Report (2018) USTR, 5 (Executive Summary).

⁴³ Special 301 Report (2018) USTR, 12.

by the Ministry of Industry and Commerce; Development is administered by the Ministry of Finance and Economic Development, and these ministries have little or no convergence. This results in a chaotic system wherein there are contradictions and conflict of priorities. There is a need for a multi-stakeholder, robust, harmonized, well-coordinated approach to the interface between Intellectual Property, on the one hand, and Trade and development policy on the other.

B. Lack of capacity to effectively negotiate favourable terms in FTAs and EPAs. In most African countries, trade negotiations are exclusively conducted by government officials, many of which have no advanced knowledge or training on the various aspects of the trade negotiations. For example, intellectual property is not a very familiar subject in most government offices in Africa and, consequently, it is not given the same attention and importance it is given by the US Administration, for example. Further, industry players are rarely involved in the policy formulation processes and therefore the policies are usually ivory-tower policies not related to the needs on the ground.

C. Sheer ignorance of the ramifications of the FTAs and EPAs is also another serious problem in Africa. There is very little strategic thinking and strategic planning at the governmental level. Governments are often engrossed in trying to get quick fix solutions to the myriad of socio-economic challenges bedeviling our countries to the extent they never stop to think of the long term ramifications of the agreements they sign. Whereas President Trump's America First approach may be considered too radical, there may be a need to adopt a strategic approach to the crafting and implementation of IP, trade and development policies in Africa.

D. Overreliance of technical support from development partners is another serious challenge for Africa. Most of the IP, trade & development policies are cut and paste templates provided by development partners which do not speak to the peculiar circumstances of African countries. Take for instance an African country that blindly depends on the US for technical assistance, and they request assistance in drawing up a trade and development policy which will govern their trade relations with the US. There is no price for guessing that

the policy will be biased towards achieving the trade objectives of the US.

9. CONCLUSION

The foregoing discourse clearly shows that FTAs seek to entrench the protection and enforcement of intellectual property rights of developed countries and to undermine the use of TRIPS flexibilities by developing countries in that they elevate the object and purpose of intellectual property protection beyond the scope of TRIPS. Instead of contributing to the promotion of technological innovation and transfer of technology and ensuring the mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare, they maintain the advantage of developed countries over developing countries.

FTAs constitute the worst risk to the utilization and enjoyment of TRIPS Flexibilities by developing countries and take away the opportunity of developing countries to leverage the IP system to further their own developmental objectives. Those developing countries who have already entered into FTAs with the US have been subjected to immense pressure through the Special 301 system.

Those countries that are negotiating FTAs must be vigilant and diligent so that they do not lose the flexibilities provided by the TRIPS Agreement. For African countries, while the menace of Free Trade Agreements has been minimal so far, with only Morocco having already entered into a Free Trade Agreement with the United States, it is important to highlight the net effect of the FTA was to erode all the flexibilities guaranteed by the TRIPS Agreement. The Southern African Customs Union (SACU) has done well to insist on FTA negotiations without IP provisions while the United States negotiators argued that this was outside their negotiating mandate hence the stalemate on the US - SACU FTA.

African countries are now aware of the adverse impacts of FTAs on TRIPS flexibilities and are in a position to safeguard them. They need to consolidate and defend the policy flexibilities enshrined in TRIPS through law reforms informed by national or regional developmental objectives. There is also a need for regional integration, harmonisation and

coordination of approaches to IP, trade & development. Capacity building is also imperative if Africa is to effectively negotiate for better terms in FTAs and EPAs.

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THE IP DIMENSION OF BILATERAL AND REGIONAL TRADE AGREEMENTS IN AFRICA: IMPLICATIONS FOR TRADE AND DEVELOPMENT POLICY

Henry Kibet Mutai*

ABSTRACT

Regional integration on the African continent has been the focus of renewed interest with initiatives such as the African Continental Free Trade Area and the Tripartite Free Trade Area currently being negotiated. These initiatives aim to go beyond the traditional trade liberalization of goods and services to include harmonization of intellectual property and competition laws. This provides a valuable opportunity for African countries to review their laws and determine the manner in which they can shape intellectual property law to serve their interests and circumstances. However, their options are to some extent circumscribed by the international arena within which they operate as well as by some of their existing regional and international obligations. The discussion in this paper highlights some of the issues that will need to be addressed in the quest to negotiate a protocol on intellectual property covering patents, trademarks, copyright, utility models and industrial designs in the context of the Tripartite Free Trade Area. Most of these issues will also need to be addressed when negotiating at the wider Continental level. The paper concludes that given the heterogeneity of the negotiating parties and the flexibilities they already enjoy, it may not be possible to arrive at new substantive obligations and the focus may need to be on facilitating the procedural aspects of the law.

Key Words: Regional Integration, Tripartite Free Trade Area, Intellectual Property, Harmonization, Patents, Trademarks, Copyright.

1. INTRODUCTION

Regional integration on the African continent is not a new phenomenon. For the most part, however, integration has primarily been concerned with facilitating the free movement of goods and services between the various African states, with intellectual property (IP) being the preserve of specialised institutions such as the African Regional Intellectual Property Organization (ARIPO) and the African Intellectual Property Organization (OAPI).

Lately, however, the desire to deepen integration between different sub-sets of African countries has led to an increased interest in the harmonization of IP laws within the different regional trade blocs. This has been reflected in the negotiations for the establishment of

larger blocs such as the Tripartite Free Trade Area (TFTA) and the proposed African Continental Free Trade Area (AfCFTA). The first phase of integration within these larger blocs has not included IP but in the second phase of negotiations, IP is expected to take a more central role. There is, therefore, an urgent need to conduct research into the implications and modalities of such harmonization for social and economic development, if it does indeed occur. Such research would look into possible areas of harmonization and the mechanisms to be employed if such harmonization is to bestow tangible benefits to the affected communities.

This paper looks at some of the options available to the States that make up the TFTA as they prepare to engage in negotiations on IP. The next section gives a brief overview of the international environment within which trade and IP matters exist. Section three looks at some of the trademark related issues before turning to patent matters in section four. Section five looks at copyright law before in section six, some of the other IP areas are examined. Lastly, section seven provides some concluding thoughts and recommendations.

2. INTERNATIONAL ENVIRONMENT

The Tripartite Free Trade Area (TFTA) brings together 26 Member States of the Common Market for Eastern and Southern Africa (COMESA), the East African Community (EAC) and the Southern African Development Community (SADC). Under the TFTA treaty, in the first phase of negotiations the parties agree to create a unified free trade area covering goods and services. In the second phase of negotiations, members agreed to negotiate in the areas of IP. This is provided for in Article 45(1) of the Agreement which states:

Recognising the need to conclude Phase II negotiations, and to provide flexibility in the implementation of the Agreement, the Tripartite Member/Partner States agree to negotiate and endeavour to conclude the following protocols within 24 months upon entry into force of this Agreement:

- a) a Protocol on Trade in Services; and
- b) Protocols on trade-related matters including Competition Policy, Cross-Border Investment, Trade and Development, and Intellectual Property Rights.¹

It should be noted that of the 26 Members making up the Tripartite FTA, 21 are members of the WTO. As such, the

* Henry Kibet Mutai is currently the Director of the Kenya School of Law. He holds Master of Laws and Doctor of Philosophy degrees from the University of Melbourne and has served as the Managing Director of the Kenya Industrial Property Institute (KIPI).

¹ Agreement Establishing a Tripartite Free Trade Area Among the Common Market for Eastern and Southern Africa, the East African Community and the Southern African Development Community, Article 45(1).

TRIPS Agreement sets out certain minimum standards members must comply with. However, Article 66(1) of TRIPS recognises the special position of LDCs and provides a period of time within which to comply with those obligations. This period has since been extended until 1 July 2021.²

Negotiations aimed at establishing a Continental Free Trade Area were launched in Johannesburg in June 2015. After several rounds of negotiations, The Agreement Establishing the Continental Free Trade Area was signed in Kigali, Rwanda in March 2018 by 44 Members of the African Union. Article 24(1) of the Agreement provides that it shall enter into force 30 days after the deposit of the 22nd instrument of ratification.³ On the 29th April 2019, the 21st and 22nd instruments of ratification were deposited by Sierra Leone and the Saharawi Republic, meaning that the Treaty officially entered into force on 30 May 2019.⁴

Table 1: Membership of International Treaties

Country	Lusaka Agreement	Banjul Agreement	Harare Protocol	TRIPS	Paris Convention	Berne Convention
Angola				☐	☐	
Botswana	☐	☐	☐	☐	☐	☐
Burundi				☐	☐	☐
Comoros					☐	☐
DRC				☐	☐	☐
Djibouti				☐	☐	☐
Egypt				☐	☐	☐
Eritrea						
Ethiopia						
Kenya	☐		☐	☐	☐	☐
Lesotho	☐	☐	☐	☐	☐	☐

Libya					☐	☐
Madagascar				☐	☐	☐
Malawi	☐	☐	☐	☐	☐	☐
Mauritius				☐	☐	☐
Mozambique	☐		☐	☐	☐	☐
Namibia	☐	☐	☐	☐	☐	☐
Rwanda	☐		☐	☐	☐	☐
Seychelles				☐	☐	
South Africa				☐	☐	☐
Sudan	☐		☐		☐	☐
Swaziland	☐	☐	☐	☐	☐	☐
Tanzania	☐	☐	☐	☐	☐	☐
Uganda	☐	☐	☐	☐	☐	
Zambia	☐		☐	☐	☐	☐
Zimbabwe	☐	☐	☐	☐	☐	☐
Total	13	8	13	21	24	21

It should be noted that despite the Continental Free Trade Area Treaty having entered into force, not all parts of the Treaty have been concluded. For instance, the Rules of Origin to be applied by Member States in determining the goods eligible for preferential treatment and the Tariff Offers between Members are yet to be agreed on. This means that in practice, the free trade area is yet to be operationalised.

Regarding intellectual property, two African institutions are significant. The first of these is the African Regional Intellectual Property Organization (ARIPO), an

² The first extension occurred in 2005 when the TRIPS Council extended the transition period to 1 July 2013. This was subsequently extended on 11 June 2013 to 2021. See <https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm>

³ The Agreement Establishing the Continental Free Trade Area, Article 24(1).

⁴ <<https://au.int/en/pressreleases/20190429/afcta-agreement-secures-minimum-threshold-22-ratification-sierra-leone-and>> accessed 19 October 2019.

international organization bringing together 19 primarily English speaking African countries. The objectives of the parties to the Lusaka Agreement that established the organization include the promotion of the harmonisation and development of IP laws appropriate to the needs of its members, fostering the establishment of a close relationship between its members in matters relating to IP and establishing such common services or organs as may be necessary or desirable for the co-ordination, harmonisation and development of IP activities among members. It is therefore clear that ARIPO has to play a central role in the harmonisation effort so far as its members are concerned. For that reason, the instruments ARIPO members have concluded amongst themselves on IP matters will be central to any negotiations.

The other significant IP organization in Africa is the African Intellectual Property Organisation (OAPI). OAPI was created by the Bangui Agreement of 2 March 1977. Its membership of 17 countries is drawn primarily from French-speaking African countries. Unlike ARIPO, the Bangui Agreement serves as the national intellectual property law for all the OAPI Member States. However, because none of its members are a part of the TFTA, discussion of its mandate and services offered is outside the scope of this paper.

1. Trademarks

This section gives an overview of a few key trademark related issues that need addressing in a TFTA Protocol on IP. The first point to note is that there are already several international legal regimes governing trademark law. The TRIPS Agreement obliges members of the WTO to comply with the provisions regarding to trademarks found in Articles 15 to 21. These provisions cover protectable subject matter, rights conferred, exceptions, term of protection, requirement of use, other requirements and licensing and assignment, respectively. WTO Members are also required to comply with the provisions regarding geographical indications found in Articles 22 – 24 of TRIPS.

For ARIPO members who signed and ratified the Banjul Protocol, that instrument will occupy a central position in determining what they can and cannot agree to do in any IP negotiations. The Banjul Protocol provides a mechanism for parties to centrally process trademark applications. One of the main challenges facing the Banjul Protocol has been the low number of signatories. Currently, it has just 10 parties and 8 are part of the TFTA negotiations.⁵

Definition of a mark

A threshold issue that should be considered by the parties regards arriving at a common understanding of what a mark is. A mark is defined by the TRIPS Agreement as

Any sign, or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings, shall be capable of constituting a trademark. Such signs, in particular words including personal names, letters, numerals, figurative elements and combinations of colours as well as any combination of such signs, shall be eligible for registration as trademarks. Where signs are not inherently capable of distinguishing the relevant goods or services, Members may make registrability depend on distinctiveness acquired through use. Members may require as a condition of registration, that signs be visually perceptible.⁶

Domestically, a review of different national laws reveals there are several distinct approaches that states have taken to define trademarks. Most TFTA countries still require a mark to be visible to be registrable.

However, a number of countries including Mozambique⁷ and Uganda⁸ allow for the registration of audible and olfactory signs.

Types of marks

Other than the regular trademark, many countries also provide for the registration of certification and collective marks. Article 7bis of the Paris Convention obliges parties to accept for filing and to protect collective marks belonging to associations, the existence of which is not contrary to the law of the country of origin. However, it does not say anything about certification marks. As a result, the legal frameworks differ from country to country. A review of some TFTA countries' laws reveals that countries like Kenya,⁹ Mozambique,¹⁰ Namibia¹¹ and Rwanda¹² provide for the registration of both collective and certification marks while others like Sudan, Swaziland and Tanzania provide for the registration of neither. This presents another opportunity for countries to harmonise their laws.

Grounds for Refusal

An application for trademark registration is no guarantee the mark will be registered. The relevant trademark offices are required to examine the proposed mark proposed and decide as to its registrability. One of the issues that can arise, therefore, pertains to grounds for refusal of grant. These generally include non-distinctiveness, similarity to another mark, similarity to well-known marks and marks that are contrary to public

⁵ The two exceptions are Liberia and Sao Tome and Principe.

⁶ TRIPS, Article 15(1)

⁷ Industrial Property Code, 2006, Article 1(i).

⁸ Trade Marks Act, 2010, section 1.

⁹ Trade Marks Act, sections 40 and 41.

¹⁰ Industrial Property Code, 2006, Article 123.

¹¹ Industrial Property Act, 2012, section 187.

¹² Intellectual Property Law, Articles 156 and 161.

order or morality. However, the interpretation of these terms is left to states.

Opposition

Once a mark has been accepted for registration, it is generally advertised in an official medium for members of the public to have an opportunity to oppose. This opposition period differs from one country to another and provides another opportunity for harmonization of laws.

Duration of protection

The TRIPS Agreement provides that "Initial registration, and each renewal of registration, of a trademark shall be for a term of no less than seven years. The registration of a trademark shall be renewable indefinitely."¹³ The Banjul Protocol, on the other hand, provides for a longer period of initial protection of 10 years, also renewable indefinitely subject to the payment of renewal fees. A review of the legal frameworks of some of the TFTA countries reveals they provide for slightly different durations of protection, with most opting for the 10-year period.

However, in terms of when protection begins, there are different approaches. For example, Botswana, Kenya, Lesotho, Namibia and Rwanda provide for protection beginning from the date of application, while others provide that protection only begins at registration.

Taking all the above into consideration, the question arises whether TFTA members would be better off seeking a protocol that will expedite the application process, while leaving substantive laws to the national legal regime, or if they should seek to harmonise substantive laws.

2. Patents

This section looks at patent law and some of the key issues that need addressing in harmonising patent law among the members of the TFTA. As is the case with trademark law, there are already a number of international agreements aiming to harmonise patent law. Under WIPO's auspices, the main instruments dealing with patents are the Paris Convention (some of whose provisions are incorporated into TRIPS by reference), the Patent Cooperation Treaty (PCT) and the Patent Law Treaty (PLT). For WTO Members, the TRIPS Agreement contains a number of provisions in Articles 27 – 34. All these address different aspects of patent law.

At a regional level, the provisions of the Harare Protocol will play a central role in the position that ARIPO members

will take in the forthcoming negotiations. The Harare Protocol empowers ARIPO 'to grant patents and to register utility models and industrial designs and to administer such patents, utility models and industrial designs on behalf of Contracting States'.¹⁴

The following are some of the patent issues where TFTA members may consider harmonising their laws:

Patentable subject matter

This is a critical issue in defining the scope of patent law. An analysis of the relevant laws shows that some TFTA countries provide a comprehensive definition of an invention incorporating the three elements of novelty, non-obviousness and utility¹⁵ while others simply define an invention as "an idea which permits in practice the solution to a specific problem in the field of technology".¹⁶

Defining what an invention is closely relates to that of determining those products or processes to be considered non-inventions. This issue arises in the context of where to draw the line between matters eligible for patent protection and those that are not by virtue of being a part of the public domain.

Section 3(10)(h) of the Harare Protocol provides some guidance here by providing that

The following in particular shall not be regarded as inventions within the meaning of paragraph 10(a):

- (i) Discoveries, scientific theories and mathematical methods;
- (ii) Aesthetic creations;
- (iii) Schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
- (iv) Presentation of information.¹⁷

Regarding the issue of computer programmes, it is worth noting that even though, as seen above, the Harare Protocol specifically excludes them from protection, not all TFTA Members have incorporated this provision into their legislation. With the growing importance of computer programs in the ICT sector, it will be important to have a common understanding regarding the best means of protecting them.

Exclusions

Not all subject matter that falls within the definition of an invention as described above is eligible for patent protection. In certain instances, countries will put in place legal mechanisms to distinguish between patentable and

¹³ TRIPS Article 18

¹⁴ Harare Protocol, Section 1.

¹⁵ For example, Kenya (Industrial Property Act, section 2), Malawi (Patents Act, section 2), and Uganda (Industrial Property Act, 2014, section 2).

¹⁶ For example, Botswana (Industrial Property Act, 2010, section 2), Lesotho (Industrial Property Order, 1989, section 2), Mozambique (Industrial Property Code, 2015, Article 1(e)), Namibia (Industrial Property Act, 2012, section 12) and Rwanda (Intellectual Property Law, 2009, Article 5).

¹⁷ Harare Protocol, Section 3(10)(h).

non-patentable inventions. This is often done as a matter of public policy and has proved to be fairly controversial, especially regarding pharmaceutical products.

Article 27 of TRIPS provides that

(2) members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.¹⁸

Article 27(3) of TRIPS also permits members to exclude from patentability:

- a) Diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- b) Plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.¹⁹

These provisions are mirrored in sections 3(10)(j)(i) and (ii) of the Harare Protocol.

An analysis of the laws of a number of TFTA countries reveals the distinction between non-inventions and exclusions is not always clearly reflected in their laws. In these countries, such as Lesotho,²⁰ Rwanda²¹ and Sierra Leone,²² categories are grouped together as not being eligible for, or excluded from, patent protection. This distinction is important because Article 27(1) of TRIPS specifies patents must be available for certain inventions subject to the allowed exceptions under paragraphs 2 and 3.²³

Pharmaceutical product exclusions

As noted above, the issue of exclusions from patentability assumes importance pertaining to the debate regarding the availability of affordable medicines in developing and least-developed countries. At least two LDCs in the TFTA region, Uganda and Rwanda, have specific legislation that excludes pharmaceutical products from patent protection. Going forward, and in the context of the TFTA, members will need to negotiate whether an exclusion for pharmaceutical products should be a part of an IP Protocol. This is likely, as it is highly improbable that

a concession obtained at the WTO will be surrendered in TFTA negotiations. With the anticipated free movement of goods within the TFTA, this has the potential to provide a conducive legal environment for these countries to establish domestic pharmaceutical industries.

New Uses

This is another area of patent law that has recently attracted controversy, with much of the debate concerning the new uses of already existing substances potentially patented. The practice of 'evergreening' has been criticised for unfairly extending the lifespan of a patent, thus preventing the public from enjoying it in the public domain. An analysis of some members' legislation shows that a few such as Namibia,²⁴ Rwanda²⁵ and Zambia²⁶ have updated their laws to include specific exclusions for new uses.

Ownership

Issues regarding ownership of patents and the legal position of the inventor, where the inventor is not the applicant, are fairly uncontroversial and would not be priority areas for harmonisation as most countries have adopted similar legislation on these issues.

Processing

Patent law is territorial in nature and patent applications can only be granted nationally. However, both the PCT and the Harare Protocol provide avenues through which parties can use WIPO and ARIPO respectively as a central focal point through which patent applications designating individual members can be processed. The PCT provides the protection of inventions in any of the Contracting States to be filed as international applications under the Treaty.²⁷ Be that as it may, the issue of patent application processing at the national level is one where negotiations can aim for a limited extent of harmonisation. From a procedural perspective, there are a number of issues that need considering.

First, there are those states which allow for a pre-grant opposition procedure while others do not. Example of each?

The second procedural issue would be whether countries should be encouraged to adopt a substantive examination position or restrict themselves to a patent registration system. South Africa has been a prominent member of those countries operating a registration system without undergoing substantive examination. However, this position is changing and South Africa is

¹⁸ TRIPS Agreement, article 27(2).

¹⁹ TRIPS Agreement, article 27(3).

²⁰ Industrial Property Order, 1989, section 4.

²¹ Intellectual Property Law, Article 18.

²² Patents and Industrial Designs Act, section 16.

²³ TRIPS Agreement, article 27(1).

²⁴ Industrial Property Act, 2012, section 17(1)(j).

²⁵ Intellectual Property Law, Article 18(5).

²⁶ The Patents Act, 2016, section 17(e).

²⁷ PCT Article 3

preparing to transition to a substantive examination system.

From the regional perspective, the Harare Protocol provides for substantive examination of applications to be carried out by ARIPO. Applications can be submitted either directly to ARIPO or indirectly through the national offices. Once the application has been examined by ARIPO, it is transmitted to the individual Member States for final determination on whether the application can be granted under their national laws.

This is therefore an area where TFTA countries can be encouraged to join an expanded ARIPO and pool their resources for purposes of facilitating the patent application process.

Disclosure

The appropriate level of disclosure needed by applicants, especially regarding the use of genetic resources (GRs) and traditional knowledge (TK) in patent applications is another issue causing some controversy.²⁸ A few countries such as Uganda²⁹ have included an obligation to disclose in their national laws. However, this is not a provision that has been widely adopted. The TFTA Protocol on IP provides an opportunity for member states to address this issue and adopt a common position.

Duration

The duration of patent protection, though generally uncontroversial, is another area where there is potential for harmonisation. The TRIPS Agreement provides that the term of protection shall not end before the expiration of twenty years from the date of filing.³⁰ The way this has been interpreted in practice by WTO members varies. While most countries provide for the term of twenty years subject to payment of fees, a few provide for an initial term of 15 years plus a renewal of 5 years.

Compulsory Licensing

Though a patent grants the owner rights to prevent others from using the invention, this right is not absolute. In certain instances, governments can make use of the invention in question. These instances include cases of national emergency, non-working and dependent patents. Article 31 of the TRIPS Agreement sets out some of the conditions that must be respected in such instances. These conditions include ensuring that the use is non-exclusive, non-assignable and predominantly for the use of the domestic market. In addition, the right holder must be paid adequate remuneration. This is also another issue proven to be controversial and should be

considered in the context of availability of pharmaceuticals.

3. Copyright and Related Rights

This section gives an overview of the areas of copyright and related rights with potential for harmonisation. As is the case with trademarks and patents, there are several international legal regimes governing copyright and related rights law, including the Berne Convention, WIPO Copyright Treaty (WCT), the WIPO Performances and Phonograms Treaty (WPPT) and the Beijing Treaty on Audiovisual Performances. For members of the WTO, the TRIPS Agreement obliges them to comply with the provisions regarding copyright found in Articles 9 – 14. On the issue of computer programs, TRIPS obliges members to protect them as literary works under the Berne Convention.³¹

Unlike trademarks and patents, there is no regional treaty, whether under ARIPO or otherwise, specifically dedicated to copyright matters. Of the 26 States that make up the Tripartite area, 21 are members of the Berne Convention.

The appropriate duration of copyright protection is one area that could prove controversial in negotiations regarding copyright. The general term of protection under the Berne Convention is the life of the author plus fifty years.³² However, this is a minimum and there are a number of countries around the world that provide for a longer term of protection (such as the life of the author plus seventy years.)

To move forward, members will need to consider establishing a minimum level of protections or whether they will aspire to raise protections to the highest possible level. On one hand, going for a minimum will ensure that members only take upon themselves the obligations they are able to implement. However, such an approach has the disadvantage of not advancing copyright laws and in the end means that each state continues to do pretty much what it wants with regards to copyright law.

4. Other IP areas

This penultimate section of the paper gives a brief overview of a few other areas of intellectual property that need consideration in harmonising intellectual property law within the TFTA. These areas are utility models, industrial designs and geographical indications.

Utility models

knowledge associated or not with those resources and that was directly or indirectly used in the making of the claimed invention without the prior informed consent of its individual or collective creators.”

²⁸ See WIPO, *Technical Study on Patent Disclosure Requirements Related to Genetic Resources and Traditional Knowledge* (2004).

²⁹ Industrial Property Act, 2014, section 21(8) provides that “The description shall contain a clear identification of the origin of genetic or biological resources collected in the territory of Uganda and that were directly or indirectly used in the making of the claimed invention as well as of any element of traditional

³⁰ TRIPS Agreement, article 33.

³¹ TRIPS Agreement, article 10(1).

³² Berne Convention, article 7(1).

It is worth noting a few things with regards to the role of utility models in the IP legal framework. The Paris Convention contains a few provisions that refer to utility model protection without defining what a utility model is. At a regional level, the Harare Protocol also allows for the protection of utility models. The Protocol defines a utility model as meaning

Any form, configuration or disposition of elements of some appliance, working tools and implements as articles of everyday use, electrical and electronic circuitry, instrument, handicraft, mechanism or other object or any part thereof in so far as they are capable of contributing some benefit or new effect or saving in time, energy and labour or allowing a better or different functioning, use, processing or manufacture of the subject matter or that gives utility advantages, environmental benefit, and includes micro-organism or other self-replicable material, products of genetic resources, herbal as well as nutritional formulations which give new effects.³³

It provides further that utility models are to be protected if they are new and industrially applicable.³⁴ A review of the laws of some TFTA members shows that even though many do provide for utility model registration, some such as Malawi, Sudan and Zimbabwe are silent on the protection of utility models

Industrial Designs

The issue of industrial designs is fairly uncontroversial as Article 5quinquies of the Paris Convention obliges all countries of the Union to protect industrial designs. Article 25 of the TRIPS Agreement also contains an obligation on the part of WTO Members to protect industrial designs. The Harare Protocol also contains provisions setting out the procedure to be used for the protection of industrial designs.³⁵ It does not however, define industrial design.

There is therefore an opportunity to harmonise the definition of an industrial design, as there are some differences in the ways the national laws define the term.

Geographical Indications

In section 3 above, it was noted that the TRIPS Agreement obliges WTO Members to comply with the requirements of Articles 22 – 24 on the protection of geographical indications. This can be either by sui generis legislation or through trademark law.

Within the TFTA, a number of countries, such as Uganda and Zimbabwe, have already enacted specific stand-alone legislation containing detailed provisions on GIs, while others have detailed provisions within broader intellectual property statutes. Other countries have

opted to protect GIs through their trademark laws. There is considerable scope for harmonisation of laws in this area that will facilitate trade in goods bearing GIs and allow value addition, especially agricultural products.

5. RECOMMENDATIONS AND CONCLUSION

Given the heterogeneity of African countries in terms of technical capacity, geographical as well as economic size and population, it is not going to be easy to achieve a harmonisation of IP laws. The fact that many are also LDCs who, under the TRIPS Agreement, have been given until 2021 to put laws in place that are TRIPS-compliant means that, for those countries, there is even less incentive to update their laws to comply with TRIPS.

For the reasons discussed above, this paper recommends the following:

1. With regard to trademarks laws, an IP Protocol should restrict itself to identifying areas where parties can harmonise both substantive and procedural aspects of their laws without necessarily aiming to establish a unitary trademark registration body. As seen above, even within ARIPO, it has proven challenging to persuade parties to sign and ratify the Banjul Protocol.
2. With regard to patent laws, there is a large scope for harmonisation of laws in any proposed IP Protocol. This is especially so in those areas where LDCs are given longer grace periods within which to enact the necessary patent laws.
3. With regard to copyright and related rights laws, the fact that copyright does not require any formalities for protection means the focus would be more on substantive rights than procedural questions in an IP Protocol. It will therefore be necessary for parties to decide whether they wish to set out any minimum level of rights.
4. With regard to industrial design and utility models, the relatively low profile that these two branches of IP law occupy means there is likely few controversial issues which need negotiation.
5. With regards to geographical indications, an IP protocol provides an opportunity for countries that have not developed a sui generis law on GIs to consider doing so as a way of harnessing the potential of this area of law.

In conclusion, the task of negotiating and concluding an IP Protocol is going to be difficult, especially if the Protocol is going to contain substantive obligations for signatories. The more likely outcome will be an instrument containing best endeavours obligations and which aims at benchmarking obligations against already existing

³³ Harare Protocol, Section 3ter(1).

³⁴ Harare Protocol, Section 3ter(2).

³⁵ Harare Protocol, Section 4.

international instruments such as TRIPS and the various treaties administered by WIPO. The flexibilities currently enjoyed by LDCs are unlikely to be interfered with or in any way limited.

That being said, there is merit in including IP as an issue to be concluded as a part of a wider treaty dealing with the free movement of goods and services because history teaches us that left unchecked, IP can be used as a non-tariff barrier to the movement of goods and services.

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THE IMPACT OF THE EXTENSIONS OF PHARMACEUTICAL TRANSITION PERIOD FOR AFRICAN LDCs ON THE IMPLEMENTATION OF TRIPS: THE CASE OF MALAWI

William Maulidi*

ABSTRACT

The World Health Organization (WHO) estimates that one-third of the people living in Least Developed Countries (LDCs) are unable to receive or purchase essential medicines that have saved and extended the lives of people in more developed countries. The 2013 UNAID Brief Report pointed out that patent protection is one of the factors which contributed to high costs, placing many essential treatments outside the reach of LDCs. TRIPS Council accords LDCs transition periods in order to allow them to develop their own viable technological base for pharmaceuticals. One would expect LDCs to take advantage of these transition periods and reform their laws to exclude pharmaceuticals from patent protection. Surprisingly, a number of these countries still provide patent protection for medicines despite the availability of the transition period. Today, about two decades into the TRIPS agreement era, LDCs continue to request for further extensions of the transition period. It is against this background that this paper aims to establish whether Malawi and other African LDC members have fully utilised the transitional period extensions for TRIPS implementation with special focus on pharmaceutical transition periods. The paper also brings to light some arguments that have been put for and against the extensions of transition period for LDCs. It also examines challenges faced by Malawi and other LDCs with respect to the implementation of TRIPS regulations and finally it discusses how these extensions have affected the

development of pharmaceutical manufacturing and research capabilities in LDCs.

Key words: TRIPS, extensions, transition period, LDCs, pharmaceuticals, intellectual property

1. INTRODUCTION

Africa is the continent with by far the largest share of Least Developed Countries (LDCs). Twenty-five of the thirty-four African LDCs are members to the World Trade Organization (WTO).¹ It is important to highlight from the onset that the adoption of TRIPS Agreement in 1994 by the global community affected the price and availability of drugs and health in most African LDCs through the imposition of certain minimum standards. The WHO estimates that one-third of the people living in LDCs are unable to receive or purchase essential medicines that have saved and extended the lives of people in developed countries. The 2013 UNAID Brief Report also pointed out that patent protection is one of the factors which contributed to high costs, placing many essential treatments outside the reach of LDCs.²

TRIPS Council accords its members transitional periods in order to allow them to develop viable technological base for pharmaceuticals, as well as protect those in need of increased assistance, investment and technological transfer from the burdens of granting and enforcing intellectual property monopolies. In order to achieve this objective, member states are allowed time to implement the applicable changes to their national laws, in two tiers of transition according to their level of development. The transition period for developing countries expired in 2005 whereas the transition period for LDCs to implement TRIPS expired in 2012 but was later extended to 2013, and until 1 January 2016 for pharmaceutical patents, before it

* **William Maulidi** is a lecturer of Intellectual Property and Assistant Coordinator of Technology and Innovation Support Centre (TISC) in the Department of Research and Innovation at Mzuzu University in Malawi. He holds a Master's Degree in Intellectual Property from Africa University, Zimbabwe and is completing his second Master's Degree in Innovation and Technology Management at the Malawi University of Science and Technology (MUST). His interests lie in the fields of Intellectual Property and Innovation. He has researched on TRIPS and Least Developed Countries (LDCs), digital environment and

music piracy, effective system of monitoring and collecting music royalties in Malawi and also university incubation and innovation centres as wellsprings of economic development. He has also presented papers on Intellectual Property in Sweden, China, South Africa and Zimbabwe.

¹ Fikremarcos Merso, *IP Trends in African LDCs and the LDC TRIPS Transition Extension*. Policy Brief No.16

² UNAIDS Issue Brief 2013 *TRIPS Transition Period extension for least-developed countries*.

was extended further until January 2033. Article 66.1 of the Agreement also provides that these transition periods are subject to further extensions upon duly motivated requests.

Today, about two decades into the TRIPS agreement era, LDCs continue to request for further extensions of the transition period. However, for developed countries, despite being aware that establishing a modern and meaningful IP legislation takes time, resources, and especially huge investment in infrastructural development, do not seem prepared to let free the LDCs from the TRIPS bondage. However, it is also still not clear whether LDCs submit requests for extensions of transition periods to implement TRIPS provisions and set up a viable pharmaceutical manufacturing base or maybe it is one way of delaying the process of becoming TRIPS compliant so as to avoid introducing pharmaceutical patents in their legislations which has been an ongoing debate in many fora and a major concern for most LDCs.

Despite providing a slightly longer extension period of seventeen years for pharmaceutical protection in LDCs as compared to the previous fourteen year transition period, literature points out that LDCs did not make full use of the previous transition period as their situation has not significantly changed since the last extension decision and that they have not been able to develop their productive capacities and have not beneficially been integrated with the world economy.³ This observation was supported by the calls from non-governmental organisations urging LDCs to actively use the created policy space this renewed transition period provides, and accordingly to take immediate steps to amend their respective national laws to exclude pharmaceutical products from patent protection and test data protection with explicit provisions that this would be a temporary allowance until 1 January 2033, or the expiry of such later transition

period that may be granted by the WTO Council for TRIPS.⁴ It also appears that since the adoption of the 2001 Doha Declaration on TRIPS and Public Health, most LDCs have been preoccupied with procuring low cost generic medicines, in particular to access medicines needed for the treatment of HIV.⁵

It is against this background that this paper aims to establish whether Malawi and other African LDC members have fully utilised the transitional period extensions for TRIPS implementation with special focus on pharmaceutical transition periods. The paper brings to light some arguments that have been put for and against the extensions of transition period for LDCs. It also examines challenges faced by Malawi and other LDCs with respect to the implementation of TRIPS regulations and finally it discusses how these extensions have affected the development of pharmaceutical manufacturing and research capabilities in LDCs.

2. RATIONALE BEHIND TRANSITION PERIOD

Article 66.1 of TRIPS Agreement states that:

In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.⁶

³ WTO, 'Communication from Haiti on Behalf of the LDC Group: Request for an Extension of the Transitional Period under Article 66.1 of the TRIPS Agreement' (5 November 2012) (IP/C/W/583)

⁴ Catherine Saez, *LDC Pharma IP Waiver Until 2033 Approved by WTO TRIPS Council*, (IP Watch, 2015)

⁵ Ellen 't Hoen, *Inside Views: Why The Request by LDCs For an Extension of the Transitional Period for*

Granting and Enforcing Medicines Patents Needs to be supported? (IP Watch, 2015)

⁶ Article 66(1), TRIPS Agreement.

Article 66.1 provides for an extension of transition periods for LDCs to apply and implement the provisions of the TRIPS Agreement. Basically, there are currently two separate transition periods in operation within which LDCs are not required to implement the TRIPS Agreement other than Articles 3 on national treatment, 4 on most favoured nation treatment, and 5 on multilateral agreements on acquisition or maintenance of protection, and these are the general transition period and the pharmaceutical period. The general transition period for LDC members was initially due to expire on 1 January 2006. However, recognizing their special needs and requirements, the TRIPS Council adopted a Decision on 29 November 2005 that extended this transition period for another 7.5 years under Article 66.1 for LDC Members until 1 July 2013. Haiti submitted a request on 5 November 2012 and on behalf of the LDC group to extend the transition period further, specifically, until a given member graduates from being a LDC.⁷ Following this request, on 11 June 2013 a Decision of the Council for TRIPS decided on an extension of the transition period under article 66.1 for LDCs until 1 July 2021, or earlier, upon graduation from the LDC category.

With respect to pharmaceutical patents protection and data protection, there have been two subsequent extensions for pharmaceutical transition periods. First, the transition period for LDCs was extended until January 2016 following the TRIPS Council's Decision to implement Paragraph 7 of the Doha Declaration. Second, the Doha waiver that specifically addressed pharmaceutical patents was further extended until January 2033 on the basis of a request from the LDC group. However, reports indicate that despite receiving strong support for the renewed extension of transition period from the United

Kingdom and the International Federation of Pharmaceutical Manufacturers (IFPMA), other organisations such as United States Trade Representative (USTR) opposed such an extension.⁸

It is important to point out that the primary benefit of an extended transition period lays in the preservation of policy space for LDCs, conserving the autonomy of LDCs to determine appropriate development, innovation, and technological promotion policies, according to local circumstances and priorities.⁹ The extension provides a window of opportunity for LDCs to put domestic policies in place in order to ensure that the implementation of TRIPS will support and not hinder their social economic development.¹⁰

The extensions granted to the LDCs based on Article 66.1 aim to provide them not merely with more time to comply, but are also meant to help LDCs develop their national policies and economies to ensure that the eventual implementation of the TRIPS Agreement will promote rather than undermine their social, economic and environmental wellbeing.¹¹ This means that LDCs have been presented with a window of opportunity to take advantage of the transition period and develop viable local production capacity for pharmaceuticals. This will in the long run reduce LDC's dependency on imported drugs from countries such as India and China.

It is of significant importance to point out that strong support for extended transition periods has been made by many international communities such as Global Commission for HIV and the Law, UNAIDS and UNDP. In its report of 2012, the Commission recommended that WTO members must indefinitely extend the exemptions

⁷ WTO Document IP/C/40

⁸ IFPMA Statement support the Extension available at <http://www.ifpma.org>

⁹ UNAIDS Issue Brief 2013 TRIPS Transition Period extension for least-developed countries.

¹⁰ Arno Hold and Brian Christopher Mercurio, Transitioning to Intellectual Property: How can the WTO

Integrate Least Developed Countries into TRIPS? World Trade Institute, October, 2012.

¹¹ 'Extension of the Transition Period for LDCs: Flexibility to Create a Viable Technological Base or Simply (A Little) More Time?' *Intellectual Property Quarterly Update*, South Centre and CIEL, (2006)

for LDC from the application of TRIPS provisions in the case of pharmaceutical products citing reasons that heavy disease burdens on LDCs provide an urgent and compelling case for the international community to take all measures possible to protect and extend health of the people living in these countries.¹² Furthermore, UNAIDS pointed out that an extension would allow the world's poorest nations to ensure sustained access to medicines, build up viable technology bases and manufacture or import the medicines they need.¹³ Nevertheless, it is important to commend the efforts made by some African LDCs such as Uganda and Rwanda to make use of existing extended transition periods to develop their legislation and subsequent manufacturing of HIV-related medicines.¹⁴

Article 66.2 of TRIPS calls on developed countries to provide technical and financial assistance to LDCs so as to effectively address the identified priority needs. However, analysts and LDC members have raised concern that the impact of Article 66.2 has been rather limited, and that the existing reporting system is insufficient to monitor the implementation of Article 66.2 in a meaningful way.¹⁵ Moreover, technical assistance for LDCs have been focusing more on capacity building for TRIPS compliance rather than on capacity building and technology transfer for development of pharmaceutical industries in these countries.¹⁶

3. ARGUMENTS FOR AND AGAINST EXTENSION OF TRANSITION PERIODS FOR LDCS

Proponents of these extensions of transition periods have argued that a series of time-limited transition periods and extensions, such as the initial ten-year transition period and the seven-and-a-half-year extension granted in 2005, has been insufficient for technological transformation and capacity building for the vast majority of LDC Members, especially in light of developed countries having failed to facilitate meaningful technology transfer as required by Article 66.2. To that end, a much longer extension is needed during which LDC Members can devote their entire attention to development objectives.¹⁷ Others have argued that the extension of the specific pharmaceutical transition period for LDCs is still very relevant today. It is one of the WTO mechanisms for increasing access to medicines that work effectively and have been used on a large scale.¹⁸

However, some quarters have argued against extension of transition periods for LDCs stating that an extension is just a convenient way for both developed and LDCs to buy time and to avoid any potential conflicts in the TRIPS council.¹⁹ Another argument against the extension of the specific pharmaceutical transition period is that LDCs are not obliged to implement the TRIPS Agreement as a whole (with the exception of some articles) until 1 July 2033. This implementation deadline may also be further extended upon request of the LDC members.²⁰ As such, the specific pharmaceutical waiver is redundant. Others have also argued that never-ending requests for extensions of transition periods would not resolve

¹² UNAIDS Issue Brief, *TRIPS Transition Period extension for least-developed countries*, (2013).

¹³ Michael Sidibe, Executive Director of UNAIDS, in UNAIDS Press Release 'UNAIDS and UNDP Back Proposal to Allow Least developed Countries to Maintain and Scale up Access to Essential', (January 2016)

¹⁴ UNAIDS Technical brief, *Implementation of TRIPS and access to medicines for HIV after January 2016: Strategies and Options for least developed countries*, (2013).

¹⁵ Suerie Moon: Meaningful Technology Transfer to the LDCs: A Proposal for a Monitoring Mechanism for TRIPS Article 66.2, April, 2011.

¹⁶ Global Academics 'Expert Letter on LDC' TRIPS Extensions Request, (April 27, 2013)

¹⁷ *ibid*

¹⁸ Ellen 't Hoen 2015 Inside Views: *Why The Request by LDCs For an Extension of the Transitional Period for Granting and Enforcing Medicines Patents Needs to be Supported?* IP Watch, (2015).

¹⁹ Arno Hold and Brian Christopher Mercurio, *Transitioning to Intellectual Property: How can the WTO Integrate Least Developed Countries into TRIPS?* World Trade Institute, (October, 2012).

²⁰ Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with respect to Pharmaceutical Products" (IP/C/25)

anything but would only further postpone the implementation of TRIPS by LDCs. Moreover, extension would undermine the credibility of the TRIPS regime and inevitably lead some to question whether LDCs will ever have to comply with TRIPS. Some have argued that the extension of transition periods is no longer necessary because LDCs are systematically included in the scope of the Medicines Patent Pool license. As such anti-retrovirals (ARVs), which are the most essential medicines in this region, are made available to these countries through licensing. Moreover, it is argued that several companies indicated that they were not going to assert their patents in LDCs.²¹ However this paper finds this argument weak because not all companies provide licenses for products that are needed in the treatment of HIV/AIDS. One study pointed out that the experience of the last decade strongly indicates that an extension alone would not lead to and resolve any IP-related improvements in LDCs but rather postpone further the implementation of TRIPS.²²

4. CHALLENGES FACING LDCS IN IMPLEMENTING TRIPS

It is equally important to point out that full utilization of the transition period under TRIPS is an important factor that can complement efforts by governments in LDCs to promote local manufacturing of medicines by ensuring that locally produced medicines are not denied market access due to the existence of patent rights. Local production of medicines may facilitate access to medicines by reducing the prices of drugs and ensuring better availability through price-based competition. Though currently most of the medicines in the LDCs are imported from abroad, the reliance on imports alone may not ensure access to the new medicines because patents can restrain generic medicines from being available even

through importation.²³ Worse still, while LDCs have not been obliged to implement the TRIPS Agreement thus far, the reality is that most of them have had patent law on the books for many years. LDCs inherited their patent laws in the post-colonial era when they gained independence from high-income countries. At the time of the adoption of the Doha Declaration in 2001, out of thirty African LDCs only two, Angola and Eritrea, did not grant patents for pharmaceuticals.²⁴

There are a number of reasons that explain why most LDCs are challenged to utilise the transition periods and their extensions. First, most LDCs are very comfortable with the arrangements they have made to procure low cost generic medicines, as such they do not seem to be in a hurry to implement their IP laws. One good example of such a country is Malawi. For example, the process of procuring generic medicines does not require legislative changes and have proven to be practical and effective. Second, the implementation of TRIPS provisions requires some considerable budgetary allocation to update legislation towards TRIPS compliance, and the accompanying recurrent as it applies to ensuring the observance of the legislation.²⁵ A study sanctioned by United Nations Conference on Trade and Development (UNCTAD) on the institutional costs of the implementation of the TRIPS Agreement showed that a country like Egypt would require USD 800,000 one-off cost and an additional annual training cost amounting to USD 1 million.²⁶ Such amounts as these might be unthinkable for most LDCs to spend on IP enforcement alone as they usually have other priority areas such as health, food availability, alarming poverty levels and unemployment.

²¹ Ellen 't Hoen, *Inside Views: Why the Request by LDCs For an Extension of the Transitional Period for Granting and Enforcing Medicines Patents Needs to be supported?* IP Watch, (2015).

²² Arno Hold and Brian Christopher Mercurio, *Transitioning to Intellectual Property: How can the WTO Integrate Least Developed Countries into TRIPS?* World Trade Institute, (October, 2012).

²³ 'Extension of the Transition Period for LDCs: Flexibility to Create a Viable Technological Base or Simply (A Little)

More Time?' *Intellectual Property Quarterly Update*, South Centre and CIEL, (2006).

²⁴ <http://apps.who.int/medicinedocs/en/d/Js2301e/12.html>

²⁵ NBT Report 2004 <https://pdfs.semanticscholar.org/6206/21fada20a5bf7f2f98bf9c915125a06729ef>.

²⁶ NBT Report 2004 <https://pdfs.semanticscholar.org/6206/21fada20a5bf7f2f98bf9c915125a06729ef>.

Regrettably for such LDCs, unlike the other conventions on IP that existed prior to TRIPs, the TRIPs agreement provides for enforcement, and is linked to the WTO obligations, meaning that violation of TRIPs provisions may lead to such punitive measures as trade sanctions.²⁷ This has led many to conclude that, the WTO-TRIPs regulations are a reflection of little awareness of development problems and the incapacities of LDCs, because the sad reality is that the money to be spent by LDCs in implementing these 'WTO rules' would be money unproductively invested.²⁸

Thirdly, formulation of relevant legislation and/or accession to regional and international agreements to a greater extent depends on institutional capacity of the countries. Lack of institutional capacity to formulate legislation reflective of the social and economic needs among LDCs is also a major challenge, which has resulted in most LDCs subscribing to stricter forms of IP protection than would otherwise be needed for their development. However, it is encouraging to note that some selected LDCs such as Burundi, Rwanda and Uganda have managed to amend their IP law over the last seven years to make use of the transition period under TRIPs and exclude pharmaceutical products from patent protection.

5. MALAWI'S PHARMACEUTICAL INDUSTRY STATUS

In Malawi, up to 90% of the population live in rural areas without access to potable water and electricity, engaging in subsistence farming activities, and relying on rain-fed agriculture. The country is landlocked and has one of the largest population densities in sub-Saharan Africa.²⁹ Currently at 18 million, the population of Malawi is expected to double in two decades time.³⁰ Malawi is a member of the Southern African Development Community (SADC). The SADC region is one of the most

heavily disease-burdened regions of the world. As an LDC, the country is often characterised by poverty, socio-economic inequalities and injustices, low human development, economic vulnerability and limited technological development.³¹ The country has poor socio-economic indicators, particularly in public health. It has a limited pharmaceutical manufacturing base and thus depends significantly upon the importation of products from foreign-based manufacturers³².

In the case of newer medicines, some of which are protected by IPRs, Malawi imports from brand name manufacturers. Where patents do not exist, Malawi relies on generic manufacturers based in India and, to some extent, in China and South Africa. With respect to anti-retroviral, Malawi's HIV/AIDS treatment programme, predominantly funded by donors, relies almost exclusively on fixed-dose combination generics imported from India. This reliance is potentially problematic because some of the components of current ARVs especially Second and Third line ARVs are still patent protected in Malawi. It would surely be laughable that in such a country like this, where no single patent has been granted to a local innovator, priority should be laid on aligning their laws to be TRIPs compliant.³³

Another potential access to medicines problem in Malawi is the increase of HIV/AIDS related cancers in Malawi. According to 2010 National Aids Commission (NAC) Report, twenty eight percent of AIDS related deaths are due to cancer.³⁴ Unfortunately Malawi is not well equipped to deal with cancer due to the absence of specialized personnel and due to the high cost of cancer drugs, some of which are still under patent protection. Worse still, only two anti-cancer drugs are on the essential medicines list. Newer anti-cancer drugs

²⁷ Lumina 2010 LDD 2.

²⁸ Finger and Schuler *The World Economy* 511.

²⁹ World Bank 2007 <https://openknowledge.worldbank.org>

³⁰ International Monetary Fund 2017 <http://www.imf.org/~/media/Files/Publications/CR/2017/cr17184>.

³¹ 'Extension of the Transition Period for LDCs: *Flexibility to Create a Viable Technological Base*

or Simply (A Little) More Time?', Intellectual Property Quarterly Update, South Centre and CIEL, (2006).

³² CIA World Fact Book, 2006

³³ Chikosa Banda, Robert-Lewis Lettington, *A survey of policy and Practice on the Use of Access to Medicines-Related TRIPs Flexibilities in Malawi*, DFID Health Systems Resource Centre, (2004).

³⁴ NAC Report, 2010.

including imatinib and sunitinib are unaffordable despite the fact that generic versions of these drugs are produced and available in India. Imatinib is sometimes available courtesy of the Glivec International Patient Assistance programme. However, this is an unsustainable way of making the drug available.

Malawi's current efforts to regularize its IP regime affecting access to medicines are ad hoc, problematic and reflect a limited technical capacity. Nonetheless, Malawi is in the process of adopting its first IP Policy through the Department of Science and Technology. The Malawi Law Commission has also embarked on the process of revising the 1957 Patents Act. Unfortunately, this project has stalled due to lack of financial resources.

There have been some initiatives to revise the Malawian Patents Act and ensure maximum access to medicines. However, efforts to reform IP law and policy will need the assistance of development partners in increasing the availability of specialist skills on issues such as IP law and international drug procurement. Further assistance in facilitating the thorough review of legislation and associated policies is also urgently required.

Malawi's patent legislation was supposed to become generally TRIPS compliant by July 2013, but this has not yet happened.³⁵ Fortunately the deadline for compliance on the part of LDCs has been extended to 2021. With respect to medicines, Malawi has some flexibility to extend its date of compliance until 2033 under paragraph 7 of the Doha Declaration and under subsequent action by the WTO. The above extensions, however, do not preclude the need for prospective domestic legislative reform to take advantage of existing TRIPS flexibilities.

The need to reflect on the progress Malawi has made towards taking advantage of the TRIPS flexibilities is imperative considering the fact that the Doha Declaration, the 30th August 2003 Decision (on the Implementation of paragraph 6 of the Doha Declaration)

and a subsequent decision of the WTO Council in proposing a congruent TRIPS amendment, Article 31bis, present a window of opportunity for countries with insufficient or no manufacturing capacity to take full advantage of TRIPS-based flexibilities to import affordable, good quality medication for their citizens.

These flexibilities include compulsory licensing, parallel importation and deferral of the patenting of pharmaceuticals to 2016. This is especially true given that LDCs have the flexibility of deferring the application of TRIPS provisions to pharmaceutical products and data protection until 2033.

Despite the above, the Malawi government has not managed to take advantage of the Doha Declaration and the 30th August Decision waiver. In particular, it has not yet taken concrete steps to amend its laws to incorporate all permissible TRIPS flexibilities. Moreover, it has maintained laws that provide stronger patent protection than the minimum required by TRIPS (TRIPS-plus). This is, notwithstanding, the fact that the TRIPS legal framework gives them room to avoid such an approach and to enact "public-health friendly" laws.

Whereas the colonial 1957 Patents Act provides for some flexibilities that can potentially be exploited to promote access to medicines, these flexibilities predate TRIPS and are ill-designed to address TRIPS-related access to medicines problems. This has impaired Malawi's ability to take full advantage of TRIPS flexibilities to promote access to medicines objectives. Likewise, despite its flaws, Malawi has also failed to amend its legislation to take advantage of the 30th August Decision or to notify the WTO of its intended use thereof. There is also very little awareness amongst Malawi policy makers of the need to advocate for a better export/import solution pursuant to Article 30 at the WTO and elsewhere.

Malawi has hitherto found it unnecessary to incorporate TRIPS flexibilities into its laws because it has been possible

³⁵ Chikosa Banda, Robert-Lewis Lettington, *A survey of policy and Practice on the Use of Access to Medicines-Related TRIPS*

Flexibilities in Malawi, DFID Health Systems Resource Centre, (2004).

to source first-generation generic ARVs without difficulties with Patent owners. These drugs are primarily sourced from India, a major generic medicines supplier that until 2005 was not obliged to provide product patent protection for pharmaceuticals. The fact that India is now obliged to comply fully with the provisions of the TRIPS will have negative implications for access to post-2005 patented medicines. This is especially given that this important source of generic medicines (90% of all generic ARVs) is increasingly becoming constrained by patent law.

Access to newer medicines has generally been problematic considering that these drugs are almost invariably under patent protection. Consequently, Malawi has opted to exclude such medicines from its essential medicines lists on the basis of cost, despite the potential utility of such drugs. This has been detrimental to its citizens who are being denied access to life-saving treatment.

The future access scenario also looks bleak given that LDCs will be required to provide patent protection to pharmaceutical products by 2016 unless the existing waiver is extended. There is therefore an urgent need for Malawi to demonstrate its commitment to the right to health by amending its laws in order to benefit from key TRIPS-compliant flexibilities. Moreover, given Malawi's current system for granting pharmaceutical patents, the right to extend the transition period for medicines will not necessarily suspend the effect of previously granted patents. Thus, provision will need to be made for granting compulsory licenses and/or authorising government use with respect to existing on-patent medicines.

The possibility of utilising transition periods to exclude pharmaceuticals from patentability offers LDCs an opportunity to develop a viable technological base for manufacturing generic pharmaceutical products. However, it is sad to point out that Malawi still provides patent protection for medicines despite the availability of

the transition period. The existence of pharmaceutical patents in a country that seeks to promote local pharmaceutical production could impact the freedom of generic companies to manufacture specific products or expand the range of products, which is crucial for utilizing the operational capacity most efficiently and recover the capital expenses incurred. Therefore, utilization of the transition period to support the development of the local pharmaceutical industry is critical for LDCs.³⁶

In addition, Malawi's underlying patent legislation reflects few of the available TRIPS public health safeguards with the exception of some provision for compulsory licenses and government use. For instance there are elements of Section 18 which are potential relevance to the question of safeguarding public health. One of them is subsection 18.1 (b), which provides that the Registrar of Patents may refuse an application where he determines that the use of the invention in respect of which the application is made would be contrary to law or morality. Subsection 18.1 clearly relates to TRIPS Article 27.2, which allows for the exclusions from patentability on the grounds of ordre public or morality but not on the basis of mere illegality³⁷. However, even where these are available, there is little, or no, capacity to implement them and thus no experience in their use.

There is minimal awareness of the flexibilities that are available, under Articles 31 and 31bis of the TRIPS agreement that Malawi can use to promote access to medicines. There is also very little awareness of the SADC position on pharmaceutical patents and how IP issues relate to the SADC Pharmaceutical Business Plan.³⁸ Where awareness does exist, there is almost no knowledge of the technical details at issue. A lack of awareness of impending TRIPS deadlines and their implications for access to medicines for the poor is also evident. Worse still, there is very little awareness on the part of the Malawian citizens of the implications of

³⁶ Nirmalya Syam, *Transition Period for TRIPS Implementation for LDCs: Implications for Local Productions of Medicines in the East African Community*, South Centre, (2014).

³⁷ Laws of Malawi, Patents Chapter 49:02

³⁸ SARPAM Report, 2013.

government inaction on their right to health. As a result there is no concerted effort on the part of Malawian stakeholders to advocate for the incorporation of TRIPS flexibilities into the Patents Act.

Moreover, Malawi was not among the nine African LDCs that have submitted their individual priority needs to the TRIPS Council. The nine countries include: Sierra Leone (2007), Uganda (2007), Bangladesh (2010), Rwanda (2010), Tanzania (2010), Senegal (2011), Mali (2012), Madagascar (2013) and Togo (2013).³⁹

Implementation of TRIPS provisions in Malawi is significantly impacted by its membership to African Regional intellectual Property Organisation (ARIPO) and party to Harare Protocol on Patents and Industrial Designs. The Harare Protocol, however, does not recognise transition periods and their extensions which are provided for under Article 66 of TRIPS Agreement. Such being the case, it is difficult for Malawi to exclude pharmaceuticals from patent protection. Some of these challenges include the following:

- i. Inadequate institutional, inter-sectoral, cross-sectoral coordination on issues relating to IP and access to medicines.
- ii. Lack of information sharing among key stakeholders.
- iii. Policy incoherence, for example, lack of harmonized policies and guidelines to support access to essential medicine in Malawi.
- iv. Exclusion of key players including Civil Society from the policy formulation and implementation processes.
- v. There is inadequate capacity and expertise in the field of IP in general and IP and access to medicines in specific.
- vi. Market and policy failure. For example, there is inadequate capacity for local pharmaceutical R&D and production.

- vii. Lack of political will and commitment to develop IP policy and legislation to take full advantage of flexibilities.
- viii. Inadequate networking among key stakeholders
- ix. Financial constraints

6. EFFORTS TO ENSURE AVAILABILITY OF ESSENTIAL MEDICINES IN MALAWI

There have been a number of efforts to ensure the availability of essential medicines in Malawi and other LDC members in the SADC region. One such effort was initiated by the Southern African Regional Programme on Access to Medicines and Diagnostics (SARPAM). SARPAM is a DFID funded regional project, which assists SADC member states to implement the SADC Pharmaceutical Business Plan 2007-2013 (PBP). The PBP was adopted by Health Ministers in 2007.⁴⁰ The overall objective of the PBP is to ensure the availability of essential medicines in the SADC region through better collaboration among states. The goal of SARPAM is to increase access to affordable essential medicines in the region through supporting the development of a more efficient and competitive regional pharmaceutical market place. The PBP envisaged the following TRIPS related activities:

1. A regional assessment of IP and medicines legislation in countries to determine their TRIPS compliance and adaptability;
2. Identification of reliable and specialized legal advice resources both within and outside the SADC region and maintain a roster of legal experts who are able to offer technical assistance on TRIPS;
3. Collaboration with development partners to enable countries to protect, include and take advantage of the flexibilities that exist in the TRIPS Agreement as well as to assist countries in bilateral trade negotiations to conclude

³⁹ United Nations Committee for Development Policy. *TRIPS Agreement: Transitional Period for Implementing the Agreement*, (Article 66.1, 2016).

⁴⁰http://www.unido.org/fileadmin/user_media/Services/PSD/BE/P/SADC%20PHARMACEUTICAL%20BUSINESS%20PLAN%20-APPROVED%20PLAN.pdf

agreements that are not detrimental to public health.⁴¹

It is important to acknowledge that activities One and Two have meanwhile been achieved. And on action point Three, SARPAM was by 2013 willing to work with other development partners to support SADC member states improving access to medicines by optimizing the flexibilities in national legislation under the TRIPS agreement.⁴²

7. CONCLUSION

The ‘never-ending’ extension requests speak volumes as to whether it is the right time for LDCs to be strict with IP protection or not, and to further reflect on whether the requirement to accede to such agreements as TRIPS is fair at this point. While LDCs have been provided with automatic extension of the transition period, few of the LDCs have made use of the general transition period that is currently available until 2021. An interactive and collaborative approach among developing countries and LDCs in seeking extensions appears to be at the moment the only sure way for surviving the impending harm which compliance to TRIPS would bring to them.⁴³

That said, the thinking of the present study remains that Malawi and most African LDCs generally have few resources for research and development and few inventions to protect and so there is little to gain from strong patent protection, for instance, until their domestic situation will have improved. LDCs should view the transition period in a broader systemic context for supporting industrial development of LDCs as that is fundamental to the development of a viable local pharmaceutical industry. Therefore, it is important to urge LDCs to make full use of the general transition period and seek further extensions of this period. More

importantly, the full use of the transition period must be seen as an integral component of national and regional pharmaceutical manufacturing plan of action for LDCs. As argued by Hold and Mercurio, an unconditional extension of the transition period for LDCs to implement TRIPS would only lead to a further postponement of LDCs’ integration into the international IP system without resolving any of the underlying issues.⁴⁴ As other scholars have argued, extending the period of TRIPS implementation is just one step in addressing the unique challenges of LDCs in Africa but above all there is a need to address the underlying issue beyond extension such as helping LDCs to build their technological base, streamline IP in socio-economic development rather than focusing exclusively on mere implementation and compliance issues.

Finally, it is important to point out that without proper utilisation of the extended period and with continuation of inadequate institutional and infrastructural capacity, building programmes will simply result more time wasted with no progress towards a viable technological base in the LDCs.⁴⁵

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⁴¹ SARPAM Report, 2013.

⁴² *ibid*

⁴³ Chaudhury and Gurbani 2002 *JHM* 18.

⁴⁴ Arno Hold and Brian Christopher Mercurio, *Transitioning to Intellectual Property: How can the WTO Integrate Least Developed Countries into TRIPS?* World Trade Institute, (October, 2012).

⁴⁵ Extension of the Transition Period for LDCs: *Flexibility to Create a Viable Technological Base or Simply (A Little) More Time?*, *Intellectual Property Quarterly Update*, South Centre and CIEL, (2006).

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Jimcall Pfumorodze*

ABSTRACT

The Agreement on Trade Related Aspects of Intellectual Property (TRIPS Agreement) is one of the multilateral agreements entered into under the auspices of the World Trade Organisation (WTO) during the Uruguay Round of negotiations. It requires Members to develop national legislation which enshrines minimum standards for Intellectual Property (IP) protection and enforcement in line with those set out in this Agreement. However, the implementation of TRIPS Agreement provisions may result in high costs of patented drugs and this may constrain access to medicines in many developing countries. In the light of this, the TRIPS Agreement has flexibilities which allows a Member to override patent protection. This paper discusses the extent to which Botswana balances TRIPS compliance with safeguards for access to medicines through the incorporation of TRIPS flexibilities. It points out that, to a large extent, Botswana has implemented TRIPS flexibilities in its national legislation. The paper also discusses major challenges faced by Botswana in the utilisation of these flexibilities. It argues that the solution to accessing cheaper medicines can be found at both national and regional level, with a need for some legislative reforms at national level, whilst regional cooperation is needed in both manufacturing and procurement of drugs. These measures would ensure that Botswana accesses cheaper and affordable medicines and this would in turn advance the right to health in Botswana.

Key words: access to medicines, Botswana, intellectual property, patent law, TRIPS flexibilities.

1. INTRODUCTION

The TRIPS Agreement is a multilateral agreement entered into under the auspices of the World Trade Organisation

(WTO) during the Uruguay Round of negotiations which requires Members to come up with national legislation which enshrines minimum standards for IP protection and enforcement which are set out in this Agreement.¹ However, the implementation of provisions of the TRIPS Agreement may result in high costs of patented drugs, which may in turn constrain access to essential medicines in many developing countries with high prevalence of serious diseases.² In Africa, for instance, there is a high prevalence of diseases especially HIV/AIDS.³ The East and Southern Africa regions are those hardest hit by HIV. Although it constitutes only 6.2% of the world's population, it has over half of the total number of people living with HIV in the world (19.6 million people).⁴ In 2016, it was estimated that there were 790,000 new HIV infections, 43% of the global total.⁵ At the same time, most African countries do not have resources to procure medicines for their people.⁶ Thus, there is a need to find ways to access cheaper medicines.

To address this challenge, the TRIPS Agreement contains some flexibilities which may be used by Members to promote access to cheaper medicine.⁷ These flexibilities include patentability criteria; ⁸() exclusion from patentability;⁹

* Jimcall Pfumorodze LLB (Honours) (UZ); LLM (UWC & Amsterdam); LLD (Pretoria). Senior Lecturer, University of Botswana.

¹ P. Van der Bossche and W Zdouc, *The Law and Policy of the World Trade Organisation* (3rd Edn, Cambridge University Press 2013) 952.

² C.M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (Zed Books, Third World Network 2000); J.E. Stiglitz, 'Economic Foundations of Intellectual Property Rights' (2008) 57 *Duke Law Review Journal* 1693; J.R. Borrell, 'Pricing and Patents of HIV/AIDS Drugs in Developing Countries,' (2007) 39 *Applied Economics* (2007), 505. (Follow the Formatting guidelines of this paper)

³ See HIV and AIDS in East and Southern Africa Regional Overview <https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/overview> accessed 21 June 2018.

⁴ HIV AND AIDS IN EAST AND SOUTHERN AFRICA REGIONAL OVERVIEW, available at <https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/overview> accessed 09/05/19.

⁵ See <https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/overview> accessed 21 June 2018.

⁶ Efforts to expand access to medicines in Africa must be intensified available at <https://www.who.int/medicines/news/2017/Efforts-to-expand-access-medicines-in-Africa-must-be-intensified/en/>

<https://www.who.int/medicines/news/2017/Efforts-to-expand-access-medicines-in-Africa-must-be-intensified/en/> accessed 09/05/2019.

⁷ Musungu, F. and Oh, C. (2005). The use of flexibilities in TRIPS by developing countries: Can they promote access to medicines? Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH), Study 4.

⁸ Article 27 of the TRIPS Agreement sets out the patentability criteria as follows:

"1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."

⁹ Article 27 (2) of the TRIPS Agreement allows Members to exclude from patentability inventions whose commercial exploitation may violate ordre public or morality. This includes the protection of health and life of plants, animals and humans as well as avoiding serious prejudice to the environment. Article 27(3) provides a non-exhaustive list of inventions which may be excluded from patentability. These include diagnostic, therapeutic and surgical methods for treatment of humans and animals; plants and animals other than micro-organisms, among others.

exceptions;¹⁰ parallel importation and exhaustion;¹¹ and compulsory licensing among others.¹² Yet, these flexibilities are not self-executing.¹³ Members need to incorporate these flexibilities into their national legislation in order to utilise them.¹⁴ It is in this context that this paper seeks to examine the extent to which Botswana has incorporated and utilised these flexibilities. It will identify the gaps and propose suggestions for reform. The next section gives the context of TRIPS flexibilities. This is followed by a historical development of patent law in Botswana and an analysis of TRIPS flexibilities in the current patent legislation. The paper will close with a conclusion and recommendations.

2. WTO TRIPS FLEXIBILITIES IN CONTEXT

The TRIPS Agreement came into effect in 1995. It is regarded as the most 'significant development in international intellectual property law.'¹⁵ It incorporates provisions for the administration as well as judicial enforcement of intellectual property rights (IPRs), and it includes provisions for the border control of trade in counterfeit and pirated goods.¹⁶ It also stipulates the minimum standards to be complied with by Members and does not require Members to implement more extensive protection than stipulated in its provisions.¹⁷ Members are free, however, to enact standards of IP protection above the stated minimum standards provided they do not contravene or derogate from the minimum standards stipulated in TRIPS.¹⁸

With respect to patent protection, the TRIPS Agreement provides protection for inventions, whether products or processes, in all fields of technology, including pharmaceuticals.¹⁹ TRIPS negotiations were long and complex.²⁰ Developing countries and Least-Developed countries resisted the inclusion of an IP regime in the WTO system because they feared that it might obstruct their developmental goals and access to important goods such as essential medicines. Ultimately, they were constrained to accept the "TRIPS package" as an indivisible component of the WTO system.²¹ The TRIPS Agreement is not self-executing and requires countries to implement proper domestic legislation so as to utilize the flexibilities.²² In order to strike a balance between patent holder protection and promotion of access to health by developing countries, the TRIPS Agreement has numerous flexibilities which if fully utilized by these countries, may promote and improve access to medicines.

3. HISTORICAL DEVELOPMENT OF PATENT LAW IN BOTSWANA

Botswana is a former protectorate of the United Kingdom (UK). Although it has a Roman-Dutch common law system, there is a great influence of English law due to its historical link with the UK. More so, its legislation on commercial matters, including intellectual property laws, were modelled along the British legislation during both the colonial and post-

¹⁰Article 30 of the TRIPS Agreement provides limited exceptions to patent rights. To ascertain whether an exception is permissible, a three step test is employed. According to this test, the exception should not unreasonably conflict with normal exploitation of the patent; should not unreasonably reduce the legitimate interests of the patent owner; and should take into account the legitimate interests of third parties.

¹¹ Parallel import may be defined as the import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country under a parallel patent.

¹² R.D. Smith, C. Correa and C. Oh, "Trade, TRIPS and Pharmaceuticals," (2009) 373 *The Lancet* 684; A. Taubman, H. Wager and J. Watal (ed), *A Handbook on WTO TRIPS Agreement* (Cambridge University Press 2012), 10.

¹³ WIPO, *Patent Related Flexibilities and the Multilateral Legal Framework and Their Legislative Implementation at the National And Regional Levels*, available at https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_5/cdip_5_4_re_v-main1.doc accessed 09/05/2019.

¹⁴ Ibid.

¹⁵ M. Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement* (Sweet and Maxwell, 1996).

¹⁶ Articles 51 and 52 of the TRIPS Agreement.

¹⁷ Article 1 provides "... members may but shall not be obliged to, implement in their domestic law more extensive protection than is required by this agreement..."

¹⁸ Article 1 of the TRIPS Agreement.

¹⁹ Article of the 27 TRIPS Agreement.

²⁰ D. Matthews *Globalising Intellectual Property Rights: the TRIPS Agreement* (Routledge, 2002); S. K. Sell *Private Power, Public Law: The Globalisation Of Intellectual Property Rights* (Cambridge University Press; 2003); J. Shubhan, 'Crossroads: Where Medicine and the Humanities Meet. The TRIPS Agreement and Public Health' [2006] *McGill Journal of Medicine*, 152.

²¹ Matthews D. *Globalising intellectual property rights: the TRIPS Agreement*. London: Routledge; 2002.

²² Correa, Carlos M. 2002. Implications of the Doha Declaration on the TRIPS Agreement and Public Health. *World Health Organization: Essential Drugs and Medicines Policy Series 12*; Victoria E. Hopkins "Analysis of International Patent Protection and Global Public Health" (2006, Vol. 17) *Journal of Public and International Affairs*, pp. 83.

colonial era.²³ This historical overview will discuss two pieces of legislation namely, the Patent and Designs Protection Act, as well as the Industrial Property Act of 1996.

A. The Patent and Designs Protection Act

When Botswana attained its independence in 1966, it inherited the Patent and Designs Protection Act, which was a piece of colonial legislation.²⁴ In terms of this Act, Botswana was obliged to respect and protect all patents which were granted in the UK and South Africa.²⁵ Botswana just provided for the registration of patents which would have been already granted in these countries, not having to assess whether an invention is patentable or not. Thus, Botswana did not deal with substantive issues on approval of patents but only with procedural aspects of entering in its register already processed and approved patents. One commentator succinctly summed up the criticism on these inherited laws in the following words:

‘Such legislation raised problems such as those pertaining to the sovereignty of the country. Why should a sovereign State be governed by the statute of another foreign State?’²⁶

Perhaps what is more appalling about the Patent and Designs Act is that it did not allow any person, including Botswana and Botswana based entities, to directly apply for patent registration in Botswana. One had to seek registration in either the UK or South Africa. Furthermore, the applicable law with respect to the patentability criteria, terms and conditions of patent protection; exceptions; infringement and remedies was based on that of either South African or the UK. This legislation was only repealed and replaced by the Industrial Property Act, 1996, 30 years post-independence.²⁷

The implication of this is that Botswana missed on 30 years of building capacity and experience in the area of patent examination and registration and in developing its own jurisprudence on patent law. Moreover, since the substantive provisions for patent protection were based on South African and UK standards, this placed a huge burden on Botswana to protect IPRs even though Botswana was a Least Developed Country at independence, from which it later graduated.²⁸

B. The Industrial Property Act, 1996

After 30 years of using a colonial piece of legislation, Botswana finally developed its first home grown patent legislation in the form of the Industrial Property Act, 1996.²⁹ The timing of this legislation is interesting in the context of the TRIPS Agreement. Botswana has been a Member of WTO since 31 May 1995³⁰ and was expected to implement the TRIPS Agreement. However, Botswana as a developing country Member of the WTO was not expected to immediately enact legislation governing IPRs in its territory. Article 65 of the TRIPS Agreement provides for transitional periods in the implementation of the Agreement.³¹ Developing country Members had up to five years to implement the Agreement.³² Furthermore, developing country Members had up to 10 years to extend product patent protection to areas of technology not so protected in their territory on the date the member applied this Agreement.³³ In the light of these provisions, Botswana was not expected to come up with new IP legislation immediately after the TRIPS Agreement came into force. However, since Botswana decided to exercise its rights and implement the TRIPS Agreement, this section will now analyze the 1996 Agreement vis-a-vis the TRIPS Agreement, with a view to

²³ S. Morolong, *Intellectual Property law: Botswana, International Encyclopedia of Laws*, (The Hague, Kluwer Law International, 2007), 42; J. Kiggundu, “Legal Aspects of Doing Business in Botswana,” in D. Campell (ed), *Legal Aspects of Doing Business in Africa*, (The Hague, Kluwer Law International, 2013).

²⁴ For a discussion of the historical development of patent law in Botswana for fifty years post-independence, see, Jimcall Pfumorodze and Emma Chitsove, ‘Major Developments in Intellectual Property Law in Botswana’ (2016) U. Botswana L. J., 197.

²⁵ See S. Morolong and T. Jobeta, ‘TRIPS and Patent Law’ (2006) 15 Lesotho Law Journal, 69.

²⁶ See R. Zikonda, ‘A Survey of Industrial Property Laws in English Speaking Africa’ [1998] Lesotho L.J p.4.

²⁷ Pfumorodze Jimcall and Chitsove Emma, ‘Major Developments in Intellectual Property Law in Botswana’ (2016) U. Botswana L. J., 197.

²⁸ Botswana graduated in 1994, https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/LDC_profile_Botswana.pdf accessed 21 June 2018.

²⁹ For a detailed discussion on compliance of the 1996 Act with the TRIPS Agreement, see S. Morolong and T. Jobeta, ‘TRIPS and Patent Law’ (2006) 15 Lesotho Law Journal, 69.

³⁰ See https://www.wto.org/english/thewto_e/countries_e/botswana_e.htm accessed 20 June 2018.

³¹ Article 65 of the TRIPS Agreement.

³² Article 65(2) of the TRIPS Agreement.

³³ Article 65(4) of the TRIPS Agreement.

ascertain the extent to which this legislation incorporated TRIPS flexibilities to promote access to medicines.

The 1996 Act provides that “novelty, inventive step and industrial application” are the criteria for patentability in line with Article 27 of the TRIPS Agreement.³⁴ The 1996 Act had a very limited scope of exclusion from patentability.³⁵ The following were excluded from patentability: a discovery; a scientific theory; a mathematical method; a dramatic and artistic work; a scheme, rule or method of doing business; a computer program; methods of treatment of the human body by surgery and diagnostic methods for treatment of human or animal body.³⁶ This is in contrast with the Industrial Property Act, 2010, which broadened the scope of exclusion from patentability as will be seen in the next section.

In terms of parallel importation and exhaustion, the Act adopted the national regime in contrast to the international exhaustion regime.³⁷ Parallel importation generally denotes a situation where goods which are under patent in one jurisdiction are imported into another state for resale without the patent holders’ consent. The provision for parallel imports is not expressly created by the TRIPS but by way of implication. Article 6 of the TRIPS Agreement states that “nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights”.³⁸ Thus, every Member has a right to determine the exhaustion regime to be adopted. By virtue of adopting the national exhaustion regime, Botswana was not able to procure cheaper patented medicines from other international markets for resale in the domestic market. Although the Act does not dictate the regime to be adopted on exhaustion, international exhaustion regime is preferable in promoting access to cheaper medicines.³⁹

The Act also provided for granting of a compulsory license. Section 30 of the 1996 Act empowers the responsible

Minister to issue a compulsory license in cases of public interest with specific reference to national security, nutrition, health or development. Section 31 of the 1996 Act provides for compulsory license on the ground of non-use of a patent.⁴⁰ However, within the context of access to medicines, this flexibility is hard to utilize. Article 31 of the TRIPS Agreement imposes stringent requirements for the utilization of compulsory license in the context of access to medicines. The medicines should be manufactured locally and supplied predominantly for the domestic market. Botswana does not have a pharmaceutical manufacturing industry, so it could not utilize this flexibility even though it had incorporated it in its domestic law

The 1996 Act provided for both civil and criminal penalties for the infringement of patent rights.⁴¹ The civil remedies provided for under the Act are: an interdict or injunction; delivery up or destruction of infringing product or article; damages and an account of the profits derived from the infringement.⁴² The Act also provides for criminal sanctions, either a fine or imprisonment or both.⁴³

The 1996 Act was repealed and replaced by the Industrial Property Act, 2010 which will be discussed in the next section.

4. TRIPS FLEXIBILITIES & THE INDUSTRIAL PROPERTY ACT, 2010

The Industrial Property Act, 2010 (2010 Act), repealed and replaced the Industrial Property Act, 1996. It came into force in 2012. The new Act was necessitated by a need to keep abreast with Botswana’s commitments at international level. By this time, Botswana was a party to the Patent Cooperation Treaty (PCT).⁴⁴ Furthermore, Botswana also revised its legislation in order to incorporate flexibilities in the implementation of the TRIPS Agreement. The discussion below focuses on the extent to which Botswana managed to domesticate these flexibilities.

³⁴ Section 8 of the 1996 Act.

³⁵ Section 9 of the 1996 Act.

³⁶ Section 9 of the 1996 Act.

³⁷ Section 24(3) (a) of the 1996 Act.

³⁸ Article 6 of the TRIPS Agreement.

³⁹ For a discussion of exhaustion under the TRIPS Agreement, see A. Taubman, H. Wager and J. Watal (ed), *A Handbook on WTO TRIPS Agreement* (Cambridge University Press, 2012), 18-20.

⁴⁰ Section 31 of the 1996 Act.

⁴¹ Section 25 of the 1996 Act.

⁴² See section 25 of the 1996 Act.

⁴³ Section 76 (6) of the 1996 Act.

⁴⁴ Botswana became a party to the PCT on 30 October 2003.

A. Patentability Criteria

Section 8(1) of the 2010 Act provides that for an invention to be patentable, it must be new, involve an inventive step and it must be capable of industrial application. This is in sync with Article 27(1) of the TRIPS Agreement. Article 27(1) of the TRIPS Agreement provides that patents are available for any inventions whether products or processes and covers all field of technology. To be patentable, an invention should be new, involve an inventive step and should be capable of industrial application. Whilst these requirements are welcome, there is a need to develop strict guidelines at the administrative level so as to ensure that the patentability criteria, when applied in the context of examination of pharmaceutical patents, would avoid frivolous and unnecessary patents which leads to ever-greening. Thus, there is a need for a thorough examination of pharmaceutical patents. However, there is another setback in ensuring a rigorous examination of patents. The 2010 Act also gives the responsible Minister the power to unilaterally grant patent rights.⁴⁵ Thus, some patents may be registered using political judgment and not scientific evidence. This can also be done in situations of patent extensions.

B. Exclusion from Patentability

Article 27(2) of the TRIPS Agreement allows Members to exclude from patentability inventions whose commercial exploitation may violate order public or morality. This include the protection of health and life of plants, animals and humans as well as avoiding serious prejudice to the environment. Article 27(3) provides a non-exhaustive list of inventions which may be excluded from patentability. These include diagnostic, therapeutic and surgical methods for treatment of humans and animals; plants and animals other than micro-organisms, among others. Although the 1996 Act had some exclusions from patentability, the 2010 Act broadens the scope of these exclusions in line with the TRIPS

Agreement.⁴⁶ This is a positive development in the context of affording access to cheaper medicines.

C. Patent Opposition

Section 21(5) as read with section 36(1) of the 2010 Act provides for pre-grant and post-grant patent opposition. Any interested party may apply and make an objection to the Registrar, opposing the grant of a patent in the manner and form prescribed by the Act or the regulations thereunder. Similarly, in the post grant phase, any interested party may apply to the Registrar or the High Court, for an invalidation of a patent, in terms of the Act. Patent opposition has the potential to improve the quality of patents and avoid ever-greening in the context of pharmaceutical patents such that frivolous and unnecessary patents may be challenged. Furthermore, the system for challenging a patent is inexpensive since one can approach the Registrar just as opposed to the High Court only. However, in practice it is difficult to utilize these provisions as there are no prescribed forms to use when making such patent oppositions.

D. Parallel Importation and Exhaustion

Parallel importation refers to the importation and resale in a country, of patented products from a country where it has been legitimately placed on the market under a parallel patent.⁴⁷ Such parallel importation is done without the consent of the patent holder who is deemed to have exhausted his rights on releasing the goods into the market. It should be recalled that one of the misgivings of the 1996 Act was that it had a national exhaustion regime. However, the 2010 Act adopted an international exhaustion regime.⁴⁸ This is a positive development since under the current legal framework patented medicines can be imported into Botswana for resale at a cheaper price. This enhances access to cheaper and affordable medicines.

E. Exceptions

⁴⁵ Section 22(2) of the IPA, 2010.

⁴⁶ For a discussion of these exclusions in the Botswana Context, see J. Pfumorodze, E. Chitsove and S.T. Morolong, 'The WTO TRIPS Agreement, Domestic Regulation and Access to HIV/AIDS Medicines in Southern Africa: The Case of Botswana and Zimbabwe' (2014) 27 UNISWA Research Journal, 145 and Jimcall Pfumorodze and Emma

Chitsove, 'Major Developments in Intellectual Property Law in Botswana' (2016) U. Botswana L. J., 197

⁴⁷ F. Musungu and C. Oh, 'The Use of Flexibilities in TRIPS by Developing Countries: Can they promote access to medicines?' Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH), Study 4, (2005).

⁴⁸ Section 25(1)(a) of the 2010 Act.

Section 25(1) provides for exceptions to the rights conferred by a patent. This part will only highlight those which are relevant in the context of access to medicines. These include international exhaustion and parallel importation which was discussed above;⁴⁹ experimentation with the subject matter of the patented invention;⁵⁰ acts done for the purpose of compliance with regulatory marketing procedures for pharmaceuticals;⁵¹ and extemporaneous preparation in a pharmacy for the purpose of individual prescription given by a medical or dental practitioner.⁵² The Act also allows acts done solely for academic, scientific research, educational or teaching purposes⁵³ as well private non-commercial use.⁵⁴

F. Compulsory licensing and the paragraph 6 system

Like its predecessor, the 2010 Act also provides for compulsory licensing. However, as noted above, Botswana does not have pharmaceutical manufacturing capacity so it cannot utilize this flexibility. However, Botswana has gone further to incorporate the paragraph 6 system in its legislation. The essence of the Paragraph 6 system is the creation of a special compulsory license system for exporting medicines. Section 32 of the 2010 Act deals with the "Importation of patented Products by government or third parties." Under this Act, Botswana can now import medicines from any legitimate alternative foreign source without the patent holder's approval if it is in the interest of public safety, or nutritional health of development. This is subject to meeting requirements to prevent the diversion of the medicines and notification requirements as well as the provision of the name and quantities to be imported. In line with the TRIPS Agreement, the 2010 Act places the obligation

to pay the patent holder remuneration on the exporting state and not on Botswana.

The domestication of the paragraph 6 system is a welcome development in Botswana considering its lack of a pharmaceutical industry. This can be utilized to ensure the importation of more affordable drugs to help fight the HIV/AIDS scourge. However, there are also challenges in the utilization of this flexibility. Botswana has to find a country with both the pharmaceutical manufacturing capacity and willingness to issue a compulsory license for import.⁵⁵

5. ANALYSIS OF THE 2010 ACT

A. Use of criminal sanctions in the 2010 Act

The Act provides for both civil and criminal penalties for the infringement of patent rights. The civil remedies provided for under the Act are: an interdict or injunction; delivery up or destruction of infringing products or articles; damages and an account of the profits derived from the infringement.⁵⁶ The Act also provides for criminal sanctions with either a fine or imprisonment or both.⁵⁷

It should be recalled that the TRIPS Agreement has the flexibility to apply or not to apply criminal sanctions in patent enforcement. Some proponents of criminalization of patent infringement have argued that it would deter illegal activities and reduce losses to patent owners.⁵⁸ Some have also argued that this would make enforcement cheaper and easier for patent holders since the state absorbs costs in criminal matters.⁵⁹ However, criminal sanctions for patent infringements are generally discouraged. It has been argued that such sanctions would be a deterrent to competitors. This, in turn, would be expensive to society since it can hinder

⁴⁹ Section 25(1)(a) of the 2010 Act.

⁵⁰ Section 25(1)(c) of the 2010 Act.

⁵¹ Section 25(1)(f) of the 2010 Act.

⁵² Section 25(1)(g) of the 2010 Act.

⁵³ Section 25(1)(i) of the 2010 Act.

⁵⁴ Section 25(1)(j) of the 2010 Act.

⁵⁵ For a discussion on some challenges with the implementation of the paragraph 6 system, see S.A. Barbosa, 'Implementation of the Doha Declaration: Its Impact on American Pharmaceuticals' [2004] Rutgers Law Journal 205; D. Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration and Public Health: A solution to the Access to the Essential Medicines Problem?' (2004) 7 Journal of International Economic Law 73; D. Matthews,

'From the August 30, 2003 WTO Decision to the December 6, 2005 Agreement on an Amendment to TRIPS: Improving Access to Medicines in Developing Countries,' (2006) 2 Intellectual Property Quarterly, 91.

⁵⁶ Section 27 of the Industrial Property Act, 2010.

⁵⁷ Section 134 (4) and (6) of the Industrial Property Act, 2010.

⁵⁸ Irina D. Manta, 'The Puzzle of Criminal Sanctions for Intellectual Property Infringement', (2011) 24 Harvard Journal of Law & Technology, 495.

⁵⁹ Harold A. Borland, 'The Affirmative Duty to Exercise Due Care in Willful Patent Infringement Cases: We Still Want It' [2005] Houston Business and Tax Law Journal, 197.

technological development in areas of public interest like public health.⁶⁰

B. Exclusion of IP law from competition law

Although the TRIPS Agreement allows Members to implement competition-based exceptions to the rights conferred by a patent,⁶¹ the Botswana competition law excludes IP from its ambit, as shown in the National Competition Policy for Botswana (2005).⁶² Section 8.1(j) (ii) (c) provides as follows:

‘The Policy recognises the important role intellectual property (patents, trademarks and copyrights) plays in Botswana’s human and economic development endeavors - and the need to protect and safeguard the interests of intellectual property rights-holders. Therefore, as a way of protecting intellectual property rights from infringement and in order to promote the development of creations and innovations, intellectual property rights will be exempted and excluded from the ambit of this policy.’

Similarly, section 3(3)(a) of the Competition Act, 2009 provides the Act not apply to any agreement to the extent that the agreement relates to the protection, exercise, licensing or assignment of rights under any law governing IPRs.

In some jurisdictions, competition law has successfully been used as a tool in advancing access to cheaper medicines. For instance, the South African Competition Act⁶³ has some mechanisms to deal with IP based competition issues, like dealing with excessive pricing.⁶⁴ For instance, in *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*,⁶⁵ the complaint was that the respondents were charging excessive prices for ARVs. It was alleged that such high prices violated

the Competition Act. The Competition Commission undertook an investigation and found a violation of the Competition Act in that the respondents had taken advantage of their dominant position to charge excessive prices as well as denying other pharmaceutical companies to manufacture generic drugs. One interesting outcome of this case was that the respondents allowed other pharmaceutical companies to manufacture generic medicines which were sold at a cheaper price in the market.⁶⁶ Thus, competition law was used as a tool to advance access to cheaper medicines.

6. PROPOSALS FOR ENHANCING ACCESS TO MEDICINE IN BOTSWANA

Proposals for enhancing access to medicine in Botswana can be divided into two, mainly those which can be done at national level and those which can be done at regional level. These proposals are discussed below.

A. Human Resources staffing and training

There is a need for continuous training for staff responsible for registration of patents especially on the criteria for patentability which should be satisfied before a product is patented as provided for in Article 27.1 of the TRIPS Agreement. These requirements are ‘novelty, inventiveness and industrial applicability’. Musungu and Oh (2005) observed that since the terms ‘novelty, inventiveness and industrial applicability’ are not defined, Members may determine how these criteria should be interpreted and applied, as well as the nature and scope of pharmaceutical inventions.⁶⁷ The implication of this flexibility for developing countries is that the TRIPS Agreement does not prevent countries from denying the patentability of new uses for lack

60 Irina D. Manta, ‘The Puzzle of Criminal Sanctions for Intellectual Property Infringement’, (2011) 24 *Harvard Journal of Law & Technology*, 495. See also WIPO, ‘Patent-Related Flexibilities in the Multilateral Legal Framework And their Legislative Implementation at the National and Regional Levels – Part IV’, 9 March 2015, available at www.wipo.int/meetings/en/doc_details.jsp?doc_id=298943 accessed 21/06/2018.

61 James Thuo Gathii, ‘Construing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers (2001) *Fla. L. Rev.*, 727.

62 Section 8 of the National Competition Policy for Botswana.

63 Act No. 89 of 1998.

64 Section 8(a) of the Competition Act

65 Competition Commission Case Number: 2002Sep226; see also *Treatment Action Campaign v Bristol-Myers Squibb Commission* Case number 2007Nov3328.

66 Jonathan Berger, Utilising TRIPs flexibilities on competition law to ensure a sustainable supply of affordable essential medicines: a focus on South Africa available at <https://www.tralac.org/images/docs/4673/berger-trips-flexibilities-comp-law-rsa-20061011.pdf> accessed 09/05/2019.

67 F. Musungu and C. Oh, ‘The Use of Flexibilities in TRIPS by Developing Countries: Can they promote access to medicines?’ Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH), Study 4, (2005).

of novelty, inventive step or industrial applicability.⁶⁸ Thus, developing countries are free to exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products. These flexibilities can be best utilized when the staff is well trained so that they ensure that only true inventions are patented. This may allow for granting of far fewer patents than would otherwise be the case if the patentability criteria were not carefully defined or where the power to refuse patenting in certain cases was not exercised.⁶⁹

B. Avoiding Political Pressure: TRIPS-plus provisions

Since TRIPS came into force, bilateral and regional trade agreements have tended to set even higher standards for IP protection.⁷⁰ Developed countries exert political and economic pressure on developing countries so that they may not utilize TRIPS flexibilities or to adopt TRIPS-plus provisions, which go beyond and effectively supersede the minimum requirements in TRIPS.⁷¹ For instance, Thailand abandoned⁽ⁱ⁾ its production plans to produce a generic HIV/AIDS drug still under patent in the United States; these plans were developed for the sole purpose of providing AIDS patients drugs at affordable prices.⁷² This is because Thailand was faced with US trade sanctions targeting its primary exports.⁷³ It is suggested that Botswana should refrain from entering into any bilateral or regional arrangements which restrict it from the utilization of TRIPS flexibilities.

The issue of TRIPS plus provisions supports the case that Botswana should have its own manufacturing capacity in the long term rather than relying on the paragraph 6 system. This is because the paragraph 6 system relies on the manufacturer in another country. A country with manufacturing capacity may enter into TRIPS plus provision restricting it from issuing compulsory license which would ultimately affect the

utilization of the paragraph 6 system. Such a country would not be able to issue a compulsory license for the manufacture of drugs for export to countries in need of drugs. It is better for Botswana to have self-sufficiency in pharmaceutical manufacturing.

C. Regional manufacturing of drugs

Given that Botswana does not have local capacity, there is some merit in pursuing regional manufacturing within the context of the Southern African Development Community (SADC). Regional manufacturing of drugs is provided for in the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of 30 August 2003⁷⁴. It states as follows:

‘6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favorable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

⁶⁸ C. M. Correa *Intellectual Property Rights and Developing Countries. The TRIPS Agreement and Policy Options* (Zed Books Ltd., 2000.)

⁶⁹ Republic of Botswana, *The Implementation of Trade Related Aspects of Intellectual Property Legislation for Strengthening Access to Medicines in Botswana*, Workshop Report, A UNDP-SARPAM-Botswana, Government Workshop, Gaborone, 25-27 March 2013.

⁷⁰ Dianne Nicol & Olasupo Owoeye ‘ Using TRIPS flexibilities to facilitate access to medicines’ (2013) 91 *Bull World Health Organ* 533.

⁷¹ Victoria E. Hopkins ‘ Analysis of International Patent Protection and Global Public Health’ (2006)17 *Journal of Public and International Affairs*, 83.

⁷² Victoria E. Hopkins ‘ Analysis of International Patent Protection and Global Public Health’ (2006)17 *Journal of Public and International Affairs*, 83.

⁷³ C. M. Correa *Intellectual Property Rights and Developing Countries. The TRIPS Agreement and Policy Options* (Zed Books Ltd., 2000.)

⁷⁴ Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.’

While the decision to allow regional manufacturing is welcome, the requirement that at least half of the members to the RTA must be LDCs is too stringent. At the moment, SADC, to which Botswana is a member, qualifies to utilize this flexibility.⁷⁵

D. Pooled Procurement

One of the methods which have been used successfully at a regional level to purchase medicines at affordable prices is pooled procurement.⁷⁶ This is where multiple countries pull their buying power and procure the drugs together. In economics terms, this would “induce supply interest and market entrants, thus creating a more competitive pricing environment and more ready access to medicines.”⁷⁷ This arrangement has been used successfully in the Caribbean region where seven different countries pooled their resources and purchased drugs jointly.⁷⁸ As a result, there was reduction of drug prices by 50 percent and this also led to a more concentrated drug knowledge.⁷⁹ Botswana may also explore the possibility of pooled procurement with other countries in the SADC region.

7. CONCLUSION

This paper has discussed the extent to which Botswana has incorporated TRIPS flexibilities. For a start, Botswana has, to a large extent, implemented TRIPS flexibilities in its national legislation. These include the patentability criteria, exclusion from patents, parallel importation and exhaustion,

compulsory licensing, patent opposition and exceptions to rights conferred by patents. This is very positive as it is the first and necessary step in the utilization of TRIPS flexibilities. However, the next step, which is the most important one and is fraught with challenges, is the utilization of these flexibilities. The major challenge is lack of manufacturing capacity in Botswana which means Botswana would rely on the manufacturing capacity of third parties should it want to utilize compulsory licensing.

From the discussion above, there are three main areas which need to be addressed. First, there is a need for information on the manner and form of patent opposition to enable the utilization of this flexibility. Secondly, Ministerial discretion on the granting of patents should be removed so that patents will only be granted when they meet the patentability criteria. Thirdly, criminal sanctions on patent infringement should be removed in order to encourage innovation. Furthermore, the Competition Act should be amended to include IP issues.

Since the challenges are diverse, their solutions are also different and the time frame ranges from short to medium to long term. In the short term, it is advisable that Botswana should consider regional pooling of resources in order to acquire essential drugs as well as the utilization of the paragraph 6 system. Training of relevant staff is also desirable in the short term. In the medium to long term, Botswana should carry out a feasibility study on local manufacturing of drugs. Where local manufacturing is not found to be viable, Botswana can consider regional manufacturing of drugs. These measures would ensure that Botswana is able to access cheaper and affordable medicines which would in turn advance the right to health in Botswana.

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THE IMPACT OF PATENT LINKAGE ON ACCESS TO MEDICINE: THE CURRENT SITUATION IN EGYPT

Fatma S Abdel Salam*

ABSTRACT

The pharmaceutical industry is one of the most important and critical industries due to its link to public health. This industry requires huge investments for research and development (R&D) of new drugs for treatment of various diseases. Multinational companies are leaders in this industry as they possess science, money and technology are leaders in this industry. In an effort to recoup investments in R&D multinational companies usually seek not only for higher levels of patent protection but also for extended protection through applying for multiple patents that cover different aspects of the same invention. This is known as “evergreening of patents”. The patent linkage system is another example of evergreening by which the regulatory authority links the drug marketing approval to the patent status of the originators. This paper discusses the linkage system in different jurisdictions, and how it affects the entry of generic products into the market. It also discusses the situation in Egypt as a model example for developing countries.

Key words: evergreening, patent linkage, Egypt, generic medicine, developing countries.

1. INTRODUCTION

Patents are one of the most important branches of intellectual property (IP), as it is linked to several industries that rely on technology, and sensitive sectors such as medicine and public health.¹ Patent system gives the inventor the legal protection for his invention so that he has the right to exclude others from making or using his invention without his consent.² This protection is limited, in most

countries it extends for 20 years from the filing date of the patent application.³

It is well known that developing a new pharmaceutical drug or new chemical entity requires testing the new compounds in assays and animal model.⁴ If the preclinical studies ensure that the new compound is safe and effective, it is subjected to clinical studies.⁵ Clinical trial phases are steps in research to determine whether the new chemical entity is safe and effective to humans or not.⁶

Companies spend tens to hundreds of millions of dollars to develop a single new chemical entity. Therefore, multinational companies that are leaders in this industry usually seek for higher levels of patent protection.

From the economic point of view, these companies often prefer to perform slight modifications on an old patented molecule and apply for multiple patents that cover different aspects of the same product allowing for an extended patent protection, rather than developing a new compound; this is known as “patent evergreening”.⁷

“Patent evergreening” is very common in the pharmaceutical industry and it can take many different forms to extend the term of patent including; applying patent applications for methods of treatment, mechanism of action, isomeric forms, packaging, dosing regimen and screening methods.⁸ Patent term extension, data exclusivity and patent linkage systems are other types of patent evergreening.⁹

Patent evergreening is considered a defensive patenting strategy that innovator companies usually follow to create obstacles for generic competitors to enter the market. One of these obstacles is the “patent linkage system” which involves linking drug marketing approval with the originator’s drug patent status and refusing marketing approval until the relevant patent expires.¹⁰ In other words, the regulatory

* **Fatma S Abdel Salam** is a Pharmaceutical Patent Examiner, Egyptian Patent Office and an Intellectual Property Trainer in the Egyptian IP Academy. She holds a Master’s degree in Pharmaceutics and industrial pharmacy (2014) at University of Cairo Faculty of Pharmacy in Egypt and a Diploma in Intellectual Property Rights at University of Helwan Faculty of Law in Egypt (2015). She participated in many workshops and conferences related to IPRs; was an expert training in the training of trainers (TOT) for the Azerbaijani and Georgian startup IP academies; and has been an online tutor for and has contributed to the customization of DL 101 and 301 according to the Egyptian law.

¹ Mina Mashayekhi, 'Intellectual Property in the World Trade Organization: Turning it into Developing Countries' Real Property' (2010) United Nations Conference on Trade and Development <https://unctad.org/en/Docs/ditctnkd20068_en.pdf> accessed 13 May 2019.

² Bronwyn H Hall, 'Patents' (2007) Contribution to The New Palgrave: A Dictionary of Economics, second edition <https://eml.berkeley.edu/~bhall/papers/BHH06_Patents_Palgrave.pdf> accessed 6 May 2019

³ *ibid*

⁴ Gamal Osman Elhasan, 'Drug Development: Stages of Drug Development' (2015) J Pharmacovigilance <https://www.researchgate.net/publication/281700675_Drug_Development_Stages_of_Drug_Development/download> accessed 6 May 2019.

<https://www.researchgate.net/publication/281700675_Drug_Development/download> accessed 6 May 2019.

⁵ Vicki L Mahan, 'Clinical Trial Phases' (2014) International Journal of Clinical Medicine <https://file.scirp.org/pdf/IJCM_2014122915372964.pdf> accessed 6 May 2019.

⁶ *ibid*

⁷ John R Thomas, 'Patent “Evergreening”: Issues of Innovation and Competition' (2010) Congress Research Service <https://www.ipmall.info/sites/default/files/hosted_resources/crs/R40917_091113.pdf> accessed 1 May 2018.

⁸ Inderjit Singh Bansal, Deeptimaya Sahu, Gautam Bakshi and Sukhjeet Singh, 'Evergreening – A controversial issue in pharmaceutical milieu' (2009) Journal of Intellectual Property Rights <<http://indiaenvironmentportal.org.in/files/Evergreening.pdf>> accessed 6 May 2019.

⁹ Thomas A Faunce and Joel Lexchin, 'Debate 'Linkage' Pharmaceutical Evergreening in Canada and Australia' (2007) Biomed Central <https://www.researchgate.net/publication/6293474_'Linkage'_Pharmaceutical_Evergreening_in_Canada_and_Australia/download> accessed 7 May 2019.

¹⁰ Ravikant Bhardwaj, K D Raju and M Padmavati, 'The Impact of Patent Linkage on Marketing of Generic Drugs' (2013) Journal of Intellectual Property Rights

authority will not allow the generic drug¹¹ to enter the market if there is a valid originator patent for that drug. As a result, the availability of generic versions of the drug with affordable prices will be delayed.

Patent linkage is considered one of the higher standards of protection negotiated in the post-Trade Related Aspects of Intellectual Property Rights (TRIPS) era known as TRIPS-PLUS commitments, as it goes beyond the minimum standards of the TRIPS agreement.¹² This article discusses the appearance of the patent linkage system in developed countries and how it spread to developing countries. It also sheds light on the effect of this system on access to medicines, with a particular focus on the situation in Egypt and its application in that context.

2. PATENT LINKAGE IN DEVELOPED COUNTRIES

2.1. Patent linkage in US and Canada

The patent system has existed for more than 500 years.¹³ By contrast, the patent linkage system developed with the passage of the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman act (1984)) in United States and the Canadian Patent Medicines (Notice of Compliance) Regulations (NOC Regulations).¹⁴

In the US the Food Drug Administration (FDA)¹⁵ lists the pharmaceutical products and medicinal uses, which are under patent in "Approved Drug Products with Therapeutic Equivalence Evaluations", commonly known as the Orange Book.¹⁶ When a generic company files for approval of an Abbreviated New Drug Application (ANDA), it must certify

one of the following four grounds: that the drug is not covered by a valid patent; the patent has already expired; the generic drug will not be released into the market until the expiry of the patent; or the patent is invalid or is not infringed.¹⁷ These grounds are referred to as paragraphs I, II, III and IV certifications.¹⁸ In the first two paragraphs, the FDA grants the approval immediately.¹⁹ In case of paragraph III, the FDA grants approval after the expiration of the patent.²⁰ Concerning paragraph IV, when there are claims of invalidity or non-infringement, the patent holder is notified and given forty-five days to file an infringement action (under section 271(e)(2)(A) of the US patent linkage system, which held up the approval of generic drug for thirty months.²¹ The first generic company that succeeds to invalidate the patent or proves that it is not infringing the patent is given 180 days of generic exclusivity.²²

Canada is considered the second country that applied the "Patent linkage system" after the US.²³ The linkage regulations in Canada are based on the US patent linkage system with a stay time of 24 months that is shorter than that in the US regulations.²⁴ Under the regulations of this system, Canada does not allow a generic company to enter the market until it proves that all of the relevant patents have expired.²⁵ The generic company has to send a Notice of Allegation to the originator claiming non-infringement of the patent. Then, the patent holder will have 45 days to file an application in the Federal court of Canada to prevent Health Canada from

<[http://nopr.niscair.res.in/bitstream/123456789/20282/1/JIPR%2018\(4\)%20316-322.pdf](http://nopr.niscair.res.in/bitstream/123456789/20282/1/JIPR%2018(4)%20316-322.pdf)> accessed 1 May 2018.

¹¹ Generic medicines are the medicine products that are bioequivalent to the originator as they have the same qualitative and quantitative composition of the active substance. They have the same safety and efficacy of the originator but at more affordable prices.

¹² Sandeep K Rathod, 'Patent Linkage and Data Exclusivity: A Look at Some Developments in India' (2011) 8(3) Journal of generic medicines 140-149 <<http://journals.sagepub.com/doi/pdf/10.1177/1741134311423461>> accessed 4 Jan 2018.

¹³ A Samuel Oddi, 'The international Patent System and Third World Development: Reality or Myth?' (1987) Duke Law Journal <<https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=3003&context=dj>> accessed 7 May 2019.

¹⁴ Ron A Bouchard, Dan Cahoy, Bengt Domeij, Graham Dufield, Tom Faunce, Aidan Hollis, Paul Jones, Feroz Ali Khader, Joel Lexchin, Heesob Nam, Juan Luis Serrano, 'Global Pharmaceutical Linkage Regulations: A Proposed Analytical Framework' (2011) 12 (2) Minnesota Journal of Law Science & Technology 1-44. <<https://www.researchgate.net/publication/228416994>> accessed 12 May 2018.

¹⁵ The US Food and Drug Administration is a governmental agency responsible for protecting the public health by ensuring the safety, efficacy and security of human and veterinary drugs, biological products and medical devices in US.

¹⁶ US Department of Health and Human Services, 'Approved Drug Products with Therapeutic Equivalence Evaluations' (2019) 39th edition Orange book

< <https://www.fda.gov/media/71474/download>> accessed 7 May 2019.

¹⁷ Judit R Sanjuan, 'Patent – registration linkage' (2006) Consumer project on technology CPTEch Discussion Paper <<http://www.cptech.org/publications/CPTEchDPNo2Linkage.pdf>> accessed 14 April 2018.

¹⁸ C Scott Hemphill and Mark A Lemley, 'Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act' (2011) Anti Trust Law Journal <<https://law.stanford.edu/publications/earning-exclusivity-generic-drug-incentives-and-the-hatch-waxman-act/>> accessed 8 May 2019.

¹⁹ Judit Rius Sanjuan (n 17).

²⁰ ibid

²¹ Brook K Baker, 'Ending Drug Registration Apartheid – Taming Data Exclusivity and Patent Registration Linkage' (2008) American journal of Law and Medicine 303, 307 <<http://journals.sagepub.com/doi/pdf/10.1177/009885880803400209>> accessed 30 March 2018.

²² C Scott Hemphill (n 18) 947

²³ Ravikant Bhardwaj (n 3) 318-319 .

²⁴ Jean F Morin and Melanie B Forcier, 'Pharmaceutical Patent Policy in Developing Countries: Learning from the Canadian Experience' in Guennif S S, Guzman A and Lalitha N (eds), Intellectual Property, Pharmaceuticals and Public Health (*SSRN Electronic Journal* 2011).

²⁵ Joel Lexchin and Marc A Gagnon, 'CETA and Intellectual Property: The Debate over Pharmaceutical patents' (2013) CETA Policy Briefs Series < https://carleton.ca/canadaeuope/wp-content/uploads/CETA-Policy-Brief_CETA-and-pharmaceutical-patents_MG_JL.pdf> accessed 8 May 2019.

issuing a Notice of Compliance (NOC) to the generic company for 24 months.²⁶

2.2. Patent Linkage in the European Union

Generic medicines play a crucial role in providing high quality and affordable prices throughout the EU.²⁷ The EU legislation states that granting of marketing authorization should be based solely on quality, safety and efficacy data and not on other criteria.²⁸ However, generic medicines access to the market in EU faces many obstacles e.g. evergreening tactics.²⁹ To overcome these obstacles the European Generic Medicine Association (EGA) was actively engaged to the European Commission's follow up initiatives in the pharmaceutical field, to promote generic medicines and increase the access of medicine in affordable prices.³⁰ As a result, one of the main objectives of EGA was to abandon any pathway that leads to patent linkage which acts as a barrier to generic medicine. This objective was justified by the EU law which stated that "It is not allowed to link marketing authorization to the patent status of the originator reference product".³¹ Therefore, the patent linkage system, which is an obstacle to the availability of generic medicines in the pharmaceutical market, is not a part of EU pharmaceutical legislation.³²

Nevertheless, there are some countries in EU which apply the patent linkage system such as Italy, Hungary, Portugal and Slovak Republic.³³

In Italy, the patent linkage system has been standing as a barrier in front of the generic medicines.³⁴ The Industrial –

Property Code 2010 stated that "a generic applicant could only start the registration procedure one year before the expiration of any protection on the active substance" which was not conformed to Directive 2001/82/EC.³⁵ In November 2012 Italy's new "Balduzzi Decree" Article 11 (1) allowed the generic drug manufacturers to register their products even during the patent term of the reference product, but the generic product cannot be classified as a reimbursable drug by the Italian National Healthcare System (SSN) as long as the patent of the reference product is still valid.³⁶ This is considered a form of patent linkage which delayed the entry of generic medicine into the market.³⁷

In Hungary, Article 7(9) of Decree 52/2005 of the Ministry of Health needs the generic manufacturer which is seeking for marketing approval to state that he is not infringing any patent or will market his product after the expiration of the patent of the originator.³⁸ In case the generic company has the marketing approval the originator company can take legal action against generic company.³⁹

2.3. Criticism of the Patent Linkage System

The objective of drug approval-patent linkage system in some countries is to facilitate research and development, and to encourage innovation by providing effective protection system for the patent owner.⁴⁰ However, this system gives one sided protection to the patent owner which resulted in abuse of the patent rights.⁴¹

²⁶ Joel Lexchin and Marc A Gagnon, 'CETA and Pharmaceuticals: Impact of the Trade Agreement between Europe and Canada on the Costs of Prescription Drugs' (2014) Lexchin and Gagnon *Globalization and Health* 10, 13. <<https://globalizationandhealth.biomedcentral.com/track/pdf/10.1186/1744-8603-10-30>> accessed 17 April 2018.

²⁷ Alan S, 'Generic Medicines: Essential Contributors to the Long-Term Health of Society' (2010) IMS Intelligence Applied <https://www.hup.hr/EasyEdit/UserFiles/Granske_udruge/HUP-UPL/IMS.pdf> accessed 1 June 2018.

²⁸ *ibid*

²⁹ Steven Simeons, 'Sustainable Provision of Generic Medicines in Europe' (2013) Simeons 2 Report <<https://pdfs.semanticscholar.org/d0b4/a5ba78141a4cea075a31f1a0e8d5052030ef.pdf>> accessed 10 May 2019.

³⁰ Greg Perry, 'The European Generic Pharmaceutical Market in Review: 2006 and beyond' (2006) *Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector* <<https://journals.sagepub.com/doi/abs/10.1057/palgrave.jgm.4950041>> accessed 10 May 2019.

³¹ European Generic Medicine Association, 'The EGA'S Thoughts on How to Improve the Legal and Regulatory Framework for Generic and Biosimilar Medicines' (2010) EGA Vision 2015 <https://www.hup.hr/EasyEdit/UserFiles/Granske_udruge/HUP-UPL/EGA_Vision_2015.pdf> accessed 10 May 2019.

³² Kristof R, Julia P, Andrew B and Stefan B, 'Patent-Related Barriers to Market Entry for Generic Medicines in the European Union: A Review of Weaknesses in the Current European Patent System and their Impact on Market Access of Generic Medicines' (2008) *Journal Of Generic Medicine* 255, 272 <https://www.researchgate.net/publication/31944163_patent-related_barriers_to_market_entry_for_generic_medicines_in_the_european_union_a_review_of_weaknesses_in_the_current_european_patent_system_and_their_impact_on_market_access_of_generic_medicines> accessed 8 May 2019.

³³ Judit R Sanjuan (n 17).

³⁴ Pieter Dylst, Arnold Vulto and Steven Simoens, 'Analysis of the Italian generic medicines retail market: recommendations to enhance long-term sustainability' (2015) *Expert Review of Pharmacoeconomics & Outcomes Research* <<https://www.ncbi.nlm.nih.gov/pubmed/25138241>> accessed 10 May 2019.

³⁵ *ibid*

³⁶ Ottavio Sangiorgio, 'Update On The "Balduzzi Law" In Italy And The Reimbursement Linkage Provision' (2015) Simmons & Simmons Elexica <<http://www.elexica.com/en/legal-topics/life-sciences-regulatory/02-update-on-the-balduzzi-law-in-italy-and-reimbursement-linkage-provision>> accessed 10 May 2019

³⁷ *ibid*

³⁸ Ravikant Bhardwaj, K D Raju and M Padmavati (n10) 318.

³⁹ *ibid*

⁴⁰ Ki Young Kim, HyunsukJin and Samuel SungMok Lee, 'The Korean Drug Approval- Patent Linkage System: A Comparison with the US Hatch-Waxman Act' (2015) Attorneys at Law <<https://www.lexology.com/library/detail.aspx?g=5619213a-4714-4307-8bfd-8e12955841e1>> accessed 13 June 2018.

⁴¹ *ibid*

The United States adopted the patent linkage system to reward pioneer pharmaceutical companies, facilitate the entry of generic medicine into the market, and to produce a kind of competition between generic companies to gain the 180 days of marketing exclusivity.⁴² However, due to costly and timely litigations before marketing approval is granted, generics entry to the market is delayed⁴³, and the high litigations cost may be passed indirectly to the consumer, through increasing the cost of generics. So, what is the value of 180 days of generic exclusivity compared to investment in costly and time-consuming litigation?

Generally, the median time for the regulatory authorities to approve a generic drug is about 4 years, e.g. it is 47 months for the FDA to approve a generic product.⁴⁴ As a result, applying patent linkage system which involves refusing generic drug marketing approval until the relevant patent expires, will delay the entry of the generic drug into the market for about four years which are required for the generic drug to be approved by the regulatory authorities.

Therefore, patent linkage system is highly effective in protecting the innovator products from competition with the generics and delaying the entry of generic drugs into the market.⁴⁵ Moreover, it extends market monopoly beyond patent protection of the innovator product.⁴⁶

Contrary to the aim of the patent system, the patent linkage system does not encourage innovation, as the pharmaceutical companies often prefer to file follow-on patents evolving from single original patent.⁴⁷ This follow-on patents are listed in patent registers in the regulatory authorities to delay generic entry under the patent linkage system.⁴⁸ This results in extended monopolies and ultimately delays access to generic medicines at affordable prices.⁴⁹

The negative effect of the patent linkage system on access to generic medicine appears greatly in those countries whose patent office's grant low quality patents, including the United States.⁵⁰ In the US, sometimes pharmaceutical companies file additional low-quality patents with the FDA to be registered in the Orange Book, which, according to the US law, grants 30 months stay extending the originator's monopoly.⁵¹

This problem clearly appears in the case of the FTC v. Bristol Myers Squibb (2003)⁵², in which the Federal Trade Commission (FTC) announced that the Bristol-Myers Squibb company has been engaged in a series of anticompetitive acts to prevent or to delay the entry of low-price generic products:⁵³ two anti-cancer drugs, namely, Taxol and Platinol, and Buspar the anti-anxiety product. Bristol-Myers filed several patents for the three drugs that did not meet the criteria for listing in the orange book.⁵⁴

3. SPREADING OF THE PATENT LINKAGE SYSTEM

The generic entry to the market is affected not only by the patent system but also by the patent linkage regulations that has spread very rapidly in some countries, especially developing countries, after it was limited to the US. The year 2011 is considered the year of the spreading of the patent linkage system on a global level including developing countries through bilateral and multinational free trade agreements (FTAs).⁵⁵

3.1. The Role of FTAs in Spreading the Linkage Regime

Before the TRIPS Agreement, pharmaceutical products were not protected by patent systems in most developing

⁴² Molly F M Chen, 'Reconsidering the US Patent System: Lessons From Generics' (2012) *Journal of Transitional Law* (Note) 1249, 1262.

<<https://www.vanderbilt.edu/wp-content/uploads/sites/78/Chen-FINAL.pdf>> accessed 1 June 2018.

⁴³ Molly F M Chen, 'Reconsidering the US Patent System: Lessons From Generics' (2012) *Journal of Transitional Law* (Note) 1249, 1252.

<<https://www.vanderbilt.edu/wp-content/uploads/sites/78/Chen-FINAL.pdf>> accessed 1 June 2018.

⁴⁴ GDUFA II: FDA Looks to Speed Up Generic Drug Approval Process <<https://www.amplexor.com/zh/resources/news/gdufa-ii-fda-looks-to-speed-up-generic-drug-approval-process.html>> accessed 11 May 2019.

⁴⁵ Kyung-Bok Son, Ruth Lopert, Deborah Gleeson and Tae-Jin Lee, 'Moderating the impact of patent linkage on access to medicines: lessons from variations in South Korea, Australia, Canada, and the United States' (2018) Son et al. *Globalization and Health* <<https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-018-0423-0>> accessed 11 May 2019.

⁴⁶ *ibid*

⁴⁷ Ronald A. Bouchard, Dan Cahoy, Bengt Domeij, Graham Duffield, Tom Faunce, Aidan Hollis, Paul Jones, Feroz A. Khader, Joel Lexchin, Heesob Nam and Juan L. Serrano, 'Structure-Function Analysis of Global Pharmaceutical Linkage Regulations'

(2011) *Minnesota Journal of Law, Science and Technology* <<https://scholarship.law.umn.edu/mjlst/vol12/iss2/3/>> accessed 11 May 2019.

⁴⁸ *ibid*

⁴⁹ Joseph A DiMasi and Laura B Faden, 'Competitiveness in Follow on Drug R & D: A Race or Imitation?' (2011) *Nature reviews Drug discovery* 23-27

<<https://www.ncbi.nlm.nih.gov/pubmed/21151030>> accessed 1 June 2018.

⁵⁰ Gaétan de Rassenfosse, Adam B. Jaffe and Elizabeth Webster, 'Low-Quality Patents in the Eye of the Beholder: Evidence from Multiple Examiners' (2016) *Center for Transformative Innovation Working Paper* 1/16 <<https://www.swinburne.edu.au/media/swinburne/duau/research/research-centres/cti/working-papers/CTI-Working-Paper-1-16-Low-quality-patents.pdf>> accessed 11 May 2019.

⁵¹ Judit R Sanjuan (n 17).

⁵² 'FTC Charges Bristol-Myers Squibb with Pattern of Abusing Government Processes to Stifle Generic Drug Competition' (Federal Trade Commission 7 March 2003) <<https://www.ftc.gov/news-events/press-releases/2003/03/ftc-charges-bristol-myers-squibb-pattern-abusing-government>> accessed 13 June 2018.

⁵³ *ibid*

⁵⁴ *ibid*

⁵⁵ Ron A Bouchard (n 14).

countries.⁵⁶ With the adoption of the agreement, all country members were obliged to incorporate the TRIPS requirements into their national legislations. This includes patent protection for all fields of technology without discrimination.

Although TRIPS agreement sets out minimum standards for protection of intellectual property, including patents for pharmaceuticals, it offers some flexibilities to remedy negative effects of patent protection or patent abuse, and decrease the barriers for access to medicine.⁵⁷

The main flexibilities built in TRIPS agreement are: Compulsory license (Article 31)⁵⁸, parallel importation (Article 6)⁵⁹ and Article 30 of the TRIPS agreement allows the member states to provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.⁶⁰

The Bolar exception is one of these exceptions that is consistent with Article 30 in TRIPS agreement.⁶¹

Bolar provision compromises between the innovator and generic pharmaceutical manufacturers.⁶² As it permits any drug manufacturer to seek regulatory approval while the relevant patent still in force.⁶³ However, if a generic or biosimilar manufacturer waits until the last day of the expiration of the term of protection of the patent covering the pharmaceutical product, the owner of expired patent will enjoy additional period of protection, until a generic manufacturer obtains market permission from the regulatory

authority. During this period expired patent may continue to charge a monopolistic price.⁶⁴

While the developing countries were adapting to the new TRIPS agreement's obligations and trying to get benefits from the TRIPS flexibilities to manage the negative effect of these obligations on access to medicine, a wave of bilateral agreements emerged. These free trade agreements (FTAs) often require higher levels of protection that include TRIPS-PLUS standards that go beyond the TRIPS agreement.⁶⁵

"Patent linkage system" is considered one of the TRIPS-PLUS standards that were rapidly spread through free trade agreements. United States FTAs are considered the first to export such system to other countries like Canada (1993), Mexico (2003), Australia (2005) and some Arab countries like Jordan, Oman and Morocco.⁶⁶

3.2. Patent Linkage in Jordan

The Jordan-United States FTA (2001) was the first free trade agreement between the US and an Arab country.⁶⁷ The patent linkage system in this agreement is less aggressive than any linkage system in any other country as it requires notifying the patent owner only.⁶⁸ However, other drug regulatory authorities are prohibited from registering generic versions of the medicine until after the patent has expired.

3.3. Patent Linkage in Morocco

The US signed a free trade agreement with Morocco in June 2004 which entered into force in 2006.⁶⁹ This agreement included the linkage system in Article 15.10.4. Unlike the Jordanian linkage system, the drug regulatory authority should not authorize the marketing approval of a generic

⁵⁶ P Boulet, J Perriens, F Renaud-Théry, Policy G Velasquez, 'Pharmaceuticals and the WTO TRIPS Agreement: Questions and Answers' (2000) UNAIDS/WHO document <<http://apps.who.int/medicinedocs/pdf/whozip18e/whozip18e.pdf>> accessed 11 May 2019.

⁵⁷ Ellen F. M. 't Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' (2003) Economics of AIDS and Access to HIV/AIDS Care <<https://www.who.int/intellectualproperty/topics/ip/tHoen.pdf>> accessed 11 May 2019.

⁵⁸ TRIPS agreement, art 31.

⁵⁹ Article 6 of the TRIPS Agreement provides that nothing in the Agreement will be considered to address the subject of exhaustion of IPRs for purposes of dispute settlement. This article didn't oblige the Members to apply certain type of exhaustion however it gives the freedom to the Members to adopt its own policies and rules on the subject of national and international exhaustion.

⁶⁰ TRIPS agreement, art 30.

⁶¹ Carlos M Corea, 'The Bolar Exception: Legislative Models and Drafting Options' (2016) The South Center <https://www.southcentre.int/wp-content/uploads/2016/03/RP66_The-Bolar-Exception_EN1.pdf> accessed 11 May 2019.

⁶² *ibid*

⁶³ Anshul Mittal, 'Patent Linkage in India: Current Scenario and Need for Deliberation' (2010) Journal for Intellectual Property Rights

<<http://nopr.niscair.res.in/bitstream/123456789/9066/1/IIPR%2015%283%29%20187-196.pdf>> accessed 11 May 2019.

⁶⁴ Carlos M Corea (n 61) 1-2

⁶⁵ Carlos M. Corea, 'Implications of Bilateral Trade Agreements on Access to Medicines' (2006) 84(5) Bulletin of the World Health Organization 399-404 <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627342/>> accessed 13 June 2018.

⁶⁶ Benjamin P Liu, 'Fighting Poison with Poison? The Chinese Experience with Pharmaceutical Patent Linkage' (2012) Journal Marshall Review Intellectual Property Law 624-630. <<https://repository.jmls.edu/cgi/viewcontent.cgi?article=1287&context=rjpl>> accessed 15 May 2018.

⁶⁷ Rohit M, 'All costs, No Benefits: How TRIPS-Plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines' (2007) Oxfam Briefing Paper <<https://oxfamilibrary.openrepository.com/.../bp102-all-costs-no-benefits-trips-210307>> accessed 20 April 2018.

⁶⁸ The agreement between the United States of America and the Hashimite Kingdom of Jordan on the establishment of a free trade area, Article 4.23.b stated that "The patent owner shall be notified of the identity of any third-party requesting marketing approval effective during the term of the patent."

⁶⁹ United States-Morocco Free Trade Agreement, U.S.-Morocco, June 15, 2004, Article 15.10.4

product until the expiration of the patent term of the originator and should also notify the originator of such an application.⁷⁰

3.4. Patent Linkage in Korea

The Korea-US FTA came into force in 2012 after 6 years of negotiations.⁷¹ The patent linkage system of the Pharmaceutical Affairs Act was revised on 15 March 2015 for the enforcement of the Korea-US FTA.⁷² The system comprises: listing of drugs on the Green list (which is equivalent to the Orange Book in the US system); and applicants for generic products must notify patent holders that an application has been submitted to the Ministry of Food and Drug Safety (MFDS) within 30 days from filing this application.⁷³ When the patent holder receives the notification, he can request a stay of sale of generic drugs.⁷⁴ If the request is accepted, sales of generics will be stayed for 9 months.⁷⁵ The first generic company that applies for marketing approval and succeeds in challenging the patent will receive 9 months market exclusivity.⁷⁶

The Korean Pharmaceutical industry relies on generic manufacturers.⁷⁷ Therefore, it was important for the Korean patent linkage system to facilitate much faster and easier entry of the generic drugs to the market. As a result, the patent linkage system was designed to be more tailored to the situation in Korea as it tried to compensate the delay of the generics by giving them an easier system to obtain generic market exclusivity than that in the US system.⁷⁸

4. PATENT LINKAGE IN SOME DEVELOPING COUNTRIES

4.1. India

“Pharmacy of the developing countries”: this is the title that India has gained due to its development of a strong and vibrant generic industry producing safe, effective and affordable generic medicines that have been exported to other developing countries.⁷⁹ The generic pharmaceutical products dominate the Indian market and reached up to 90% of the sales.⁸⁰

The Indian government succeeded to make a balance between patent protection and its own generic drug production. Generally, the Indian patent law intended to control evergreening of pharmaceutical patents under section 3(d)⁸¹ making use of the TRIPS flexibilities and including Bolar provision in section 107 A and the compulsory license in section 84 (1) of the Patents Act 1970.⁸²

India does not apply patent linkage system as it is not a part of drug approval process under the Health ministry or within its patenting process and it cannot be read in the Patents Act 1970.⁸³ This was assured since the courts have rejected attempts by big pharmaceutical companies to create such system. As an example, the court rejected Bayer’s argument against Cipla and confirmed that there is no “patent linkage” regulation in India.⁸⁴

4.2. Brazil

The Brazilian government encourages generic medicines industries in order to provide better access to medicine in affordable prices.⁸⁵

⁷⁰ ibid

⁷¹ Young Sun Cho, HyunsukJin, Yoon and Yang LLC, ‘Overview and Implications of the Drug Patent Approval Linkage System in South Korea Regulations’ (2014) Practical Law <[https://content.next.westlaw.com/Document/1699f6bf2b36911e398db8b09b4f043e0/View/FullText.html?contextData=\(sc.De.fault\)&transitionType=Default&firstPage=true&bhcp=1](https://content.next.westlaw.com/Document/1699f6bf2b36911e398db8b09b4f043e0/View/FullText.html?contextData=(sc.De.fault)&transitionType=Default&firstPage=true&bhcp=1)> accessed 10 June 2018.

⁷² Yoon Suk Shin, ‘Past, present and future of pharmaceutical patents under Korea–US Trade Agreement’, (2016) 5(4) Pharmaceutical Patent Analyst <<https://www.ncbi.nlm.nih.gov/pubmed/27338849>> accessed 10 June 2018.

⁷³ Young Sun Cho, HyunsukJin, Yoon and Yang LLC (n 66).

⁷⁴ Yoon Suk Shin (n 68).

⁷⁵ Kyung-Bok Son, Ruth Lopert, Deborah Gleeson and Tae-Jin Lee (n 45) 11

⁷⁶ Yoon Suk Shin (n 68)

⁷⁷ Ki Young Kim (n 40) 15.

⁷⁸ Ki Young Kim (n 40).

⁷⁹ Sidonie Descheemaeker, ‘India, Pharmacy of the Developing World IP, Trade and the Access To Medicine’ (2013) JuraFalconisJg <<https://www.law.kuleuven.be/apps/jura/public/art/49n3/descheemaeker.pdf>> accessed 15 May 2018.

⁸⁰ Ravinder Gabble and Jillian Clare Kohler, ‘To patent or not to patent? The case of Novartis’ cancer drug Glivec in India’ (2014) 10(3) Gabble and Kohler Globalization and Health <<https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-10-3>> accessed 20 May 2018.

⁸¹ Section 3(d) in the Patents Act, 1970 ‘the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.’

⁸² Aditya Kant, ‘Section 3(d): ‘New’ Indian Perspective’, (2009) 14 Journal of Intellectual Property Rights 385-396 <<https://pdfs.semanticscholar.org/d779/642cc0a5953b4a40c77219458137a7d66a01.pdf>> accessed 1 September 2018.

⁸³ Sandeep K Rathod (n 4).

⁸⁴ ‘Bayer Corporation and Ors V. Cipla, Union of India (UOI) and Ors’ (2009) <<https://indiancaselaws.wordpress.com/2013/12/14/bayer-corporation-and-ors-vs-union-of-india-uo-and-ors/>> accessed 13 June 2018.

⁸⁵ Natalia Arzeno, Rebeca Diaz and Sandra Gonzalez, ‘Brazil’s Generic Drug Manufacturing Success and the policies that permitted it’ (2004) 6.901 Final Project <https://ocw.mit.edu/courses/electrical-engineering-and-computer-science/6-901-inventions-and-patents-fall-2005/projects/brazil_gen_drug.pdf> accessed 12 May 2019.

When the TRIPS agreement came into force in 1994, several challenges emerged which threatened the Brazilian's policy of the access to generic medicine at affordable prices especially the country's policy of universal access to AIDS medicines.⁸⁶ Therefore, the Brazilian Intellectual Property Law (BIPL) included some of the TRIPS flexibilities that are related to public health such as compulsory licenses, parallel imports, Bolar exception, experimental use and health sector participation in analyzing pharmaceutical patent claims.⁸⁷ Moreover, there is no patent linkage system in Brazil according to Law 10,603/2002, art 13 and Industrial Property Law, article 43, VII.⁸⁸

4.3. South Africa

As a member of the WTO, South Africa was obliged to uphold minimum standards of IP protection as mentioned in the TRIPS agreement.⁸⁹ South Africa used depository system for granting patents, which requires only correct formalities and paying the required fees to get a patent.⁹⁰

As a result, South Africa gave the opportunity for the pharmaceutical companies to gain multiple patents on an individual product which may be rejected by other countries in the same region.⁹¹ This granting of excessive number of patents resulted in evergreening of monopoly periods and hindrance of access to medicine in affordable prices.

In a comparative study between the number of granted pharmaceutical patents in Argentina, Brazil, Colombia, India and South Africa, it was found that in South Africa 2442 patents were registered in 2008, however, in Argentina 951 pharmaceutical patents were granted in 2000-2007; in Brazil, 278 patents were granted in 2003-2008; in Colombia 439, in 2004-2008 and in India, 2347, in 2005-2008.⁹² This study revealed that in South Africa patents are simply registered without substantive examination and this explains the large number of patents issued in one single year in comparison to other countries which perform substantive examination.⁹³

The Patent Act and its regulations as well as the judgments of the Court of the Commissioner of Patents (CCP) are biased to the patent owner.⁹⁴

However, in August 2017, the situation began to change and the department of Trade and Industry published a draft of the IP National Policy.⁹⁵ This IP Policy sets out a number of proposals related to the patent law and public health, which encourage substantive search and examination and highlight the flexibilities which are in the Patent Act for example; parallel importation, Bolar provision and compulsory license.⁹⁶ Moreover, the South African Medicines and Related Substances Act avoids patent linkage, and it cannot be read in view of the South African's Patent Act.⁹⁷

5. THE SITUATION IN EGYPT

5.1. Pharmaceutical Industry in Egypt

In the early sixties, the pharmaceutical industry in Egypt passed through several stages. Currently Egypt's domestic pharmaceutical industry has flourished, with the presence of about 120 pharmaceutical companies; most of them are generic companies.⁹⁸

Like many other countries, the pharmaceutical products were excluded from patentability before the TRIPS agreement. In January 1995, the agreement on Trade Related Intellectual Property Rights became into force. From this moment member states including Egypt were obliged to adapt their national IP laws to comply with the TRIPS requirements.

The TRIPS agreement gave all countries transitional period to adapt their laws to the minimum standards of the agreement. And it provided the developing countries additional period for five years from 2000 to 2005, for patent protection of the products in areas of technology that had not been protected before the TRIPS agreement, like pharmaceutical products.⁹⁹

This put an obligation on Egypt to protect pharmaceutical products as well as the process using the patent system by

⁸⁶ Gabriela Costa Chaves, Marcela Fogaça Vieira and Renata Reis, 'Access to Medicine and Intellectual Property in Brazil: Reflections and Strategies of civil society' (2008) *International Journal of Human Rights* 163,167 <http://www.scielo.br/scielo.php?pid=S180664452008000100009&script=sci_arttext&tlng=en> accessed 20 April 2018.

⁸⁷ *ibid* 163-167

⁸⁸ Shivam Vashisth, Govind Singh and Arun Nanda, 'A Comparative Study of Regulatory Trends of Pharmaceuticals in Brazil, Russia, India and China (BRIC) countries' (2012) 9 (3) *Journal of Generic Medicines* <<http://journals.sagepub.com/doi/abs/10.1177/1741134312459187>> accessed 8 June 2018.

⁸⁹ Catherine Tomlinson, John Ashmore, Anele Yawa and Julia Hill, 'Reforming South Africa's procedures for granting patents to improve medicine access' (2015) *South African Medical Journal* <<http://www.scielo.org.za/pdf/samj/v105n9/17.pdf>> accessed 12 May 2019.

⁹⁰ *ibid*

⁹¹ *ibid*

⁹² Carlos M Corea, 'Pharmaceutical Innovation Incremental Patenting and Compulsory Licensing' (2011) *South Center*

<<http://apps.who.int/medicinedocs/documents/s21395en/s21395en.pdf>> accessed 12 May 2019.

⁹³ *ibid*

⁹⁴ Jonathan Berger and Andrew Rens, 'Innovation and Intellectual Property in South Africa: The Case for Reform' (2018) *University of Cape Town Intellectual Property Unit* <<http://ip-unit.org/wp-content/uploads/2018/05/Innovation-IP-in-SA.pdf>> accessed 12 May 2019.

⁹⁵ *ibid*

⁹⁶ *ibid*

⁹⁷ Catherine Tomlinson, Yuan Qiong Hu, Julia Hill and Claire Waterhouse (n 89) 16.

⁹⁸ Public strategy and government relations specialists, 'Egypt's pharmaceutical sector following bold economic reforms: Challenges and opportunities' (2017) *N Gage Consulting* <http://www.ngage-consulting.com/downloads/Pharmaceutical_PDF_Final_Version_K_and_A.pdf> accessed 13 June 2018.

⁹⁹ World Health Organization, 'Intellectual Property Protection: Impact on Public Health' *Access to Medicine* (2005) *WHO Drug Information*

January 2005. This obligation was an alarm to the Egyptian pharmaceutical industry that depends mainly on generic medicines.

Egypt made use of the transitional period and modified its National Legislation to implement the TRIPS agreement and to include TRIPS flexibilities and safeguards to manage the negative effect of the TRIPS obligations on the availability of generic medicines.¹⁰⁰

Bolar provision in the Egyptian IP law no. 82/2002 article 10/5, is one of the TRIPS flexibilities which stated that "The following shall not be considered as infringements of that right when carried out by third parties: 5- Where a third party proceeds, during the protection period of a product, with its manufacturing, assembly, use or sale, with a view to obtain a marketing license, provided that, the marketing starts after the expiry of such a protection period."¹⁰¹

This provision allows the generic producer to obtain the marketing license which usually takes long time even if the patent of the originator product still in force. This gives the opportunity for the generic producer to release its generic product immediately after the expiration of the patent. However, if the generic producer waits until the patent covering a pharmaceutical product has expired, the owner of the expired patent will enjoy extra period of monopoly power, until the generic product obtains market approval from the Ministry of Health (MOH).¹⁰²

Exhaustion is another TRIPS flexibility that limits the rights of the patent holder in controlling the importing, exporting and distribution of the patented product.¹⁰³ This flexibility is included in the Egyptian IP law no. 82/2002 Article 10, which states that the patentee's right in excluding others from importing, exporting, using, selling, or distributing the product "shall be exhausted if the patentee marketed or licensed said product to third party/others."¹⁰⁴

Moreover, article 23 in the Egyptian legislation applies to compulsory licensing under certain circumstances and

criteria.¹⁰⁵ Compulsory licensing is a mechanism used by the governments to allow third parties to produce a product that is protected by a valid patent under certain circumstances.¹⁰⁶

5.2. Patent Linkage in Egypt

Although the Egyptian IP law no.82/2002 does not include a patent linkage provision, some multinational companies are trying to put pressure on the MOH to prevent the registration of the equivalent generic products during the patent term in an attempt to apply the linkage system.¹⁰⁷

There are some court cases between generic companies and innovators that are still pending. We are waiting for adjudication that ensures that there is no patent linkage system in Egypt and it cannot be read in view of the present law.

5.3. Problems with Patent Linkage in Egypt

Firstly, the role of the patent offices is to register and issue patents¹⁰⁸, while the regulatory authorities are responsible for ensuring safety and efficacy of the pharmaceutical products.¹⁰⁹ Applying the patent linkage system, will make the MOH responsible for detecting patent infringement. This will be problematic, as the MOH lacks the resources and the expertise to assess the validity of the patents whether it is infringed or not.¹¹⁰

Secondly, patent rights are private rights; they should be enforced by the right holders not by the government¹¹¹ but the patent linkage system will make the MOH responsible for detecting the infringement.¹¹²

Thirdly, the linkage system will undermine Bolar provision as it will inhibit the registration of generic products before the expiration of the patent of the equivalent originator.¹¹³ As a result, this will delay the entry of the generic products for 2 or 3 years after the expiration of the equivalent patent and will extend the patent protection term.

<<https://www.who.int/medicines/areas/policy/AccessstoMedicineIPP.pdf?ua=1>> accessed 12 May 2019.

¹⁰⁰ Mahmoud Diaa, 'Egypt Pharmaceutical Country Profile' (2011) Ministry of Health of Egypt in collaboration with World Health Organization

<https://www.who.int/medicines/areas/coordination/Egypt_PS_CPNarrativeQuestionnaire_27112011.pdf> accessed 12 May 2019.

¹⁰¹ Egyptian IP law no. 82/2002, art 10/5.

¹⁰² Carlos M Corea (n 60) 1-2.

¹⁰³ Sahar Aziz, 'Linking Intellectual Property Rights in Developing Countries with Research and Development, Technology Transfer, and Foreign Direct Investment Policy: A Case Study of Egypt's Pharmaceutical Industry' (2003) ILSA Journal of International and Comparative Law

<<https://scholarship.law.tamu.edu/cgi/viewcontent.cgi?article=1121&context=facscholar>> accessed 12 May 2019.

¹⁰⁴ Egyptian IP Law no. 82/2002, art 10.

¹⁰⁵ Egyptian IP Law no. 82/2002, art 10

¹⁰⁶ Anshul M, 'Patent linkage in India: Current scenario and need for deliberation' (2010) Journal of Intellectual Property Rights 187-196

<<http://nopr.niscair.res.in/bitstream/123456789/9066/1/JIPR%2015%283%29%20187-196.pdf>> accessed 1 April 2018.

¹⁰⁷ 'Urgent appeal to the Prof. Dr. Prime Minister, Prof. Dr. Minister of Health and Population and Prof. Dr. Minister of Investment' *News Today* (Egypt, 21 December 2013) 2.

¹⁰⁸ Academy of Scientific Research and Technology, 'Egyptian Patent Office' (2017) <<http://www.asrt.sci.eg/index.php/asrt-departments/egpo>> accessed 12 May 2019.

¹⁰⁹ Erica Lessem, 'An Activist's Guide to Regulatory Issues: Ensuring Fair Evaluation of and Access to Tuberculosis Treatment' (2015) Treatment Action Group <<http://www.treatmentactiongroup.org/sites/default/files/201512/TB%20Regulatory%20Guide.pdf>>

¹¹⁰ World Health Organization, 'Briefing Note Access to Medicines' (2006) <http://www.searo.who.int/entity/intellectual_property/data-exclusively-and-others-measures-briefing-note-on-access-to-medicines-who-2006.pdf> access 11 May 2018.

¹¹¹ *ibid*

¹¹² *ibid*

¹¹³ Anshul M (n 63) 191.

Fourthly, if a generic medicine is manufactured under a compulsory license, it will not be registered before the expiration of the patent.¹¹⁴

6. CONCLUSION

The patent linkage system began in US then spread to other countries through free trade agreements. It varies from country to country. Linkage system strengthens the rights of the patent owners and the abuse of these rights has negative implications on access to generic medicines at affordable prices especially in developing countries.

Egypt as the model example of developing countries in this paper (although it is not a member of any FTAs and does not have a patent linkage provision in the present IP law), is subjected to pressure from the multinational companies to prevent generic medicines from entering the market during the patent term.

By analyzing the current Egyptian IP legislation, it was found that it includes many of the TRIPS flexibilities like Bolar provision and the compulsory licensing which balance the situation between the rights of the patent holder and the rights of the public to access affordable drugs. Therefore, the patent linkage system cannot be read in view of the current law.

Egypt can learn from the Indian experience in which the court final decisions assured that India has no patent linkage system. There are some court cases which are still pending and if the Egyptian courts don't manage to appropriately react to the pending cases in which the originator's companies want to prevent the generics from entering the market, Bolar provision and the compulsory licensing will be undermined, and the generic drugs will be delayed for at least 2 years after the expiration of the equivalent patent. Ultimately, the patients will be the victims of this system as they will not be able to get the more affordable generic medicines until much later.

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¹¹⁴ Anshul M (n 63).

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OPTIONS FOR THE PROCUREMENT OF PATENTED ESSENTIAL MEDICINES BY SADC MEMBER STATES AFTER TRIPS ARTICLE 31BIS¹

Lonias Ndlovu*

ABSTRACT

This paper exposes and explores the possible essential medicines procurement options Southern African Development Community (SADC) Member states now have after the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement was amended through Article 31bis. After an expository account of the events that led to the amendment, the paper looks at the options presented by Article 31bis against the membership matrix and other contextual factors obtaining in the SADC as a regional trade agreement (RTA) and concludes that it is now possible for SADC to rely on Article 31bis in order to ameliorate the precarious access to essential medicines situation in the region. The options presented here may inspire other similarly placed RTAs in Africa and the rest of the developing world to take advantage of Article 31bis.

Keywords: Essential medicines, compulsory licenses, Procurement, SADC, TRIPS Article 31bis

1. INTRODUCTION

The Southern African Development Community (SADC) - constituted by Angola, Botswana, the Democratic Republic of Congo (DRC), Lesotho, Swaziland, Namibia, South Africa, Malawi, Mozambique, Seychelles,

Madagascar, Mauritius, Tanzania, The Union of Comoros,² Zambia and Zimbabwe - faces a massive disease burden. The most prevalent diseases are tuberculosis, HIV/AIDS, malaria and most recently cancer and other lifestyle diseases such as heart disease. In South Africa, apart from HIV/AIDS and tuberculosis, other diseases to watch out for are stroke, ischaemic heart disease, hypertensive heart disease, diabetes and renal disease.³ Furthermore, the Ebola epidemic that has ravaged parts of West Africa in the past and the DRC recently, also poses a huge threat to the region.⁴ The HIV disease burden is not uniformly spread across the region because some countries like South Africa and Botswana carry the highest HIV/AIDS prevalence burden while Zimbabwe, Mozambique and Zambia still have an inexplicable malaria prevalence which is not easy to justify in a modern society.⁵ SADC members are also in various stages of economic development and about 50% of the membership consists of Least Developed Countries (LDCs).⁶

The disease burden is made dire by the lack of access to essential medicines, including generic drugs, in most SADC Member states. This is also compounded by poverty and weak political and other institutions in the region

* **Lonias Ndlovu** (Zimbabwe in South Africa) is currently an Associate Professor and dean of the School of Law, University of Venda, Thohoyandou, in South Africa. He has previously worked at other South African universities, namely, Fort Hare, Zululand and North-West, as a lecturer, senior lecturer and associate professor respectively. He obtained the degrees LLB (2003) and LLM (2005) from the University of Fort Hare and LLD (2014) from the University of South Africa. His doctoral thesis examined the extent to which selected Southern African Development Community (SADC) Member states have incorporated TRIPS flexibilities into their patent laws in order to improve citizens' access to essential medicines. His teaching and research interests lie in intellectual property law generally, intellectual property and public health, human rights and access to medicines, commercial law and international trade law. He is an advocate of the High Court of South Africa and runs a limited commercial law practice and consults for government, international organizations and NGOs on IP and public health.

¹ This is a revised version of a paper that was presented at the WIPO/WTO Regional Colloquium for Teachers of Intellectual Property held at the main Campus of the University of South Africa from 9 to 12 April 2018. However, the views expressed herein are those of the author and cannot be attributed to the organisers of the colloquium.

² Southern African Development Community, *The Union of Comoros becomes the 16th SADC Member State* (SADC

Secretariat) at <<https://www.sadc.int/news-events/news/union-comoros-becomes-16th-sadc-member-state/>> accessed 27 June 2018.

³ V Pillay-van Wyk, R. E Dorrington and D Bradshaw, 'Rapidly changing mortality profiles in South Africa in its nine provinces' (2017) 107 South African medical journal = Suid-Afrikaanse tydskrif vir geneeskunde 168.

⁴ Gloria C. Nwafor and Anthony O. Nwafor, 'Right to Healthcare of Victims of Ebola Virus Disease: The West African Nations' Experience' (2016) 24 African J Intl & Comparative Law African Journal of International and Comparative Law 389

⁵ SADC *Harmonized Surveillance Framework for HIV and AIDS, Tuberculosis and Malaria in the SADC Region* (2009) 6–20 <https://www.sadc.int/files/9214/1171/8930/Harmonised_Surveillance_Framework_forHIV_and_AIDS_Tuberculosis_and_Malaria_in_the_SADC_Region.pdf> accessed 19 May 2019.

⁶ In the context protecting pharmaceutical patents, WTO Members which are LDCs can choose whether or not to protect pharmaceutical patents and clinical trial data until January 2033 (see WTO "WTO members agree to extend drug patent exemption for poorest members", <https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm> accessed 19 May 2019. SADC LDC members are Angola, Malawi, Madagascar, Mozambique, Lesotho, Tanzania, DRC, The Comoros and Zambia.

which are unable to contain wasteful government expenditure and hold the policy makers to account. Essential medicines are those that are necessary to satisfy the priority health care needs of the population.⁷ Their selection is based on “public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness”.⁸ With specific reference to access to medicines, the most important instruments in the SADC context of access to medicines are the SADC Protocol on Health (hereafter referred to as the Health Protocol),⁹ complemented by the Implementation Plan for the SADC Protocol on Health,¹⁰ SADC Pharmaceutical Business Plan¹¹ and the Draft SADC Strategy for Pooled Procurement of Essential Medicines and Commodities.¹² The above instruments are identified as crucial in the enhancement of regional integration in the context of health and have been developed to underpin the implication of the SADC health programme.¹³ The health programme has been developed taking into account global and regional health declarations and targets.¹⁴

This paper focuses on the pharmaceutical procurement options that are now available for the SADC region to exploit post the adoption of Article 31bis by WTO Members in 2017. In order to give a complete contextualised account of the options, the paper focuses on the historical evolution of Article 31bis, its tenets in the context of access to medicines, the SADC regional integration matrix and how it relates to the options and

an evaluation of the options before optimistically concluding that Article 31bis is now the potent arsenal in the SADC access to medicines armoury and must be used without fear of retaliation.

Before talking about the modalities of procuring essential medicines for SADC under Article 31bis, it is essential to give a brief expository account of the events that triggered and led to the adoption of Article 31bis.

2. LEGAL HISTORICAL EVOLUTION OF TRIPS ARTICLE 31bis

The evolution and adoption of Article 31bis is inseparable from the Doha Declaration on TRIPS and Public Health,¹⁵ adopted by the 2001 WTO Ministerial Conference on the 14 November of the same year. Through the Doha Declaration, WTO Members affirmed that there is nothing in the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) which prevents a WTO Member from taking legislative and other measures to protect public health in order to improve citizens’ ability to access affordable medicines.

The Declaration was followed up in August 2003 with further refinement and amendment enabling Members to use compulsory licenses to supply other countries with insufficient or no pharmaceutical manufacturing capacity rather than for the predominant supply of the domestic market.¹⁶ This problem was identified in Paragraph six¹⁷ of the Doha Declaration and a solution thereto was

⁷ WHO Expert Committee on the Selection Use of Essential Medicines Meeting, 'The selection and use of essential medicines' (2003).

⁸ PharmacoEconomics & Outcomes, 'WHO releases new edition of Model List of Essential Medicines' (2015) 728 PharmacoEcon Outcomes News PharmacoEconomics & Outcomes News 8.

⁹ SADC Protocol on Health (1999) signed in Maputo, Mozambique on 18 August 1999 and came into force on 14 August 2004.

¹⁰ SADC Protocol on Health (1999) signed in Maputo, Mozambique on 18 August 1999 and came into force on 14 August 2004. The Implementation Plan provides an overall framework for effecting the provisions of the SADC Protocol on Health <http://www.sadc.int/index.php?cID=1&blD=1283&arHandle=Sidebar&ccm_token=1383736029:41bfb778708ee17dc30b95e83826bc93&btask=passthru&method=signmeup> accessed 6 April 2018.

¹¹ SADC Pharmaceutical Business Plan 2007–2013, published by the SADC Secretariat on 27 June 2007.

¹² Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013–2017, published by the SADC Secretariat in September 2012.

¹³ See executive summary of the SADC Pharmaceutical Business Plan (par 2) 3.

¹⁴ *Ibid* (par 2) 3.

¹⁵ Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), available at <https://www.wto.org/english/thewto_e/minist_e/min01_e/mi_ndecl_trips_e.pdf> accessed 26 June 2018.

¹⁶ Compulsory licenses fall within what the TRIPS characterises as “other use without the authorisation of the patent holder”. Article 31 (f) of TRIPS prescribes that “any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use”.

¹⁷ This is now famously referred to as “the Paragraph six System”. See Muhammad Z. Abbas and Shamreeza Riaz, 'WTO “Paragraph 6” system for affordable access to medicines: Relief or regulatory ritualism?' (2018) 21 JWIP 32 for a detailed discussion and critique of the system.

proposed through a waiver introduced by the General Council Decision of 2003.¹⁸ In order to actualise the spirit of the August 2003 Decision, an amendment to the TRIPS Agreement was proposed in 2005 and opened for ratification by WTO Members.¹⁹ It is important to point out that the proposed amendment explicitly stated that “reservations may not be entered” in respect of any of its provisions without the consent of the other WTO Members.²⁰ Once fully ratified, the amendment would introduce Article 31bis of the TRIPS Agreement, to override the pre-existing proviso in the TRIPS Agreement that compulsory licenses may only be granted for the predominant supply of the domestic market.²¹

Article 31bis became part of the TRIPS Agreement after acceptance of the Protocol amending the TRIPS Agreement by two thirds of the WTO’s Members.²² The amendment took effect on 23 January 2017 and replaced the 2003 waiver for Members who have accepted the amendment.²³ For those WTO Members who are yet to accept the amendment, the 2003 Decision (waiver) still applies.

In the SADC, Botswana, Congo, Lesotho, Madagascar, Malawi, Mauritius, Seychelles, South Africa, Tanzania and Zambia have accepted the Protocol Amending the TRIPS Agreement (now Article 31bis). This is good news considering that if ten out of sixteen SADC Member states have signed, this translates to an acceptance figure of more than 60% of the membership. However, mere acceptance is not enough, there is need to domesticate the provisions of Article 31bis into the IP legislations of

individual countries in order to take full advantage of the Article. Unless the SADC Member seeking to take advantage of Article 31bis is an LDC, it will be practically impossible to issue a compulsory license to manufacture and export generic drugs in terms of the Article in the absence of domestication. However, such a Member may use the waiver (not Article 31bis) as an importer from another WTO Member that has domesticated Article 31bis. The period for the acceptance of Article 31bis, which period was extended for the fifth time to 21 December 2017,²⁴ has now been extended for the sixth time to 31 December 2019,²⁵ and it is hoped that other SADC Members would have accepted it by then.

To fully contextualise this paper, it is important to give a brief exposition of the pharmaceutical procurement options presented by Article 31bis, before looking at how these options are likely to practically apply in the SADC context.

3. OUTLINE OF THE OPTIONS PRESENTED BY ARTICLE 31bis

The salient aspects of Article 31bis, which are relevant to this paper may be summed up as follows:²⁶

- Subject to the terms outlined in paragraph 2 of the Annex to the TRIPS Agreement, an exporting Member will be exempt from complying with the provisions of TRIPS Article 31(f) [relating to issuing compulsory licenses for the predominant supply of the domestic market] to the extent necessary to produce

¹⁸ The waivers relate to Members ensuring that products produced under compulsory licenses must be for the predominant supply of the domestic market and the obligation imposed by Article 31(h) of TRIPS on importing Members to pay adequate remuneration to the right holder if a compulsory license is granted.

¹⁹ See WTO General Council WT/L/641 8 December 2005 decision entitled “Amendment of the TRIPS Agreement” <https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm> accessed 19 May 2019.

²⁰ *Ibid* para 3 of the Protocol amending the TRIPS Agreement.

²¹ Per Article 31(f) of the TRIPS Agreement.

²² See WTO “Intellectual Property: Trips and Public Health Amendment of the TRIPS Agreement” <https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 19 May 2019.

²³ *Ibid* para 3.

²⁴ See WTO General Council Decision WT/L/965 of 2 December 2015

<https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 19 May 2019.

²⁵ See <<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/78.pdf>> accessed on 16 June 2018.

²⁶ For more details, see the ANNEX TO THE PROTOCOL AMENDING THE TRIPS AGREEMENT read together with the ANNEX TO THE TRIPS AGREEMENT and the APPENDIX TO THE ANNEX TO THE TRIPS AGREEMENT all available at <https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm> accessed 26 July 2018.

pharmaceutical products and export them to eligible importing Members.

- Where an exporting member grants a compulsory license under the system provided for in Article 31bis and the relevant annexes, adequate remuneration, as specifically mandated by Article 31(h), shall be paid in that member taking into account the economic value of the IP to the importing member. Where a compulsory license is granted for the same products in the eligible importing member, the obligation to pay adequate remuneration shall fall away if such payment has been made in the exporting member.
- In order to harness economies of scale and enhance the purchasing power and facilitate the local production of pharmaceutical products, where a developing or least developed WTO Member is party to an RTA as categorised in Article XXIV of the GATT 1994, the obligation imposed by Article 31(f) shall not apply to the Member to the extent necessary for the exportation of a pharmaceutical product produced or imported under a compulsory licence to fellow developing and least developed Members that share the same health problem in the RTA, provided that at least 50% of Members in the RTA qualify as least developed countries.
- Measures taken in conformity with the provisions of Article 31bis and the accompanying annexes will not be challenged in terms of the dispute settlement procedure provided for in Article XXIII of the GATT 1994, as amounting to either a non-violation complaint or the existence of any other situation.²⁷

- It is also important to highlight that Article 31bis and the attendant annexes “are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement²⁸ other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health..., and to their interpretation”.²⁹

It is additionally important to emphasise that Article 31bis must be read together with the Annex to the TRIPS Agreement and the Appendix to the Annex to the TRIPS Agreement. The Annex and the Appendix elaborate and explicate Article 31bis. The Annex gives definitions of important terms such as ‘pharmaceutical product’, ‘eligible importing member’ and ‘exporting member’ in addition to outlining the terms for bypassing Article 31(f) of TRIPS in the appropriate context. Very importantly, the Annex lays down the obligations of the importing and exporting members including safeguards against abuse of the system,³⁰ such as the diversion of pharmaceutical products to other markets.

The Appendix deals with how pharmaceutical manufacturing capacity will be assessed and the default position is that all LDCs are deemed to have insufficient or no manufacturing capacity in the pharmaceutical sector.

An expository account of the salient aspects of Article 31bis was necessary in order show that the system will easily be applicable in the SADC RTA context, which is briefly outlined below.

²⁷ Sub paras (a) –(c) of Article XXIII (1) of the GATT 1994 deal with the “nullification or impairment” of benefits accruing to a WTO Member as a possible trigger of the dispute settlement mechanism of the WTO.

²⁸ For a full list of these flexibilities, see Lonias Ndlovu, ‘Domesticating the World Trade Organisation’s Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities to

access essential medicines: any lessons for the SADC from Botswana?’ (2017) 50 Comparative and International Law Journal of Southern Africa 347.

²⁹ Per para 5 of Article 31bis.

³⁰ For a full discussion of the safeguards, see Antony Taubman, Hannu Wager and Jayashree Watal, *A handbook on the WTO TRIPS agreement* (Cambridge University Press 2012).

4. THE CONTEXT OF SADC AS A REGIONAL TRADE AGREEMENT

Regional Economic Communities (RECs) like SADC have been helping member states to implement TRIPS flexibilities.³¹ The SADC membership is composed of at least seven developing and nine least developed Members. Article 31bis was passed with developing and least developed WTO Members in mind, hence it primarily must serve the health interests of countries in this category of economic and other development. The fact that more than 50% of SADC Members are LDCs implies that the region can take advantage of paragraph 3 of Article 31bis and issue compulsory licenses for the export of required drugs within the region.

Additionally, SADC Members share the same or similar disease burden, with HIV/AIDS, tuberculosis and malaria being the most common diseases across the region. Ebola, which recently broke out in the DRC, a SADC Member, can be highly contagious and easily spread and become a common health problem for the region. SADC Members may therefore use the existence of similar health problems to take advantage of the procurement options presented by Article 31bis.

Finally, although there is evidence of modest pharmaceutical manufacturing capacity in the region in countries such as Botswana, Malawi, Mozambique and Zimbabwe,³² with South Africa having significant capacity, on average, the region has insufficient or no pharmaceutical manufacturing capacity. This presents a window of opportunity for many countries in the region to use Article 31bis as eligible importing members. The presence of some pharmaceutical manufacturing capacity also presents an opportunity for generic drugs to be produced within the region and exported to other areas of need in the region.

The SADC region is therefore a proper candidate for the deployment of Article 31bis because of the nature of the membership configuration, the existence of some pharmaceutical manufacturing capacity and common health problems that make the disease burden intra-regional.

5. AVAILABLE PROCUREMENT OPTIONS IN THE SADC CONTEXT

The options available for SADC Member states to procure essential medicines may be outlined taking into account the following variables. A SADC Member may want to procure a drug to deal with a national emergency, to boost drug stocks and be self-sufficient, to produce a drug locally if pharmaceutical manufacturing capacity exists or to produce or import a drug for the benefit of other neighbouring countries.

Whether or not a generic version of a specified drug will be imported or produced locally will depend on three important factors. Firstly, depending on the patent status of the medicine in the SADC Member in need of it, it may be possible to import the drug from within or outside the region. Secondly, the status of a SADC Member as a developing or least-developed country will determine the utility of Article 31bis. Thirdly and finally, the absence or presence of pharmaceutical manufacturing capacity in a SADC Member will determine the extent to which it can utilise the flexibility introduced by Article 31bis.

Depending on the three factors mentioned immediately above, various options are available for SADC Members to procure essential medicines and ensure access thereto.

³¹ Caroline B. Ncube, 'Three Centuries and Counting: The Emergence and Development of Intellectual Property Law in Africa' in Rochelle Dreyfuss, Justine Pila and Caroline B. Ncube (eds), *The Oxford Handbook of Intellectual Property Law* (The Oxford Handbook of Intellectual Property Law, Oxford University Press 2017) p.10.

³² Zimbabwe and Mozambique have demonstrated the existence of this capacity in their local contexts as illustrated by Giuliano Russo and Geoffrey Banda, 'Re-Thinking Pharmaceutical Production in Africa; Insights from the Analysis of the Local Manufacturing Dynamics in Mozambique and Zimbabwe' (2015) 50 *St Comp Int Dev Studies in Comparative International Development* 258.

5.1. Option 1: The Generic Version of the Needed Drug can be Produced within SADC

In accordance with the conventional sanctity of intellectual property rights (IPRs), if a SADC non-LDC Member with pharmaceutical manufacturing capacity is desirous of producing a generic version of a needed drug in its territory and such a drug is protected by a national or regional patent, then such a SADC Member may issue a compulsory licence in terms of its IP laws and regulations, and produce the essential medicine locally. A good example of such a SADC Member will be South Africa, which does have pharmaceutical manufacturing capacity. This type of compulsory license will be the one contemplated by Article 31(f) of TRIPS (predominant supply of the domestic market) accompanied by the payment of adequate remuneration to the patent holder as mandated by Article 31(h) of TRIPS. In this scenario, there is no need to invoke Article 31bis, for it will not be applicable.

Further, as a Member of SADC in which nine out of sixteen Members are LDCs (about 56%), the SADC Member described above may also authorise the manufacture of the needed generic drug to address the health needs of fellow Members sharing the health problem in question. This regional waiver is permitted under paragraph 3 of Article 31bis for countries belonging to RTAs in which more than 50% of the Members are LDCs. The SADC as a regional grouping does meet this prescribed threshold. The generic drug produced under compulsory license by the SADC Member with pharmaceutical manufacturing capacity may then be exported to other Members within the region without restriction. However, in order to export to other SADC Members in terms of the cited paragraph of Article 31bis, the SADC Member must comply with its own IP laws, and where applicable, domesticate Article 31bis so that compulsory licenses go beyond the predominant supply of the domestic market.

Still focusing on this option, SADC LDCs or those other non-LDC Members in which the drug in question is not patent-protected can simply import it from the Member with manufacturing capacity through their usual import

procedures. Where a patent exists for the drug in a SADC LDC or any other Member, the drug may only be imported after the importer has issued a compulsory license. However, the importing member will be excused from the obligation to pay adequate remuneration in terms of TRIPS Article 31(h) if the patent holder has already been paid in the SADC Member with manufacturing capacity.

5.2. Option 2: The Generic version of the Needed Drug cannot be Produced within SADC

Assuming that no pharmaceutical capacity exists within the region to produce the generic drug, SADC Members may import the drug from wherever in the world it is readily available. Since patents are territorial or regional, it can happen that medicines patented elsewhere may be available in other countries as generics. A good example of such a source for generics could be India, which did not grant patents on pharmaceuticals until 2005.

Once again, under this option, the first sub-option will be for SADC Members in which the drug is not protected by any national or regional patent to import the drug using normal import procedures. LDCs may simply indicate that they want to take advantage of the extended transition periods (see option 4 below) and import the drug without restriction. In this case, the LDCs will have to formally indicate their intention to take advantage of the transition period and ensure that safeguards are in place to prevent the diversion of the drug to undeserving non-LDC Members. For those other non-LDC Members, if national or regional patents are an impediment, compulsory licences will have to be issued nationally.

5.3. Option 3: Where no generic version exists

It can happen that a SADC Member is faced with a health problem which can be remedied through a drug for which generic versions do not exist. The first option will be to import the drug from the supplier at exorbitant prices. This option will not be viable for developing and least-developed SADC Members.

However, in terms of the first paragraph of Article 31bis, it is now possible to issue a compulsory license for the

benefit of a third country, without being constrained by the provisions of Article 31(f) of TRIPS.³³ This however is subject to the conditions imposed by Article 31(h) of TRIPS.

To make use of this option, SADC Members (both developing and LDC) may notify the rest of the WTO membership about their dire need for a specific drug which:

- Is too expensive or not available in the region;
- cannot be manufactured in the region because there is insufficient or no pharmaceutical manufacturing capacity in the regional pharmaceutical sector; and
- cannot be replaced by imported quality generics because they do not exist.

In this particular context, SADC Members may rely on other countries outside the region to supply them with cheaper generic versions of the drug. In terms of Article 31bis, the SADC Members may ask other WTO Members (probably developed ones) to issue compulsory licenses for the manufacture and exportation of the drug to the SADC region. The exporting country will have to notify the rest of the WTO membership of its intention to use the system for the benefit of SADC countries as an exporter, while SADC countries will become eligible importing Members. Realistically speaking, the exporter must be enabled by its own domestic legislation to use the procedure outlined herein,³⁴ and the eligible importing SADC Member must also adhere to its own laws relating to the use of compulsory licences,³⁵ and if the drug is

patent-protected in the SADC Member, then a compulsory license must be issued.

Good examples of candidate drugs that may be imported under this procurement option, at least in the South African context could be Trastuzumab for cancer, Linezolid for tuberculosis and Entecavir for hepatitis B. In the context of Ebola, the experimental vaccine rVSV-ZEBOV³⁶ may be imported by the affected SADC Member, such as the DRC, using this procurement option. The importing SADC Member will be expected to take reasonable steps within its means to prevent re-exportation of the imported drug.

5.4. Option 4: The Case of SADC LDCs

This last procurement option may read as repetitive, if not superfluous here in light of the three other options discussed above. However, when one considers the fact that legally, LDCs may avoid applying and enforcing IP rights on pharmaceutical products until 2033,³⁷ then the unique case of LDCs merits a separate discussion. The other important consideration is that nine out of sixteen SADC Members (56%) are LDCs, hence this option will only be available for invocation by LDCs, with likely positive access to medicines spinoffs for the rest of the SADC membership as illustrated below.

The table below, adapted from Olasupo Oyodeji Owoeye's initial analysis,³⁸ outlines TRIPS measures which have been adopted in favour of least developed countries to date.

³³ A good example of this approach is what happened in Rwanda in 2007, as outlined by Béatrice Stirner and Mélanie Bourassa Forcier, 'Twelve years after Canada's access to medicines regime : should South Africa follow the path?' (2015) 132 South African Law Journal 313.

³⁴ For example the Indian Patents Act, 1970 (incorporating all amendments till 23-06-2017) provides for compulsory licences for manufacture and export of patented pharmaceutical products to any country having insufficient or no pharmaceutical manufacturing capacity in the pharmaceutical sector to address public health problems, provided that a compulsory license has been granted by the importing country or through notification, such a country has allowed the importation of the patented pharmaceutical products from India.

³⁵ Botswana for example, has domesticated Article 31bis in section 32 of the Industrial Property Act No. 8 of 2010.

³⁶ According to the WHO website <<http://www.who.int/news-room/detail/23-12-2016-final-trial-results-confirm-ebola-vaccine-provides-high-protection-against-disease>> accessed 28 June 2018; rVSV-ZEBOV was developed by the Public Health Agency of Canada. The vaccine was licensed to NewLink Genetics, who in turn licensed it to Merck & Co.

³⁷ Catherine Saez, 'LDC Pharma IP Waiver Until 2033 Approved By WTO TRIPS Council' (2015) Intellectual Property Watch 2015.

³⁸ Olasupo Ayodeji Owoeye, 'Compulsory patent licensing and local drug manufacturing capacity in Africa' (2014) 92 *bulletin of the World Health Organization* 214.

Measure	Purpose
1. LDCs obligations under Art. 70.9 Of TRIPS with respect to pharmaceutical products. ³⁹	This 8 July 2002 WTO General Council decision exempts WTO LDC Members from the obligation to grant and enforce patents on pharmaceutical products or to protect test data until 1 January 2016.
2. Extension of the transitional period under Art. 66.1 of TRIPS for LDCs.	This 2013 decision extends the time for LDCs to implement minimum standards for IP required by TRIPS to 1 July 2021 (with exceptions of Arts. 3, 4, & 5 related to national treatment and most-favoured nation treatment), or until such a date on which they cease to be LDCs, whichever date occurs first.
3. Further extension of transitional period under Art. 66.1 of TRIPS for LDCs.	This 2015 Council for TRIPS decision extends the period during which key provisions of TRIPS will not apply to pharmaceutical products in LDCs until January 2033. ⁴⁰

The first measure, which presented an opportunity for LDCs to deal with pharmaceutical products in the context of their national interests, has now been overtaken by events and deserves no commentary beyond this.

The second and third measures, which are still current, have the same implications for the SADC LDC Members. Because both decisions concern the entire TRIPS Agreement, LDCs can choose whether or not to protect pharmaceutical patents and clinical trial data before 2033. The decision also leaves an open option for LDCs to negotiate for further extensions beyond 2033.

Practically speaking, the implication is that a SADC LDC may freely produce generic versions of any patented drugs, both for local needs and export within and outside the region, without any IP restrictions, as if no patent exists for the drug concerned. Imports of any generic medicine into the SADC LDC will also be possible without any IP restriction. The last two measures therefore present an opportunity for SADC Members to take advantage of Article 31bis and produce essential medicines (as generics) for local use or export within the region. This will be done through the instrumentality of LDCs, which can invest in pharmaceutical manufacturing capacity between now and 2033 if not beyond, and replicate India's pharmaceutical manufacturing capacity success story.⁴¹

A few valedictory practical points must be made with specific regard to the implementation of the LDC transition periods highlighted above.

Unless the SADC Member concerned has a monist legal system,⁴² where international law automatically applies domestically as any other law, there will be a need to formally inform other WTO Members that it intends to make use of the transition periods. This can be done through appropriate formal decisions such as a decree, legislative amendment, a rider or any other intervention citing the specific WTO decision and indicating that the

³⁹ WTO (2002) 'Least-Developed Country Members — Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products', GENERAL COUNCIL WT/L/478 12 July 2002, at <https://www.wto.org/english/tratop_e/trips_e/art70_9_e.htm> accessed 29 June 2018.

⁴⁰ WTO (2015) 'WTO members agree to extend drug patent exemption for poorest members' at <https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm> accessed 29 June 2018.

⁴¹ It will be recalled that India did not provide for pharmaceutical patents until 2005, when it started making its IP laws TRIPS-compliant.

⁴² On the subject of monism and other approaches to the application of international law in municipal law, see generally Gerrit Ferreira and Anél Ferreira-Snyman, 'The Incorporation of Public International Law into Municipal Law and Regional Law against the Background of the Dichotomy between Monism and Dualism' (2014) 17 Potchefstroom Electronic Law Journal 1470.

exemption to pharmaceutical patents and test data will last until 2033 or as long as the country remains an LDC, unless there is a WTO decision to the contrary. Considering that some SADC countries are Members of the African Regional Intellectual Property Organisation (ARIPO), the legislative amendment must refer to the relevant provisions of the Harare Protocol.⁴³

6. CONCLUDING REMARKS

It is heartening to report that a number of SADC Members now recognise the importance of article 31bis, and have accepted the protocol amending the TRIPS Agreement, while others, such as Botswana, have gone the extra mile and passed legislation that domesticates Article 31bis.

In a nutshell, this paper showed that Article 31bis is a welcome intervention because for SADC Members, it is now possible to issue compulsory licenses to supply drugs beyond the domestic market; where a SADC Member imports a drug using Article 31bis or the waiver, adequate remuneration may be paid by the exporting country; to harness economies of scale in the SADC pharmaceutical context in which more than 50% of the membership is composed of LDCs, it is now possible to issue a regional compulsory license; measures taken pursuant to Article 31bis or the waiver will not be subject to the WTO dispute settlement system provided for in Article XXIII; SADC Members still reserve their right to invoke other TRIPS flexibilities to access essential medicines and Article 31bis procedures and processes may be used taking into account the terms, conditions and safeguards provided for in the Annex and Appendices to the Article.

This paper further established that it is possible for SADC Members to rely on Article 31bis in the context of the four procurement options, namely, where a generic drug may be produced within the region; where it is not possible to produce the generic drug within the region; where no generic drug exists and where LDCs can take advantage of

the unique pharmaceutical patent and test data exemptions extended to them until 2033 and possibly beyond.

The options outlined in this paper are practical and viable because they suit the SADC RTA situation, the common disease burden and the modest pharmaceutical manufacturing capacity. The region must consider investing in pharmaceutical manufacturing capacity to take full advantage of Article 31bis. This can then dovetail into the SADC Strategy on Pooled Procurement, making bulk procurement of pharmaceutical products a reality.

If SADC can seriously consider the options presented here, other African RTAs may learn from it and consider replicating the options in their contexts as well. In the Common Market for East and Southern Africa (COMESA), the East African Community (EAC) and the Economic Community of West African States (ECOWAS), it is possible to rely on paragraph 3 of Article 31bis due to the LDC compositions of the RTAs. 70% of COMESA members are LDCs, while for the EAC and ECOWAS, the figure is 80%. The Southern African Customs Union (SACU), with 40% LDC membership, will not qualify.

Article 31bis therefore, is what the doctor ordered for SADC, taking into account the procurement options presented above.

⁴³ In terms of section 3(6) of the Harare Protocol, each ARIPO Member state can write to ARIPO and inform it that a patent shall have no effect in its territory for a specific reason, such as the invocation of the relevant TRIPS transitional period for LDCs. In

this case, the applicable provision will be section 3 subsection 6 paragraph (a) subparagraph (ii), on the basis that, 'because of the nature of the invention, a patent cannot be registered or granted or has no effect under the national law of that state'.

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TRIPS FLEXIBILITIES AND THE EVOLUTION OF THE MOZAMBICAN INDUSTRIAL PROPERTY SYSTEM: PROSPECTS AND CHALLENGES FOR IMPLEMENTATION

Télio Murrure¹

ABSTRACT

This article aims to analyse the evolution of the Mozambican industrial property system. The research probes the level of adoption and implementation of the flexibilities provided in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in the Mozambican industrial property system, bearing in mind the fact that Mozambique is a Least Developed Country (LDC) that joined the World Trade Organization (WTO) in 1994. The paper provides an overview related to the Mozambican industrial property system before the accession to WTO, and it subsequently addresses the compliance of Mozambique with general TRIPS obligations and then focuses on the adoption and implementation of TRIPS flexibilities within the context of the Mozambican industrial property legislation.

Key words: Industrial Property System, TRIPS, Flexibilities, Adoption, Implementation, compulsory licenses.

1. INTRODUCTION

Mozambique was colonized by Portugal and attained its political independence in 1975. Before and soon after independence it did not join any international intellectual property (IP) agreement. In 1994, Mozambique ratified the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) and this became the first international legal Agreement related to Intellectual Property Rights (IPRs) that the country acceded to.²

TRIPS required the establishment of a minimum standards on copyrights and related rights (including computer programs and databases), trademarks,

geographical indications, industrial designs, patents, integrated circuits, and undisclosed information (trade secrets) for WTO member states.³ Such standards include the availability of rights as well as to their enforcement in sense that Member countries may not confer a lower level of protection than provided under TRIPS, in the same way as the Member states cannot be obliged to provide higher protection, as per Article 1.1.⁴ TRIPS brought specific obligations related to administrative and judicial procedures including, among others, provisions on evidence, injunctions, damages, measures at the border against counterfeiting, and penalties in case of infringement.⁵

The Mozambique accession to TRIPS gave raise to enormous obligations for the government in a context that there was no an IP system in Mozambique. In this regard, Mozambique took significant steps to comply with TRIPS, such as the adoption of the first Industrial Property Code post-independence in 1999⁶ and the establishment of the Industrial Property Institute (IPI) in 2003.⁷ Mozambique subsequently acceded to other international agreements on industrial property within the World Intellectual Property Organization (WIPO) framework such as the Paris Convention for the Protection of Industrial Property of 1883.⁸ At the regional level, Mozambique joined the African Regional Intellectual Property Organization (ARIPO)⁹ and acceded to the Harare Protocol for the Patents and Industrial Designs Registration of 1982.¹⁰

¹ Télio Murrure (Mozambique), Master's degree in Intellectual Property in the Institute of Peace Leadership and Governance - Africa University - AU (Zimbabwe). Degree in Law at Faculty of Law of Eduardo Mondlane University – UEM. Lawyer and Consultant at Sal & Caldeira Advogados, Lda – A Law Firm Member of DLA Piper Africa Group. Trademark and Patent Attorney. Lecturer of Intellectual Property Law at Polytechnic University and Technical University of Mozambique.

² Resolution of the Council of Ministers n.º 31/94 of 20 September 1994 adherence of Mozambique to the World Trade Organization.

³ Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (Third World Network, 2000) 1.

⁴ *Ibid* 2.

⁵ *Ibid* 3.

⁶ Industrial Property Code approved by Decree n.º 18/1999 of 4 May (published in BR I Series - No. 17 of 4 May 1999).

⁷ National Institute of Industrial Property, established by Decree n.º 50/2003 of December 24, (published in BR I Series - No. 52 of 24 December 2003).

⁸ Mozambique ratified the Paris Convention on 1997 through the Resolution of the Council of Ministers n.º 21/97 of 12 August 1997, authorizing the ratification of Paris Convention for the Protection of Industrial Property of 20 March 1883.

⁹ Resolution of the Council of Ministers n.º 34/99 of 16 November, authorizing the adherence of Mozambique to Lusaka Agreement, which established African Regional Intellectual Property Organization.

¹⁰ ARIPO, *Compendium of ARIPO Basic Documents, Containing the Lusaka Agreement, Harare Protocol, Banjul Protocol and Swakopmund Protocol*, (2014 Edition, 2014), 5.

As other LDCs, the Mozambican socio-economic challenges determined the needs to strike a reasonable balance between the interests of the IPR owners and the public interest such as public health, food security and knowledge access. In this sense, for most of African countries IP has often been considered as an obstacle to access to essential goods and services which are protected by the IP system.¹¹

This article attempts to portray the context and circumstances, which influenced Mozambique's accession to TRIPS, and how the country has attempted to comply with the TRIPS obligations. On the other hand, how the flexibilities have been used to strike a balance between the IPRs protection and the public interests.

The remainder of the paper is organized as follows: The first section provides an overview of the Mozambican industrial property system before the accession to the TRIPS Agreement. The second deals with the general compliance of Mozambique with TRIPS minimum standards. The third section then focuses on the adoption and implementation of TRIPS flexibilities within the context of the Mozambican industrial property legislation. The fourth section shall focus on some relevant aspects related to the issuance of the compulsory licence in Mozambique, given the pros and cons around it, considering that various African countries rely on this TRIPS flexibility. And finally, a conclusion and some salient recommendations will then be drawn from the foregoing.

2. MOZAMBIKAN INDUSTRIAL PROPERTY SYSTEM BEFORE TRIPS

The history of the development of the Mozambican industrial property system runs parallel with its colonial

history, independence and post-independence. During the first millennium, Bantu speakers migrated to Mozambique, and subsequently Arab and Swahilis traders settled the region and later Portugal initiated the colonization process in 1505.¹²

During the colonial period, the industrial property system was much active compared to the period immediately after independence. This can be attributed to the fact that during colonialism, the management of the system was guaranteed by a local department through the Pre-Registration System, which consisted of the first registration made in Portugal and subsequently extended to Mozambique.¹³ This mechanism has negatively influenced the Mozambican industrial property system by discouraging local creativity and concentrating the competence of attribution and management of industrial property rights in the metropole - Portugal.¹⁴ In this sense, during this period, only Portugal was able to reap the benefits from the established industrial property system.

After the proclamation of independence in 1975, Mozambique inherited the weaknesses related to inadequate expertise to implement the Industrial Property Code adopted during the colonial period.¹⁵ The proclamation of independence also culminated with the adoption of the first Constitution of Mozambique inspired by the ideology of collective ownership, being that this did not include any provision on IP.¹⁶

The government in power shortly after independence gave itself the tripartite role, namely the role of planner, regulator and producer. The planning role consisted in the fact that it was responsible for designing the plans, programs and strategies for socio-economic development

¹¹ George M. Sikoyo, Elvin Nyukuri and Judi Wakhungu, *Intellectual Property Protection in Africa: Status of Laws, Research and Policy in Ghana, Kenya, Nigeria, South Africa and Uganda*, (Acts Press, 2006) 5. <https://www.africaportal.org/documents/12653/ecopolicy16_1.pdf>, accessed 29 May 2018.

¹² Fernando dos Santos, Julieta Nhane and Filipe Siteo, *African Copyright and Access to Knowledge Project ACA2K Country Report – Mozambique – Chapter 6 Access to Knowledge in Africa: The role of Copyright* (the International Development Research Centre (IDRC), the Shuttleworth Foundation and the LINK Centre,

Graduate School of Public and Development Management (P&DM), Wits University 2009). 8.

<https://www.fakongjian.com/int_doc/laws/20160601/2133/m_z023en20160601213305.pdf> accessed 08 May 2018.

¹³ Télio Murrure, *Direito da Propriedade Intelectual* (W Editora, 2017) 114.

¹⁴ Ibid.

¹⁵ Industrial Property Code - Approved by the Decree nº 30.679 of 24 August 1940, which became applicable to Mozambique further to enactment of 'Portaria' n.º 17043 of 20 February 1959.

¹⁶ Dos Santos, Nhane and Siteo (n 10) 16.

of the country. In the regulatory role, it determines the conditions and the actions of the various economic agents; and in the role of producers, it is responsible for providing all products and services to satisfy the collective needs.¹⁷ Within this frame, industrial property matters were not considered a priority notwithstanding the inherited Industrial Property Code.¹⁸

The nationalised economic model was characterised by lack of sustainability since the country was plunged in an economic crisis around 1980. In this context, Mozambique turned to the international community for the aid. Capitalist economies, such as the United States and other western countries expressed interest in making donations. It raised the needs for economy shift towards a market-oriented economy and Mozambique joined the International Monetary Fund and World Bank.¹⁹

The alteration of the economic approach was sealed by the constitution approved in 1990, which brought a radical transformation, in the social, economic and political landscape.²⁰ The 1990 constitution was the first to establish the protection of IP in Mozambique.²¹

The end of the civil war in 1992, and the first multi-party and democratic elections in 1994 culminated in the election of the first government. The elected government prioritized IP as a tool for economic development. In this regard, the Ministry of Industry, Trade and Tourism carried out a series of actions to empower IP.²²

It is important to note that during that period, Mozambique was not bound to any international agreements related to IP. There was no institutional

framework, and the only IP legislation available was the Industrial Property and Copyright Codes inherited from the colonial period. The inherited industrial property code focused, essentially, on the Portuguese context and not necessarily on the Mozambican reality.

3. THE GENERAL COMPLIANCE OF MOZAMBIQUE WITH TRIPS MINIMUM STANDARDS

The establishment of World Trade Organisation (WTO) and the roping in of IPRs in world trade through TRIPS provided minimum standards for the protection of IPRs. The developments brought new challenges for the Sub Saharan African countries, since IP was intricately linked to trade, competition, industrial growth and economic development.²³ African countries generally subscribed to the WTO and attempted steps towards complying with its rules out of compulsion occasioned by their needs to participate in the international trade system.²⁴

The Mozambican accession to WTO and the implementation of TRIPS may also be seen within this context of globalization since the country aspiration was to align itself in the race to secure a place in the international trade system.²⁵ This is one of the cases if considering that in 1994, the first democratically elected government aimed at redefining the direction of the country in terms of socio-economic and political policies.

Neither did TRIPS constitute a uniform law nor it was an exhaustive codification of IPRs at the international level. In fact, TRIPS merely dealt with some IP issues and left out many other aspects on which consensus was not reached.²⁶ While for the Developed Countries TRIPS

¹⁷ Council of Ministers, *National Intellectual Property Strategy: 2008 - 2018, approved in 23.^a Ordinary Session of Council of Ministers, in 28 August 2007* (2007). P 190.

¹⁸ Dos Santos, Nhane and Siteo (n 10) 16.

¹⁹ Joseph Hanlon and Teresa Smart, *Há Mais Bicicletas – Mas Há Desenvolvimento?* (Missanga Ideias & Projectos Lda, 2008) 35.

²⁰ The 1990 Mozambican constitution was the second one approved after the independence and is the one which brought a new vision on the economic and political ground since it has established the multiparty system in substitution of the mono party system and established the open market system in substitution of the centralized system.

²¹ Article 7 of 1990 constitution establish that: "1. Every citizen shall have the right to freedom of scientific, technical, literary and

artistic activity." 2. The State shall protect the rights inherent in intellectual property, including copyrights, promote and practice the diffusion of letters and the arts."

²² Joseph M Wekundah, *A study on Intellectual Property Environment in Eight Countries, Swaziland, Lesotho, Mozambique, Malawi, Tanzania, Uganda, Kenya and Ethiopia*, (African Technology Policy Studies Network, Working Paper Series n. 66, 2012) 52.

²³ Sikoyo, Nyukuri and Wakhungu (n 9) 1.

²⁴ Adronico Adede, *Trips and Development: Origins and History of the TRIPS Negotiations*, (ICTSD, 2003) 30.

²⁵ Murrure (n 11) 122.

²⁶ Carlos Correa, *The TRIPS Agreement and Developing Countries: The World Trade, Legal Economic and Political Analysis*, (2005),

minimum standards are deemed crucial in order to mitigate the piracy and counterfeiting that may affect negatively their industries, for LDCs TRIPS impositions are less obvious.²⁷ The statistics of Patent Cooperation Treaty indicate that most of patent applications come from North America and Europe, it may be the reason for discussions in some African countries in relation to what extend the IPRs may be seen as barriers for accessing medicines and other essential goods and services, considering the critical socio economic challenges of LDC's like Mozambique.²⁸

In this regard, Mozambique's accession to TRIPS was unavoidable since the establishment of the WTO almost coincided with the establishment of the first government in Mozambique, which had the mission to guide the country to socio-economic stability.²⁹ This also implied, somehow, the need for the government to take decisions which appeared, at the moment, to be efficacious in pulling the country along the economic competitiveness path. With the view to enable TRIPS compliance, Mozambique adopted three Industrial Property Codes, the first was approved in 1999, the second in 2006³⁰ and the last in 2015.³¹

Compliance of Mozambique with TRIPS may be questionable bearing in mind that, theoretically, TRIPS make more sense for stronger economies since it may be a relevant tool to their industrialised realities. Compliance was, however, understandable due to the Mozambican context at the time, given that the social, economic and political circumstances did not give room to different decision.

Sihanya citing Gervais, explains that TRIPS addresses, essentially, about seven doctrines, namely copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout designs (logo graphics) of integrated circuits and protection of undisclosed information.³² The Mozambican industrial property system has provided for the majority of TRIPS doctrines.

The 1999 Industrial Property Code provides for trademarks regime, as well as the 2006 and 2015 Industrial Property Code. Besides, the 1999 Industrial Property Code and the 2006 Industrial Property Code mention geographical indications and appellation of origin as one of the industrial property categories, however, they did not provide for an exhaustive regulation about it. In 2009 the government approved a sui generis instrument to cover that aspect.³³ This autonomous regulation was repealed with the entering into force of the 2015 Industrial Property Code, given that it incorporated, entirely, the content of the Regulation of Appellation of Origin and Geographical Indications.³⁴ The 1999 Industrial Property Code also provided for an industrial designs regime, this is also the case of the 2006 and 2015 Codes. The patent regime was provided for in the three Industrial Property Codes. In addition, the Mozambican industrial property system provides for the protection of undisclosed information as trade secrets. The 1999 Industrial Property Code did not provide for the protection of trade secret. The 2006 and 2015 Industrial Property Codes provide for provisions of protection of trade secret. However, none of the Mozambican Industrial Property Codes has provided for layout designs

19. <https://www.researchgate.net/publication/227107105_The_TRIPS_agreement_and_developing_countries> accessed 1 June 2018.

²⁷ Paul J Heald, *Moving the playing field: addressing information distortion and asymmetry in the TRIPS game*, (88 Minnesota Law Review Foundation 249, 2003) 1.

²⁸ Sikoyo, Nyukuri and Wakhungu (n 9) 8.

²⁹ Murrure (n 11) 122.

³⁰ Decree n. ° 4/2006 of April 12, approving the Industrial Property Code (published in BR I Series – n. ° 15 of 12 April 2006).

³¹ Decree n. ° 47/2015 of 31 December, approving the Industrial Property Code (published in the BR I Series – n. ° 104 of 31 December).

³² Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Transferring Technology for Sustainable Development*, (Sihanya Mentoring & Innovative Lawyering, 2016) 64.

³³ Decree n. ° 21/2009 of 3 June, approved the Regulation of Appellation of Origin and Geographical Indications (published in BR I Series – n. ° 22 of 12 June 2009).

³⁴ In May 2018 the industrial property institute has concluded the process of the registration of the first Mozambican geographical indication, namely the Tete's Goat – "*Cabrito de Tete*."

of integrated circuits, and it is not protected through a sui generis system.

Apart from the doctrines aforementioned, TRIPS demands for specific obligations related to administrative and judicial procedures, including, among others, provisions on evidence, injunctions damages, measures at the border against counterfeiting, and penalties in case of infringement.³⁵ In this regard, Mozambique has given competence for the specialized sections of the Judicial Provincial Courts (that is the Sections of Trade Matters) to deal with the litigation related to IP.³⁶ From an administrative point of view, the National Inspection of Economic Activities has the competence to enforce the infringements of the industrial property rights and according to the IPI, customs agents have systematically been trained so that they may be able to enforce counterfeit goods in the Mozambican borders.

The compliance of Mozambique to TRIPS doctrines may be confronted in the table below, as follows:

Enforcement

Generally, in terms of enforcement, TRIPS provide for Administrative measures, Civil Enforcement, Criminal Action and Alternative Dispute Resolution. The Mozambican jurisdiction provides for administrative enforcement through the IPI and National Inspection of Economic Activities, Civil enforcement is provided by the three industrial property codes, Criminal enforcement is, somehow, provided by the Penal Code. And apart from the judicial courts, alternatively the IP disputes may be addressed in the arbitration, conciliation and mediation forum. Finally, the boarder measures are under the responsibility of customs agents.

4. ADOPTION AND IMPLEMENTATION OF TRIPS FLEXIBILITIES

From the establishment of TRIPS, there has been political and economic pressure for the increase of IP protection and awareness in LDCs, and such pressures have had implications for the industrial property system, especially when it comes to policies in LDCs.³⁷ The strengthening of the system to the levels that are more suitable for Developed Countries brought certain gaps and there are reflections of this in the Mozambican system. The Mozambican IP Strategy provides that its main objective is to create an environment where the results of scientific research are utilized to improve the scientific, technological, economic, cultural and social development.³⁸ This strategy also states that IP is a tool that may be used to stimulate and protect creativity and innovation to promote the country's economic, scientific, technological and cultural development.³⁹

The Mozambican industrial property system has taken cue and provided for some of the TRIPS flexibilities, namely, compulsory license, parallel importation, and transitional periods. And it also adopted other mechanisms that may be deemed as flexibilities, namely utility model. The specificities of these flexibilities in Mozambique are addressed in much detail below.

4.1. Exhaustion Regime and Parallel or Grey Imports

The exhaustion of rights is founded in the fact that exclusive rights lapses after the first sale act of distribution.⁴⁰ The idea behind is related to a fact that once a person has legitimately obtained an item protected, such person is entitled to sell, transfer or distribute this item without asking for authorization of the right holder.⁴¹ The exhaustion of IPRs may vary according to national, regional and international modalities. Article

³⁵ Correa (n 3) 2.

³⁶ Murrure (n 11) 283.

³⁷ Jeremy de Beer, Chidi Oguamanam and Tobias Schonwetter, *Innovation, Intellectual Property and development Narratives in Africa, Innovation & Intellectual Property: Collaborative dynamics in Africa*, (UCT Press, 2014) 2.

³⁸ Council of Ministers (n 15) 18.

³⁹ Fernando dos Santos and Simão Pelembe, *The state of Biofuel innovation in Mozambique, Innovation & Intellectual Property: Collaborative Dynamics in Africa*, (UCT Press, 2014) 254.

⁴⁰ World Trade Organization, *A Handbook on the WTO TRIPS Agreement*, (Cambridge University Press, 2012) 18.

⁴¹ Ibid.

6 of TRIPS states that member states have the sovereignty to adopt any exhaustion modality according to its priorities and context.⁴²

The flexibility of parallel importation is linked with the exhaustion modality. In case of Mozambique, the industrial property system has adopted a national exhaustion regime. This is evidenced by the fact that the three Mozambican Industrial Property Codes adopted the following provision:

'The following shall not be within the scope of the patent: (...) b) Acts related to products placed on the market in Mozambique by the proprietor of the patent or so placed with the proprietor's consent; (...).'

Most African countries would like to protect their consumers and third parties arguing that their laws provide that once a patentee has authorized a manufacture or sale, anywhere in the world the patentees' rights are exhausted.⁴³ The national exhaustion regime adopted by Mozambique is more suitable for Developed Countries considering their interest in enforcing the IPRs all over the world.⁴⁴

Parallel imports take place when a third-party import and sells IPRs protected products from a country where they were lawful distributed by a right holder to another country with the rights holder's permission.⁴⁵ This flexibility makes sense when we face differential pricing of a product in different markets. It may happen as result of local manufacturing costs, market conditions, among other factors. Thus, there are several advantages of allowing parallel imports, principally for LDCs.⁴⁶

Considering the above scenario, we realize that the advantages of parallel imports may be obvious to Mozambique. First, in the public health context, the

importation of a patented medicine from a country where it is sold at a lower price will enable more patients in an importing country to gain access to the product. Second, at the same time, the patentee is not prevented from receiving the remuneration for the patented invention in the country where the product was first sold.⁴⁷

It is possible to argue that the WTO should impose on all WTO members a generalized and compulsory system of international exhaustion without any possibility to rely on national or regional regimes to boost economic integration of all WTO member states.⁴⁸

4.2. LDC Transition Periods

There are substantive flexibilities and time-based flexibilities.⁴⁹ TRIPS offered member states transitional periods so that they could accomplish the obligations stated in the agreement, and such transitional periods vary according to the stage of development of each country.⁵⁰ The transitional period was essential for many LDCs since it allowed them to introduce new legislation and adapt the economic sector to the regulation derived from the IP legal framework.⁵¹ TRIPS came into force on 1 January 1996 for Developed Countries, on 1 January 2000 for Developing Countries and finally on 1 January 2006 for LDCs.⁵² Transitional periods constitute a modality of flexibility that deals with time arrangements in order to permit local preparation so that the country may be able to fully comply with TRIPS obligations.

The dates of transitional periods were changed in the WTO Ministerial Conferences of Doha and Hong Kong.⁵³ As a result of the Doha Declaration, which focused on TRIPS and Public Health, it was decided in 2002 that the LDCs transitional period in respect to pharmaceutical products would be extended to 1 January 2016, and then it was extended to 1 January 2033. In parallel, upon a

⁴² Correa (n 3) 83.

⁴³ Sihanya (n 30) 129.

⁴⁴ Ibid.

⁴⁵ Leonel Bentley and Brad Sherman, *Intellectual Property Law*, (3rd Edition, Oxford University Press, 2009) 14 – 15.

⁴⁶ World Trade Organization (n 38) 19.

⁴⁷ Ibid.

⁴⁸ Enrico Bonadio, *Parallel Imports in a Global Market: Should a Generalised International Exhaustion be the Next Step?* European

Intellectual Property Review, (Vol. 33, No. 3, 2011) 156 <<https://ssrn.com/abstract=1762900>> accessed 29 June 2018.

⁴⁹ Dos Santos, Nhane and Siteo (n 10) 19.

⁵⁰ World Trade Organization (n 38) 21.

⁵¹ Correa (n 3) 10.

⁵² Sihanya (n 30) 64.

⁵³ Ibid.

request in 2005, the LDCs transitional period for the application of all other provisions of TRIPS, with exception of Article 3 to Article 5 regarding non-discrimination, was also extended until 2013 and then until 2021.⁵⁴

The implementation of IP legal and policy framework requires a supportive infrastructure, which includes trained personnel, office resources, judicial and legal practitioners. The industrial property legislation must be aligned with the other imperatives such as trade, economic growth and competitiveness.⁵⁵ It is noteworthy, however, that the issue of unavailability of local production of medicines is largely beyond the industrial property system. As such, according to the Mozambican Ministry of Health, most of the medicines in the national health system are imported given the weakness of the local capacity of producing medicines.

4.3. Utility Models

TRIPS do not provide for the protection of utility models.⁵⁶ Citing Correa, Sihanya explain that under article 27 of TRIPS, member states are free to shape a system in accordance with its own reality, meaning that utility model may be a sui generis regime. Utility models are also seen as an alternative to the patent regime since their requirements are less rigid than patents requirements.⁵⁷

This industrial property category differs from patents because it does not demand for stronger requirements (like inventive step required for patentability) and it has a shorter term (patent duration is 20 years while utility model duration is 15 years in the Mozambican legislation).⁵⁸ A utility model is also less expensive and quicker to obtain.⁵⁹

The three Mozambican Industrial Property Codes provided for utility model protection. This mechanism may address the inventions of small dimension if its novelty is examined nationally, involving an inventive step and capable of industrial applicability. This could be a useful alternative for the Mozambican context since it tries to overcome the rigidity of the patent system.

The Mozambican manufacturing capacity and the research activities are limited and would benefit more from the lower standards of invention as found in utility models. Most registered patents in Mozambique are not local. In 2017, 20 patents were registered through National System, 1 through Paris Convention, 25 through Patent Cooperation Treaty and 519 through Harare Protocol.⁶⁰

The Small and Medium Enterprises (SMEs) constitute an important entrepreneurship block in Mozambique, covering 98.6% of the Mozambican market. Thus, the economic growth, increase of employment rates and reduction of poverty depend on boosting the SMEs.⁶¹ Utility model addresses properly the dynamics of SMEs given the non-hardship of the protection requirements, thus, with this option the Mozambican SMEs could be able to enhance their innovation capacity and get it protected through an easier legal procedure.⁶²

Other flexibilities such as bolar exceptions were not adopted in law because as a matter of fact they demand for technical capacity when it is coming to researching capacity, which Mozambique still largely lacks in.

⁵⁴ World Trade Organization (n 38) 23.

⁵⁵ Sikoyo, Nyukuri and Wakhungu (n. 9) 14.

⁵⁶ Sihanya (n 30) 139.

⁵⁷ Murrure (n 11) 200.

⁵⁸ World Intellectual Property Organization, *WIPO Intellectual Property Handbook*, (WIPO Publication, 2004) 40.

⁵⁹ Sihanya (n 30) 137.

⁶⁰ Information provided by the Trademark and Patents Directorate of the Mozambican Industrial Property Institute.

⁶¹ Baker Tilly Moçambique, *PME em Moçambique: Oportunidades e Desafios*, (Mozambique Support Program for Economic and Enterprise Development - Speed 2014), 21.

<<https://pt.scribd.com/document/361725742/Relatorio-PME-Em-Mocambique-Oportunidades-e-Desafios1>> accessed 6 May 2018.

⁶² In Mozambique, while for patent application the timeframe for registration is about 22 months the utility model registration takes about 6 months. While the cost for patent application costs about 5.400,00 Meticals, the application for utility model costs about 1.850,00 Meticals. In addition to that, the inventive is required for patentability while the utility model regime does not impose the inventive step since it just deals with small innovation around already patentable products, systems and process. See Murrure (n 15) 202 – 203.

4.4. Compulsory License

Compulsory license is an authorization given by the government entity to a person who is not the patent holder, so that this person may produce, import, sell or use the patent protected product without prior consent of the patent holder.⁶³ TRIPS provide for this flexibility in Article 31 and the original designation is “use without authorization of the right holder”.⁶⁴ The three Mozambican Industrial Property Codes provide for it. In all codes, the issuance of compulsory license is justified by public interest whenever it is of great importance to public health, national defense and technological development.

However, the only issuance of a compulsory license in Mozambique was in 2004 to Pharco Mozambique, a local company. The justification was the need to address the very critical situation of extreme urgency related to HIV/AIDS through retroviral drugs, namely stavudine, lamivudine and nevirapine.⁶⁵ With approximately 29 million people, Mozambique has a national HIV prevalence that is estimated at 11.5%, with substantial variation in regional prevalence ranging from 17.8% in the Southern Region to 5.6% in the Northern Region.⁶⁶ However, in the case of Mozambique, there are not evidences that the issuance of the compulsory license in 2004 has contributed to the reduction of the HIV national prevalence. In fact, the initiative was abandoned because of the higher price of active pharmaceutical ingredients, which rendered the production economically unfeasible.⁶⁷ It is noteworthy that, surprisingly there were no patents for such products in Mozambique thus bringing into question the validity and enforceability of the compulsory licence.

As a matter of fact, the issuance of the compulsory license by the Mozambican authorities in 2004 deserves a special analysis either by the context in which it was issued or by the degree of compliance of the requirements for it to be issued, but above all, because it is the only TRIPS flexibility which was effectively implemented to address public health in Mozambique. In this manner, this part will probe the efficacy and the fulfilment of the requirements in relation to the option of the Mozambican authorities relying on this mechanism.

The issuance of a compulsory licence resembles a prohibition to the patent owner on excluding third parties to work its patent under a decision of the national authority based on the safeguarding of public interest.⁶⁸ This mechanism is provided by Article 31 of TRIPS as “other use without the authorization of the right holder”, being an exceptional situation through which a patent may be exploited.⁶⁹ This provision covers both compulsory licences granted to third parties for their own use and use by or on behalf of government without the authorization of the right holder.⁷⁰

Many African countries are keen to have the power of granting compulsory license to the pharmaceutical products.⁷¹ These licenses are relatively common in the African countries however, are not publicized.⁷² The notable cases of compulsory license issuance in Africa took place between 2001 and 2005, for instance South Africa in 2001, Zimbabwe in 2002, Mozambique, Swaziland and Zambia in 2004, Cameroon, Ghana, Guinea, Eritrea in 2005.⁷³ On the other hand, the purpose of the compulsory license issuance in those countries are related to importation and manufacturing of pharmaceutical, for instance Ghana, Guinea, Eritrea for

⁶³ World Trade Organization (n 38) 109.

⁶⁴ Ibid.

⁶⁵ Dos Santos, Nhane and Siteo (n 10) 19.

⁶⁶ U.S. President Emergency Plan for AIDS Relief, *Mozambique Operational Plan (COP/ROP) 2017, Strategic Direction Summary* (2017). 5. <https://mz.usembassy.gov/wp-content/uploads/sites/182/2017/04/SBU_Moz-SDS-2017_3.02.17-SUBMITTED-v2-PUBLIC-1.pdf> accessed 2 March 2018.

⁶⁷ Patrick Lumumba Osewe, Yvonne Korkoi Nkrumah, Emmanuel Sackey, *Improving access to HIV/AIDS medicines in Africa: Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities*

utilization, (The World Bank, 2008) 17.

⁶⁸ Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights* (Kluwer Law International, 2002), 231.

⁶⁹ Correa (n 3) 241.

⁷⁰ World Trade Organization (n 38) 109.

⁷¹ Sihanya (30) 65.

⁷² James Packard Love, *Recent Examples of the Use of Compulsory Licenses on Patents*, (Knowledge Ecology International, Research Note 2, 2007), 15-17. <https://www.keionline.org/misc-docs/recent_cls_8mar07.pdf> accessed 10 May 2019.

⁷³ Ibid.

importation, Cameroon for importation and manufacturing, Zimbabwe to import, Mozambique and Zambia for manufacturing.⁷⁴

Considering the international legal framework, namely the CUP and TRIPS, virtually all countries around the world allow compulsory license in their national legislation.⁷⁵ Mozambique therefore is part of those agreements thus, may utilize this flexibility specially to address situations of public interest.

According to the wording of the compulsory license n. 01/MIC/04, the government of Mozambique decided to grant it based on its quality of WTO member, thus bound by TRIPS.⁷⁶ The foreword of TRIPS suggests that the special needs of LDCs were taken into account given that it conferred maximum flexibility in the domestic implementation of laws and regulations capable to enable these countries to create technological base and strike balance between IP and public interest.⁷⁷ Article 7 and 8 of TRIPS transmits the idea that, at least theoretically, TRIPS aimed to safeguard sensitive matters such access to food, to medicines and to knowledge, especially for LDCs like Mozambique.⁷⁸

The possibility of issuing a compulsory license by WTO members was always available in TRIPS however, this issue was enhanced by the Doha Declaration in sense that the concern of World Health Organization and WTO was to amplify the access to medicines to address diseases such as HIV AIDS, tuberculosis, malaria among others.⁷⁹ Doha Declaration has drawn the grounds under which the WTO members may apply for compulsory licences, namely: (i) national or situation of extreme emergency,

(ii) dependency of patents, (iii) licences to remedy anti-competitive practices, (iv) lack of or insufficient working of the patent, (v) refusal to deal, (vi) public interest and public health. However, such grounds ought to be prescribed under national patent law.⁸⁰

Article 92 of the Mozambican Industrial Property Code prescribe that an invention may be exploited by authorization of the Minister of Trade and Industry without consent of the patent holder, to address public interest, according to this article the invention deemed to public interest whenever it is of fundamental relevance to the following situations: (i) public health, (ii) national defence and (iii) economic and technological development. In fact, the ground mentioned by Mozambican authorities to grant the compulsory n. 01/MIC/04 was the extreme emergency. The declaration of the emergency may be done either by a competent authority or by the authority which grant the compulsory licence.⁸¹ The Mozambican Industrial Property Code does not point the authority with competence to declare such emergency, in this case, the extreme emergency was declared by the competent authority to grant compulsory licence namely the Ministry of Trade and Industry.

There are different approaches on whether the compulsory licences are capable of boosting dissemination of patented technologies. Some argue that it is crucial to foster transfer of technology from industrialized countries to LDCs. Others defend that it harms patent holders, depriving them of exclusive rights on their own invention apart from reducing the incentives for LDCs to invest in research and development.⁸² Other

⁷⁴ Love (n 70) 15 – 17.

⁷⁵ Esther Van Zimmeren and Geertrui Van Overwalle, *Compulsory Licence Regimes for Public Health in Europe* (Center for Intellectual Property Rights), 8. <<https://www.eolss.net/Sample-Chapters/C17/E6-58-10-05.pdf>> accessed 8 May 2019.

⁷⁶ See translated text of the compulsory licence available at: <<http://cptech.org/ip/health/c/mozambique/moz-cl-en.pdf>> accessed 10 May 2019.

⁷⁷ Correa (n 3) 217.

⁷⁸ Murrure (n 11) 125.

⁷⁹ Carlos Correa, *Implications of the Doha Declaration on TRIPS Agreement and Public Health*, (University of Buenos Aires, 2002) 5.

<<https://apps.who.int/medicinedocs/pdf/s2301e/s2301e.pdf>> accessed 9 May 2019.

⁸⁰ Carlos Correa, *Guide for the Application and Granting of Compulsory Licences and Authorization of Government Use of Pharmaceutical Patents*, (World Health Organization, 2009) 9. <<http://apps.who.int/medicinedocs/documents/s19902en/s19902en.pdf>> accessed 10 May 2019.

⁸¹ Ibid.

⁸² Enrico Bonadio, *Compulsory Licensing of Patents: The Bayer/Natco Case* (European Intellectual Property Review, Issue, 2012) 12. <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=215747> accessed 9 May 2019.

argument is that compulsory licence issuance might even be useless in scenarios that patentees have developed and not disclosed in the application, a significant know how on how to work the invention. In such cases there is no possibility to materialize the alleged transfer of technology.⁸³

In case a WTO member decides to apply for and grant a compulsory licence, there is a need to observe the respective formalities. One of the main preconditions for the application of a compulsory licence is that the required product is patented and the purchasing party is seeking to obtain the product from the source of different patent owner of his licensees or other authorized parties.⁸⁴ If the product is not patent-protected in the country where the importation will occur, there is no limitation to import such product.⁸⁵ It means that there are principles and rules which should be followed by WTO member to grant a compulsory licence given that it constitutes an exceptional procedure.

Patents are territorial, being valid only in the countries where they have been applied for and granted, it means that there is no need to apply for a compulsory licence if the patent is not in force in the country of importation irrespective of the existence of such patent in other countries.⁸⁶ The relevant issue for applying for a compulsory licence is to determine the existence of enforceable patents in the importing country.⁸⁷ The most practical way to verify whether a relevant and valid patent exists and whether a compulsory licence is needed is to consult the patent office. The point is that, industrial property offices may take much time to undertake the search and, in many cases the results may not be conclusive due to the lack of appropriate records.⁸⁸

One of the curiosity in the issuance of the compulsory licence in Mozambique is that, according to information given by the Mozambican Industrial Property Office, the

compound under which the compulsory licence was granted was not even patented, in the moment it was granted.⁸⁹ The wording of the compulsory licence n. ° 01/MIC/04 states that:

“Considering further that a triple compound of lamivudine, stavudine and nevirapine has proved, in the last few years, to be one of the most effective and economical anti-retroviral treatment, but the three different international owners of such single drugs failed to reach an agreement to produce this combination.”

Since patents are territorial in nature there should be no automatic assumption that a patent applied for or granted in a foreign country has been applied for or granted domestically.⁹⁰ The wording of the compulsory licence n. ° 01/MIC/04, then proceed stressing that:

“Therefore, the Ministry of Commerce and industry of the Republic of Mozambique, making use of the provision of article 70 n. ° 1 point b) of Decree n. ° 18/99 of 4 May, has decided to grant the compulsory licence n. ° 1/MIC/04 to the company Pharco Moçambique Lda, which has already presented a project for local manufacture of the mentioned triple compound under the names of PHARCOVIR 30 and PHARCOVIR 40.”

In attention to the fact that the Mozambican Industrial Property Office had not registration about any patents on the triple compound of lamivudine, stavudine and nevirapine conjugated with the fact that a legal entity, namely Pharco Moçambique Lda, drafted and submitted a project to manufacture it, it is believed that there was not need to grant a compulsory licence, contrary the company which was granted the compulsory licence could be assisted to carry out the manufacturing of this compound and subsequently protect it through patent in

⁸³ Ibid.

⁸⁴ Correa (n 77) 5.

⁸⁵ Ibid.

⁸⁶ Correa (n 77) 5.

⁸⁷ Correa (n 77) 7.

⁸⁸ Correa (n 77) 8.

⁸⁹ An open-ended interview to the head of patent and trademark services in the Mozambican Industrial Property Institute.

⁹⁰ Correa (n 77) 8.

Mozambique and probably extend such protection abroad.

Other detail which raises attention is the one related to the moment in which the compulsory licence n.º 01/MIC/04 was issued - 2004. LDCs has enjoyed special situation because of the transitional periods, in this regard, the purchase and importation of such products could be made without compulsory licences.⁹¹ Mozambique, as LDC, was not bound by TRIPS obligations till 2005, however, the compulsory licence n.º 01/MIC/04 was issued in 2004, thus within the transitional period.

The issuance of the compulsory licence n.º 01/MIC/04 appears to be out of the requirements for it, either in terms of substantial requirements or in terms of timing requirements – transitional period.

Even if the requirements for applying for and granting of this licence were neglected, it would be possible to raise the question on whether such granting was efficacy or not. Proponents of compulsory licences only look at the issue in terms of diminution of consumer price, although what they fail to realise is that these benefits would be small in the long term.⁹²

The percentage of ARV distribution in the Mozambican hospitals was 2% in 2004, when the compulsory licence n.º 01/MIC/04 was issued and 65% in 2015.⁹³ However, this improvement is not necessarily related to the production of the compound under which the compulsory licence n.º 01/MIC/04 was granted to Pharco Moçambique, Lda given that the most visible attempt of local production of ARV in Mozambique is headed by a project sponsored by Brazilian government under the cooperation project started with an economic feasibility study which took

place between 2005 to 2007 followed by effective action from 2008.⁹⁴ At present, the Combined Fixed Dose of ARV drug combinations available in the Mozambican health system is zidovudina (AZT), lamivudina (3TC) e abacavir (ABC).⁹⁵ While the compulsory licence n.º 01/MIC/04 focus on the combination of lamivudine, stavudine and nevirapine.

It gives the impression that the provision of compulsory licences stated in the Mozambican Industrial Property Code was not interpreted correctly, in sense that the attention was only given to the fact that situations related to public interest would be addressed by this mechanism, however the substantial and timing requirements were neglected. In addition to that, the manufacturing of the compound under which the compulsory licence was issued was not effective.

5. CONCLUSION

Even though the colonial industrial property system in Mozambique was established to facilitate the interests of Portugal as the colonizer, the same system had an influence on the Mozambican industrial property system since it formed the initial basis of establishment of a local system. This is visible especially after independence in 1975 when the pre-colonial Industrial Property Code remained in force in Mozambique despite minimal application. The inadequacy in use was attributable to several factors including lack of awareness, inadequate human capital, institutional inefficiencies as well as non-prioritisation in political and economic policies. TRIPS therefore offered an opportunity for Mozambique to re-examine its system considering the need to comply with minimum TRIPS standards since subscription to WTO was

⁹¹ Correa (n 77) 6.

⁹² Stephanie Skees, *Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic?* (Pace International Law Review, Volume 19, 2007) 285. <<https://core.ac.uk/download/pdf/46711699.pdf>> accessed 6 March 2019.

⁹³ Ministério da Saúde, *Resposta Global à SIDA, Relatório do Progresso, Moçambique*, (Conselho Nacional de Combate ao SIDA, 2016) 28.

⁹⁴ Antonielli, A B, *Conferência Desafios da Investigação Social e Económicas em Tempos de Crise, a Transferência de Tecnologia*

do Brasil para Moçambique para a Fabricação Local de Medicamentos Genéricos: Condições Práticas de uma Cooperação em Saúde Pública e Tecnologia, (2017). <http://www.iese.ac.mz/wp-content/uploads/2017/11/VConfIESE_Antonielli.pdf> accessed 14 April 2019.

⁹⁵ Ministério da Saúde, *Tratamento Antirretroviral e Infecções Oportunistas do Adulto, Adolescente, Grávida e Criança*, (2016). <https://aidsfree.usaid.gov/sites/default/files/mz_tratamento_arv_infecoes.pdf> accessed 14 April 2019.

necessary due to the government's desire to accede to the facilities of the international trademark.

The institutional framework was established in 2003 through the IPI because of the legal framework that had been established in 1999 with the approval of the first Industrial Property Code, then deeply altered in 2006 with entering into force of the second Industrial Property Code and finally revised in 2015 with the third Industrial Property Code which is still in force. All the instruments contain TRIPS minimum standards in terms of protection of IPRs at least for the doctrines of trademarks, geographical indications and appellation of origin, industrial designs, patents and protection of undisclosed information. However, there is no provision for layout design of integrated circuits.

The fact that Mozambique is an LDC confers the opportunity to use flexibilities to strike a balance between the IPRs minimum standards and the social economic challenges. Some flexibilities such as compulsory license, voluntary license, parallel imports, transitional periods and utility models were generally adopted in the Mozambican industrial property system. However, in the particular case of compulsory license it was not implemented in the best way since the requirements were not fulfilled, considering the prominent example of the issuance of the compulsory licence n. ° 01/MIC/04 which appeared to be inopportune, the result has not met the expectation of Mozambican priorities. On the optimistic side, the Mozambican industrial property system has shown signals of consolidation notwithstanding the implementation of the TRIPS flexibilities not playing the desired role. To sum up, there is a need to redouble efforts to overcome lack of awareness, low capacity of local research and development policy.

Télio Murrure, TRIPS Flexibilities and the Evolution of the Mozambican Industrial Property System: Prospects and Challenges for Implementation

EVOLUTION	DOCTRINES				
	Trademarks	Geographical Indications - Appellations of Origin	Industrial Designs	Patents	Protection of Undisclosed Information
TRIPS	<p>Scope Article 15 - Any sign or combination of signs, capable of distinguishing the goods or services.</p> <p>Duration Article 18 - No less than 10 years, renewable indefinitely.</p>	<p>Scope Article 22 - Indications which identify a good as originating in the territory of a Member, or a region or locality where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.</p> <p>Duration No time limitation.</p>	<p>Scope Article 25 - Industrial Designs that are new or original.</p> <p>Duration Article 26 - At least 10 years.</p>	<p>Scope Article 27 - Any inventions, if they are new, involve an inventive step and are capable of industrial application.</p> <p>Duration Article 33 - Shall not end before 20 years.</p>	<p>Scope Article 39 - Any information which is secret, have commercial value and have been subject to reasonable steps.</p> <p>Duration No time limitation.</p>
1999 Mozambican Industrial Property Code	<p>Scope Article 1, paragraph f) defines trademark as a distinctive sign clearly visible or audible, capable of graphic representation, allowing to distinguish products or services.</p> <p>Duration Article 105 - 10 years, renewable indefinitely.</p>	<p>Scope Silent on this doctrine.</p> <p>Duration Silent on this doctrine.</p>	<p>Scope Article 83 - Any set of lines, colors, or any shape in three dimensions, associated or not with lines or colors, provided that this set or shape gives a special aspect to an industrial or craft product. Also, it has to be new and not illegal or offensive.</p> <p>Duration Article 91- 7 years.</p>	<p>Scope Article 20 - Inventions which has novelty, inventive step and industrial applicability.</p> <p>Duration Article 62 - 20 years.</p>	<p>Scope Silent.</p> <p>Duration Silent.</p>
2006 Mozambican Industrial Property Code	<p>Scope Article 1, paragraph f) define Trademark as a distinctive sign clearly visible and or audible, capable of graphic representation, allowing to distinguish products or services from different companies.</p> <p>Duration Article 120 - 10 years, renewable indefinitely.</p>	<p>Scope Silent</p> <p>Duration Silent. However, in 2009 a separate regulation was approved, namely the Decree n.º 21/2009 of 3 June, approving the Regulation of Appellation of Origin and Geographical Indications.</p>	<p>Scope Article 98 - Define Industrial Design as any combination of lines or colours or three-dimensional form, which gives a new and original appearance to a product and serves as a model for the industrial or craft manufacture. Also, it has to be new and not illegal or offensive.</p> <p>Duration Article 107 - 5 years, renewable for the same periods up to a maximum of 25 years.</p>	<p>Scope Article 24 - Inventions which has novelty, inventive step and industrial applicability.</p> <p>Duration Article 66 - 20 years.</p>	<p>Scope Article 174 - information which is secret, have commercial value and have been subject to reasonable steps</p> <p>Duration No time limitation.</p>
2015 Mozambican Industrial Property Code	<p>Scope Article 1, paragraph i) defines a Trademark as a distinctive, clear visible, audible or olfactory sign, capable of being represented graphically and distinguishing the goods or services.</p> <p>Duration Article 139 - 10 years, renewable indefinitely.</p>	<p>Scope Article 1, paragraph c) and f) - Describes GIs as the name of a region, a specific place or in exceptional cases a country, which has become known as for the production, transformation, extraction or creation of a product or the rendering of a particular service. Appellations of Origin are defined as a name of a country, a region or a specific place used to designate a product originated in that country, region or place, whose qualities, characteristics or reputation are exclusively or essentially due to the geographical location, including either natural or human factors.</p> <p>Duration Art 164 - No time limitation.</p>	<p>Scope Article 105 - Define Industrial Design as any combination of lines or colours or three-dimensional form, which gives a new and original appearance to a product, provided that it is new and not illegal or offensive.</p> <p>Duration Article 118 - 5 years from the date of filing, renewable for the same periods up to a maximum of 25 years.</p>	<p>Scope Article 32 - Inventions which has novelty, inventive step and industrial applicability.</p> <p>Duration Article 73 - 20 years.</p>	<p>Scope Article 213 - information which is secret, have commercial value and have been subject to reasonable steps.</p> <p>Duration No time limitation.</p>

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UTILIZATION OF INDUSTRIAL DESIGNS AND UTILITY MODELS IN AFRICA: A CASE STUDY OF KENYA

Rose Adhiambo Mboya*

ABSTRACT

Most African countries have laws in place that protect industrial designs and utility models; however, the role of these intellectual property rights (IPRs) in the growth of the economy is yet to be known. The said IPRs are the first step towards the technological capability of a country. Industrial designs and utility models have made great contributions to the growth of many advanced countries. This paper determines the level of utilization of industrial design and utility model protection in Africa with specific reference to Kenya. The paper presents the key role of the utility model and industrial design applications for the development of local technological capabilities for cutting edge technologies and achieving the technological catch-up with more advanced countries. It is envisaged that this paper contributes to the design of instruments, processes and procedures allowing African countries to benefit from the global opportunities presented by the intellectual property (IP) system.

Key words: intellectual property, utility models, industrial designs, utilization, Kenya.

1. INTRODUCTION

Developed and some developing countries have, over the years, used the intellectual property (IP) system to foster their economic and technological development. Countries including the United States of America, Japan,

China, German, Brazil, India, Korea and Norway, amongst others, have become power houses in the knowledge-based economy as a result of using the IP system as a tool for economic development.

The role of IP in fostering growth can well be illustrated through the comparison of various countries which at one point had the same per capita GDP. For example, in 1957 Ghana and South Korea had about the same per capita GDP. Where South Korea had a national leadership focused on the development of state institutions concentrated on rapid, technology-intensive economic development, Ghana has had no programme of a similar nature on record. Taiwan's economy underperformed under Japanese colonial rule between 1895 and 1945.¹ In the 1950s, the country was an agrarian economy with the same living standard as Congo.² But by 2010, it had overtaken its former colonial master to become the number one producer of semi-conductors in the world.³

Whereas there are other factors which led to the growth of these countries, the effective use of IPRs to foster innovation, creativity and economic development cannot be understated.

Industrial designs are the rights granted by many countries upon registration to protect the original ornamental and visual appeal of articles manufactured in an industrial manner. Protection of industrial designs rewards and serves as an incentive to the investment of resources in fostering the design element of production.⁴

A utility model, on the other hand, is a form of patent-like protection granted for minor or incremental innovations

* **Rose A. Mboya** is Head of Intellectual Property Division at Kenya Industrial Research and Development Institute (KIRDI). She is an intellectual property (IP) expert and registered patent agent with Kenya Industrial Property Institute. She has presented several conference papers on IP related topics at national, regional and international fora mostly organized by the World Intellectual Property Organization. She has a wealth of knowledge and experience on: formulation of institutional and national IP policies and strategies; IP Audit; IP licensing; patent drafting; trademark; industrial designs; utilization of patent information; IP and SMEs; technology transfer from universities and research institutions to the industry; commercialization of IP; IP education and Entrepreneurship. Combining her knowledge and experience on IP and entrepreneurship, she works closely with researchers and small and medium

enterprises in improving their competitiveness through use of IP. She holds Bachelor of Science in Wood Science and Technology, Masters in Intellectual Property and is a PhD student in Entrepreneurship.

¹ Sandile Swana and Lumkile Mondli, 'What's needed to take Africa from Third to First World in 25 years'(University of Witwatersrand Johannesburg July 2016)<<https://www.wits.ac.za/news/latest-news/in-their-own-words/2016/2016-07/whats-needed-to-take-africa-from-third-to-first-world-in-25-years.html>>accessed 7 May 2018

² Sandile and Lumkile (n 1).

³ Sandile and Lumkile (n 1).

⁴ Kenya Industrial Property Institute, 'Industrial Designs' (KIP) <<https://www.kipi.go.ke/index.php/industrial-design>>accessed 10 May 2018.

that do not meet the three criteria of patentability but are novel and industrially applicable.⁵

Utility models systems vary from country to country with regards to areas and terms of protection. Protection for utility models is shorter than patents and varies from country to country; for example, in France, utility models are protected for six years⁶ while in Brazil, they are protected for a longer period of fifteen years.⁷

Utility models provide innovators with many advantages including: granting exclusive rights to the owner; enabling securing protection for innovation that do not meet the stricter novelty and inventive step requirements of patent law; protection makes it possible to increase the role of traditional innovators and artisans in economic development; acts as a catalyst to enhance levels of innovation; utility models are cheaper to acquire than patents and contribute to the technological information.⁸

Currently, a significant number of countries such as Germany, Denmark, France, Italy, Netherlands, Finland, Spain, Portugal, Japan, China and Korea, to mention a few, provide for utility model protection. These countries have used utility models successfully to promote their technological development.⁹

However, despite the existence of laws protecting industrial designs and utility models in most African countries, their role in contributing to the growth of the economy is unknown to date.

This paper attempts to analyze the level of utilization of industrial designs and utility models protection in Africa. To achieve this, an analytical review, drawn from current research on the level of utilization of industrial designs and utility model protection in Kenya is carried out.

Analysis of data from Kenya Industrial Property Institute for the period 2000 to 2017 complimented with other

literature review to give insights into innovation, research and development (R&D) happening in Kenya with a view of getting in-depth information on the legal frameworks, the trends of industrial designs and utility models applications and to identify the conceptual issues and challenges for policy formulation of an effective IP regime in Kenya.

Comparison with countries such as Germany, China, Japan, South Africa, Nigeria, Tunisia, Egypt and Ghana are used to put forward the arguments, draw conclusions and make recommendations for strengthening the IP system in Kenya.

The paper therefore provides a synthesis of the findings on the level of utilization of industrial designs and utility models in Kenya and has four parts. The first part is comprised of the introduction, the background to the study, a synopsis of the problem, justification, methodology and scope and limitations of the study. The second part conceptualizes IP, putting the study within context. Part three provides the findings, analysis of the results and discussion. The fourth part concludes with the IPR needs and gives recommendations based on study findings.

2. LEGAL FRAMEWORKS FOR PROTECTION OF INDUSTRIAL DESIGNS AND UTILITY MODELS IN KENYA

2.1. International and Regional Treaties on Industrial Designs and Utility Models

At an international level, Kenya is signatory to IP treaties that govern protection of industrial designs and utility models and are administered by the World Intellectual Property Organization (WIPO) including the Paris

⁵WIPO, 'Utility Models' (WIPO) <https://www.wipo.int/patents/en/topics/utility_models.html> accessed 12 May 2018.

⁶Intellectual Property Code (consolidated version as of June 1, 2019).
⁷"[A] utility model patent [shall remain in force] for a period of 15 (fifteen) years from the date of filing." Law No. 9,279 of May 14, 1996 [hereinafter "Brazilian Law No. 9,279] art. 40,

⁸ WIPO, 'Protecting Innovations by Using Utility Models' (WIPO) <http://www.wipo.int/sme/en/ip_business/utility_models/utility_models.htm> accessed 20 April 2018.

⁹ Suthersanen Uma, 'Utility Models and Innovations in Developing Countries' (2006) <http://unctad.org/en/docs/iteipc20066_en.pdf> accessed on 13 March 2018.

Convention,¹⁰ the Hague Agreement,¹¹ the WIPO Convention¹² and the Locarno Classification¹³.

At a regional level, Kenya is a signatory to the Harare Protocol¹⁴ and the Lusaka Agreement.¹⁵ The African Regional Intellectual Property Organization (ARIPO) protects industrial designs and utility models for the English-speaking countries through the Harare Protocol on Patents and Utility Models. The Harare Protocol empowers ARIPO to grant patents and register industrial designs as well as utility models on behalf of the 19 member contracting states.

2.2. National Laws on Industrial Designs and Utility Models in Kenya

The industrial design and utility model legal frameworks in Kenya include the constitution,¹⁶ various laws,¹⁷ regulations,¹⁸ statutes,¹⁹ guidelines²⁰ and rules²¹ all of which are administered by the Kenya Industrial Property Institute (KIPI).

The Industrial Property Act 2001 of Kenya provides for the definition of industrial design. **22** A registered design provides exclusive rights to the registered owner for up to

a maximum of 15 years from the filing date of the application.

The above Act provides that a utility models certificate is granted for an invention²³ that is new and industrially applicable. The owner of the utility model shall have the right to preclude any person from exploiting the protected invention without prior authority from the right owner.²⁴ A registered utility model provides exclusive rights to the registered owner for ten years.²⁵

3. FINDINGS, ANALYSIS OF RESULTS AND DISCUSSIONS

3.1 Summary of findings

The findings of the study have been summarized in three tables obtained from the Kenya Industrial Property Institute (KIPI) data base.²⁶ The tables also provide the numbers for residents, non-residents and applications filed through ARIPO.²⁷

¹⁰ Paris Convention for the Protection of Industrial Property, adopted in 1883.

¹¹The Hague Agreement governs the international registration of industrial designs. First adopted in 1925, the Agreement effectively establishes an international system – the Hague System—that allows industrial designs to be protected in multiple countries or regions with minimal formalities.

¹²The WIPO Convention, the constituent instrument of the World Intellectual Property Organization (WIPO), was signed at Stockholm on July 14, 1967, entered into force in 1970.

¹³The Locarno Classification, established by the Locarno Agreement 1968, is an international classification used for the purposes of the registration of industrial designs.

¹⁴Harare Protocol on Patents and Industrial Designs within the Framework of the African Regional Intellectual Property Organization (1982).

¹⁵Lusaka Agreement on the Creation of African Regional Intellectual Property Organization (ARIPO).

¹⁶ The 2010 Constitution of Kenya recognizes intellectual property rights.

¹⁷ Laws include Industrial Property Act of 2010 as amended up to Act No. 11 of 2017 and the Industrial Property Act, 2001 (Act No. 3 of 2001).

¹⁸ Industrial Property Regulations, 2002 (Revised Edition 2016)

¹⁹ Statutes includes: The Statute Law (Miscellaneous Amendments) Act, 2017; The Statute Law (Miscellaneous Amendments) Act, 2007; The Statute Law (Miscellaneous Amendments) Act, 2002.

²⁰ Guidelines for the Examination of Patents, Utility Models, and Industrial Designs 2007.

²¹ Industrial Property Tribunal Rules, 2002.

²²"any composition of lines or colours or any three dimensional form whether or not associated with lines or colours, provided that such composition or form gives a special appearance to a product of industry or handicraft and can serve as pattern for a product of industry or handicraft".

²³ An invention means a solution to a specific problem in the field of technology.

²⁴ (a) when the utility model has been granted in respect of a product— (i) making, importing, offering for sale, selling and using the product; or (ii) stocking such product for the purposes of offering it for sale, selling or using the product. (b) when the utility model has been granted in respect of a process— (i) using the process; or (ii) doing any of the acts referred to in the Act.

²⁵ "A registration certificate for a utility model shall expire at the end of the tenth year after the date of filing of the application in respect thereof, and shall not be renewable".

²⁶ Kenya Industrial Property Institute, 'Kenya IP Statistics 2000-2018' (KIPI) <<https://www.kipi.go.ke/images/docs/Kenya%20IP%20statistics%202000-2018.pdf>> accessed 10 May 2018.

²⁷ It should be noted that numbers for industrial designs applications from ARIPO are from 2010 to 2017. ARIPO did not send online data applications to WIPO immediately it started operating.

3.1.1 UTILIZATION OF INDUSTRIAL DESIGNS IN KENYA

The levels of utilization of industrial designs by various actors are presented in Table 1 and 2 below.

Table 1: Industrial Designs Applications for Period 2000-2015

Year	Residents	Non-Residents	ARIPO
2002	73	12	-
2003	43	10	-
2004	44	11	-
2005	102	15	-
2006	54	18	-
2007	42	32	-
2008	39	10	-
2009	76	14	-
2010	69	7	17
2011	86	28	38
2012	93	10	118
2013	78	8	165
2014	78	17	19
2015	73	12	67
Total	950	206	424

Table 2: Industrial Designs Registered for the Period 2002-2015

Year	Residents	Non-Residents	ARIPO
2002	1	0	-
2003	8	8	-
2004	5	0	-
2005	59	7	-
2006	34	13	-
2007	16	19	-
2008	33	15	-
2009	90	13	-
2010	39	11	21
2011	38	9	27
2012	31	12	33

2013	30	8	107
2014	31	3	213
2015	52	5	83
Total	467	123	484

Table 1 and 2 above provides industrial designs applications and registrations respectively. It should be noted that in some instances the number of registrations is more than applications. In the year 2015 a total of 67 applications were received through ARIPO yet in the same year a total of 83 applications were registered. This is attributed to the fact that not all applications received in a given year are registered in that year. For example an application that does not meet formality examination will have a back and forth communication between the applicant and the ARIPO as opposed to an application that meets all the formality requirements. Applications with corrections will therefore delay even in registration and hence the same may not be captured in the year it was filed but at a later date.

3.1.2 Utilization of Utility Models in Kenya

The number of utility model applications and registrations are presented in Table 3 below.

Table 3: Utility Models Application

Year	Residents	Non-Residents	ARIPO
2002	14	0	
2003	12	0	
2004	13	0	
2005	11	0	
2006	19	0	
2007	16	0	
2008	18	1	
2009	29	1	
2010	28	0	0
2011	51	0	1
2012	68	0	2

2013	78	0	3
2014	53	0	4
2015	114	1	0
Total	453	3	10

More than 90% of utility model applications were by the residents from 2002 to 2015. A review of the KIPI records indicate that during the period, a total of 95 utility model applications were registered as follows: residents 85, ARIPO 10 and no application was received for non-residents. There is a significantly low number of utility models applications translating to registrations.²⁸

3.2 Analysis of Results and Discussions

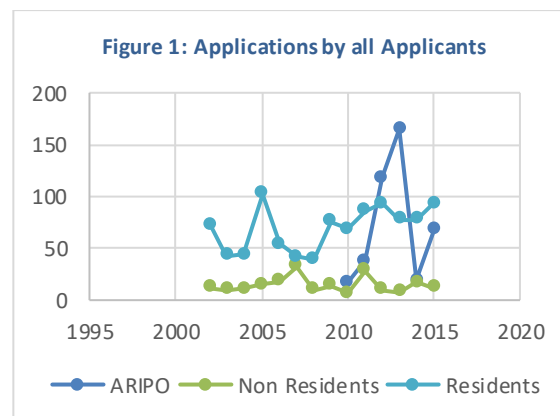
This section provides analysis of the results and discussion of those results.

3.2.1 Trends in Industrial Designs Applications in Kenya

Figures 1, through 5 provides a clear picture of the level of utilization of industrial designs by the various actors and addresses the key issues such as the sources of applications, success rates of such applications, major players in the field, main Locarno classes utilized and implications of said classes on Kenya's economy.

A. Sources of Industrial Design Applications

It is evident from Figure 1 on applications by all applicants that Kenyan residents are the main applicants for industrial designs, constituting 60% of the applications with non-resident applicants doing poorly.²⁹ The key applicants in the industrial designs in Kenya are the small and medium enterprises (SMEs), constituting 70% of industrial designs applications.



B. Top Three Foreign Applicants

From 2010-2017, Unilever,³⁰ Gillette Company³¹ and Watertec Malaysia³² were the main foreign companies leading in industrial designs applications in Kenya.

C. Success Rate of Industrial Design Applications

From 2002 to 2015, out of 1580 industrial designs applications, 1074 have been registered and the success rate of industrial design applications is 67%.

D. Intellectual Property Rights Commonly used by Residents

In terms of ranking based on level of applications, trademarks, patents, and industrial designs took the 1st, 2nd and 3rd positions respectively. In some years, such as 2004, 2005, 2007, 2008 and 2009 the number of applications went down for patents, trademarks and utility models. Generally, the trends of applications by residents in the three mentioned IP rights have been growing. The highest numbers of applications were received in 2006, with the lowest number of applications received in 2009.

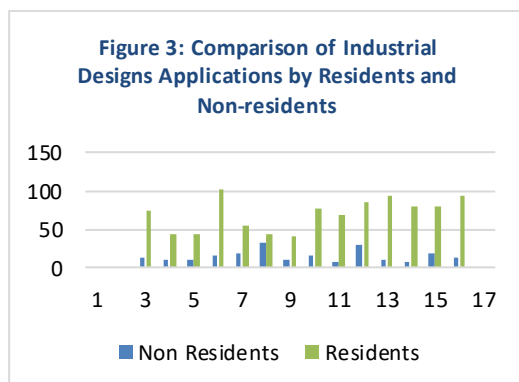
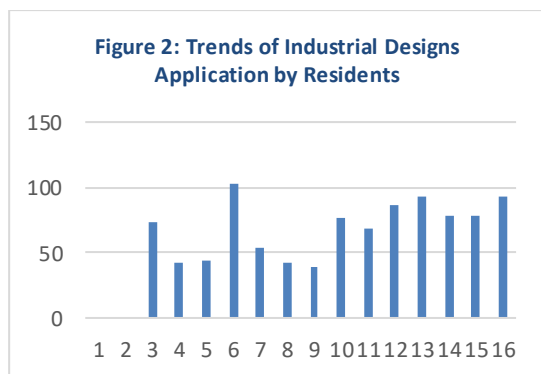
²⁸ Whereas the office received a total of 463 applications, only 95 applications were registered. This may be attributed to poor drafting of utility model applications, applications that do not meet the utility models registration requirements for instance not being novel amongst others

²⁹ Whereas during the period the residents made a total of 980 industrial designs applications, the non-residents had only 206 applications

³⁰ Unilever had filed a total of 12 industrial designs

³¹ Gillette company had filed a total of 7 applications

³² Water Tec Malaysia had filed 4



During the period of review, the numbers of industrial design applications from residents were more than those from foreign applicants.

E. Performance of Industrial Designs Applications in the Various Locarno Classes

The Locarno classification includes 32 classes of industrial designs. Analysis of industrial designs applications for 2014, 2016 and 2017 from the Kenya Industrial Property Journals revealed a total of 12 classes did not receive any applications during the three-year period. These classes were 1,4,14,15,16,17,22,24,29,30,31 and 32. The inactive classes constitute 37.5% of Locarno classes.

Some Locarno classes may seem on the face to have performed better than other classes in terms of the number of applications, as is the case of classes 20, 25 and 26, with total applications of 27, 28 and 22 when compared to class 2 that only received a total of 15 applications from 12 different applicants; however, in terms of the number of individual clients that filed in a

given class, class 2 received more clients than class 20, 25 and 26 whose bulk of applications were from one company, Adopt A Light, with 19 applications targeting the three classes.

Key Sectors in Industrial Designs Applications

The highest number of industrial design applications in 2014, 2016 and 2017 were in Locarno class 9 (67 applications), followed by class 7 (30 applications), and class 2 (18 applications). Consequently, the top 3 Locarno classes accounting for the major shares in Kenya were class 9 (26%), class 7 (12%) and class 2 (7%).

Grouping Locarno classes into industry sectors highlights the most important sectors for industrial design in Kenya as: packages and containers for the transport or handling of goods (26%); household goods, not elsewhere specified and especially china, glassware, dishes and other articles of a similar nature (12%); and articles of clothing and haberdashery (7%). More than 45% of all industrial designs applications belonged to the three sectors.

F. Poor Performance of Furniture Sector in Kenya

In 2016, the Locarno classes accounting for the largest shares of the world total were furnishings (10.8%), articles of clothing (8.6%) and packages and containers (7.3%). More than a quarter (26.7%) of all design applications belonged to one of these three classes.³³

Despite the furniture sector performing well in the world chart of industrial applications, the said sector ranked 7th in Kenya based on the total number of applications in 2014, 2016 and 2017. This sector filed a total of 13 applications in 2014, 2016 and 2017. Out of the 13 applications, 6 were from one company.³⁴

G. Plastic Bottles as Major Industrial Player

Packages and containers for the transport or handling of goods is the main player in industrial design applications in Kenya. Plastic bottles constituted more than 80% of

³³ WIPO, *World Intellectual Property Indicators 2017* (WIPO 2017)153

³⁴ During this period Ali Baba Furnishers, a company manufacturing furniture filed a total of 6 industrial designs

industrial designs applications in this sector in 2014, 2016 and 2017. This sector seems to be very competitive with a lot of innovative design created by the various players.

H. Companies that are Key Players in Industrial Design Applications

Interestingly, most of the previous key applicants of industrial designs from 2002-2009³⁵ are no longer the major players and new entrants have emerged.³⁶ Analysis of the top ten small and medium enterprises for industrial designs applicants from KIPi's monthly Journal for 2010-2017 were as follows: Adopt A Light³⁷ (19); Safepark³⁸ (19); Mahesh Chandaria³⁹ (13); Unilever (12); Paul Muimi Mutemi (10); Sameer Africa (9); Kenstar Plastic Industries (9); Umoja Rubber (7); J.L. Pearl Limited (7); John Paul (6); Alibaba (6); and Royal Mabati Factory (6).

I. Frequency of Industrial Design Applications

From 2010 to 2017, 75% of the applicants only filed one application. The study shows a tendency of companies' filing more than one application at once and then the companies no longer file any applications⁴⁰. It was noted further that only a few companies continued over the years to file for industrial design registrations⁴¹. Since innovations takes place at a firm level, the low number of repeated industrial design applications could be an indication of low levels of incremental innovations on industrial designs taking place in Kenya.

The top five industrial designs applicants according to the frequency of applications from 2010-2017 were: Safepark (8); Kenstar Plastic Industries (7); Unilever (6); Mahesh Chandaria, Umoja Rubber Products and Paul Muimi Mutemi with (4). This shows that most of the industrial

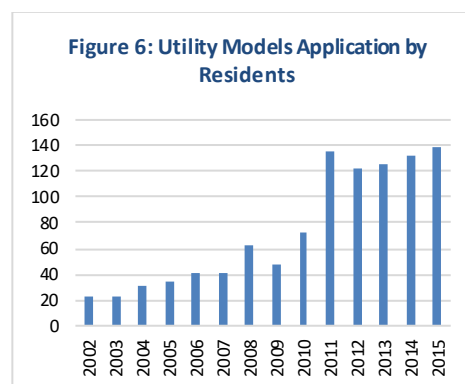
designs registrations are from the same applicants. This can be attributed to existing knowledge amongst the applicants on intellectual property.

3.2.2 Trends in Utility Model Applications

Figures 6, 7, 8, 9, 10 and 11 provide a clear picture on the level of utilization of utility models by the various actors. The figures clearly illustrate key issues such as the sources of applications, success rates of such applications and performance of utility models relative to other IPRs and implications of the said findings on the utility model system in Kenya.

A. Utility Models Applicants

The steady increase in the number of utility model applications over the years indicates increased technological innovation activities across firms in Kenya.



B. Trends of Utility Model Applications by Universities and Research Institutions

There is a growing trend in utility model applications compared to patents by universities and research institutions in Kenya.⁴²

³⁵ During the period 2002 to 2009 the key players in the industrial designs applications were companies such as Crown Foods, Kentainers.

³⁶ The new entrants in the industrial designs applications include Safepark Company limited, Chandaria Industries Limited and Adopt Alight.

³⁷ Adopt A light is a company mainly dealing with street lights filed 19 industrial designs applications.

³⁸ Safepark a company manufacturing plastic related products filed 19 industrial designs application

³⁹ Chandaria Industries Limited deals mainly with Tissue and Hygiene products manufacturer in Kenya, East and Central Africa. The company had filed 13 industrial designs applications

⁴⁰ Companies such as Adopt a light and Ali Baba Furnishers amongst others visited the national IP office once and filed many industrial designs applications.

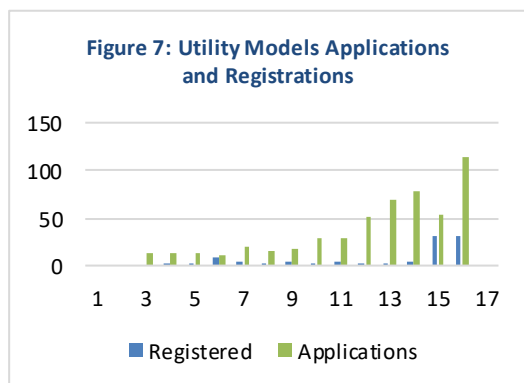
⁴¹ Companies such as Safepark limited, Umoja rubber shoes, Mahesh Chandaria have over the years continued to file industrial designs applications.

⁴² For instance in 2016, the total number of utility models applications from universities and research institutions was 29 against a total of 25 patent applications from these institutions.

This could partly be attributed to the removal of substantive examination for utility models in 2014⁴³ which initially was a big hindrance to protection and further, the many IP sensitization programs to the public, including academics, by the KIPI. Many innovators presently find utility models a better option for protection as opposed to patents due to the significantly lower cost involved in protection, fast processing of getting a registration certificate within one year and protection granted for ten years

C. Success Rate of Utility Model Applications

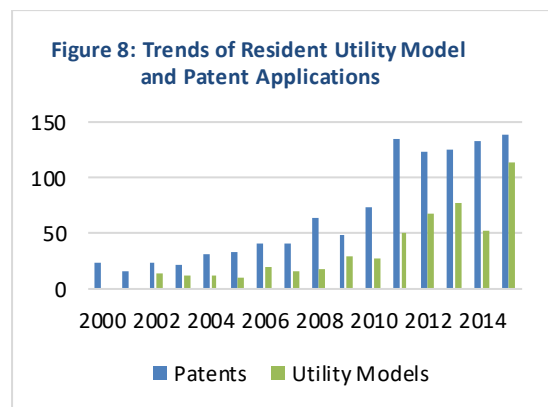
Prior to 2015 when substantive examination was carried out on utility models, the success rate of the applications was very low. For example, out of 450 utility model applications, only 85 were registered. The success rate therefore was 18.8%. This could be an indication of inadequate skills in drafting applications and inadequate skills in responding to office actions.



In Figure 7, the numbers 1-16 on the horizontal axis represent the years 2001 to 2016.

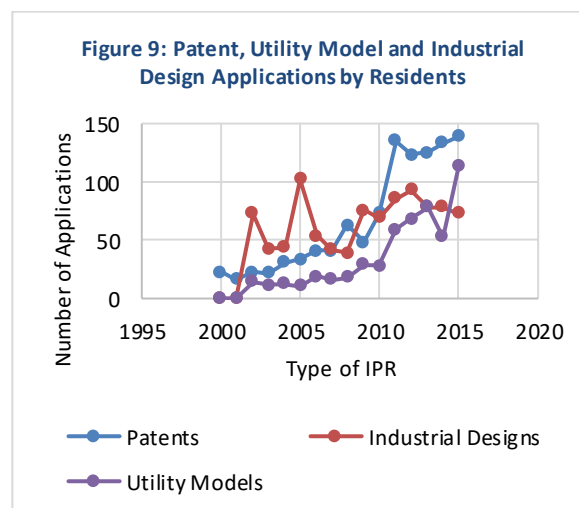
D. Performance of Utility Models in Comparison to other Intellectual Property Rights

Compared to patents and industrial designs, the use of utility model is still low by residents,⁴⁴ as shown in Figures 8 and 9.



Some of the factors potentially contributing to the low level of utilization of utility models were previous continuous over-emphasis by the national IP office on the desirability of patent and industrial designs applications as opposed to utility models.

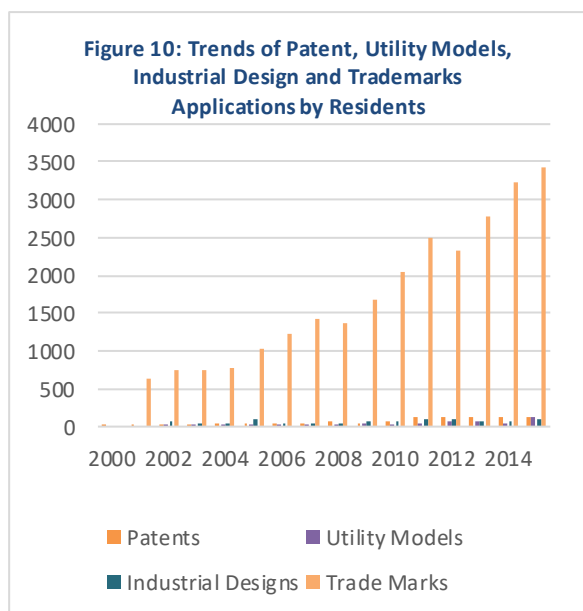
This resulted in a negative perception of utility models as a lesser form of innovation with a weak level of protection.



Similarly in 2017, the number of utility models applications were 22 compared to 19 patents.

⁴³ The 2014 April edition of the Kenya Industrial Property Institute (KIPI) journal, announced that KIPI will no longer do any substantive examination of Utility Model Certificate (UMC) applications.

⁴⁴ During the period of study a total of 453 utility models applications were made compared to 1070 for patents and 950 industrial designs.



From Figure 10, it is evident that residents are very active in filing trademarks,⁴⁵ patent, industrial designs and utility models, in that order. The number of patent applications is almost the same as those of industrial designs. The large number of trademark applications compared to the other industrial property rights could be attributed to the immediate commercial value of trademarks as perceived by the residents. It gives them a faster way to enter the market. Most businesses have a name for their products and services.

3.3 Comparison of Trends in Patents and Utility Models Applications in Various Countries

Having discussed the Kenyan scenario on the trends of patents, utility models and industrial designs applications, comparisons of the trends in various other countries such

as Germany, China, Japan, South Africa, Tunisia, Egypt, Nigeria and Ghana is necessary.

Germany⁴⁶, China⁴⁷ and Japan⁴⁸ have, over the years, had high numbers of utility models, patents and industrial design applications by residents. Thus, trends in the number of applications for the three types of industrial property applications would provide lessons for Kenya to learn.

Nigeria and South Africa are considered economic giants in Africa. These two countries do not carry out substantive examination for patents applications. The trends in the number of patent and utility model applications in these countries, especially by residents, would provide an insight regarding the role of substantive examination on the level of functional designs and patents applications.⁴⁹

Egypt⁵⁰ and Tunisia⁵¹ have done considerably well with high numbers of industrial property applications compared to Kenya.⁵² Similar to Kenya⁵³, the IP laws for Egypt⁵⁴ and Tunisia⁵⁵ provide for substantive examination of patent applications. Hence, the trend in patents and utility models applications in these countries would interest Kenya in establishing a similarity in the level of innovation in these countries or otherwise.

Ghana is the least developed country, the trends in patent, utility model and industrial design applications in Ghana will be compared to ascertain whether it follows any of the above countries.

⁴⁵ Trademarks applications from residents during the period of 2000 to 2015 were a total of 25,914.

⁴⁶ WIPO, 'Statistical Country Profiles- Germany' (WIPO 2017) < https://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=DE > accessed 8 May 2018.

⁴⁷ WIPO, 'Statistical Country Profiles- China' (WIPO 2017) https://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=CN accessed on 9 May 2018.

⁴⁸ WIPO, 'Statistical Country Profiles- Japan' (WIPO 2017) https://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=JP accessed 9 May 2018.

⁴⁹ Patents and the Designs Act 195 of 1993 for South Africa does not have a system to protect utility models but the same are referred to as functional designs.

⁵⁰ WIPO, 'Statistical Country Profiles- Egypt' (WIPO 2017) < https://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=EG > accessed 13 May 2018.

⁵¹ WIPO, 'Statistical Country Profiles- Tunisia' (WIPO 2017) < https://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=TN > accessed 13 May 2018.

⁵² WIPO, 'Statistical Country Profiles- Kenya' (WIPO 2017) < https://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code >=KE accessed 13 May 2018.

⁵³ Industrial Property Act 2001.

⁵⁴ Law No. 82 of 2002 on the Protection of Intellectual Property Rights.

⁵⁵ Law No. 2000-84 of August 24, 2000, on Patents for Tunisia.

A. Germany

In Germany, utility model law was established in 1891⁵⁶ and is the oldest. The law provided protection to such inventions which had low levels of inventiveness, non-substantive examination systems and gave shorter periods of protection. As a result, utility model applications for a long period were more than patent applications.⁵⁷

The numbers of patent, utility model and industrial design applications by residents from 2007 to 2016 were as follows: patents 663,759; utility models 124,567 and industrial designs 617,139.⁵⁸ The high number of patent applications compared to utility models is an indication that as a country advanced technologically,

B. Japan

Japan has had the utility model system as part of the business strategy since 1905.⁵⁹ In fact, the system was designed to encourage incremental and adaptive innovations. The utility model law has been fully utilized by Japanese companies to enhance competitiveness and to advance technology.⁶⁰ Today, Japan stands very high in technological development, with the number of applications for the grant of patents continuously and rapidly increasing.⁶¹

The number of patents, utility models and industrial designs applications by residents during the period of 2007 to 2016 were as follows: patents 2,880,370; utility models 64,936 and industrial designs 272,811.⁶²

C. China

The Patent Law in China was adopted on March 12, 1984 but came into force April 1, 1985.⁶³ The law governs patents, utility models and industrial designs. The utility model and industrial design system has been utilized very effectively in China since the number of applications filed by residents for these IP rights have been more than those filed by non-residents. From 2004 to 2008, the numbers of patent applications by residents were more than those of utility models. Similarly, during the same period, the number of patent applications by non-residents was higher than those of utility models. The average filing of patents in the last ten years indicates that 84% of applications are filed by residents and 16% by foreign applicants.⁶⁴

The numbers of patent, utility model and industrial design applications by residents from 2007 to 2016 were as follows: patents 5,018,465; utility models 6,770,071 and industrial designs 4,827,032.⁶⁵ These figures were better than those applications filed by non-residents.⁶⁶ More industrial designs applications were filed abroad by Chinese applicants as compared to those filed by residents and non-residents within the country.⁶⁷

D. South Africa

The Patents Act 57 of 1978 provides for the protection of patents and the Designs Act 195 of 1993 provides for the protection of industrial designs, which includes aesthetic and functional designs. The Patents Act and the Designs Act provide for the registration of patents and designs upon the applications meeting the formality examination.

⁵⁶ Suthersanen Uma, 'Utility Models and Innovations in Developing Countries' (2006) <http://unctad.org/en/docs/iteipc20066_en.pdf> accessed on 13 March 2018.

⁵⁷ Suthersanen (n 57).

⁵⁸ WIPO, 'Statistical country profiles' (WIPO 2017) <http://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=ZA> accessed 13 May 2018.

⁵⁹ KS Kardam, *Utility model –A tool for economic and technological development: A case study of Japan (IPI India 2007) 44.*

⁶⁰ Kardam (n 44).

⁶¹ WIPO, *WIPO IP Facts and Figures 2018 (WIPO) 13.*

⁶² WIPO, 'Statistical Country Profiles- Japan' (WIPO 2017) https://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=JP accessed 13 May 2018.

⁶³ Patent Law of the People's Republic of China (promulgated by the Presidential Order No. 11 of March 12, 1984.

⁶⁴ Suthersanen Uma, 'Utility Models and Innovations in Developing Countries' (2006) <http://unctad.org/en/docs/iteipc20066_en.pdf> accessed on 13 March 2018.

⁶⁵ WIPO Statistical country profiles-China (WIPO 2017) http://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=CN accessed 13 May 2018.

⁶⁶ WIPO (n 66).

⁶⁷ Ibid at 66.

The numbers of patent and industrial design applications by residents from 2007 to 2016 were as follows: residents - 9794; non-residents - 66326 and filings abroad 12,474 for patents. During this period, a total of 106 utility models were filed abroad with none locally. Similarly, the number of industrial designs applications were as follows: residents 8,367; non-residents 10,773 and abroad 15,566.⁶⁸

This is not an indication of the preference by the residents to file patents in South Africa as opposed to utility models, as no system for utility model protection exists in South Africa. The functional design protection only pertains to the pattern, shape or configuration having features necessitated by the function which the article to which the design applies is to perform.⁶⁹ It is significant that South Africans file utility models abroad. This is an indication that there are technologies that can be protected as utility models, but since the country does not have law in place to protect utility model, the South Africans protected utility models abroad

As opposed to the trend of industrial design filing in other countries like Nigeria, Egypt and Kenya, where more applications are received from the residents, the situation in South Africa is different since the applications received from non-residents were more than those of residents.

The small difference in industrial designs applications between residents of South Africa and non-residents is an indication that South African residents' products are competing comparatively well with those of non-residents.

From the above figures, it is evident that more South African residents are filing patents and designs abroad compared to those filed within the country. This is an indication of the expansion of South Africa products to other markets. It could also be an indication that the formal patent examination in South Africa is inadequate.

E. Nigeria

The history of patent and designs law, like trademark and copyright law and most other laws in Nigeria, finds its roots in the common Law of England, the Doctrines of Equity and Statutes of General Application, enacted as of 1st January 1900. The other statutes enacted after that date could be extended to apply in Nigeria by an enabling Order-in-Council. Patent law was first enacted in 1900 for the Colony of Lagos and Southern Nigeria and then in Northern Nigeria in 1902.⁷⁰

The Patents and Designs Act Chapter 344 Laws of the Federation of Nigeria 1990 contain comprehensive provisions for the registration and proprietorship of Patents and Designs in Nigeria.

Section 4 sub section 2 provides that:

'Where the examination mentioned in subsection (1) of this subsection shows that a patent application satisfies the requirements of section 3(1) and (3) of this Act, the patent shall be granted as applied for without further examination and, in particular without examination of the questions as to whether:

- (a) the subject of the application is patentable under section 1 of this Act;
- (b) the description and claims satisfy the requirements of section 3(2) of this Act; and
- (c) a prior application, or an application benefiting from a foreign priority, has been made in Nigeria in respect of the same invention, and whether a patent has been granted as a result of such an Nigeria and other matter ancillary thereto.⁷¹

In a nutshell, Nigeria grants patent certificates when the applications meet the formality requirement.

From 2007 to 2017, patent applications were filed as follows: residents 156; non-residents 2,292 and abroad

⁶⁸ WIPO, 'Statistical Country Profiles- South Africa' (WIPO 2017) < https://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=ZA > accessed 13 May 2018.

⁶⁹ Patents and the Designs Act 195 of 1993.

⁷⁰ Patents Ordinance No. 17 of 1900 and the Patents Proclamation Ordinance No. 27 of 1900.

⁷¹ Patents and Designs Act Chapter 344 Laws of the Federation of Nigeria 1990.

197. During the same period, there were 3 utility models filed. Similarly, industrial designs were filed as follows: resident 2,265; non-resident 356 and abroad 390.⁷²

Patent filings are still low by residents compared to non-residents. There is a preference by Nigerians for filing of patents abroad.

The trend of industrial designs applications indicates that residents file more applications than non-residents and prefers Nigeria as a market compared to those markets abroad. This is an indication that Nigerian designs have not penetrated other markets outside the country.

F. Egypt

The roots of Intellectual Property in Egypt go back to 1951 when it was established by Law No. 132/1949.⁷³

Currently, protection for patents and utility models in Egypt are provided for in Law No. 82 of 2002 on the Protection of Intellectual Property Rights.⁷⁴

A summary of the patent and utility model applications from 2007 to 2011 in Egypt show a total of 22,288 patent applications were filed as follows: residents 6,422; non-residents 14,804 and abroad 1,062. During the same period, a total of 14 utility model applications were filed abroad. No utility model applications were filed by the residents and non-residents within the country. Industrial design applications were filed as follows: residents 21,248; non-residents 15,808 and abroad 2,181.⁷⁵

The low number of patent applications abroad is an indicator of a preference by Egyptians to file within the country. Similarly, the lack of utility model applications in the country indicates non utilization of utility models as a means of protection.

The low number of industrial designs filed abroad indicates a greater preference by residents to protect in the local market rather than abroad. As a result, few Egyptian products are competing in the global market.

G. Tunisia

In Tunisia, patents and industrial designs are protected through two separate laws: Law No. 2001-21 of February 6, 2001 on the Protection of Industrial Designs and Law No. 2000-84 of August 24, 2000, pertaining to patents.

A summary of the filing from 2007 to 2017, patent applications were as follows: residents 1063; non-residents 4592 and abroad 331. There were 3 utility models filed. Industrial designs applications during the same period were: residents 1,279, non-residents 10,461 and abroad 1,354.⁷⁶

The trend in industrial designs applications by residents in Tunisia is similar to those of South Africa, where the number of applications by residents are less than those of non-residents. The number of industrial designs applications by non-residents is 9 times that of residents, which could imply more foreign products exist in the Tunisian market.

H. Ghana

In Ghana, the Patent Act of 2003 (Act 657) provides for protection of patents and utility models. For a long time, the National IP office did not receive any patent applications; as such, from 2006 to 2015, patent applications were mainly filed abroad. The total number of applications filed abroad during this period was 47. In 2016, the National IP Office in Ghana received patent applications as follows: resident 14 and non-resident 17. During the same year, a total of 103 patents were filed in

⁷² WIPO, 'Statistical country profiles-Nigeria' (WIPO 2017) <http://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=NG> accessed 13 May 2018.

⁷³ Egyptian Patent Office, 'Academy of Scientific Research and Technology' <<http://www.asrt.sci.eg/index.php/asrt-departments/egpo>> accessed 13 May 2018.

⁷⁴ Egypt Law Number 82 on the protection of intellectual property rights.

⁷⁵ WIPO, 'Statistical country profiles-Tunisia' <http://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=TN> accessed 13 May 2018.

⁷⁶ WIPO, 'Statistical country profiles-Tunisia' (WIPO 2017) <http://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=TN> accessed 13 May 2018.

other countries by citizens of Ghana. There were only 2 utility models filed in total in 2016.⁷⁷

3. LESSONS FROM COUNTRIES OF COMPARISON

The countries' comparisons have provided very interesting insights and lessons regarding the trends on the utilization of patents, utility models and industrial designs, as discussed below.

A. General Trends in Utility Models and Patents Application in Germany, China and Japan

Looking at the trends of patents and utility models applications in Japan (1905-1980), Germany (to 2016) and China (1985-2003), there were more utility model applications by residents compared to patent applications by residents.

Comparisons of the three countries from 2007 to 2016 reveal a very interesting scenario. In Germany⁷⁸ and Japan,⁷⁹ the number of utility model applications by residents has been decreasing. During this period, the number of utility model applications was significantly lower than patents. Interestingly, the reverse is shown in China. During the same period, the number of utility model applications from Chinese residents was more than the patent applications and are in the tens of thousands.⁸⁰

B. Relationship between Utility Models and Technological Development of a Country

Although there is no evidentiary proof that utility model applications have any relationship with the technological and economic development of Japan, there is a trend in the growing number of utility model applications in Japan from the time when utility law was established in 1905 to

1981 that provides some indication of growth. For instance, during this period, Japan's economy was growing at a very high rate.⁸¹

Since the technological innovations created by Japanese innovators were of the nature which was not protected under patent law, the utility model law was fully utilized to protect such small inventions.⁸² Therefore, it can be inferred that utility model protection played a very important role in the economic as well as technological development of Japan.

C. Trends in Industrial Design Applications in Africa

The comparison of the use of industrial designs and utility models points to the fact that most African countries such as South Africa, Tunisia, Egypt, Ghana, Nigeria and Kenya have had continuous growth in the number of industrial design applications. Except in South Africa and Tunisia, the residents in these countries are major players in industrial designs applications.

D. Control of Local Markets

It is emerging from the comparison on the utilization of industrial designs and utility models that most of the African countries are trying to grow and protect their own products and hence, they are laying foundations for technological development in the near future. A case in point is Kenya, Egypt, Nigeria and Ghana, where residents file more industrial design applications than non-residents.

Even though in South Africa, the number of industrial design applications by residents is less than those of non-residents, the difference is narrow.⁸³ While in Tunisia, the gap between the residents and non-residents filings is

⁷⁷ WIPO, 'Statistical country profiles-Ghana' (WIPO 2017) <http://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=GH> accessed 13 May 2018.

⁷⁸ WIPO, 'Statistical country profiles-Germany' (WIPO 2017) <http://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=DE> accessed 13 May 2018

⁷⁹ WIPO, 'Statistical country profiles -Japan' (WIPO 2017) <http://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=JP> accessed 13 May 2018.

⁸⁰ WIPO, "Statistical Country Profiles-China (WIPO 2017) <http://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=CN> accessed 10 May 2018.

⁸¹ KS Kardam, *Utility model –A tool for economic and technological development: A case study of Japan (IPIndia 2007) 40.*

⁸² Kardam (n 81).

⁸³ Number of industrial designs applications by residents in South Africa was 8367 compared to non-resident of 10773 there is a narrow margin of 2406 between applications by residents and non-residents

significant.⁸⁴ Comparatively, South African residents are doing better than Tunisia residents whose markets seems to be largely controlled by foreigners going by the high number of non-resident applications of industrial designs that is 9 times that of residents.

E. Reversed Trends of Patents and Utility Models Applications in Most African Countries

Interestingly, in Kenya from 2001 to 2015, the trend is that the number of patent applications by residents has been more than utility models. The same trend is found from 2006 to 2016 in South Africa, Tunisia, Egypt, Ghana, Nigeria, Japan and Germany. However, the trend is the reverse for China, where the number of utility model applications are more than those of patents from 2007 to 2016.

F. Role of Substantive Examination on Filing of Patents and Utility Models by Residents

The low level of utility model applications compared to the high number of patent applications in South Africa and Nigeria indicates a preference by residents to file for patents as opposed to utility models. This could be a result of ease of obtaining patents due to lack of substantive examination for patent applications in those regimes.

3.5 Future Trends of Patents and Utility Models Applications by Residents in Kenya

From the analysis of the results on patent and utility model applications in Kenya in comparison to other countries discussed, it is projected that with time the trends in the number of utility model applications by residents in Kenya will increase steadily and surpass those of patents (that will also continue to grow but at a level lower than utility models.) It is expected the high number of utility model applications will result in an increased level of technological development that will subsequently

lead to the re-emergence of high numbers of patent registration.

4. CONCLUSIONS

Lessons from Germany, Japan and China show that industrial designs and utility models have the potential to act as tools to spur innovation; this will ultimately promote local industrial growth by residents.

Given the number and low level of applications in the five countries namely Nigeria, South Africa, Egypt, Tunisia and Ghana, it is evident from the study that African countries do not adequately use utility models. The low level of success rates for industrial design and utility model applications by residents in Kenya could be the result of lack of skills and capacity in drafting utility model specifications and preparing documentation for industrial design applications.

WAY FORWARD

A. Policy Orientation

African countries should develop policies with emphasis on the use of industrial designs and utility models by residents.

B. Use of Multi-Faceted Approach

Promote a complementary use of patents, utility models and industrial designs. African countries should promote the use of patents, utility models and industrial designs by residents to protect the various features of innovations. The IPRs should be used to complement one another and as one package and not separately, since they all depend on each other; such an approach will increase the effectiveness of the IP system.

C. Sectorial Approach in IP Sensitization

There is need for increased sensitization by the IP offices on the use of utility models and industrial designs by SMEs.

⁸⁴ Number of industrial designs applications by residents was 1,279 compared to non-resident of 10,461, there is a wider

margin of 9,182, between applications by residents and non-residents

Given the 12 inactive Locarno classes in Kenya, it is evident there is a need for targeted sectorial IP sensitization to these industrial sectors. Through the analysis of inactive Locarno classes, countries can identify these sectors, presenting opportunities for targeted IP sensitization programs by the National IP Offices.

D. Capacity Building

There is need for capacity building in preparing documents for Industrial Design applications and drafting Utility Model applications. National IP Offices should make industrial design protection easier by reducing the numerous filing requirements. This will increase the number of industrial design registrations.

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**COPYRIGHT IN IMAGE CAPTURING (PHOTOGRAPHY)
AND RIGHT OF SUBSEQUENT USE: ADDRESSING THE
CLASH OF RIGHTS THROUGH REFORM OF THE
COPYRIGHT LAW**

Abdulwasiu Ojo Akorede Yusuff*

ABSTRACT

This research explores copyright in photography and image capturing as between the photographer and the individual or subject captured in the photograph. The paper particularly examines the nature, scope and limits of rights that the photographer can exercise vis-a-vis the rights of the person in the photograph. Copyright law in most countries of the world generally assigns copyright ownership to the author of a photograph. The implication is that the photographer-author reserves a somewhat exclusive right to manage the photograph as she/he deems fit, and this right includes the rights to produce, reproduce, publish, commercialize, distribute, license and so on. The paper poses important questions as to whether copyright law takes cognizance of how this might impact the subject captured in the photograph, the issue of image rights and whether the photographer owes any duty or obligation to the subject and ultimately whether copyright law should attempt to balance these occasionally opposing rights. These questions become pertinent in the digital age, where photography has become everyone's favorite pastime, and photographs can be distributed and viewed on several online and offline platforms having almost unlimited global reach. Indeed, on such platforms, photographs are used in a variety of rapidly growing industries including modeling, advertisement, product endorsement, sponsorship, character merchandising, entertainment and other related industries. The paper advances the cause of balancing these rights and suggests that this should not be left to judicial evolution or private contract but should be made through the reform of copyright law.

Key words: Celebrity, Copyright, Digital Revolution, Photograph, Privacy, Publicity, Rights.

1. INTRODUCTION

In the copyright law of most States in Africa and beyond, copyright in a photograph belongs to the photographer, who generally exercises the basic rights of a recognized author/owner of the work. The right of the author/owner of a photograph includes the right to reproduce, distribute or commercialize the work. In the particular instance of photography or image capturing, not much is mentioned with respect to the image and the rights that such an individual or subject possesses or might claim. If the right of the photographer means that she/he can use the image without consulting the subject of the photograph or obtaining his/her permission, then a clash of interests or rights is inevitable in some cases at least, absent prior legal agreement. The focus here is directed at uses of the image which might be harmful, offensive or impact on other interests of the subject in one way or another. Privacy and image rights, considered generally or in the particular context of photography, transcends a simple discourse of copyright law. It might depend on what use the photograph is put to, following snapping/capturing, and extend into the realm of torts law, criminal law, constitutional law and so on. Hence, the paper attempts to narrow the issue to this context as much as is possible.

Copyright law envisages the possibility of a prior agreement between the photographer and the person at whose instance or for whose purpose or interest the photograph was taken, with respect to ownership and control of subsequent dealings with the photograph. This contract is usually made in the context of an employer/employee relationship or commissioned photographs, such as a portrait. This allowance, however, suffers two important limitations. First, the employer or the commissioner of the photograph might not necessarily be the subject captured in the photograph. Secondly, photographs can be taken and are very often taken outside of employment or commissioned arrangements; indeed, they can be taken without the knowledge or consent of the subject or, as the case may be, the person in control of the object of the photograph. Consequently, in the absence of clear and mandatory legal provisions in copyright law, the issue of rights or

transfer of rights of ownership in photographs in the specific context under examination remains a grey area that should be addressed through legal reform. This is imperative and urgent, considering the massive explosion of the entertainment, advertising and creative industries in the world, Africa inclusive, coupled with an unprecedented expansion and utilization of the digital environment, where this kind of conflict occurs or is expected to occur with increasing frequency. This paper thus throws a searchlight on this area with a view to advancing the law to balance the conflicting rights.

2. THE BASIC FOUNDATION OF COPYRIGHT LAW

The need to legally protect certain products of human creativity in the form of literary and artistic works has been recognized for well over a century now. The core areas recognized for protection have however increased from the first generation of rights such as patents, copyright, trademarks and designs, to the newer generation of rights such as geographical indications, confidential information, trade secrets, traditional knowledge, genetic and scientific resources as well as works created by or through the use of artificial intelligence. Some of these newer IP rights are accommodated under the well-known first-generation headings but have somehow managed to attract special attention while some others are accorded special recognition. Regardless of this perspective, the basic

foundation for intellectual property protection is a recognition that 'everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author'.¹ Protection of intellectual property is justified upon a fairly well articulated basis which largely centers on the concept of the entitlement of creators to the fruits of their efforts, balanced against benefits to the society at large.² Hence, a concept of authorship/ownership has developed by which entitlement to the benefit of the legal protection under copyright is determined. The field of IP is so vast however, that a meaningful and reasonable consideration of the current subject matter necessitates a focus, in this paper, on copyright law, and even at that, a narrow aspect of it.

Without necessarily taking the historical approach,³ copyright may generally be described as the legal right given to creators of certain works resulting from their intellectual effort and made available for the enjoyment of the society. It may also be defined as the 'statutorily granted right exercisable by certain groups of persons on some designated works of art upon some terms and conditions specified by law for some period of time'.⁴ Works in this context may be in area of arts and literature, music, films and so on.

Copyright grants an exclusive right to authors to do or to authorize or control the doing of certain 'restricted acts' with respect to their protected works.⁵ Before

* **Dr. A. O. Akorede Yusuff** (Nigeria) is an Associate Professor in the Department of Public Law, Faculty of Law, Obafemi Awolowo University, Ile-Ife, Nigeria. He was the acting Head of the Department between 2012 and 2016. He was called to the Nigerian Bar in 1995 and started working as an academic member of staff in Obafemi Awolowo University in 1997. He has the LL.M degrees of the Obafemi Awolowo University, Ile-Ife and the University of Toronto, Canada. He equally obtained the PhD degree of Obafemi Awolowo University in 2008. Dr. Yusuff teaches, conducts research and publishes in his core areas of scholarly interest, namely, Intellectual Property Law, Health/Medical Law and Policy and Criminal Law. He is an alumnus fellow of the Canadian Institutes of Health Research (CIHR), a member of the International Academy of Collaborative Professionals (IACP), a member of the Law and Society Association (LSA) and a lover of nature, culture and literature.

¹ United Nations Universal Declaration of Human Rights, 1948, Art. 27 (2).

² For a robust and interactive discussion of justifications for Intellectual Property Rights (IPRs), see Tanya Aplin and Jennifer Davis, *Intellectual Property Law: Texts, Cases and Materials*,

(Oxford University Press 2009) 4-13; A O Oyewunmi, *Nigerian Law of Intellectual Property* (University of Lagos Press 2015) 8-14.

³ There is however a reasonable measure of consensus among authors that copyright as it is known today evolved at the inception of the industrial era with the development of the printing press as a means of large-scale production of written materials as well as increase in literacy in the early societies. Extensions of copyright relevance beyond written or printed materials, for example musical, literary and artistic works and so on, naturally followed further social and technological developments. See generally W R Cornish, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (3rd ed Sweet and Maxwell 1996) 297-303; Tanya Aplin and Jennifer Davis (n 2) 41-44; A O Oyewunmi (n 2) 24; H Klopper, T Pistorius, B Rutherford, L Tong, P van der Spuy and A van der Merwe, *Law of Intellectual Property in South Africa* (LexisNexis 2011) xxii.

⁴ A O Yusuff, 'Computer Technology and Copyright Eligibility under the Nigerian Copyright Law' (2005) 3 *Igbiniedion U L J* 44.

⁵ D Bainbridge, *Introduction to Computer Law*, (3rd ed Financial Times Pitman Publishing 1996) 12.

considering this however, it is worthy to note that there are certain categories of works recognized by the law as eligible for copyright protection, as well as conditions for their eligibility. Under the Copyright Act of Nigeria,⁶ for example, works are generally categorized as

- (a) Literary works;
- (b) Musical works;
- (c) Artistic works;
- (d) Cinematography films;
- (e) Sound recordings; and
- (f) Broadcasts.⁷

These categories might look definitive and restrictive but, as noted by Asein, each recognized work is broadly defined to embrace a wide range of creative efforts and materials.⁸ Creative works falling within the Literary, Musical and Artistic categories must satisfy certain conditions to be protected.

According to s. 1 (2) (a) & (b) of the Nigerian Copyright Act⁹

‘A literary, musical or artistic work shall not be eligible for copyright unless

- (a) sufficient effort has been expended on making the work to give it an original character;
- (b) the work has been fixed in any definite medium of expression now known or later to be developed, from which it can be perceived, reproduced or otherwise communicated either directly or with the aid of any machine or device’.

The first of these conditions is usually referred to as the concept of ‘originality’ while the second is referred to as the concept of ‘fixation’. Originality in the copyright sense means that there is a direct creative link between the author’s mental conception and the work which emanates from his hand. Thus, the author must have

expended some meaningful skill and sufficient effort in the process of making the final work to make it distinct from any other similar work. It does not mean though, that the work must be entirely new, novel or spectacular but that it was independently created.¹⁰ It is not very clear what degree of effort would be considered ‘sufficient’ as a basis for recognition of a work but it might be suggested that a minimum standard of personal involvement, use of skill, talent, judgment and distinct taste in the creation of the work would be necessary. In the words of Oyewunmi, ‘a low threshold of originality as required under the Act does not mean that commonplace factual information without any creative input in terms of a unique arrangement, style or order of presentation should be accorded protection’.¹¹

With regard to the second condition, copyright does not subsist in a literary, musical or artistic work unless and until it is recorded in writing or made to exist in some other material form.¹² This requirement for ‘material embodiment’ is otherwise referred to as fixation and it further reinforces the general nature of copyright, namely that it does not protect ideas simpliciter, but the expression of those ideas in a more or less permanent form.¹³ The work must be fixed in a medium where it can be seen, read, heard, or felt, being media that would not only aid the perception and attribution of the work, but also enable its reproduction, publication and communication to the public.

Given these background concepts, this paper will now address the primary focus of copyright in image capturing or photographs more specifically.

⁶ Copyright Act, Cap C28, Laws of the Federation of Nigeria, 2004 (As amended).

⁷ Ibid s.1(1).

⁸ J O Asein, *Nigerian Copyright Law and Practice* (2nd ed Books and Gavel Publishing 2012) 45. In this sense, computer program is generally recognized as Literary work while photographs, the subject of this paper, is recognized as Artistic work. See also, F O Babafemi, *Intellectual Property-The Law and Practice of Copyright, Trademarks, Patents and Industrial Designs in Nigeria* (1st ed Justinian Books 2007) 9-10.

⁹ Copyright Act (n 6), which is consistent with international copyright law and copyright law of most countries of the world in this regard.

¹⁰ A O Yusuff (n 4) 46-47. See also, J Asein (n 8) 75-78.

¹¹ A O Oyewunmi (n 2) 39. See also a detailed and well-articulated discussion of these issues in J Asein (n 8) 75-78.

¹² C Gringras, *The Laws of the Internet* (Butterworths 1997) 165.

¹³ H Klopper . T Pistorius , et al (n 3) 164; J O Asein (n 8) 82-85.

3. COPYRIGHT IN PHOTOGRAPH AND IMAGE CAPTURING: RIGHTS OF AUTHOR/OWNER

Photography is more ubiquitous now, than when it was developed over a century ago. Advances in information and communication technology translated to camera-capability for most handheld and mobile gadgets and devices, such as phones, tablets, personal computers, wrist watches, pens, audio/video recorders and so on. The result is that it has turned everyone with such devices into photographers. It is therefore so easy now to take pictures and to use any of the available photoshop or photo-editing applications or software to modify the pictures and enhance their qualities as desired. It was not so in the beginning, where the aesthetic quality, appeal and distinctiveness of individual pictures were dependent on how dexterous or talented the photographer was. However, regardless of the quality of photographs, copyright law classifies photographs as artistic works and confers authorship on the person who took the photograph.¹⁴ Authorship is hinged on the belief that she/he must have exercised judgment 'as to what to photograph, the arrangement of a scene, including positioning, lighting and other exercise of judgment, skill, or labour in taking the photograph'.¹⁵ It is thus the creativity and arrangements involved which determines the assignment of copyright in the photograph. As Lloyd J reasoned in *Creation Records Limited v News Group Newspapers*:

It seems to me that ordinarily the creator of a photograph is the person who takes it. There may be cases where one person sets up the scene to be photographed (the position and angle of the camera and all necessary settings) and directs a second person to press the shutter at a moment chosen by the first, in which case

it would be the first, not the second, who creates the photograph. There may also be cases of collaboration between the person behind the camera and one or more others in which the actual photographer has greater input, although no complete control of the creation of the photograph, in which case it would be the first, not the second, who creates the photograph. There may also be cases of collaboration between the person behind the camera and one or more others in which the actual photographer has greater input, although no complete control of the creation of the photograph, in which case it may be a work of joint creation and joint authorship.¹⁶

The photographer owns copyright in the photograph as a consequence of being recognized as the author of it. However, an author is only the first owner of copyright as the author might choose to alienate any or all of the rights that are recognized as exclusive to the author. Besides, an author of a photograph might not be the owner or able to exercise ownership rights over it if the photograph was created in the course of an employment or if she/he was commissioned to take the photographs, provided that an agreement exists to this effect.¹⁷ In this case, the employer or the commissioner owns copyright over the photograph, although the photographer may always be acknowledged as the author. Asein noted

It must be stressed that there is a clear difference between the author of a work and the owner with both having different legal consequences. Apart from the so-called moral rights, which are expressly reserved for the author, the economic benefits of copyright are

¹⁴ Copyright Act of Nigeria recognizes that artistic work includes, irrespective of artistic quality, photographs not comprised in a cinematograph film and further provides that author, in the case of a photographic work means the person who took the photograph. See s. 51 (1) Copyright Act, Cap C 28, Laws of the Federation of Nigeria 2004 (As amended). Similarly, s.1 (1) of the Copyright Act 98 of 1978 of South Africa provides that author, in

relation to a photograph is the person who is responsible for the composition of the photograph.

¹⁵ A O Oyewunmi (n 2) 39.

¹⁶ [1997] EMLR 444; [1997] EWHC Ch 370; See also a discussion of the case at <http://www.cjil.law.cam.ac.uk> accessed on 1 June 2018.

¹⁷ See s. 10 Copyright Act of Nigeria (n 6)

reserved for the owner rather than the author per se.¹⁸

Furthermore, as explained by Oyewunmi¹⁹

...copyright is deemed to be vested in the author of works made in the course of employment or pursuant to a commission, unless the case falls within the exceptions provided under the Act. Thus, a graphic artist who works full time as an employee for an advertising agency will own copyright in the drawings he makes for the firm's business purposes, unless he enters into a written contract which provides otherwise. Similarly, where an independent contractor/free lance writer is paid to do a write-up on another, or a free lance photographer, painter or artist is commissioned to take a photograph, paint a portrait or make a sculpture, as the case may be, ownership of the resulting works lie in the author/writer, photographer or artists respectively, and not in the person appearing in the work or the one who commissioned it.²⁰

Generally, an author or owner of copyright exercises either or both of two broad rights, namely, right of exploitation/commercialisation and what is called moral rights. In Nigeria, an author of an artistic work has the exclusive right to do or authorize the doing of any of the following acts,

(i) reproduce the work in any material form;

(ii) publish the work;

(iii) include the work in any cinematograph film;

(iv) make an adaptation of the work....²¹

A photographer, deemed to be the owner of a photograph, can exercise all rights incidental to that status, including the right to reproduce, publish or exploit the work as she/he may deem fit. As such, the photographer may distribute, share, exhibit, commercially exploit, duplicate and make use of the photograph in any other professional respect. Oftentimes, controversies break out between the photographer and the subject of the photograph who might find out that the photographer is not only freely using, utilizing and commercially exploiting the photograph containing her/his details without permission but is also able to restrict or control the use to which the person could put her/his own image, and especially able to sue a person for reproducing his/her her image!²² Oyewunmi noted that this default consequence, in the absence of a contrary and prior agreement, is definitely protective of the interest of authors but may 'run contrary to the reasonable expectations of members of the public who patronize creators, as they may find themselves being liable for infringing copyright in a work commissioned and paid for by them'.²³

Copyright ownership in situations where a photographer takes a photograph of a person who is aware that her/his photograph was being taken, someone who posed for the photograph or commissioned it, as explained above, is to a large extent, clear. Copyright is vested in the photographer who is employed or commissioned to take the photograph, except where a prior contract or

¹⁸ J O Asein (n 8) 125.

¹⁹ Op cit (n 2)

²⁰ Ibid 64; see also a detailed discussion of the general rule of ownership of copyright as well as ownership in the context of employee or commissioned works in Asein, (n 8) 125-132; Joe Walsh, 'who owns the copyright the photographer or the client' available online at: <http://www.own-it.org/news/who-owns-the-copyright-the-photographer-or-the-client> accessed 23 August 2016.

²¹ Ibid s.6. See also *Peter Obe v. Grapevine Communications Ltd* (2003-2007) 5 I P L R 354.

²² This was the experience of Tu Face Idibia, a music artiste, performer and award winner well-known in and outside Nigeria.

Tu Face got married with many celebrities in attendance as well as photographers, invited and uninvited. A particular photographer attended the wedding and took pictures, samples of which he sent to Tu Face who allegedly reproduced and shared the pictures without the consent or permission of the photographer. This irked the photographer who subsequently sued Tu Face and his wife for N120 million. It is not certain if they were able to reach an amicable settlement out of court or if the matter proceeded to trial. See R Oladimeji, 'Copyright: Photographer sues 2-Face, wife for N120m', *The Punch*, (Nigeria March 21 2016) 7.

²³ Oyewunmi (n 2) 64.

agreement exists to the contrary.²⁴ Where a contract exists, terms would normally specify what rights are accorded to the photographer, if any, after the work is done and submitted. In this case, the person whose image was captured exercises all rights in the photograph. In many cases, however, no prior contract exists and the person whose image is taken is left dazed that another owns the copyright in her/his image and can exercise extensive liberties over the image. It has been suggested that in the case of employee or commissioned works (photographs) without a prior contract, a licence to use the work freely might be inferred on behalf of the employer or commissioner, in short, the person whose photograph was taken, or alternatively that such an employer or commissioner might be deemed to be the equitable owner of copyright in the work.²⁵ This runs contrary to the clear position and provisions of copyright law. It is quite uncertain if courts would generally be willing to adopt such a liberal attitude except as justice of a particular case require. Therefore, the general position still prevails, regardless of how unfair it might seem.

A different scenario however, is where a photographer takes the photograph of individuals in a public or a private place, without permission, or indeed the knowledge of the individual. A related case would be where the individual is aware but is indifferent to the fact that his/her photograph is being taken. It is also possible, in the case of a group photograph, that persons concerned have no choice and cannot object to being captured in the photograph. In all these scenarios, the general rule presumably still applies. The photographer owns copyright in the photograph, since the scenarios preclude the existence of any contract or agreement about the photographs.²⁶ The natural consequence is that the photographer in the exercise of right of ownership in the photographs, might publish, share, exploit, distribute or

otherwise deal with the photographs in spite of the interest or rights of those captured.

The next segment of this paper examines the interests and rights of those whose photographs are taken by photographers, whether with their full knowledge and consent or otherwise, and limits that might be set to the exercise of rights of copyright owners in the photographs. Focus is specifically placed on privacy and publicity rights of individuals whose images or photographs are taken.

4. PRIVACY, PUBLICITY AND OTHER RIGHTS OF SUBJECT OF THE PHOTOGRAPH

In Nigeria, it is very common to attend social functions or festivities such as wedding ceremonies, funeral or burial programmes, conferment of chieftaincy or other titles of honour, high profile birthday bashes, house dedications, graduation ceremonies and so on, which are heavily photographed events. One could have been completely unaware of the time that the photographers took his/her pictures and would subsequently face the dilemma of accepting and paying for the unauthorized photographs or rejecting them and consequently leaving the image in the hands of complete strangers. One would have no inkling what it might subsequently be used for or where it would end up, and so naturally feel uncomfortable or concerned for any eventuality with respect to the photographs. Many such photographs have ended up published in newspapers as illustrations for how or how not to dress or behave while attending a public function. Besides, a person might accidentally be captured in a photograph or pose for a photograph that might be used by the photographer outside of the context it was taken or for commercial purposes. Furthermore, photographs could be taken in a purely private setting, possibly without permission to capture personal property such as the picture of a building, automobile, garden, animal/pet,

the photograph as there would be no privity of contract with the individual whose image was captured by the photographer were there to be a prior contract between the photographer and the employer or the commissioner, as the case may be.

²⁴ See s. 10 (2) Copyright Act of Nigeria (n 6).

²⁵ Oyewunmi (n 2) 65. The author cited in support of these positions, *Blair v. Osborne & Tomkins* [1971] 1 All ER 468 and *Pasterfield v. Denham* [1999] F S R 168.

²⁶ It makes no difference to this situation if the photographer was an employee of or commissioned by some other person to take

among others. Strictly speaking, ownership of copyright in the photographs taken in all these cases will remain with the photographer. However, individuals involved might claim privacy or publicity rights or generally, a right to control subsequent uses the photographer might make of the photographs.

A photographer might make use of the photograph in a manner that is harmful or offensive to the reasonable sense of dignity, honour, or reputation of the subject of the photograph. The photographer may for instance, lend the use of the picture, over which she/he owns copyright, to a cause morally objectionable or offensive to the conscience of the subject in the photograph, she/he might also put the photograph to a use that might expose her/him to public ridicule or opprobrium. Hence, the subject of the photograph would have a genuine concern and a justifiable interest in having some measure of control or restraint over how the picture is used. Consequently, a sort of moral right recognized in favour of the subject in such photographs seems appropriate.

Privacy right is generally considered as the right an individual has to be left alone, free from unwanted intrusion or access to his/her person or information.²⁷ It can be described as the state of reasonable desired in access or freedom from unwanted access. In this case, access means perceiving a person with one's senses (seeing, hearing, touching), obtaining physical proximity to him or her and or obtaining information about him or her.²⁸ Privacy also entails that information about an individual or an individual's activities should not be collected, disseminated or shared with any other person.²⁹ Consequently, it amounts to a breach or an invasion of an individual's privacy to take his/her picture,

particularly without the individual's knowledge, consent and/or permission. It might be assumed that no individual is entitled to a claim of privacy if that person is in a public place and consequently that it is not an invasion of privacy to take a picture of that individual in the public place. This might hold feebly as a general rule but whether a person is entitled to privacy in a public place or not depends on if that person has a reasonable expectation of privacy in the public place.³⁰ It might be okay to take the pictures in a public place and capture along with other persons and objects in the picture, people who come within the focus of the photographer's camera. It is a different issue however, if the photographer deliberately lines up a direct and clear shot of an unsuspecting or innocent person in the public place. The public character of a place is generally determined by its open accessibility to the entire community.³¹ Thus, streets, public parks, playgrounds, public transit systems, areas where educational institutions are located and hospitals are usually classified as public places.³² Access to such places could be free or based on the satisfaction of some conditions, payment of fees for example; it would still be a public place as long as anyone is at liberty to go to such a place. The implication is that, regardless of ownership rights in resulting photographs, photographers and photo-journalist must appreciate the limits of their liberties to take pictures of individuals in public places. It should not be subject to any debate however, that photographers cannot freely take or distribute pictures of things or persons in private residences and places.³³ This is more important because, in Nigeria as in most other countries, the right to privacy is basically constitutional while ownership right in photographs is statutory under the Copyright Act.³⁴ Hence, privacy right generally carries

²⁷ Don R Pember, *Mass Media Law* (Mc GrawHill 2003-2004) 230-241.

²⁸ N A Moreham, 'Privacy in Public Places', *Cambridge Law Journal*, (2006) 65 (3), 617.

²⁹ *Ibid.*

³⁰ For a very detailed analysis and discussion of the concept of 'reasonable expectation of privacy' as well as claims of privacy in public places, see A O Yusuff, 'Legal Issues and Challenges in the Use of Security Cameras (CCTV) in Public Places: Lessons from Canada', (2011) *SLJIL*, 23, 33-75.

³¹ *Ibid.*

³² See, 'Rules for use of Surveillance Camera in Public Places by Public Bodies in Quebec', available at: http://www.cai.gouv.qc.ca/06_documentation/01_pdf/new_rul_es_2004.pdf accessed 17 February 2007.

³³ Samuelson-Glushko, 'Copyright in Photographs' available online at: https://cippic.ca/en/FAQ/Photography_Law accessed 23 August 2016.

³⁴ S. 37 of the 1999 Constitution of the Federal Republic of Nigeria provides that 'The **Privacy** of citizens, their homes, correspondence.....is hereby guaranteed and protected' (emphasis, mine); while s. 1 (3) of the same constitution states

more weight. Where a photographer's capturing and distribution of an individual's photograph amounts to an improper use or causes some loss or damage to the individual, this might further give rise to a civil or possibly criminal remedy³⁵ against the photographer notwithstanding the photographer's copyright in the photograph.

Furthermore, individuals may also claim or be entitled to publicity right. This, more or less emerging right, is the right of any living person to forbid the use of her/his name, photograph, likeness or image for commercial purposes without his or her consent.³⁶ Privacy and publicity rights reflect separate and distinct interests from copyright interests. 'While copyright protects the copyright holder's property rights in the work or intellectual creation, privacy and publicity rights protect the interests of the person(s) who may be the subject(s) of the work or intellectual creation'.³⁷

The issue in contention was clearly analysed thus:

The distinctions among privacy rights, publicity rights, and copyright are best illustrated by example, as follows: An advertiser wishes to use a photograph for a print advertisement. The advertiser approaches the photographer, who holds the copyright in the photograph, and negotiates a license to use the photograph. The advertiser also is required to determine the relationship between the photographer and the subject of the photograph. If no formal relationship (e.g., a release form signed by the subject) exists that permits the photographer to license the use of the photograph for all uses or

otherwise waives the subject's, sitter's or model's rights, then the advertiser must seek permission from the subject of the photograph because the subject has retained both privacy and publicity rights in the use of their likeness. The privacy right or interest of the subject is personal in character, that the subject and his/her likeness not be cast before the public eye without his/her consent, the right to be left alone. The publicity right of the subject is that their image may not be commercially exploited without his/her consent and potentially compensation.³⁸

It is clear therefore, that a photographer must recognize that an individual who has been photographed might also be entitled to publicity rights, which make it imperative that the photographer refrain from exercising too much liberty with the photographs over which she/he claims copyright. The right of publicity, for instance, forbids anyone taking photographs of a performer in a live performance without prior authorization or permission, for that would be an illegal fixation of the performance which is tantamount to an infringement of the right of the performer.³⁹ In the words of Rich Stim,

The right of publicity grew out of the general principles of invasion of privacy that prohibit using a person's name or likeness to gain a benefit. Within the past few decades, the right of publicity has emerged as an independent type of claim that a person can make when his or her name or likeness is used for commercial purposes. Although the right of publicity is

that 'If any other law is inconsistent with the provisions of this Constitution, this Constitution shall prevail, and that other law shall to the extent of the inconsistency be void'.

³⁵ Such remedies include civil damages for invasion of privacy, injunction from further invasion of privacy or dissemination of offending material, civil or criminal suit for defamation, demand for apology and/or retraction of the offending material.

³⁶ The Library of Congress (American Memory), 'Privacy and Publicity Rights' available at <https://memory.loc.gov/ammem/copothr.html> accessed 23 August 2016.

³⁷ Ibid.

³⁸ Ibid.

³⁹ The Copyright Act of Nigeria provides in s. 26 (1) that a performer shall have the exclusive right to control, among others, the 'recording' or the reproduction of his performance in 'any material form'. It is unarguable that taking still photographs of a performance is a reproduction in a material form. See also the case of *Zacchini v Scripps-Howard Broadcasting* 433 U.S. 562 (1977).

commonly associated with celebrities, every person, regardless of how famous, has a right to prevent unauthorized use of their name or image to sell products. This right also prohibits any implication that a person endorses a product (without the person's permission).⁴⁰

A similar sentiment was expressed when Lynne M. J. Boisineau stated,

On the most basic level, the right of publicity is an individual's right to prevent others from commercially exploiting his or her identity without permission. Given the way that this area of law has been trending, that right is available to virtually everyone, not just to A-list celebrities. If you violate someone's right of publicity, you can be forced to take down the content in question and/or pay monetary damages to that individual.⁴¹

It can therefore be seen that right to privacy, publicity rights and the right to have one's reputation untainted act as restraints on the right of photographers in the use of photographs in which they have copyright ownership.⁴² As a general rule, a photographer may always exercise the

rights of an author and owner of the photograph under the copyright law, including the right to share, reproduce and commercially exploit the photograph. However, important limits are and should be set to regulate the exercise of these rights in the contexts discussed above and given the prevailing astronomical growth in the modeling, advertisement, product endorsement, sponsorship, character merchandising and other related industries.⁴³ In its work on IPRs in the advertising industry, the World Intellectual Property Organization (WIPO) cautioned advertising agents and their corporate clients to note that a 'person's identity, such as his or her name, photograph, image, voice or signature may be protected by publicity or privacy rights'.⁴⁴ Furthermore, the unprecedented expansion and utilization of the digital environment, social media in particular, makes it imperative to note and address the inevitable clash of rights and interests between photographers and the people captured in their photographs.⁴⁵

5. CLASH OF RIGHTS AND INTERESTS WITHIN AND OUTSIDE THE DIGITAL ENVIRONMENT

As demonstrated in the section above, in jurisdictions where such rights are recognized and enforced,

⁴⁰ Rich Stim, 'The Right of Publicity' available at <http://www.nolo.com/legal-encyclopedia/the-right-of-publicity.html> accessed 23 August 2016.

⁴¹ Lynne M.J. Boisineau, 'Intellectual Property Law: The Right of Publicity and the Social Media Revolution', available at http://www.americanbar.org/publications/gp_solo/2013/may_june/intellectual_property_law_right_publicity_and_social_media_revolution.html%22.html accessed 23 August 2016.

⁴² In setting out the differences between the right to privacy and publicity as causes of action under the appropriation tort, Pember (n.27) 234 stated

The differences between the two are small but important. The right to privacy protects an individual from the embarrassment and humiliation that can accrue when a name or picture is used without consent for advertising or trade purposes....The right to publicity, on the other hand, protects individuals from the exploitation of their name or likeness for commercial purposes. In other words, someone is making money by using another individual's name or photo. The right to privacy protects a personal right; the right to be free from such humiliation or embarrassment. The right to publicity protects a property right; the economic value in a name or likeness.

The right to have one's reputation untainted is enforced through the tort law of defamation.

⁴³ With respect to character merchandising and publicity rights see a very detailed and cross jurisdictional analysis and discussions in Tanya Aplin and Jennifer Davis (n 2) 339-379. For robust judicial decisions on the nature and implications of the right of privacy and publicity see also the following cases- *Haelan Laboratories, Inc. v Topps Chewing Gum, Inc.* 202 F. 2d 866 (2nd Cir. 1953); *Eastwood v. Super. Ct. (National Enquirer, Inc.)*, 149 Cal. App. 3d 409, 417 (1983); *Michaels v. Internet Entertainment Group, Inc.*, 5 F. Supp.2d 823, 837 (1998); *KNB Enterprises v. Matthews*, 78 Cal. App. 4th 362, 374-75 (2000). The core principle established by the courts in these cases is that it is actionable against a person or entity to create false and misleading impression that a celebrity or another person is associated with or endorsing a product or service.

⁴⁴ World Intellectual Property Organization, Managing Intellectual Property in the Advertising Industry, Creative Industries-Booklet No. 5, 34-38.

⁴⁵ Writing on information revolution and the digital explosion, E Lederman, *Infocrime- Protecting Information Through Criminal Law*, (Edward Elgar Publishing 2016) 13ff stated

Never before has there been such an immense quantity of accumulated information expressed in an assortment of regular and electronic communicative messages, including writings, electronic data, recordings, photographs and drawings covering a wide range of issues and fields. Nor has there ever been such a surge in the production, storage, processing and distribution of that information.

celebrities have publicity rights and every other person equally has this right in addition to privacy rights and the right to the protection of personal information and reputation from defamation. Photography has been an enduring preoccupation through the ages; as a distinctive profession and as a hobby. There have been meteoric advances in information and communication technology (ICT). There have also been notable innovation and developments in digital and internet compatible devices.⁴⁶ Consequently, most mobile/electronic devices now come with cameras with the capability to capture and store images and sounds. Furthermore, nearly all social media platforms have buttons or icons which one can hit to 'send', 'forward', 'copy' and/or 'share' content, whether still images (photographs), sounds or videos. The result of this trend is the creation of enhanced opportunities to take photographs and have them used and distributed far beyond the imagination and reach of the photographer.

Yet, there is potentially a lot of financial value or commercial worth in photographs, whether of ordinary, everyday people or of celebrities.⁴⁷ In Nigeria today, the entertainment sector, especially the movie and music industries have grown into a multi-billion naira sector. Artistes, performers, actors, actresses, 'On-Air Personalities' and other celebrities earn significant sums of money from service and product endorsements, sponsorship and advertisements. Many of them are appointed as brand 'ambassadors' by big companies and multinationals, such as the telecommunication giants;

MTN, Globacom, Etisalat (Now, 9-Mobile); Banks and Finance Houses; Automobile companies; and many others. More often than not, the appointments are made under contracts which exclude the use of the image or association of the particular individual with any other brand, whether in a competitive business or not. It is then easy to imagine what financial disaster could befall a celebrity or other individual if a photographer would take a photograph, share it and have it deliberately or fortuitously associated with a contract infringing product or service. The exercise of the right of the photographer to share and deal with the photograph of which she/he is the author or owner will thus spell doom for the interest of the person photographed.

Contracts between the photographer and the photographed person, specifying the scope of rights and entitlements of both parties can go a long way to preempt, prevent and resolve potential conflicts. For example, a photo release⁴⁸ agreement signed prior to or during the course of taking the photograph will cede control or ownership of the photograph to the individual photographed, while a model or celebrity photo release contract⁴⁹ will enable a photographed person to use and clearly specify the parameters of such use a photographer might make of the photograph. The position of the law where a photograph was taken under a contract of employment or while commissioned is quite clear and largely settled. It is in instances where the signing of a prior contract between the photographer and the subject of the photograph is impossible or was never even

⁴⁶ Africa, particularly Nigeria, have been drawn into the mainstream of this developments and her residents, regardless of the level of education or literacy, are taking full advantage to participate and enjoy all that the ICT and internet systems have to offer. See A O Yusuff, 'Employing Legal and Policy measures to tackle electronic Infringement of Copyright in Nigeria', (2008) 6 *Igbinedion U LJ*, 124-125.

⁴⁷ A couple of years ago in Nigeria, a young woman hawking bread on a street in Lagos, accidentally walked into a photo-shoot by a Photographer and her team. The young woman, Olajumoke Orisaguna, was thus captured among the pictures taken by the photographer contracted for the photo-shoot, who promptly saw the modeling potential of the young woman. Subsequently, she was invited and became an instant hit when the photographer arranged for her to model. Within a very short time, Olajumoke Orisaguna became a celebrity and started

earning big money beyond her wildest imagination and far from what she could possibly earn in decades of hawking bread. See 'Olajumoke Orisaguna-Biography' available at https://en.wikipedia.org/wiki/Olajumoke_Orisaguna accessed 30 May 2018; See also 'Former Bread Seller Olajumoke Orisaguna Goes back to her root to give back for the new year' available at <https://www.informationng.com/2018/01/former-bread-seller-olajumoke-orisaguna-goes-back-root-give-back-new-year.html> accessed 30 May 2018.

⁴⁸ See Photo Release Form, available at <http://www.studiobinder.com/blog/photo-release-form-template/> accessed 23 August 2016.

⁴⁹ See Model Release Form, available at <http://www.studiobinder.com/blog/model-release-form-template/> accessed 23 August 2016.

considered, that copyright law is required to clarify ownership.

This paper has largely proceeded, before now, on the assumption that ‘photographers’ are basically professionals, people who make photography their vocation and derive their living from it. Another loose assumption is that the photographs under discussion are of living persons. It is however worthy of note that the discourse is equally relevant to, and more particularly affects amateur photographers, freelance photographers, those who pursue photography as a hobby, everyday users of phones and other mobile or handheld devices with camera capability, and even kids playing with cameras.⁵⁰ The discourse is also applicable to pictures of objects and things (whether or not in the care or custody of identifiable individuals), with which prior contracts are inconceivable.⁵¹ Professional photographers are expected to be fairly familiar with copyright and other legal rules affecting their work and so might not be so much at a loss as to what legal rules obtain in specific instances. This expectation is less likely where other categories of ‘photographers’ are concerned. Iconic pictures can be taken quite accidentally and by persons who know little or nothing about rules of photography, including rules as to how to take the best photographs and rules as to legal implications and applicable principles.⁵² All these instances have been the key focus of this paper and precisely the reasons reform or additional copyright rules with respect to photographs are imperative.

6. CONCLUSION

The foundation of copyright is a balancing of rights - a balance of the right of the copyright owner and the right of society to access and enjoy the benefit of advances in the arts, science and technology. Copyright has equally, over time, been stretched to accommodate new methods of creative expression and other cases deemed deserving of protection as intellectual or industrial property. This balancing role and equitable flexibility of copyright should come into play in handling the clash of rights between photographers and people captured in their photographs. Several cases have been decided, especially in North America where rights to privacy as well as publicity rights are recognized. The cases do not seem to establish clear and predictable directions in resolving cases involving clashes between copyright, privacy and publicity rights. In any case, issues are still arising and developing in this area; more people will take to photography whether as a hobby or as a profession. At the same time, the expectation is that the entertainment, advertisement and creative industries would continue to explode in Africa similar to other parts of the world, having photography and image capturing at its center, coupled with unprecedented expansion and utilization of digital platforms, including the social media. It is thus imperative that copyright law should adapt to the prevailing realities of the century and attempt to balance these competing but not necessarily opposing rights and claims. Over time, copyright law had demonstrated the ability to adapt and accommodate changing templates of creativity. In the current situation, the balancing act should not be left to judicial evolution.

⁵⁰ It is indeed possible for an animal to take photographs as was the case when in 2011 ‘Naruto’, a rare macaque monkey, shot a ‘selfie’ where it appears to be smiling when it picked up a British photographer, David Slater’s camera. See Samuel Osbourne, ‘Monkey selfie Case: Photographer wins two year legal fight against Peta over the image copyright’ available at <https://www.independent.co.uk/news/world/americas/monkey-selfie-david-slater-photographer-peta-copyright-image-camera-wildlife-personalities-macaques-a7941806.html> accessed 30 May 2018. See also ‘Monkey who snapped viral selfie Doesn’t own copyright, Rules US Court’ available at <https://www.ndtv.com/offbeat/us-court-rules-monkey-naruto-doesnt-own-selfie-peta-cries-discrimination-1842394> accessed 30 May 2018.

⁵¹ For example, a Californian jury ordered a beverage company to pay the sum of \$710,000 to a cat over the unlawful use of its identity. The owner of the cat, Tabatha Bundesen filed and won the lawsuit on its behalf. See ‘Cat wins \$710,000 in Copyright lawsuit’ available at <http://punchng/cat-wins-710000-in-copyright-lawsuit> accessed 5th February 2018.

⁵² In the matter of Naruto selfie photograph, (n.50) controversy broke out as to who would be the author of the photograph taken by the monkey. A San Francisco court, in agreement with the US Copyright office, determined that human authorship is a requirement for copyright protection and therefore Naruto cannot own photographs it took!

One of the situations that should attract reform attention is the extant provision of copyright law relating to copyright ownership of photographs in the absence of a prior written contract. The current position is that the photographer is the author and possibly the owner of copyright in the photograph she/he took, but the question is whether there can be a room for shared rights between the photographer and the individual captured in the photograph.⁵³ This is comparable to and can be an extension of the existing rule of copyright ownership in employee or commissioned photographs. Thus, it could be provided that where there is no prior contract between a photographer and the person captured in the photograph, the author/photographer is obligated to obtain the permission of the person before sharing the photograph and where the photographer chooses to commercialise/exploit the photograph, she/he would be obliged to share part of the proceeds with the photographed person. If this is made a general provision of the copyright law, it then becomes immaterial that there was no prior contract between the parties. The result would be less conflict in this still growing area.

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⁵³ Wherever this sense is created in this paper at this stage, it should be taken to include persons in charge or in custody of the objects or things captured in the photograph.

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DIGITAL COPYRIGHT ISSUES IN MOROCCAN SCIENTIFIC RESEARCH AND HIGHER EDUCATION: THE NEED FOR UP-TO-DATE LEGISLATION

Khalid Chaouch*

ABSTRACT

In spite of being a developing country, Morocco has adopted a substantial number of intellectual property (IP) laws closely modelled on most international conventions and treaties that deal with copyright and related rights. In the last twenty years, Morocco has reinforced its legal framework with adequate legislation in the field of intellectual and industrial property. Yet, it is still in need of more efficient and up-to-date provisions on digital copyright protection in the field of scientific research. Passing new legislation to complement the existing laws will certainly fill the current legislative gap on the management of digital copyright in scientific research and higher education. The present paper intends to show how the adoption of this legislation will certainly strengthen the protection of the works of researchers and higher education institutions, especially in Morocco. The aim is to attract the attention of Moroccan policy makers to the urgent need to provide more robust and up-to-date legislation in matters of digital copyright management for Moroccan academics and scientific researchers, both as individuals and as institutions. Facilitating innovation and the effective protection of works in the digital realm will certainly empower researchers to publish their digital works and protect them against new forms of digital infringement.

Keywords: Copyright, IP, Morocco, Digital, Higher Education, Scientific Research, Academia.

1. INTRODUCTION

With the advent of the Internet and developments in information technologies, various issues related to copyright have arisen. Many of these issues are still

developing and have not yet been addressed by legislators at the national level. Though a developing country, Morocco has adopted a substantial number of IP laws closely modelled on most international conventions and treaties that deal with copyright and related rights. Yet, it is still in need of clear, efficient, and up-to-date provisions on digital copyright protection in the field of academic scientific research in particular.

The aim of this paper is to draw Moroccan policy maker's attention to the fact that there is an urgent need to provide more efficient and up-to-date legislation in matters of digital copyright management for Moroccan academics and scientific research both as individuals and as research labs and research centres. The paper also intends to address new forms of piracy and infringement that have emerged with the continuous advancements in digital and cyber technology. Some of the solutions suggested in this context would empower the Moroccan Copyright Office to reconsider copyright management and make it more efficient, especially in the context of academia.

These issues require the collaboration of many stakeholders, including Moroccan researchers and academics themselves as there is, indeed, a strong need for more dissemination of copyright culture and increased IP awareness amongst academics. At the regional level, Morocco is urged more than ever to opt for more collaboration with African countries in matters of copyright protection and innovation in a globalized world.

2. COPYRIGHTABLE DIGITAL WORKS IN MOROCCO

Morocco has a significant progress trajectory in recent years within the ranking of the Global Innovation Index 2015 where it currently ranks 72nd out of 141 countries. It is positioned as one of the highest ranked in North Africa. It is particularly distinguished for the protection of the results of university scientific research.¹ More recently,

* **Dr. Khalid Chaouch** is currently teaching Moroccan Anglo-American Relations, Drama and Theatre, and Film Analysis at Sultan Moulay Slimane University, Beni Mellal, Morocco. He has

contributed to national and international journals with papers on cross-cultural studies, film analysis, and travel writing.

the US Chamber International IP Index ranked Morocco 21st among the 49 countries included in the report.² Based on 23 indicators, Morocco showed a remarkable progress in the areas of industrial patents and trademarks; its efforts to preserve intellectual and industrial property, at the levels of legislation and enforcement are also significant. These achievements indicate the potential of the Moroccan economy and underline the importance of scientific research and its results in the economic sector. Moroccan academia's entry into the global digital hub should be bolstered by the adoption of special IP management provisions. The protection of academic research in digital form is in need of efficient and up-to-date legislation more than ever.

2.1. Protection of scientific research and academic production

Scientific research and academic productions in Morocco are regulated and organized by the 01.00 framing Law (19 May 2000) on higher education. This text, however, says very little about the protection of university scientific research. The only mention of academic IP comes in the context of the relation between universities and the business sector. According to this law, universities can provide – by convention – services in return for remuneration; can create innovative business incubators; exploit patents and licenses; and commercialize the products of their activities.³

At the institutional level, Morocco has implemented a series of measures since the beginning of the 21st century to reform its academic research system. These have mainly included reorganizing the National Centre of Scientific and Technical Research (CNRST) in 2000, establishing the Permanent Inter-ministerial Committee for Scientific Research and Technological Development in 2001, creating the Moroccan Institute for Scientific and

Technical Information (IMIST) in 2001, establishing Hassan II Academy of Science and Technology in 2004, reorganizing the Higher Council for Education, Training and Scientific Research in 2006, as well as establishing the Moroccan Foundation for Advanced Science, Innovation and Research in 2007.⁴

At the level of national IP legislation, the protection of authors' rights in scientific research and academic production is mainly provided for in Law n° 2-00 (15 February 2000) on copyright and related rights, which was first amended by Law n° 17-97 (14 February 2006) and Law n° 79-12 (20 May 2014) on the right to make a private copy. According to these laws, the scope of protection includes all literary and artistic works as well as all intellectual creations, such as written works, oral communications, allocutions, sermons, dramatic, musical and audio-visual works illustrations, geographical maps and designs (Article 3 of Law 2.00/2000). As for remuneration, Article 48 stipulates that, with regard to copying carried out by bookstores, the first edition may be subject to a lump sum fee given an express written agreement with the author. That framework is permitted in the cases of scientific and technical books, anthologies and encyclopedias, prefaces, annotations, introductions, presentations, illustrations of works, and limited luxury editions.

Articles 7, 15, 17 and 23 provide for exceptions for particular matters in education and teaching, namely as regards use and reproduction of "lawfully published work such as illustration in publications, radio broadcast programs or sound or visual recordings, journal papers" as long as they are destined for teaching and scientific research. The arrangement under this law also allows

¹ Caroline Rolshausen, 'La Propriété Intellectuelle au Maroc', Institut National de la Propriété Industrielle (INPI), France. June 2017, 5. <<https://www.inpi.fr/fr/la-propriete-intellectuelle-en-afrrique-du-nord-maroc>> accessed 27 March 2018.

² U.S. Chamber of Commerce's Global Innovation Policy Center, *US Chamber International IP Index – 6th Edition* – February 2018.

<https://www.uschamber.com/sites/default/files/023331_gipc_ip_index_2018_opt.pdf> accessed 25 March 2018.

³ Article 07 of Law 01.00/2000.

⁴ Conseil Supérieur de l'Éducation, de la Formation et de la Recherche Scientifique. *Rapport thématique. Évaluation du cycle doctoral pour promouvoir la recherche et le savoir*. Rabat, 2017, 9.

“public performance of a work when this is done within the framework of the activities of an educational institution, for personnel and students of such institution, if the audience is composed exclusively of personnel and the students of the institution, or the parents or the supervisors or other persons directly linked to the institution’s activities”.⁵

Patents can also be products of academic scientific research in Moroccan universities. They are regulated by Law n°17-97 (18 March 2004) on the protection of industrial property as amended and supplemented by Laws 31-05 (14 February 2006) and 23-13 (21 November 2014), with nearly 60 Articles (30-89 in Chapters II and III) on patent provisions.⁶ Most of these articles conform to those of the Paris Convention for the Protection of Industrial Property (1883) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement, 1994) on the scope of patent protection and patentability.

Though this law does not mention directly the university as a source of and incubator of patents, it organizes the relation between the creator of a patent and its user. Among the provisions that could be of relevance to universities' scientific research, this law stipulates that the inventions made by the employee in the performance of either an employment contract involving an inventive mission corresponding to his/her actual duties, or studies and research, belong to the employer. It also provides that the conditions under which the employee (the inventor of the invention) benefits from additional remuneration are determined by collective agreements and individual work contracts (Article 18 of Law 17-

97/2004). These and other provisions in this Article apply to cases where the inventor is an employee of a business from the public sector.

When it comes to university researchers, it is hard to determine whether this law applies because, in the Moroccan context, university staff are public sector employees. Moroccan university teachers and researchers have not the same status as employees in the private economic sector. As the Moroccan public university is not yet fully independent 'enterprises', further legislation is needed to provide for its researchers.

More recently, the role of the universities in increasing valorization of research results has been reconsidered. The recent National Strategy, issued by the Ministry of Higher Education, encourages universities to carry out research and development for the benefit of companies, especially small and medium-sized enterprises, in order to help them achieve innovation-based development.⁷ The Strategy mainly calls for the building of a national system of research and innovation (SNRI) that would be equipped with the necessary capabilities to generate valuable research results, transform these into inventions or other intellectual works through R&D processes. The system also aims to valorize these inventions and intellectual works in innovations by incubation projects and innovating companies.⁸ This implies that the relationship between university scientific research and the industrial sector is still at a phase of launching new strategic plans and programs. The situation is further worsened by the “absence of tax incentives for Moroccan companies to conduct R&D and innovation” which consequently means that “a long way is needed to move towards a knowledge-based economy”.⁹

⁵ Saïd Aghrib, Noufissa El-Moujaddidi and Abdelmalek El-Ouazzani, *ACA2K Country Report, Morocco* (African Copyright and Access to Knowledge Project 2009) 17 <<http://www.aca2k.org/attachments/ACA2K%20Morocco%20C.R.pdf>> accessed 28 April 2018.

⁶ Law 31-05, amending Law 17-97 on the Protection of Industrial Property, promulgated by Dahir 1-05-190 of 14 February 2006, BO 5400/316; Law 23-13, amending Law 17-97 on the Protection

of Industrial Property, promulgated by Dahir n°1.14.188 of 21 November 2014, BO 6358/2885.

⁷ Ministère de l'Enseignement Supérieur, *Stratégie nationale pour le développement de la recherche scientifique à l'horizon 2025*, 15.

⁸ *ibid* 16.

⁹ Conseil Supérieur de l'Éducation [4] 49.

Repositioning Moroccan universities within IP legislation and empowering their role within the economic sector pose indeed a challenge. Facilitating innovation and promoting patentability among researchers and academicians will certainly empower them to publish their works in digital form and to protect them from the new forms of digital infringement.

2.2. Protection of digital works in Morocco

Morocco has substantially developed the area of IP legislation, which is consistently updated to reflect most international conventions and treaties in copyright and related rights (since 1916), including the TRIPS Agreement, the WIPO Performances and Phonograms Treaty (WPPT, 1996) which Morocco acceded to in April 2011, and the WIPO Copyright Treaty (WCT, 1996), which Morocco signed in July 2011. The WCT, which deals with ‘the protection of works and the rights of their authors in the digital environment’, also provides legislation on some other subject matters to be protected by copyright: ‘computer programs, whatever the mode or form of their expression’ (Article 4), and ‘compilations of data (databases)’ (Article 5). The WPPT and WCT, known as the ‘Internet Treaties’, were designed to face the new challenges posed by the digital environment that began to influence the Copyright concept in the mid-1990s.

Authors’ rights in Morocco are also governed by most of the other international agreements such as the Berne Convention for the Protection of Literary and Artistic Works (1888), and its subsequent Acts. The country is also a signatory of the Anti-Counterfeiting Trade Agreement (ACTA), signed in Tokyo in 2011, designed to provide for more effective anti-counterfeiting measures on a global scale and to develop international standards and enforcement procedures of IP legislation especially in the digital environment. In 2013, Morocco hosted and signed (in 2014) the Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually

Impaired or Otherwise Print Disabled (Marrakesh VIP Treaty), which also includes provisions for the access of the ‘blind and visually impaired or otherwise print disabled’ to digital materials.

This long tradition in IP legislation was nationally commemorated by the IP week in Casablanca (13-18 May 2016) to mark the centenary of the first law on Industrial Property in 1916. Moroccan involvement in most of the treaties concerned with IP protection, on the one hand, and the significant legislative corpus that it has developed, on the other hand, attest to the importance that this country confers on the matter. Both facts have certainly been decisive tools in promoting innovation and facilitating Moroccan immersion in global economic networks. From a benchmarking perspective, Morocco has attained a good position among developing countries.

At the institutional level, two national bodies are concerned with the management and protection of intellectual and industrial property in Morocco: the Moroccan Copyright Office, known as BMDA (Bureau Marocain du Droit d’Auteur) and the Moroccan Office of Industrial and Commercial Property, known as OMPIC (Office Marocain de la Propriété Industrielle et Commerciale). The BMDA was created in 1965 as a replacement for the two former offices created during the colonial period.¹⁰ The fact that this institution works under the Ministry of Culture and Communication is a very positive point, as it places this Moroccan CMO, the BMDA, at the heart of the communication hub. Yet, the project of transforming the Moroccan Copyright Office (BMDA) into a public autonomous institution might very well be a better solution as it will put it above the possible pressures and influences of organizational or political lobbying.

2.3. The rise of new digital materials

It goes without saying that information technologies have revolutionized not only education but the techniques of

¹⁰ The two colonial-era offices were the ‘Bureau africain des droits d’auteurs’ and the ‘Bureau africain des gens de lettres et auteurs de conférences’, both created in 1943.

scientific research themselves. While these technologies have provided researchers with access to unprecedented amounts and systems of digital material, multimedia and information, they have exposed the results of their works to challenging modes of exploitation and use. Even the notion of authorship is under significant transformations with the unprecedented possibilities given to users and learners side by side with authors and creators, to the extent that the traditional division between them are more and more flimsy. Richard Hooper is right to observe that, in the analog world, “users and creators were two different species”, while “in the digital world those species have blended – users are creators and creators are users”.¹¹ In such a digital context, machine learning, for instance, involves using and analyzing data sets that may include in some cases material protected by copyright. So there should be sensible limitations as these “non-expressive and intermediate uses of copyrighted works cause no harm to the market for copyrighted works”.¹² This is rather a good example of “how well-designed limitations on copyright can and should help spur economic growth, competition and innovation.”¹³

In their efforts to profit from the growing scope of the digital economy, more particularly for the development of electronic commerce, some institutions of higher education have already established their own structures to be in tune with the rising demands of this digital hub. These include the National Institute of Post and Telecommunications, the International University of Rabat and its future Digital University, Ibn Zohr University in Agadir with its Moroccan Virtual Campus (known as CVM), higher Business Schools, in addition to the National Centre of Scientific and Technical Research (CNRST).¹⁴

Moreover, most of the Moroccan universities have now developed a digital campus that facilitates eLearning.

This proliferation of digital learning and the possibilities of connecting academia to industry are posing new challenges at the level of IP protection and management. Indeed, one of the reasons that pushed the Moroccan legislator to amend the 2000 law was the rise of some digital and internet issues at the beginning of the millennium. Though the amendments made to the 2000 law were mainly on the extension of the term of protection (70 years instead of 50), the electronic forms of certain objects of protection were also stressed. This is the reason why the clause “including the temporary storage in electronic form” is repeated in the amending law in Articles 10 (a), 50 (d), and 51 (a); the clause “electronic rights management information” comes to amend Article 65 (h); and the clause on an “e-mail and the electronic signature” is twice mentioned to amend and complete Article 65 (6.13 (6) and 65-14 (B.6)).

Moroccan academia is now producing copyrightable digital works in the form of literary and scientific works, including novels, theatre plays, illustrations, scientific papers and reports. Both national legislation and international treaties to which Morocco is a signatory (the TRIPS Agreement and the WCT, in particular) provide for the protection of computer programs and compilations of databases.¹⁵ Yet, issues of authorship of certain computer outputs (whether in source code or in machine readable forms) need to be clearly defined, and their copyright ownership need to be assigned as an IP asset to professors-researchers, or to the university to which they belong, or to both of them. In addition, a plethora of other digital materials have emerged such as online applications (Apps), creative dynamic websites (either

¹¹ Richard Hooper, ‘UK’s Copyright Hub: a license to create’ (2016) *WIPO Magazine* 2, 32.

¹² Fred Von Lohmann, ‘Google on what is driving creativity and innovation in the digital economy’ (2016) *WIPO Magazine* 2, 28.

¹³ Ibid.

¹⁴ Alain Ducass and Jean-Marc Kwadjane, *Le Commerce électronique en Afrique Maroc, Tunisie, Sénégal et Côte d’Ivoire. Recommandations pour l’intégration régionale en Méditerranée*. Institut de Prospective Economique du Monde Méditerranéen

(IPEMED), 2005, 34. <http://www.ipemed.coop/admin/ipeмед/media/fich_article/1460888627_ipemed-commerce-en-afriquebd.pdf> accessed 2 April 2018.

¹⁵ Moroccan copyright Law n° 2.00 and its amendments provide for computer programs and compilations of data in Articles 3 (b), 5 (b), 10 (d), 12 (c,d), 16, and 21. TRIPS Agreement provides for them in Article 10, and WCT in Articles 4 and 5 respectively.

protected by password or not), and tutorials. At the level of teaching, a number of pedagogical methods and tutorials, in the form of machine learning, online courses and MOOCs, and Moodle platforms courses and media have also come to diversify the pedagogical activities of academia. Added to this, a set of modes and practices have arisen with the technical advancements in ICT, mainly having to do with downloading, uploading, and transforming copyrighted or copyrightable material. These new 'derivative' and 'transformative' works also need to be addressed in clearer legislative provisions that would meet the requirements and particularities of the Moroccan academic contexts.

2.4. The need to update national legislation

Morocco has recently reinforced its legal framework with adequate legislation in the field of commercial and industrial property, but it needs more efficient and up-to-date legislation on digital copyright protection in the field of academic scientific research. There is a pressing need to adopt additional provisions to address digital matters in harmony with more recent international rules and standards. Providing new legislation to complement existing Moroccan law, and the setting of African frameworks in this sense, all in harmony with international legislation, will certainly fill the existing gaps in the national legislation on the management of digital copyright works on scientific research and higher education.

As a case in point, the Moroccan law on industrial property (17-79/2004) regulates the relation between the patent inventor and the institution to which they belong. However, the relevant provisions in Articles 18 and sub. can be more applied to the case where the patent inventor is an employee of a particular business; when it comes to the university researcher, this law cannot apply because, in this case, the inventor is at the same time an employee of the public sector and a functionary of the

university, which has not yet acquired all its financial independence and entrepreneurial autonomy. The possible solution, in this case, would be to provide special legislation that would 'calculate' the possible share of each (the university and the researcher) in the patent assignment or licensing revenue etc. A reconsideration of the way university patents are managed is also to be provided for.

New provisions on the rising digital issues will have to guarantee a possible reconciliation and more fluid connection between academia and the socio-economic sectors. In a rapidly-evolving digitized world, Morocco is called to adopt additional national legislation in digital matters in harmony with the international laws and conventions. For instance, according to the PCT Applicant's Guide – International Phase – Annex B1, the Moroccan Copyright Office has not yet "accept[ed] the filing of documents by means of telecommunication" and has not yet "accept[ed] evidence of mailing a document, in case of loss or delay, where a delivery service other than the postal authorities is used";¹⁶ these are provisions pending to conform to PCT Rules 92.4 and 82.1 of the Regulations under the Patent Cooperation Treaty (as in force from July 1, 2017).¹⁷

What this country needs more urgently is a national updated legislative framework that is equivalent to the WCT in order to be in tune with more recent international legislation in matters of digital copyright, especially at the level of scientific research and academic production. Such legislation should, however, make provision for more extensive exceptions and limitations for the sake of research and innovation, especially in an emerging country like Morocco. A focus should be on striking a balance between the free and fluid circulation of academic knowledge and scientific findings, on one hand, and the protection of IP rightsholders, on the other hand. This balance between "the effective protection of the

¹⁶ WIPO, *PCT Applicant's Guide – International Phase – Annex B1* (2017) <www.wipo.int/pct/guide/en/gdvol1/annexes/annexb1/ax_b_ma.pdf> accessed 3 June 2017.

¹⁷ WIPO, 'Regulations under the Patent Cooperation Treaty' (2017) <http://www.wipo.int/export/sites/www/pct/en/texts/pdf/pct_regs.pdf> accessed 3 June 2017.

rights of authors and the larger public interest, particularly education, research and access to information”¹⁸ is also one of the main concerns of the Marrakesh VIP Treaty, which insists, among other things, on the “effective and timely access to works for the benefit of persons with visual impairments or with other print disabilities” as stated in the Marrakesh VIP Treaty.¹⁹

3. MEASURES IN THE MOROCCAN CONTEXT

While urgent measures are to be given priority by Moroccan legislators, more particularly to catch up with the international legislation in the new digital environment, it is important to decide on a number of points of debate at the national level. Questions of who owns what, of the impact of digital globalization on university scientific research, and of the relation between academia and industry are to be decided and to be provided for with adequate legislation in the context of scientific research and higher education.

3.1. The debate over ownership

Teachers and researchers produce a set of copyrightable works that fall within the existing legislation on IP. A large part of this corpus is produced within the framework of scientific research subsidies that are allocated to research groups, labs and centers in the different Moroccan universities. The question raised here is about who owns the rights of scientific results and digital programs produced in this context: is it the researcher/teacher, the university, or both? This question should be clearly settled for the sake of a stronger protection of these works and their rights holders. Similar to this point is the question of fair use that should prevail in the academic context and the hitherto hardly-sought balance between the rights of researchers as copyright owners, and the requirements of economic and intellectual development of the country.

A particular point of debate has to do with the impact of globalization on the rights of authors and creators and university researchers in Morocco, especially in the absence or lack of the necessary tools to make them competitive at the international level. The same thing can be said about the access of these researcher to the patenting process. In many cases, they find it difficult, if not impossible, to patent and thus protect their inventions because of difficulties, including the high cost of applying for a patent and, at times, complicated patenting procedures, while their peers in the developed world cherish more simplified modes of protecting their inventions thanks to the fluid legislation and to the technical and financial support provided by their universities.

Another point of debate is whether the university should be subordinated to economic and commercial demands or not. Some argue that if so, fundamental scientific research will be negatively affected and even undervalued as it has no direct impact on immediate patent filings and that, consequently, national applied scientific research will be subservient to global economic networks and agendas. This is, indeed, both a universal and a national debate, namely whether Universities should stick to their traditional tasks and roles or reinforce their position in industrial fields for the sake of more participation in the economic and intellectual development of the country.

This is, indeed, part of the present debate among academicians over the implications of industry-sustained scientific research, with the risk of putting scientific research at the service of the economic sector. Advocates of the reticent attitude argue that Morocco is bound by a number of agreements with international monetary funds and that any strategy of academic scientific research involving the relation of business and industry may affect the independence of academia at the level of applied

¹⁸ Preamble to Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled.

¹⁹ *ibid.*

scientific research. In the absence of more sensitizing campaigns on the vital role of academic scientific research in the development and promotion national economy, such fears will prevail.

The debate over this point should not be given much more importance than it deserves since digital developments have revolutionized even the relation between academia and the economic sectors. Universities in developed countries have already found ways to regulate this relationship. A case in point, in this regard, is the Lambert Toolkit “for universities and companies that wish to undertake collaborative research projects with each other.”²⁰ This British resource, which is widely used in Europe, proposes ways of negotiating industry-sponsored research and choices of possible agreements for both parties. Though Moroccan Universities have not yet reached the necessary degree of networking and collaboration with the industrial sector, compared to universities in developed countries, the new version (2016) of the Lambert toolkit, or a similar resource, could be of some help in the Moroccan context, especially at the technical and financial levels. It is up to the Moroccan decision-makers to opt for the most suitable agreement, among the different choices proposed by this toolkit, to help facilitate more collaborative networking and more fluid connectivity between academic research and industrial companies in the present Moroccan context.

3.2. Deciding on the new copyrightable digital material in academia

Higher education and academic scientific research in Morocco are faced, more than ever, with the challenges that have emerged with the revolutionizing developments in digital technologies. Most Moroccan universities are now using Moodle platforms for eLearning programs to face the growing number of

students and to profit from the pedagogical possibilities offered by these technologies. The wide access to information and communication technologies (ICTs) and the extensive use of digital resources and applications, such as MOOCs, in particular, are posing new questions and issues for copyright. Due to the proliferation of the digital economy, these new questions and cases, such as big data, data protection, cloud computing, governance of the internet in an academic context, etc. arise. These emerging issues must be addressed on an urgent and regular basis at the legislative level.

It is necessary to decide, in more detail, on new copyrightable and other digital issues at the levels of scientific research and higher education. *Shloss v. Estate of James Joyce*²¹ is a famous example of how new and unpredictable digital practices and the unlimited possibilities they offer can affect even long-standing and well-established legislation. The case resulted in admitting Shloss’s right to use James Joyce’s published and unpublished works for critical purposes and to host them in a scholarly website despite the opposition of the author’s estate on copyright grounds. It has become a significant example of how fair use in education should be a right to be reconsidered at the legislative level in the light of the limitations that should be extended to academia with regard to the new digital environment. David Olson, supervising attorney on the case, commented: “It’s time that academics’ fair use of quotations from James Joyce in their scholarship become a practical right, not just a theoretical right that can only be claimed by those able to spend hundreds of thousands of dollars defending a lawsuit.”²²

Another example has to do with the close relationship between scientific research and teaching activities, especially at the postgraduate levels. In Master programs, most of the teaching syllabi are closely related to

²⁰ ‘Master the details to effectively manage industry-sponsored research negotiations’ (2017) *ISRM* 1 (9) <<https://techtransfercentral.com/reprints/isrm/1217-industry-sponsored-research-negotiations/>> accessed 5 June 2018

²¹ Shaheen E. Lakhan and Meenakshi K. Khurana, ‘Intellectual property, copyright, and fair use in education’ (2008) *JAL* 6(4) 9-10.

²² Stanford Law School, ‘*Shloss v. the Estate of James Joyce*’. 12 June 2006 <<https://law.stanford.edu/press/shloss-v-the-estate-of-james-joyce/>> accessed 17 May 2018.

scientific research findings. In this context, any eLearning process entails the use of scientific research works, especially in their digital forms. Being encouraged to work in an environment of sharing/shared knowledge, any student may use their scanner or cellphone to scan a copyrighted work and share it among their peers by uploading it on the net. Hence, the necessity to address these practices in provisions on copyright related to the acts of 'downloading' and 'uploading' for scientific research and teaching activities. In the absence of clear national provisions on such issues, on one hand, and a lack of adequate enforcement of the existing legislation, on the other hand, the rights of authors, researchers and academics are infringed on a daily basis. The question of who has the right to upload a particular scientific work (the teacher/researcher, the student, or both?) is one of the issues that should be addressed. The hazy limits between fair use and unfair copying, rights and limitations, plagiarism and self-quoting, are further blurred by the lack of a copyright culture among some academic users themselves. Hence, these multiple perspectives underscore the necessity to act and address these issues.

These are important issues that are facing the whole world, and legislative reform has to be in pace with the ever-changing modes of eLearning, machine learning, ULearning, etc. Fred Von Lohmann argues that online techniques and applications of machine learning are services that are "compelling in their own right" and that "the value of that which has not yet been invented always exceeds the value of everything invented so far."²³ He even affirms that machine learning "may well be a key component of the next leap forward in innovation and economic growth."²⁴ In this regard, one of the important points of national debate in Morocco is the use of protected material in eLearning modes. Some advocate the necessity "to extend the limitations and exceptions relating to education and teaching for these new modes

of learning."²⁵ This is one of the ways in which academia can take advantage from the new digital techniques while protecting the rights of inventors and authors.

Other aspects that should be addressed in adequate legislation in Morocco include transformative works based on protected works of university teachers and researchers, copyright vesting in PhD theses, which can be publicized with or without the supervisor's consent, or the researcher's, and the making of a private copy in the context of the digital university.

3.3. Empowering the Moroccan CMOs: BMDA and OMPIC

Though Morocco has considerable achievements at the legislative level, there are still to be made before reaching a more adequate, efficient management of rights. Granted, there are efforts to improve the collective management of rights (CMR) both at the institutional and the procedural levels, and BMDA and OMPIC are at the center of these efforts. However, the issues posed by the digital environment related to academia are not yet given due importance. IT Service and Information Systems, the only service that pertains to the digital management of rights in the Moroccan Copyright Office is unfortunately a minor subdivision of another branch, the Department of Perception and of Exploitation of the Repertoire. This position should be reviewed to be in line with the present legislative reforms on the nature and scope of copyrightable works. This scope should be reviewed to exceed the domain of musical and artistic works, which presently seems to be the main focus of the Moroccan Copyright Office activities.

What is needed, on the part of BMDA, is a more active approach that would promote and encourage creativity and innovation, instead of the present approach that is acting as post-fact actions mainly limited to licensing and the collection of royalties. To reach this phase, Morocco's IP offices, BMDA and OMPIC, should be empowered with

²³ Lohmann [11] 28.

²⁴ *ibid.*

²⁵ Aghrib et al [5] 17.

both adequate legislation and efficient technology as regards the protection of academic works and the products of scientific research. This will undoubtedly help universities, academies, and research centers to secure and benefit from the results of their research. One of the main issues to address is making the collective management of digital copyright works more efficient, especially now that the advancement in digital and cyber technology is much faster than ever.

At the technical level, in addition to the improvements that are required at the hardware level, more technological know-how is needed to address the challenges posed to scientific research and academic knowledge by Big Data and open source digitized material. As a case in point, data mining algorithms are used to acquire knowledge and up to date information on the most recent scientific research findings; they can also be applied to Big Data. The efficient role of artificial intelligence applications and data analytics in analyzing large amounts of IP information is undeniable. Moroccan copyright offices are called on to take advantage of the different uses and applications that are proposed by these and other algorithms. The new applications related to data mining analytics are all susceptible to revolutionize the legal framework of IP and the management of its rights.²⁶

The digital race is probably felt in the domain of IP more than in any other sector (after the military sector). The enhanced management of rights has resulted in an increase in profits from the new possibilities offered by the latest digital technologies. The legislature is trying to regulate these developments as those that infringe and circumvent are profiting from the same developments. In Morocco, it is now difficult to give a precise detailed account of the statistics and nature of piracy and

plagiarism because of the possibilities offered by computer techniques to falsify, hack and plagiarise works. Hence, the necessity of more sophisticated information technologies and programs to protect the different works of academia and the production of university scientific research.

In spite of efforts to fight against piracy and counterfeiting, such as the creation of special commissions on combatting these phenomena, the National Copyright Office (BMDA), the OMPIC, the Ministry of Communication, and the Ministry of Higher Education and Scientific Research²⁷ have not yet elaborated a clear strategy to fight against the new digital forms of copyright infringement in the fields of university scientific research and academic production. The focus on the fight against piracy in this field is justified by the drastic effects that this phenomenon leaves both on the researchers' economic and moral rights and on the quality and reputation of their works. Some of the possible repercussions of plagiarism and piracy on the academic level can be summarized in, first, the loss of efforts in legal actions and opposition procedures instead of focusing on the production of knowledge and scientific research per se and, second, in the disappointment of researchers and academicians, a fact which will discourage them from producing more academic and scientific works as there is little or no guarantee that their works will be recognized and protected.

The protection of younger researchers' works, especially in the form of PhD theses, should be provided for with utmost urgency. In its assessment of the doctoral cycle in Morocco, the Higher Council for Education, Training and Scientific Research notes in its 2017 Assessment Report that most leaders of the Centers for Doctoral Studies (CED) are attracting attention to the amount of plagiarism

²⁶ On the possible uses of data mining analytics in the field of IP, cf. Jacob Arber, 'Machine Learning and Intellectual Property,' (2016) *CSTLR* April 10. <<http://stlr.org/2016/04/10/machine-learning-and-intellectual-property/>> accessed 2 June 2018 and Leonidas Aristodemou and Frank Tietze, 'A Literature Review on the state-of-the-art on Intellectual Property Analytics (IPA)' (November 2017) 2 *CTM*.

<https://www.repository.cam.ac.uk/bitstream/handle/1810/268007/17_02_Aristodemou_et_al.pdf?sequence=6> accessed 2 June 2018.

²⁷ Since 2016 this Ministry has become part of the Ministry of National Education, Professional Training, Higher Education and Scientific Research.

that is plaguing the scientific community: “Very few CEDs provide anti-plagiarism control once the thesis is submitted for defense. This task, which is so complex, demanding and cumbersome, is tacitly assigned to the rapporteurs of the thesis, because of the lack of software and of competent specialists to perform this task”.²⁸ However, instead of addressing the legislative side of this complex situation, this Assessment Report – emanating from a national advisory council on the matter – simply gives technical response by suggesting the two (commercial and free) categories of plagiarism checkers and anti-plagiarism online services that are available. In its efforts to secure more protection and a better management of Doctoral theses, the Moroccan Institute of Scientific and Technical Information (IMIST) has, on its part, launched an ambitious website (otrohati.imist.ma) that would be a watchtower of all Moroccan PhD theses registered and defended in Moroccan universities. Access to this website is, however, ‘temporarily unavailable’ to this date. In the absence of efficient coordination between the Moroccan Copyright Office and the concerned academic decision-makers, the management of IP in the Moroccan university will still suffer from the new forms of piracy and copyright infringement.

3.4. A CMO for Moroccan academics and university researchers

University researchers and academicians should be empowered with the necessary legislative and institutional tools to reach higher standards of competitiveness both at intellectual and economic levels. The aim is to enable them to make their research results more profitable and to provide effective protection both nationally and internationally and to create the adequate climate for the dissemination of their publications, patents, and innovative and creative works. One of the problems with Moroccan scientific research is the scarcity of ties between applied scientific research made in Moroccan universities and the business and economic

sectors and “the difficulty of reaching the industrial stage of the products of research.”²⁹ Many reasons contribute to this deficiency, but the absence of a clear national strategy on the issue seems to be the most prominent factor.

One of the possible solutions would be to endow university researchers and academicians with a specific collective management organization (CMO) that would act as the sole representative for all academicians and manage all matters of university IP and would, at the same time, act as a counselling body that helps link these researchers to the industrial sector. This will reinforce the two Moroccan existing offices, OMPIC and BMDA and will further act as the equivalent of what is known in some American and European universities as the ‘Technology Transfer Office’. This can play an important role in familiarizing university teachers and researchers with the related legal issues of copyright and, more particularly, in reducing and simplifying for them the procedures of drafting and filing patents. Among the suggestions related to these procedures, there is the creation of a patent service in each university, the rewarding of researchers who excel in patenting and inventive activities, and the payment of patent fees by the university according to clearly defined standards benefitting both the researcher and the university.

In the absence of this CMO, some universities, such as Mohamed V University and the International University of Rabat, created their own ‘Valorization Structures’, mainly designed to help protect and disseminate the results of scientific research, especially patents and inventions, and to promote the culture of IP among university researchers, students, and personnel. The aim, according to them, is to “gain a certain visibility at the national and international levels, attract and secure academic and industrial partnerships, and to ensure a return on

²⁸ Conseil Supérieur de l’Éducation [4] 23-24.

²⁹ Rolshausen [2] 5.

investment by creating wealth and added value”.³⁰ In addition to a national CMO for university researchers and academicians, every university should have its own CMO, which would be concerned with the follow-up of all IP issues of the university and the transfer and marketing of research results in socio-economic areas.

In this digital environment, both national copyright offices and university decision makers are called to leverage the up-to-date technologies for their effective use in the management of rights in academia, which is the space par excellence of knowledge and information. Considerable research is being done on decision-aid systems in the field of information management. Bibliometrics, as a case in point, is an invaluable research tool that would help profile and classify university researchers and teachers with their copyrightable works and creations. The new technical devices should also be adopted as necessary tools in the management of rights and in the protection against all forms of infringement.

4. RECOMMENDATIONS FOR POLICYMAKERS AND RESEARCHERS IN MOROCCO

In the process of reviewing legislation, the TRIPS Agreement can be a good example of how legislation should rather not be “envisage an entirely static legal instrument” since its negotiators ‘included several provisions within the Agreement that set out a work programme for the future – the so-called “built-in agenda”’.³¹ Within the review process of Moroccan legislation on matters of digital copyright and the related rights issues, the guiding spirit is rather to be one of positive exceptions that would prevail over provisions narrowing the scope of free access to knowledge and scientific creativity. Both present and future developments should be considered, especially that technology is challenging legislation on a daily basis.

4.1. More legislation and more sensitization

More legislation

Morocco is currently restructuring the bodies of the collective management of intellectual and industrial rights. A greater need is the codification of all laws and fragmented provisions related to IP into one *Mudawwana*, an IP special code that would encompass all national IP legislation pertaining to academia, including new legislation relevant to the current changes brought about by digital technologies. There is a persistent need for more IP protection of academic and scientific research productions in the digital environment, but at the same time more limitations and exceptions are expected in favor of academia as regards the use of materials for teaching and scientific purposes. The spirit that is supposed to govern future provisions regarding academia should be more in favour of safe-harbor legislation as long as the aim is to facilitate research and the access to knowledge in this emerging country. Other possible solutions and choices should also be offered to university researchers in line with the digital changes and challenges; open-source platforms and resources, for instance, can at the same time satisfy the needs of students, teachers, and other researchers while a minimum of rights is retained by owners.

On private copying, academia-related exceptions are recommended. The adoption on 26 April 2013 of the 79-12 law completing the 02-00 law on copyright and related rights, was primarily meant to establish the legal provisions regulating the right to remuneration for private copying. This law aims to promote creativity and protect the interests of various stakeholders, and to repair the damage caused to authors and rightsholders due to increased forms of reproduction of works fixed on phonograms and on video for personal use. While this law focuses on the rights of singers, performers and artists, it does not stipulate clearly the rights of writers, researchers and all the authors of electronic publications. This law may also be criticised nationally because it may limit the individual’s right to make a personal copy of

³⁰ International University of Rabat, ‘Valorisation Et Transfert’ <WWW.UIR.AC.MA/Valorisation-Et-Transfert> Accessed 27 May 2018.

³¹ Antony Taubman, Hannu Wager and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (Cambridge University Press, 2012) 196.

works in a digital format. Works in digital form fosters access to knowledge.

More sensitization

In addition to the need to enact adequate legislation, there is a need for an enhanced IP culture and awareness amongst Moroccan academics: teachers, researchers, students, and university decision makers. While the IP system is increasingly efficient and protection mechanisms are there to defend these rights, enforcement is slower due to a lack of familiarity with IP law. In addition to the main issues of copyright, teachers and researchers are to be sensitised about the close relation between IP and innovation, the importance of patents and clusters, and the potentials of university scientific research and academic production in profiting from IP services to protect, value, and promote and disseminate their works both at the national and international levels. Attention should be drawn to acceptable standards of citation to protect authors' paternity rights and to the revolution of big data. IP culture will certainly be an important preventive tool against the pitfalls of plagiarism and a helpful companion to foster respect, consideration, and recognition of copyright as a full legal property right. The challenge is not only to protect IP but also to protect students from plagiarism, which is the 'academic' form of IP infringement.

Both BMDA and OMPIC, the national institutions of intellectual and industrial property, can play great roles in raising awareness among academicians and encouraging them to profit from their IP rights as a strategic tool not only for IP protection but also for the promotion of creativity and innovation. These institutions can promote IP expertise amongst university scholars and researchers, and can also disseminate the culture of industrial property rights within Moroccan enterprises as well. The Moroccan Academy of Intellectual and Commercial Property, the AMAPIC,³² can play a major role in this

awareness raising by organizing campaigns for Moroccan universities. Universities should also include in their syllabi the new challenges posed to IP teaching by the digital environment.

The role of NGOs in these campaigns is no less important. The Moroccan Coalition of Intellectual Property, as a case in point, was mainly created to provide both government institutions and the private sector with proposals and programs in matters of IP protection and management. Its scope of action, which is presently mainly focused on the cultural and artistic fields, should also include academia and target researchers and teachers as well.

The teaching of IP at Moroccan universities is mainly entrusted to the Faculties of Law. Some private institutions of higher education and business schools also give some courses on more business-related aspects of IP: patents, models, designs, trademarks etc. AMAPIC offers a more detailed program of teaching and training sessions. In fact, IP is now touching all fields of academic and scientific creativity; and all the components of academia are concerned, in one way or another, with IP issues. It is high time to generalise IP syllabi to all the other fields of learning and research. The introduction of a transversal, cross-disciplinary course on IP for all disciplines, with a focus on issues related to each academic/scientific field, will be a highly practical contribution in the dissemination of IP culture amongst students as future authors, artists and inventors. More focus will be on the respect of others' intellectual and moral rights since law enforcement has become very difficult in a digitally subverted and challenged academia. In the fields of science and technology, this special course on IP may focus on patents, industrial designs, the protection of integrated circuits, and trademark protection, while in the fields of human and social sciences the course may focus more on authors' rights, the public domain, copyright infringement, limitations, exceptions, the three-step test, etc. Needless to say that

³² Academie Marocaine de la Propriété Intellectuelle et Commerciale.

scholars in the branches of computer science and cybernetics need to acquire IP notions related to data analytics and new digital copyright issues.

4.2. The role of WIPO and WTO

International IP organizations such as WIPO and the WTO can play an important role in backing the efforts made at the national level in the promotion of IP. In addition to the follow-up of all treaties and agreements, these institutions can facilitate and foster the introduction of new tools in the management of digital copyright in the academic context of developing countries like Morocco. This can be done, for instance, by training sessions conducted by the WIPO academy and the WTO, in collaboration with OMPIC and BMDA, for the benefit of teachers, researchers, academia personnel, and future patent examiners.

The Moroccan IP academy, AMAPIC, is bound with a series of partnerships with the WIPO Academy, and organises workshops in collaboration with different participants, including experts from OMPIC and university professors. Furthermore, following a Memorandum of Understanding between Morocco and WIPO, in November 2016, the Moroccan Copyright Office (BMDA) launched WIPOCOS³³, a database for collective management organizations or societies, developed by WIPO. The latter is currently developing a new set of resources to support academic institutions in their use of intellectual property, the IP Toolkit for Academic Institutions – Connecting Academic Research with Economy and Society. This represents a “comprehensive set of documents and training support tools for those involved in drafting institutional IP policies, technology managers, and IP professionals engaged in asset management and knowledge transfer.”³⁴ Similar partnerships, databases and software, and toolkits are to be extended to academia.

4.3. African Perspectives

In recent years, Moroccan foreign policy has reoriented its focus on African countries for the sake of fostering collaboration and exchange at the economic and cultural levels. It has re-joined the African Union Organisation and is part of the African Economic Community (1991). The Charter of this Community calls for the adoption of a common policy in scientific research (Article 6 (2) (e)) and invites its Member States to “harmonize their national policies on scientific and technological research’, “coordinate their programs in applied research’, “carry out a permanent exchange of information and documentation and establish community data networks and data banks”.³⁵ At the level of IP, the Charter stipulates clearly that any Member State “may impose or continue to impose restrictions or prohibitions affecting the protection of national treasures of artistic or archaeological value or the protection of industrial, commercial and intellectual property”.³⁶

However, little is done on the part of Morocco at the level of IP cooperation with African countries. This country is neither a member of the African Regional Intellectual Property Organization (ARIPO) nor of the African Intellectual Property Organization (OAPI). This is not a normal situation in the age of clustering and global networking. Morocco is called on more than ever to opt for more south-south IP collaboration at the African level to promote cooperation and exchange with African countries in matters of copyright protection and more protected innovation in a globalized world. Joining these regional organizations will definitely help pool resources and contribute to African programs of development and research and development policies.

Systems of collaboration and coordination should also be established between African CMOs themselves to achieve their mutual interests and face common challenges. Once

³³ Software for Collective Management of Copyright and Related Rights.

³⁴ WIPO, ‘Upcoming IP Toolkit for Academic Institutions’ (2017) <<http://www.wipo.int/about->

ip/en/universities_research/news/2017/news_0001.html> accessed 25 March 2018.

³⁵ Article 51 (1) (a, c, and e) of the *Treaty Establishing the African Economic Community* 1991.

³⁶ *Ibid*, Article 35.

again, the roles of regional IP organizations, such as ARIPO and OAPI, and international ones, WIPO and the WTO in particular, are vital in this context. The aim is to capitalise on the new opportunities of African and regional free trade agreements, on the one hand, and more particularly, to harmonise national IP systems as regards the promotion and protection of scientific research and academic works and agree on African standards in the ways of managing IP rights in the digital academic context. One of the possible suggestions in this regard is the creation of an African IP structure similar to the British 'Copyright Hub', which emerged in Great Britain in the early 2010s as a reaction to "the immense difficulty of IP management in the digital age".³⁷

The collaboration between African universities is further dictated by the fact that this continent abounds in rich traditions and folklores whose protection is at stake in this digital age. But the new digital environment can be turned into a positive tool to bring incremental change in the ways of managing and preserving these traditional cultures. As early as the mid-1970s, the Cultural Charter for Africa (1976) of the Organization of African Unity (now the African Union) called African governments to "develop the exchange of information, documentation and cultural material" by "strengthening the Association of African Universities" and by "university and specialists exchange".³⁸ Universities can play a prominent role in this regard as they can contribute in transforming these cultures into digitally accessed forms, which will have highly rewarding impacts both on academicians and on entrepreneurs: "The digital revolution will grant Africa's creative entrepreneurs a unique opportunity to translate Africa's folklore traditions into engaging, creatively packaged digital content which can be shared with

millions of consumers around the world at the click of a button."³⁹

The notion of territoriality is one of the issues to be reconsidered in the African context because of the common challenges the World Wide Web has posed to this concept, which must be reviewed in the national laws of African countries with the aim of greater harmonisation between these laws. Some measures proposed by the European Parliament on this matter can be highly inspiring in this context. Their approaches are "to foster cross-border online access and the portability of content across borders and to prohibit some specific territorial restrictions (for instance, the unjustified practice of geo-blocking).⁴⁰ The latter practice, which is very common among some African nations, takes the form of blocking all websites that bear the Internet country code top-level domain of a potential 'undesired' country. This may seriously affect the fluid exchange of academic and scientific research results and interests. On the contrary, common provisions should make of the current digital environment a golden occasion with undreamt-of possibilities for African researchers and academics to do research on common issues posed to Africans.

5. CONCLUSION

Certain provisions of Moroccan legislation on university scientific research and academic production need to be reviewed on a continuous basis to face the new digital issues posed by ever-changing technologies and to help academia engage in, and profit from the new forms of the digital economy. The rising challenges of piracy and IP infringement, on the one hand, and the need for a safer and fluid immersion of Moroccan academia into the global digital hub, on the other hand, are pressing factors for an urgent updating of some national laws.

³⁷ Copyright Hub, 'History of the Copyright Hub' <<http://www.copyrighthub.org/about/history/>> accessed 14 June 2018.

³⁸ Article 31 (b) of the *Cultural Charter for Africa* (1976).

³⁹ George Twumasi, 'Building an African digital content industry' *WIPO Magazine* (2016) 2, 35.

⁴⁰ Tambiama Madiaga, 'EU copyright reform: Revisiting the principle of territoriality', European Parliamentary Research Service. September 2015, 1 <[http://www.europarl.europa.eu/RegData/etudes/BRIE/2015/568348/EPRS_BRI\(2015\)568348_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/BRIE/2015/568348/EPRS_BRI(2015)568348_EN.pdf)> accessed 12 May 2018.

Nevertheless, more participatory approaches are to be followed in the processes of suggesting and drafting new laws, especially when it comes to elaborating provisions pertaining to cyber activities and the digital environment. This is of necessity due to the growing particularity and complexity of these domains and the wide spectrum of the involved stakeholders and target groups. Also, one of the possible remedies is the codification of all the scattered and fragmented IP provisions related to university and scientific research into one legal code.

Raising more awareness on IP issues among Moroccan teachers, researchers, students, and academic decision-makers is a must in this context. A deeper understanding on these parts, of IP issues both at the national and international levels will certainly help establish the ever sought-after balance between the rights of owners, on one hand, and the research and intellectual needs of academia in the new digital context, on the other hand. IP culture can be best disseminated in the academic and scientific sectors by the introduction of a special complementary course on the different aspects of IP in all disciplines. These pedagogical and provisional regulations can certainly be best implemented in collaboration with African countries. More practical African networking and collaboration are needed to cope with the new legal and technological issues posed by the digital environment to the countries of this Continent.

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**BEIJING TREATY ON AUDIOVISUAL PERFORMANCES:
A PANACEA FOR TRADITIONAL RIGHTS HOLDERS?**

Caroline Joelle Nwabueze*

ABSTRACT

The adoption of the Beijing Treaty on Audiovisual Performances ('the Treaty') in 2012 was applauded all around the world. Many have seen in it the panacea for troubles experienced by performers. It was said that the Treaty came to strengthen the precarious position of performers in the audiovisual industry by providing a clearer legal basis for the international use of audiovisual productions, both in the traditional media industry and in the field of traditional cultural expressions (TCEs). The pledges formulated for traditional rights holders were based on the inclusion of performers of expressions of folklore as beneficiaries under the Treaty. The present paper questions the veracity of this assertion by analysing the capacity of the Treaty to protect TCEs from misappropriation. The incompatibilities between the ancient features of TCEs and the creativity-based system of intellectual property (IP) have left TCEs without adequate protection within the IP system for decades. Meanwhile, with the advent of new technologies, the rich creativity embodied in indigenous designs, performances, art and music is constantly exposed to freeriding by third parties, which raises issues of authorship, access and use. This paper firstly discusses the recognition of indigenous property rights over their performances under the Treaty. The paper then critically appraises the scope of existing limitations pertaining to indigenous control over such performances, as well as the access and use by third parties. Suggestions are made for the management and enforcement of TCEs and audiovisual performances beyond the copyright and related rights regimes for a right of recognition of indigenous performers, to whom any benefits arising from these rights should accrue.

Keywords: Beijing Treaty – audiovisual performances – traditional cultural expressions – traditional rights holders – control – access – use – intellectual property

1. INTRODUCTION

Traditional cultural expression (TCE) is a term originating from the World Intellectual Property Organization (WIPO)

Intergovernmental Committee (IGC) on Genetic Resources (GR), traditional knowledge (TK), and TCEs. According to article 2 of the WIPO-IGC draft gap analyses for the protection of traditional cultural expressions, in the second revision of the text,¹ an alternative definition was proposed by a group of Least developed countries (LDCs) as:

the various dynamic forms which are created, expressed or manifested in traditional cultures and are integral to the collective cultural and social identities of the indigenous local communities and other beneficiaries.

Performers include actors, singers, and musicians other actors singing, delivering or playing in literary or artistic works.² Performances related to traditional cultural heritage generally extend to performing arts, social practices, rituals and festive events.³ Several studies have demonstrated the incompatibility between TCEs and IP laws, based on the fact that the requirements of novelty, creativity and authorship in terms of the patent and copyright system do not match the features of inherited cultural expressions transmitted from generation to generation.⁴ Performances received historical recognition within the conventional IP system under the Rome Convention in 1961⁵, the WIPO Performances and Phonograms Treaty in 1996 (WPPT), and the TRIPS Agreement⁶ in 1995 under a related rights regime. Those treaties enhance the protection of music performers, but still without proper identification of traditional cultural expressions related performers as subject of rights. The turnaround came in July 2012 in Beijing, when the international IP community applauded the ratification of

* **Caroline Joelle Nwabueze** is a post-doctorate research fellow under the South African Research Chair in Law, Society and Technology. College of Law. University of South Africa; Currently senior lecturer at the Law Faculty of Enugu State University of Science and Technology in Nigeria. This paper draws the content of the author's paper presented during the WIPO-WTO Colloquium for Intellectual Property Teachers and Researchers in Africa, April 9 to 12, 2018, University of South Africa, Pretoria. The author acknowledges the sponsorship by the National Research Foundation of South Africa (NRF), the Department of Science and Technology (DST), and the South African Research Chair in Law, Society and Technology (SARChI), University of South Africa

¹ WIPO/GRTKF/IC/33/4

² Art. 3(a) Rome Convention for the Protection of Performers, Producers, Phonograms and Broadcasting Organizations, 1961.

³ Art. 2(2)(b)(c) UNESCO Convention for the Safeguarding of Intangible Cultural Heritage, 2003.

⁴ Caroline Joelle Nwabueze, 'The Protection of Traditional Cultural Expressions in OAPI States' (LLM thesis, University of Turin WIPO 2011)

⁵ Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, (1961)

⁶ Trade Related aspects of Intellectual Property Rights Agreement (1995)

the Treaty with respect to audiovisual performances. Cultural actors rejoiced for two reasons:

- Traditional performances appeal to the eyes and the hearing. Therefore, a treaty on audiovisual performances will definitely strengthen the local industry and advertise cultural patrimony.
- The Treaty specifically refers to the protection of singers and dancers of expressions of folklore.⁷

In addition, the rights granted were for fixed and unfixed performances.

This research paper questions the suitability of the Treaty to enhance the protection of traditional rights holders in the case of audiovisual performances.

The following brief analysis of the impact of the Treaty on traditional performers examines to what extent the Treaty enables the protection of traditional performances, and whether the Treaty has gone beyond the WIPO Copyright Treaty (WCT)⁸ and the WPPT to permit traditional rights holders to reap the fruit of their creativity. An overview of the restricted scope of protection granted to traditional performers under the Treaty is followed by an exploration of subsequent legal protection alternatives under other existing IPR categories, to enable effective adaption for the benefit of traditional rights holders' interests in audiovisual performances.

2. POLICY DEVELOPMENT TO VEST INTELLECTUAL PROPERTY RIGHTS IN TRADITIONAL PERFORMERS

There has been a long series of discussions relating to the IPRs of traditional rights holders both as traditional rights under the WIPO-IGC, and as performances under performers' treaties.

2.1. WIPO-IGC

WIPO's website points out that:

The current international system for protecting intellectual property was fashioned during the age of industrialization in the West and developed subsequently in line with the perceived needs of technologically advanced societies. However, in recent years, indigenous peoples, local communities, and governments, mainly in developing countries, have demanded equivalent protection for traditional knowledge systems.⁹

Even though TCEs are often works that involve genuine creativity, they have been denied full recognition under the existing IP legal framework since they do not fulfil the requirements of creativity/novelty.¹⁰ Traditional artistic knowledge on an inter-generational transfer basis precludes traditional performers from IP protection based on authorship.¹¹

To remedy the injustice embedded in the current legislative framework's failure to protect tradition-based works, WIPO-IGC current text-based negotiations are taking into consideration key points for the protection of traditional works, including¹²: (i) what to protect; (ii) why to protect; (iii) who will benefit; and (iv) how to protect. Two types of protection have been envisaged in the course of the negotiations, namely a positive protection to acquire IPRs in order to meet the objectives of protecting traditional works, and a defensive protection to prevent others from acquiring IP rights to traditional knowledge (TK) and/or TCEs.

Meanwhile, a pressing concern exposed by Jane Anderson is the commensurate economic reward for maintaining community traditions,¹³ which has been

⁷ Beijing Treaty of Audiovisual Performances (2012) Art. 2(a)

⁸ World Intellectual Property Organization Copyright Treaty (1996)

⁹ www.wipo.int (accessed on the 5th day of April 2018)

¹⁰ C J Nwabueze, *Copyright and Data Authenticity in the Digital Preservation of Heritage: The Case of OAPI States* (IJH Vol. 12, 2017) 98

¹¹ Jane Anderson, 'Developments in Intellectual Property and Traditional Knowledge Protection' in U Popova-Gosart (ed)

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¹²For example, the WIPO-IGC texts negotiations on TCEs Issues relevant to *sui generis* systems of protection include: Definition of the subject matter (Article 1 of the *Draft Provisions*), Formalities (Art. 7), Illegal acts (Art. 3), Exceptions and limitations (Art. 5), Beneficiaries (Art. 2), Management of rights (Art. 4), Transitional Measures (Art. 9).

¹³ *ibid* (n 10)

coupled with the misuse and misappropriation of traditional performances.

The expansion of digital technology adds an additional impetus for the protection of performers' rights in the online environment.¹⁴ If the configuration of TCEs in an audio visual format enables the growth of the tourism sector, the advertising of national cultural patrimony, etc., it nevertheless could cause sustainable harm, including the migration of all cultural content to the internet and unauthorised use of traditional performances in audio-visual media such as television, film and video. The result is several cases of misappropriation of traditional performances. In the absence of an international legally binding instrument enhancing the recognition of traditional works as a rights category under the IP system, it is important to examine under the existing related rights framework the feasibility of protection granted to traditional performers.

2.2. Recognition of performers of TCEs in audiovisual works: historical legal framework under the WCT and WPPT

Traditional performances are often expressed through pantomime, choreographic works, drama, impromptu/unrecorded dancing, etc. With the advent of new technologies and the internet, traditional performances have been increasingly shared from one part of the globe to the other without the knowledge of the communities from which they originate, and sometimes out of their cultural context. The internet grants users of audiovisual performances the ability to easily copy and share works, which may infringe on existing holders' rights. This raises numerous issues pertaining to the control of data flows. Users could be held liable of contributory liability based on their distributing a product with alternative lawful or unlawful

uses or be guilty of secondary liability based on acts of inducement of copyright infringement.

A case on this subject arose in *MGM Studios, Inc. v. Grokster*,¹⁵ which involved a decentralised software system that enabled users to make available and share content files residing on various users' computers. *Grokster* was not protected because it actively induced the use of its system to infringe copyright.¹⁶

Performers are beneficiaries under related rights, otherwise called neighbouring rights¹⁷, or the French term 'Droits Voisins'. Article 7 of the Rome Convention prescribes the minimum protection to be given to performers.¹⁸ Under the convention, and based on the fact that they do not fulfil the requirement of authorship, performers cannot prevent broadcasting and communication to the public of their fixed performances without their consent.¹⁹ They therefore cannot prevent any use that is made of their fixed performances, whether the fixation was intended for cinema showing or for television.²⁰ As illustrative example, a performer of traditional choreography recorded for use on a movie soundtrack cannot prevent further use once the recording has been released. A payment for subsequent audiovisual use is neutralised by the dispositions of section 12 of the Rome Convention, which stipulates: 'once a performer has consented to the incorporation of his performance in a visual or audio-visual fixation, Article 7 shall have no further application.'

Pistorius mentioned that audiovisual performers were deprived of any significant protection for their fixed performances.²¹ The WPPT improved the traditional performers' protection, firstly through the extension of the definition of performers to include performers of expressions of folklore. WPPT defines the performer as 'performers are actors, singers, musicians, dancers, and

¹⁴ Tana Pistorius, 'The Beijing Treaty on Audiovisual Performances' in IA. Stamatoudi (ed) *New Developments in EU and International Copyright Law* (Kluwer 2016)

¹⁵ [2005] 545 US, 913, 919-23.

¹⁶ RT Nimmer, *Information Wars and the Challenges of Content Protection in Digital Context*, 847.

¹⁷ *Understanding Copyright and Related Rights*, WIPO Publication (2016) 27

¹⁸ P Goldstein, B Hugenholtz, *International Copyright- Principles, Law and Practice* (2nd edn, Oxford 2010) 259.

¹⁹ *Ibid* (n4) Art. 7

²⁰ WIPO Publication, *Guide to the Rome Convention and the Phonograms Convention* (No. 617, 1981)

²¹ *ibid* (n 13) 143

other persons who act, sing, deliver, declaim, play in, interpret, or otherwise perform literary or artistic works or expressions of folklore'.²²

Under the Rome Convention, performers were defined as 'actors, singers, musicians, dancers, and other persons who act, sing, deliver, declaim, play in, or otherwise perform literary or artistic works'.²³ This definition was not favourable to performers of traditional cultural literary and artistic works, since the requirements for protection of "works" such as underlined by the Berne Convention did not accommodate expressions of folklore. The conditions of authorship and terms of protection in particular, preclude the recognition as right category of ancient, inherited, and collectively recreated folkloric works²⁴

Additionally, the WPPT enables the protection of performances and fixations of folklore. Under article 15, performers of folklore and producers of phonograms recording folklore shall enjoy the right to a single equitable remuneration for the direct or indirect use of phonograms published for commercial purposes for broadcasting or for any communication to the public.²⁵

Apart from these two innovations with respect to performers' rights, the WPPT has merely reproduced the provision of the Rome Convention, with a restriction of the scope of protection granted to transmission by wireless means,²⁶ communication to the public by any medium,²⁷ and the embodiment of sounds, or of the representations thereof.²⁸

The TRIPS Agreement did not remedy much of the legal gap noticed at the international level prior the adoption of the Agreement. Article 14 of the TRIPS Agreement grants performers rights to communication to the public of live performances.²⁹ It is regrettable and of importance that the historical framework has evolved without due consideration being given to audiovisual fixation. Traditional performances express rich creativity and are vectors of the cultural identity of indigenous peoples. Performers' creative intervention gives life to motion pictures and musical or choreographic works, which therefore represents a justifiable interest in the protection of their individual interpretation under IP law.³⁰ Having become vulnerable prey in misappropriation schemes using the internet and information communication technologies, traditional performers needed to benefit from the audiovisual performances protection granted in China in 2012. The entry into force of the Treaty ratification constitutes a drastic turnaround in the freeriding noticed in the use of performances from local communities and indigenous people.

3. SCOPE OF PROTECTION UNDER THE BEIJING TREATY

The 21st century, otherwise identified as the internet age, has witnessed a high flow in the production and consumption of digital cultural products. The intangible aspects of cultural heritage have not been exempted: Performances as conduits through which indigenous people's values and heritage are brought to the external

²² (Art 2(a) WIPO Performances and Phonograms Treaty (1996)

²³ *ibid* (n18) (Art. 3(a))

²⁴ Berne Convention Paris Act (Vol. 1161, 1-18338, 1971) Art 2(1):

The expression "literary and artistic works" shall include every production in the literary, scientific and artistic domain, whatever may be the mode or form of its expression, such as books, pamphlets and other writings; lectures, addresses, sermons and other works of the same nature; dramatic or dramaticomusical works; choreographic works and entertainments in dumb show; musical compositions with or without words; cinematographic works to which are assimilated works expressed by a process analogous to cinematography; works of drawing, painting, architecture, sculpture, engraving and lithography; photographic works to which are assimilated works expressed by a process analogous to photography; works of applied art; illustrations,

maps, plans, sketches and three-dimensional works relative to geography, topography, architecture or science.

²⁵ *Ibid* (n21); Agreed Statement 13 concerning article 15

²⁶ *Ibid*. Art. 2(f).

²⁷ *Ibid*. Art 2(g)

²⁸ *Ibid*. (n21) Art. 2(c)

²⁹ *Ibid* (n5) Article 14 (1): *In respect of a fixation of their performance on a phonogram, performers shall have the possibility of preventing the following acts when undertaken without their authorization: the fixation of their unfixed performance and the reproduction of such fixation. Performers shall also have the possibility of preventing the following acts when undertaken without their authorization: the broadcasting by wireless means and the communication to the public of their live performance.*

³⁰ *ibid* (n16) 28

world are constantly shared via digital platforms. Multiple affordances of digital technologies have fuelled misappropriation, illegal distribution and freeriding of sacred values. The Treaty attempts to remedy this state of unfair use of audiovisual performances by recognising a universal right of audiovisual performers to benefit from the exploitation of their performances. This right extends to both economic and moral rights and is recognised with respect to fixed and unfixed performances.

3.1. Recognition of traditional audiovisual performances within the scope of protection

The protection of traditional cultural performances is a human rights imperative. Recognising the cultural rights of indigenous peoples, the Committee on Economic, Social and Cultural Rights purposefully mentioned:

Indigenous peoples have the right to act collectively to ensure respect for their right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literature, designs, sports and traditional games, and visual and performing arts.³¹

The dual dimension of traditional audiovisual performances has been taken into account by the Treaty. This is done firstly through the recognition of performers of expression of folklore as a category of performers. Under the Treaty, 'performers' are actors, singers, musicians, dancers, and other persons who act, sing, deliver, declaim, play in, interpret, or otherwise perform literary or artistic works or expressions of folklore.³²

Secondly, article 2(b) of the Treaty defines the term audiovisual as the embodiment of moving images, whether or not accompanied by sounds or by the

representations thereof, from which they can be perceived, reproduced or communicated through a device. This consideration is of inestimable importance for traditional performances. Audiovisual content appeals to two senses: sight and hearing, which are fundamental in the expression of cultural diversity embodied in traditional performances. Audiovisual is the most vibrant platform for expressing cultural creativity, and therefore a powerful vehicle of cultural performances. Moving images constitute an excellent instrument for the expression of cultural creativity, as they unveil the beauty of cultural performances.

3.2. Recognition of economic rights and moral rights of traditional performers to audiovisual performances

The innovations under the Treaty extend fundamentally to the recognition of the numerous economic rights of the performers to fixed and unfixed performances and equitable remuneration for making the performances internationally available. The Treaty equally grants a moral right in the case of audiovisual performances.

3.2.1. Economic rights to fixed and unfixed performances

With the passing of the Treaty, traditional performers have the exclusive right to authorise the fixation of unfixed performances.³³ This implies, for example, that during the yearly traditional Chieftaincy of the Sultan in Fouban West Cameroon, traditional performers, beautified by richly dressed horses and riders accompanying the king, have the exclusive right to grant permission for a video/film to be made of their performances.

A part of economic rights is the exclusive right to give approval for broadcasting and communicating any unfixed performances to the public. Examples could be the traditional performer's authorisation for the live broadcasting of performing arts; social practices, rituals.³⁴

³¹ The Committee on Economic, Social and Cultural Rights General Comment No. 2 (para. 37)

³² Ibid (n6)

³³ *ibid* Art. 6

³⁴ *ibid* (n13) 161

Economic rights under the Treaty extend to:

- The right of authorising commercial rental to the public of copies of the performances.³⁵
- The right of authorising the making available to the public of the performances by wire or wireless means.³⁶
- The right of broadcasting and communication of performances to the public.³⁷
- A right to equitable remuneration for the direct or indirect use of performances fixed in audiovisual fixations for broadcasting or for communication to the public internationally.³⁸

3.2.2. Recognition of performers' moral rights to audiovisual performances

Moral rights allow authors and creators to take certain actions to preserve and protect their link with their work.³⁹ Moral rights include the author's right to claim authorship of the performance, as well as the right to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, the said performance, which would be prejudicial to the performer's honour or reputation.⁴⁰ The Treaty innovates by establishing the above rights of attribution and of integrity of audiovisual performers.⁴¹

Traditional performances usually embody the spirit of a cultural group and the heart of its cultural identity transferred from generation to generation. Therefore, the performance of rituals and social events usually relate to sacredness. The distribution of traditional performances without a performer's approval could

violate community rules, especially in the case of online sharing on foreign websites.

Performers' moral rights could be exercised to prevent the unauthorised use of cultural images and to protect the sacredness and secrecy embodied in traditional performances. For example, TCEs in Malaysia are represented through traditional dances. The Sewang of the Semai community is an illustrative example. The performances combine elements of rituals, songs, dance and music. The Sewang is practised for rituals and medicinal purposes as well.⁴² Moral rights could be used in this context to prevent use outside customary rules, which could amount to distorted use of the performance under the Treaty.

The unfair performance of Ngajat of the Iban community in Malaysia constitutes a case of the violation of performers' rights to their traditional performances. The performance of Ngajat as portrayed in the media is inauthentic based on the fact that the steps for Ngajat in welcoming people are different from dances performed for other functions.⁴³ As a sacred dance, Ngajat is an art of respect and not just a 'show' to outsiders. Reports indicate that as the association is a small group, it cannot do much against the adulteration of their cultural performances. The ascertaining of moral rights can serve as a tool to enhance the authenticity of Ngajat in this context.

The protection of actors, musicians and performers in an audiovisual work has definitively improved since 2012. Prior to the adoption of the Treaty, such benefits were restricted solely to audio and music performers. The Treaty equally innovates by providing remuneration for

³⁵ *ibid* (n31) Art. 9(1)

³⁶ *ibid* Art. 10

³⁷ *ibid* Art. 11

³⁸ *ibid* Art. 11(2)

³⁹ *ibid* (n16) 9

⁴⁰ Berne Convention Art.6; *ibid* (n6) Art. 5(1)

⁴¹ *ibid* (n31) Art. 5:

the performer shall, as regards his live performances or performances fixed in audiovisual fixations, have the right: (i) to claim to be identified as the performer of his performances, except where omission is dictated by the manner of the use of the performance; and

(ii) to object to any distortion, mutilation or other modification of his performances that would be prejudicial to his reputation, taking due account of the nature of audiovisual fixations.

⁴² IM Azmi, Ismail SF, J Jalil, H Hamzah, M Daud, *Misappropriation and Dilution of Indigenous People's Cultural Expression through the Sale of Their Arts and Crafts: Should More Be Done?* Social Science and Humanities 23 (University of Malaysia Press 2015) available at [www.pertanika.upm.edu.my/Pertanika%20PAPERS/JSSH%20Vol.%2023%20\(S\)%20Nov.%202015/15%20JSSH%20Vol%2023%20\(S\)%20Nov%202015_pg165-178.pdf](http://www.pertanika.upm.edu.my/Pertanika%20PAPERS/JSSH%20Vol.%2023%20(S)%20Nov.%202015/15%20JSSH%20Vol%2023%20(S)%20Nov%202015_pg165-178.pdf) accessed on the 17th May, 2019.

⁴³ *Ibid*. 168

the use of audiovisual works internationally, and through the recognition of moral rights.⁴⁴

Against the background of existing legal insecurity for the protection of TCEs at international level, can we then conclude that the Treaty constitutes a relevant panacea for rights holders in the field? In other words, does the Treaty enable recognition of the rights of traditional performers under the IP system?

The next section underlines the limits in the Treaty preventing a full return on creativity in the case of traditional audiovisual performances.

4. EXISTING RESTRICTIONS OF TRADITIONAL PERFORMERS' RIGHTS UNDER THE TREATY

Despite its innovations applauded by the international community relating to the recognition of performers' rights to audiovisual performances, the Treaty has not resolved the question of equitable management of IP interests of audiovisual performers. This serves as an obstacle to the reward of creativity of traditional creators as subjects of rights under the IP system. In addition, the Treaty enforces a term of protection as well as a restrictive approach to the moral right granted to the performer.

4.1. Traditional performer - producer: the saga of transfer of rights

Audiovisual content represents a powerful vehicle for unlocking cultural tourism,⁴⁵ especially in a developing context with culture-based economies. Once the copyrighted work in audiovisual performances is created and the exclusive right granted to the author subsists in the work, those rights statutory provided constitute property. As such, the audiovisual performance may

boost the producer's financing efforts and value the traditional performer's economic potential on the marketplace. The successful appropriation and exploitation of IP rights is source of huge economic impact.⁴⁶ The IP right related to the audiovisual performance, as all IP right categories can be transferred. The Beijing Treaty on Audiovisual Performances organizes the transfer of rights between performers and producers. Generally, under the Treaty, a performer can agree to the fixation of his or her performance in an audiovisual fixation. Such agreement automatically operates transfer of the performer's exclusive rights to the producer⁴⁷, unless both parties have agreed otherwise by way of contract.

This disposition does not clearly stipulate when does a consent leaves the forum of private negotiations to become officially binding, and constitutive of transfer of rights. The sanctity and consensual formalism characteristics of contractual agreements have not been respected in this case. In the absence of clear information and notification to the performer of the impact of his or her consent, this disposition is subject to abuse of the performers' intellectual rights.

IP can not engineer economic development in the absence of a successful management. If IP management has the ability to turn IP in a power tool⁴⁸, does the Beijing Treaty enable a good management of the traditional performer's rights in audiovisual performances?

4.2. Inherent power imbalance in contractual relation performer-producer

Inherent disproportion of power within the relationship between performer and producer greatly impair the performer's capital and bargaining skills.⁴⁹ The traditional performer more specifically, usually considers display of cultural heritage values as a spiritual assignment or

⁴⁴ Rafael Ferraz, 'The Beijing and Marrakesh Treaty (LLM Lecture Notes, University of Turin, October 2015)

⁴⁵ P Lanteri, WIPO Copyright Law Division, *The Role of International Copyright Framework and Its Benefits*; WIPO, Bangkok (2017)

⁴⁶ G. Gabison and A. Pesole, 'An Overview of Models of Distributed Innovation', JRC and Policy Reports. Report EUR

⁴⁷ Art. 12(1) Beijing Treaty

⁴⁸ A. Krattiger and S. P. Kowalski 'Principal Factor Driving Innovation' in WIPO, 'in WIPO Intellectual Property Management. Module 8. Unit 8.1. WIPO/OMPI p. 2.

⁴⁹ See generally, Vettori, M-S (2005), Chapter 2 The Function of Labour Law, P. 24 University of Pretoria etd – Available at <https://repository.up.ac.za/bitstream/handle/2263/29308/02chapter2.pdf?sequence=3>. Accessed on 10/5/18

cultural duty. In addition, it is not common factor having a traditional performer versed in literacy and conscious of the value of the intellectual creativity related to cultural performances. In a context where the financial ambitions of powerful producers dictate the tune of transfer of rights over intellectual creativity, abuse and unfair exploitation are common practice. To palliate to such unethical behaviors, certain countries like Australia have set councils for the management of indigenous interests. The Aboriginal and Torres Strait Islander Arts Board of the Australia Council made mainly indigenous scholars is an illustrative example⁵⁰.

International intellectual property legal normative is an indispensable impetus for the recognition of creativity in presence of unequal forces and discrimination of vulnerable performers. In the absence of management binding legal framework, how can member states enhance due reward of genius creativity in contracts regulating the exploitation audiovisual performances?

This paper argues that Beijing Treaty has failed to set a framework of binding rules regulating the contractual relationship between two principal subjects of the cultural industry in the information age: the performer and the producer. The Treaty's drafters missed the legal opportunity to build the normative framework for the existence and operations of all the parties in an important sector of the cultural industry. Unfortunately, this important task was left over to national legislations.

4.2.1. Failure of Beijing Treaty to regulate unequal forces in the contractual relation performer-producer

Beijing Treaty has established a legal formalism for the contract of transfer of rights between the performer and producer. The Treaty's dispositions stipulate the feasibility of a consent given to be in writing and signed by both parties to the contract or by their duly authorized

representatives.⁵¹ In addition, concerning the making available or broadcasting and communication to the public of any fixed audiovisual performance, the Treaty emphasizes on the provision of a right to royalties for the performer, or a right to equitable remuneration for any use of his or her performance.⁵²

Unfortunately, these requirements are just soft standards set for States parties, without any peremptory force. The use of the expressions "Contracting Party may provide in its national law" or "may require" has demonstrated the Treaty's intention not to make these important dispositions binding as a matter of law. They are therefore left over to the sovereign appreciation of member States. In this context, it will be difficult to alleviate discriminations extended to creativities authored by feeble traditional performers, - denying recognition of created works. Copyright has fell here to prevent the weak traditional performer from being eaten by predatory producers.

It seems not to be the end of the tunnel for several cases of the misappropriation of audiovisual performances, especially with the expansion of information technology and the internet enabling easy access/downloading without the performer's knowledge, and illegal communication to the public without acknowledgement.

Peter Sculthorpe's case of the misappropriation of indigenous musical material in Australia in the early 1980s is a relevant example. The court qualified such misappropriation as culturally insensitive and unethical.⁵³

The author of the fixation can successfully prosper under the Treaty, but not the traditional rights holder because he has been deprived of ownership under the system.

In the following part of this article the existing term of protection, which represents another impediment to the realisation of traditional performers' rights, will be discussed.

⁵⁰ Terri Janke, "Minding Culture- Case Studies on Intellectual Property and Traditional Cultural Expressions", WIPO Publications, 2003. P. 160

⁵¹ Art. 12(2) Beijing Treaty

⁵² Art. 12(3) Beijing Treaty

⁵³ Jonathan Paget, *Has Sculthorpe Misappropriated Indigenous Technologies?* Vol. 35, No. 1 (Musicology Australia 2013) 86-111

4.3. Existing term of protection

Western principles of copyright protection include term limits in order to ensure a public domain of works and to maintain the copyright balance.⁵⁴ Under the TRIPS Agreement and the WPPT, the rights of performers are protected for 50 years from the date of the fixation or the performance. The Treaty equally provides for a term of protection of 50 years. The existing term of protection contravenes the cultural ownership values as symbol of cultural identity belonging to a particular people. Depriving the people of such identity after a term contravenes the international standards of cultural and human rights relating to self-determination and to cultural identity. It is a universal will and a common concern to safeguard the intangible cultural heritage of humanity, of which communities' traditional performances are part.⁵⁵ This paper suggests the remedy for this failure through the abolishment of a term of protection and the introduction of perpetual protection with respect to traditional works.

The existing term of protection does not enhance a proper protection of TCEs. TCEs are the living treasure of the spirit of a community. This is so because in addition to establishing a term of protection, calculators should underline the date of the first publication of the performance creation, which is usually not available for traditional performances.⁵⁶

4.4. Restricted moral rights

The Treaty for the protection of audiovisual performances failed to adopt a straightforward standard with respect to a performer's moral rights.

As was underlined above, article 5(1) of the Treaty does grant the performer a right to paternity as well as a right to the integrity of the audiovisual performances. Nevertheless, under article 5, the moral rights so described are limited by restrictive factors where the

omission is dictated by the manner of the use of the performance and taking due account of the nature of an audiovisual performance. Three fundamental restrictions were identified:

- (i) The normal modification of the performances arising in the course of their exploitation and including editing, compression, dubbing, or formatting, in existing or new media or formats, and that are made in the course of a use authorised by the performer, would not amount to modifications within the meaning of article 5(1)(ii).
- (ii) In the event that a change of the performance is not objectively prejudicial to the performer's reputation in a substantial way, it does not amount to change.
- (iii) The mere use of new or changed technology or media, as such, does not amount to modification within the meaning of article 5(1)(ii).

The Treaty adopts a large conception of acceptable modifications, which could prejudice the performers' interest. In addition, the change when recognised shall fulfil an additional requirement of 'objectively prejudicing the performers' reputation'.

Pistorius argues that such a language of ambiguities could give rise to discrimination in the management of actors with small roles.⁵⁷

In the absence of an international standard-setting instrument for the protection of traditional performers' rights, the lack of a strong regional mechanism in several developing countries for the protection of traditional rights holders' audiovisual performances creates opportunities for misappropriation. This paper goes further to examine ways of protection of TCEs beyond the Treaty, firstly, within the existing IP system, and secondly, outside the IP system.

⁵⁴ Peter Jaszi, 'Protecting traditional cultural expressions – some questions for lawmakers' (2017) WIPO Magazine. www.wipo.int/wipo_magazine/en/2017/04/article_0002.html Accessed 17th June, 2018.

⁵⁵ Preamble, UNESCO Convention for the Safeguarding of Intangible Cultural Heritage, 2003.

⁵⁷ *ibid* (n23)160

5. EXISTING PROTECTION MEANS WITHIN THE IP SYSTEM AND BEYOND

While international dialogue evolves regarding the adoption of an internationally binding instrument aimed at the recognition of traditional rights holders' rights under the IP system, it is important to look firstly within the IP system and then beyond the IP system for legal means suitable to palliate the unfair use of traditional performances without recognition, attribution or economic reward. With the advent of new technologies and the extension of the concept of property rights to new areas such as traditional societies, the IP system has become more integrated.⁵⁸ This part of the article envisages the manner in which various modes of IP protection as well as non-IP legal systems have become a potential tool for the protection of new rights under a traditional system.

5.1. Enhancing the protection of traditional audiovisual performances outside the copyright related rights regime and within the IP system

Digital distribution resulting from the audiovisualisation of traditional performances raises the possibility of mass dissemination and therefore infringement of traditional rights. Performers play, act, and interpret original works of authorship, which they bring to life.⁵⁹ In this vein, they relate to the copyright regime. Goldstein and Hugenholtz point out that the object of a performance must be a 'work' in the sense of the Berne Convention of the UCC.⁶⁰ This justifies the recognition of a copyright-like property right,⁶¹ with the same effect of copyright principles of ownership and authorship.⁶² Litman notes that the massive distribution of works on the internet is enabled

without the assistance of professional distributors via direct author-to-consumer and consumer-to-consumer dissemination.⁶³ This leads to a reconsideration of the conventional copyright model.⁶⁴

On another side, copyright incentive is generally understood as based on the author's ability to monetize⁶⁵ the distribution of the work of authorship. The absence of recognised authorship in the case of traditional performances precludes deriving benefits and questions the whole concept of copyright.

These two hypotheses underline the failure of copyright and related rights to sustain the IP protection objective which is to reward creativity. Meanwhile, performances are distinctive intellectual and creative life that is as valuable as other knowledge systems.⁶⁶ It therefore becomes imperative to look beyond the copyright regime for suitable means to manage traditional performers' rights under existing IP categories.

5.1.1. Unfair competition

Unfair competition actions based on misappropriation require a much higher standard of protection against audiovisual performances than the one granted under the Treaty. Unfair competition laws under article 10 Bis (2) of the Paris Convention prevent any act of competition contrary to honest practices in industrial or commercial matters, as it constitutes an act of unfair competition. Tribunals may prohibit unfair competitive conduct affecting audiovisual performances of traditional rights holders on this ground.

5.1.2. Extension to TCEs of access and benefits sharing of the CBD

⁵⁸ Merges, Menell, Lemley, *Intellectual Property in the New Technological Age* (4th edn, Aspen 2006) 953

⁵⁹ *Ibid* (n13) 144

⁶⁰ *Ibid* (n17) 234

⁶¹ *Ibid* (n16) 29

⁶² *Ibid* (n17); note for example that in U.S., a performance will be protected under copyright law as long as it is fixed in a tangible medium of expression and meets the Copyright Act's modest originality standard. 235.

⁶³ Jessica Litman, 'Sharing and Stealing' in RS Gruner (ed), *Intellectual Property and Digital Content* (2013) 125

⁶⁴ *Ibid*.

⁶⁵ "Copyright law has long been premised on the assumption that economic incentives to produce creative works are a principal reason for enacting intellectual property protections", Richard Chused, "Sculpture, Industrial Design, Architecture, and the Right to Control uses of Publicly Displayed Works, 17 NW.J. Tech. & Intell. Prop. 55 (2019). P. 114

⁶⁶ S. Rama Rao, 'The Relationship between Intellectual Property and the Protection of traditional Knowledge and Cultural Expressions' in U Popova-Gosart (ed), *Traditional Knowledge & Indigenous Peoples*. (WIPO Publication 2009) 145

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity (CBD) has been adopted as a supplementary agreement to the Convention on Biological Diversity. The protocol is based on a transparent legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising from the utilisation of genetic resources. This represents a valuable contribution to the conservation and sustainable use of biodiversity.

The present paper argues that no principle of fairness in resources management via the benefits sharing (ABS) has been adopted in the context of TCEs. ABS was solely drafted for the context of traditional knowledge and genetic resources. The author emphasises the need of recognition of the benefit-sharing approach within the scope of TCEs, and more specifically on the online distribution platform. This could be translated to benefit sharing of outputs each time a community's audiovisual performance is used for commercial purposes. ABS in this context could be regarded as 'use and benefits sharing'.

5.1.3. Labels of authenticity and geographical indications as indicators of origin of original performances

A primary function of a trademark is to distinguish the goods or services offered by one undertaking from those offered by another.⁶⁷ A trademark may consist of labels of authenticity. The use of a name of a community or region could serve as a label authenticating the origin of the performance/social practice/festive event of the relevant community. The label used as a certification mark is evidence that the festival is related to the place where the performance originates.

The use of the label by cultural industries, broadcasting organisations, the movie industry, etc. could serve as an

indicator of origin and prevent any misuse of the performances. In addition, the use of labels could attract some royalties, which could be sent back to the originating community as instrument of social development, building of hospitals, indigenous education, etc. An example of festival labels is Europe for festivals.



Geographical indications (GIs) constitute an important method of indicating the origin of goods and services under the IP system.⁶⁸ The reputation of a performance could be viewed as an autonomous, commercially valuable intangible.⁶⁹ In this case the reputation of audiovisual performances can be protected against unfair labour practices.⁷⁰

GIs represent an added value scheme for TCEs. Some products identified by a GI may represent characteristic elements of the traditional artistic heritage developed in a given region and manifested through performances. Advantages are numerous for traditional performances:

- GIs are a sustainable tool for recognition of the cultural creativity of traditional performances.
- GIs design a scheme for the performance through code of practice or regulations of use.
- GIs provide protection for audiovisual performances against misleading and deceptive trading practices.

Essama Pierette argues that GIs could perfectly valorise TCEs in the case of several communities owning the same cultural value or promoting a cultural heritage common to the same region.⁷¹ The Igbos Masquerade Drama and Festivals Performances is a relevant example. This social

⁶⁷ DL 101 WIPO/OMPI Trademarks.

⁶⁸ DL 101 WIPO/OMPI Geographical Indications

⁶⁹ Dev S. Gangjee, "From Geography to History: Geographical Indications and the Reputational Link," in I Calboli, WL Ng-Loy

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⁷⁰ *Ibid.*

⁷¹ E. Pierette, Intervention during the first WIPO-WTO African IP Teachers, (University of South Africa, April 2018)

practice is a common cultural heritage to the Anambra, Abia, Imo, Ebonyi, and Enugu communities within the Federal Republic of Nigeria. Even though the practising of the festivities could differ in a few respects, the Masquerade Drama represents similar characteristic elements of all the Igbos people in Nigeria. GIs could therefore valuably enhance protection against unfair trade practices.

5.2. Beyond the existing IP framework

5.2.1. Codes of conduct and community protocols

Since article 6Bis of the Berne Convention protecting moral rights cannot really be used, one could recommend a code of conduct to prevent distortion and promote acknowledgement and ethical use of the performances in line with community rules.

Protocols are about setting codes of conduct or establishing behavioural norms⁷² for the management of traditional performances in the online environment or for use by third parties. Jane Anderson underlines the importance of protocols in Australia in a context where legislation alone could not solve the problem of the misappropriation of indigenous values.⁷³

5.2.2. Traditional IP rights under customary laws

Customary standards can be used to re-draft the concept of ownership, with due consideration to the community dimension such as envisaged by indigenous customary systems. This is the position of some academic scholars, including Professor Thomas Cottier and Marrion Parrizon of the World Trade Institute, who promote traditional intellectual property rights (TIPR) as a means to rescue traditional rights holders from the unfairness displayed under the existing IP system.

Communities could draft the IP rights relating to their performances with cancellation of the terms of authorship and creation that preclude them from partaking in the fruit of IP protection. The terms of individual ownership have been inserted in the national

legal systems in Africa, for example by assimilation of the colonial master's legal system after a country's access to independence. An illustrative example is article 32 of Annex VII of the Bangui Agreement, regulating ownership of audiovisual work, referring to the condition of authorship. Meanwhile, none of the 17 member states of the African organisation of IP have an individual property management approach to its cultural values.

CONCLUSION

This paper argued that the Beijing Treaty constitutes a relevant innovation in the international IP system as precursor to rights for audiovisual performers of traditional cultural expressions. Nevertheless, maintaining conditions of authorship/ownership and terms of protection like several IP treaties disqualify traditional performers in the race for recognition as a subject of IP rights.

The Treaty makes the exigency of ownership a condition for the traditional performer to be granted protection. For example, article 5, relating to performer's moral rights, refers to 'his' performances. As were previously underlined, traditional performances, like other categories of TCEs, are communally owned, and not based on individual authorship. In addition, they are passed down from generation to generation, therefore inherited, not created.⁷⁴ Those characteristics are the antipodes of the substantive requirement for the protection of performances under the copyright and related rights.

The Treaty promotes cultural diversity, without recognising the traditional performer as the subject of rights under the IP system. The relevant recognition of the rights of performers, including actors and singers, is fundamental. This legal incapacity is reinforced by the existence of several restrictions to the enforcement of the performer's moral right.

⁷² Ibid (n10) 62

⁷³ Ibid.

⁷⁴ Ibid (n3)

Copyright-related rights seem to have failed as an enabler of cultural richness. The traditional IP systems fail to recognise the particular nature of indigenous audiovisual performances that encompass inherited spiritual, economic and social connections to their lands and territories. Meanwhile, with the advent of new technologies, indigenous audiovisual performances are constantly misused and misappropriated.

The WIPO-IGC's work has been directed at evaluating if and what additional protections are warranted for TK and TCEs, besides those already provided for in existing agreements. While waiting for an international instrument/s that is binding and regulates the protection of traditional rights holders, and in order to fill this existing legal gap, this paper recommends, firstly, that a look beyond the copyright system in existing IP rights categories be taken to remedy the Beijing Treaty in recognising traditional performers' interests. Secondly, means of protection beyond the conventional IP system and in the field of protocols and traditional IPRs could provide sustainable remedies.

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GEOGRAPHICAL INDICATIONS AS A SOURCE OF COMPETITIVENESS FOR LEAST DEVELOPING COUNTRIES: A CASE OF ZAMBIA AND MOZAMBIQUE

Chanda Ashley Mwali*

ABSTRACT

Geographical Indications (GIs) have been recognised since time immemorial and have also been used as mechanisms for securing the link between quality and other aspects of a product and its region or geographical origin. The connection between the good and the region allows producers of such goods to adopt strategies of niche marketing and differentiation of their products. On the other hand, to consumers, GIs may be understood to denote the origin and the quality of products. Article 22 of the Agreement on Trade Related Aspects of Intellectual Property (TRIPS)¹ provides, inter alia, that regarding GIs, WTO Members shall prevent the use of any means that indicate or suggest a good originates in an area other than the true place of origin. Such an inappropriate use constitutes an “act of unfair competition within the meaning of Article 10bis of the Paris Convention (1967). However, there are exceptions to this rule. In implementing the TRIPS provisions, countries should design appropriate legislation; establish monitoring mechanisms for the quality of production methods against standards, and strengthen enforcement mechanisms. Other forms of international legislation include: the Paris Convention, Madrid Agreement, and the Lisbon Agreement for Appellation of Origin. This article will examine the relevance of GIs in economic development in the context of developing countries.

Key Words: Geographical Indications, TRIPS Agreement, Protection, Product differentiation, Enforcement, standards

INTRODUCTION

Although geographical indications (GIs) may have been in use for a long time, their protection as a form of intellectual property came in 1994 after the GATT in 1994. (GATT, 1994).² However, the first appearance of geographical indications in any legal instrument was at the Paris Convention (Paris Convention 1883), though

Article 1(2) of the convention makes use of appellations of origin and indications of source instead of GIs. This therefore means that GIs have been recognised for a long time. Despite their presence in the legal instruments in Zambia, their use arguably precedes the establishment of the legal system of the country. Land was used as a mechanism for securing a link between quality and other aspects of a product and its region or geographical origin (FAO, 2017). The connection between the goods and the region allows producers of such goods to adopt strategies of differentiating their products and develop market niches.

From the perspective of Lisbon Agreement and sometimes consumers, GIs are understood to denote the origin and the quality of products.³ Many GIs have acquired valuable reputations (Champagne, Cognac, stilton, etc.) which, if they are not adequately protected, may be misrepresented by dishonest competitors. False use of GIs by unauthorised parties may be damaging to consumers and lawful producers. The former deceived and led into believing they are buying a genuine product with a particular source, specific qualities and characteristics when in actuality they are not. The latter, in addition to passing off by false attribution of source, suffer economic losses because valuable business is taken away from them and the established reputation of their products is also lost.

Often, GIs can lead to higher value-added products through product differentiation based on quality and can provide consumers with certified information regarding product attributes. GIs can further enhance and preserve the identity and cultural heritage of a region where a

* Chanda Ashley Mwali is a Legal professional specialised in Intellectual Property and International Trade Law. Possess vast experience in intellectual property management, Protocol administration, Land conveyance and acquisition, contract drafting and negotiation. High level of diplomacy and international relations acquired through various work portfolios and international exposure. Hold the following qualifications: Master in Intellectual property (Zimbabwe), LL.M in International Trade Law (Turin), and LL.B (Zambia). Other qualifications include; Diploma in Diplomatic studies, and Monitoring and Evaluation. Currently a member of the IP policy implementation Committee for ZESCO Limited. I work for ZESCO limited as a Legal Officer.

¹WIPO:

http://www.wipo.int/wipolex/en/other_treaties/text.jsp?file_id=305736

² The General Agreement on Tariffs and Trade is a legal agreement between many countries whose overall purpose was to promote international trade by reducing or eliminating trade barriers such as tariff or quotas

³ The Lisbon Agreement for the protection of Appellations of Origin and their International Registration (As amended on Septemebr 28, 1979)

product is produced⁴. GI products are a result of decades (sometimes centuries) of hard labour and require investment (costs associated with abiding by strict production rules, ensuring quality, etc.), and as such, the state authorities must ensure a mechanism is put in place to grant a monopoly right over the commercial use of these geographical names for the benefit of communities and the state economy at large⁵. Evidence from the market and literature shows that promoting and protecting products under GIs may also result in higher economic gains, quality production and impartial distribution of profits for LDCs rural communities.⁶ GIs encourage the preservation of biodiversity, traditional know-how and natural resources. Leveraging on biological and cultural diversification, the implementation of GIs may represent a unique opportunity to encourage collaboration among the various players along the value chain, including producers, government authorities and researchers⁷. There is a need for countries to develop a legal framework on GIs as a legal instrument for trade development that could assist rural communities in branding their products, which may result in a cultural and commercial rebirth of their territories. This paper will explore the potential socio-economic benefits as discussed at the international level and proceed to discuss in brief the potential difficulties in measuring the impact of GIs. This paper will further attempt to highlight some challenges GIs in developing countries are likely to face, and which could impede their ability to harness the proposed benefits. This paper also reviews the Zambian situation regarding GI legislation and highlights some potential products that may benefit from the GI legal framework. Case studies of Mozambique will be discussed

to reinforce the benefits and implementation of GIs in the context of LDCs.

DEFINING GEOGRAPHICAL INDICATIONS

The protection of GIs as defined in the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) is conditional on the “quality, reputation or other characteristic” of the good being linked to the territory.⁸ Article 22 to 24 of the TRIPS agreements in Part II of the agreement prescribes the protection of GIs. According to Article 22 of the TRIPS Agreement, unless a geographical indication is protected in the country of its origin there is no obligation under this Agreement for other countries to extend reciprocal protection.⁹ But Article 23 of the Agreement provides additional protection to geographical indications only in cases of wines and spirits, meaning they should be protected even if there is no risk of misleading or unfair competition. Article 23 imposes an obligation upon member countries to legislate to prevent the use of geographical indications regarding wines or spirits, which do not originate in the place indicated. The imbalance of protection is the focal point around which the issues of geographical indications revolve. Articles 22, 23 and 24 prescribes the minimum standards countries need to accord to geographical indications. According to Article 22, unless a GI is protected in the country of origin, there is no obligation under this agreement for other countries to extend reciprocal protection. In essence, Article 23 imposes an obligation upon member countries to legislate to prevent the use of GIs regarding wines and spirits which do not originate in the place indicated. Article 24 discusses exceptions and limitations. Champagne, Cognac, Roquefort, Chianti, Pilsen, Havana, Tequila, Darjeeling are some of the well-known examples

⁴ J. Innocensia, E. Henrik & L. Razack, 2015: *Tanzanian Food Origins and Protected Geographical Indications (GI)*; Berlin, Germany “Management of land use systems for enhanced food security: Conflicts, controversies and resolutions” -September 16-18, 2015.

⁵ N.B Monique and V. Massimo, 2011. *Practical Manual on Geographical Indications for ACP Countries*; A publication by CTA and origin

⁶ UNCTAD report, *Why Geographical Indications for Least Developed Countries?* (UNCTAD/ALDC/2015/43)

⁷ UN, 2016: *Why Geographical indications for least developed countries?* UNCTAD Publications.

⁸ TRIPS Article 22 defines a standard level of protection of all products; Article 23 provides an enhanced level of protection for geographical indications for wines and Spirits ; and Article 24 provides exceptions to the protection
⁹https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/1_tripsandconventions_e.pdf

of names which are associated throughout the world with products of a certain nature and quality. One common feature of all these products is their geographical connotation. However, when we hear these names, most often we think of products rather than the places they designate¹⁰. The above examples show that GIs can acquire a high reputation and thus may be viable commercial assets. It is important to note that a variety of concepts exist with regards to GIs. For example, the Paris Convention for the Protection of Industrial Property does not contain the notion of geographical indication. Article 1 paragraph (2) of the Paris Convention¹¹ defines as subjects of industrial property, inter alia, indications of source and appellations of origin.

According to this terminology, the following distinction is advanced between indications of source and appellations of origin: "indication of source" means any expression or sign used to indicate that a product or service originates in a country, region or specific place, whereas "appellation of origin" means the geographical name of a country, region or specific place which serves to designate a product originating therein the characteristic qualities of which are due exclusively or essentially to the geographical environment, including natural or human factors or both natural and human factors¹². To provide more clarity on the two terminologies, the use of an appellation of origin represents a quality link between a product and its area of production attributed to certain characteristics of a product which are exclusively or essentially due to its geographical origin, such as climate, soil or practices of traditional methods of production. On the contrary, the use of an indication of source on a given product is merely subject to the condition that this product originates from the place designated by the indication of source¹³.

When considering geographical indications as a special kind of distinctive sign used in commerce and thus as a particular category of intellectual property, it is important to distinguish them from trademarks. Where a trademark identifies the enterprise which offers certain products or services on the market, a geographical indication identifies a geographical area in which one or several enterprises are located which produce the kind of product for which the geographical indication is used. Thus, there is no "owner" of a geographical indication in the sense that one person or enterprise can exclude other persons or enterprises from the use of a geographical indication, but each and every enterprise which is located in the area to which the geographical indication refers has the right to use the said indication for the products originating in the said area, but possibly subject to compliance with certain quality requirements such as prescribed, for example, in administrative decrees governing the use of appellations of origin¹⁴.

INTERNATIONAL PROTECTION OF GIS AND TRIPS PROVISIONS

The introduction of GIs into the World Trade Organisation (WTO) TRIPS agreement has resulted in unprecedented recognition of this type of Intellectual Property (IP) right internationally.¹⁵ Raustiala and Munzer (2007) posit that the protection of GIs has, however, been controversial in many respects and the means and scope of protection has strongly been contested.¹⁶ Chon (2006), Correa (2000) and Cerkia (2011) agree and posit that, within the broader debate on whether TRIPS has the ability to bring about balanced and equitable economic benefits, a large body

¹⁰ WIPO, 2004: WIPO Intellectual Property Handbook-PUBLICATION No. 489 (E), Reprinted 2008.

¹¹ WIPO: http://www.wipo.int/edocs/lexdocs/treaties/en/paris/trt_paris_001en.pdf

¹² WIPO, 2004: WIPO Intellectual Property Handbook-PUBLICATION No. 489 (E), Reprinted 2008.

¹³ Ibid.

¹⁴ Ibid.

¹⁵ https://www.researchgate.net/scientific-contributions/41858_Daniel_J_Gervais

¹⁶ https://www.researchgate.net/publication/228204121_Relocating_Geographical_Indications

of literature has developed on the justification for and rationale behind GIs.¹⁷

The EU has come out strongly in WTO fora on the point that GI protection can bring about benefits worldwide, with particular reference to developing countries.¹⁸ However, a mutual position is yet to be reached on the actual impact of GIs and the extent to which the prospective benefits can be harnessed in a developing country context.

With regards to protecting GIs, Article 22 of the TRIPs Agreement¹⁹ provides, inter alia, that regarding GIs, WTO Members shall prevent the use of any means that indicate or suggest that a good originates in an area other than the true place of origin. Such an inappropriate use constitutes an “act of unfair competition within the meaning of Article 10bis of the Paris Convention²⁰ (1967)”. However, Article 24 spells out the exceptions to the rules; that is, situations when a WTO Member may decide not to protect GIs. A good example is in Article 25 (5) (b) of the TRIPS Agreement, which allows WTO Members not to protect GIs if a trademark was already registered prior to the protection of the GI in its country of origin.²¹

In line with GI protection, current international debates have sparked proposals calling for the extension of higher GI protection beyond wines and spirits to other products, such as handicrafts, agricultural products and other beverages.

According to Calboli and Gervais, they assert that despite the push for stronger GI products for non-wine products, many developing countries have encountered difficulties in complying with TRIPs obligations including those relating to GIs.²² Designing appropriate legislation and

getting the resources necessary for legal implementation has been a major challenge. Another problem relates to monitoring to ensure the quality of production methods matches the standards required to protect the GIs reputation and its economic value.

GIS AS AN OPPORTUNITY FOR LEAST DEVELOPED COUNTRIES

Zambia, like most LDCs, is struggling to implement the GI legislation and drive the economic and social benefits from this form of IP system.²³ According to an UNCTAD report (2016), most LDCs have limited product diversification and also face fluctuating market values of their traditional products.²⁴ The foregoing are issues that have greatly affected trade flows of LDCs for many decades. In spite of limited product and export diversification, mainly consisting of raw and low value-added products (primarily commodities), a valuable diverse range of traditional products and preparations is available in selected LDCs, including Zambia, which may have potential to graduate to products of excellence and compete globally. However, bringing small local producers upfront in the global value system does not necessarily carry them beyond subsistence. Competition in global markets is generally fierce and many LDCs have recognised the need to develop quality names for the use of certain food products, such as through the protection of GIs, to secure higher returns from sales²⁵. As the case for most LDCs, Zambia is endowed with vast biological and cultural diversity which, when exploited, can result in greater economic benefits and improved social welfare of its people especially the rural community.

Biological and cultural diversities are fundamental for revalorizing traditional food or handicrafts products

¹⁷http://193.5.93.81/edocs/mdocs/geoind/en/wipo_geo_lim_11/wipo_geo_lim_11_9.pdf

¹⁸ Working Paper on developing countries in GATT/WTO Negotiations 2002

¹⁹ WIPO:
http://www.wipo.int/wipolex/en/other_treaties/text.jsp?file_id=305736

²⁰ WIPO:
http://www.wipo.int/edocs/lexdocs/treaties/en/paris/trt_paris_001en.pdf

²¹https://www.wto.org/english/docs_e/legal_e/27-trips_04b_e.htm

²²https://ink.library.smu.edu.sg/cgi/viewcontent.cgi?article=3902&context=sol_research

²³ http://www.ipica-project.eu/sites/default/files/wipo_journal_3_2.pdf

²⁴https://unctad.org/en/PublicationsLibrary/ldc2016overview_en.pdf

²⁵ UN, 2016: Why Geographical indications for least developed countries? UNCTAD Publications

having the potential to benefit rural communities, and in that way supporting them to cope with current challenges (e.g. food security). While traditional knowledge of indigenous and local communities has been recognized as being essential for understanding biological and cultural diversities, attention should be paid when they access and use biological and cultural diversities to ensure fair and equitable benefits and to contribute to sustainable development²⁶.

ECONOMIC VALUE OF GIS AS MARKETING TOOLS

Countries that have embraced GI protection, such as Switzerland (Gruyère Cheese), France (Champagne) etc. have created value for themselves through product branding. Other countries outside of Europe that have effectively utilized GIs include Ghana and Ivory Coast with cocoa, Indian Basmati Rice, etc. The aspect of branding has great potential to upgrade local products from the domestic market to competitive international markets and contribute to local economies through foreign exchange earnings and reduction in the balance of payment which normally exist between the LDCs and developing countries. At the domestic level, the producers will have improved living standards and welfare.

The need for branding is based on identification and differentiation. The identification is achieved through the name, term, sign or symbols associated with a product, and the differentiation comes from unique features / characteristics/ benefits of the product. GI is a powerful tool which can be leveraged, both for identification and differentiation of products.

Success stories on GIs demonstrate that GIs, if properly managed, are intangible assets with great potential for the creation of added value, as well as spin-off effects in areas related to the primary product with which they are associated. Leveraging GI in branding strategy can be a powerful tool because it results in differentiation due to

quality/product differences attributable to their unique geographical origin. It leads to the creation of brand equity by aiding recognition and increased awareness, establishing quality perceptions, creating desired brand associations and building customer loyalty.

Developing a brand based on the GI can greatly assist producers and exporters to effectively exploit the commercial potential of their products. A brand helps sellers create a unique identity and thereby gives indications to customers on criteria that matter to them such as product features, origin, quality, uses, etc. Branding adds value for consumers, as it gives quality assurance and the benefit of authenticity. They help prevent unfair competition from non-genuine products. Because of better value and assurance, the buyers tend to prefer sellers with branded products and buy more from them²⁷.

Learning from the global context and at the regional level, Zambia should take advantage of the unique benefits of implementing a GI system and reap the social and economic benefits from its vast natural resources, agriculture products and handicrafts which have remained undeveloped for a long time.

CASE STUDY ON ZAMBIA

Zambia stands to benefit from the GI system through the various mechanisms highlighted above. Zambia's climatic conditions and rich soils have greatly contributed to agricultural production which the country has experienced for a number of decades. The climatic conditions and resulting agricultural potential have led to a number of unique products which are potential candidates for GI protection. One such example of a potential GI is Pineapple in Mwinilunga of North western Province of Zambia. The soils of the area (predominantly Kalahari contact soils) are generally acidic and of low productivity, but specific crops such as pineapples and cassava can thrive on them. The soil types also vary across

²⁶ UN, 2016 pg.5: Why Geographical indications for least developed countries? UNCTAD Publications

²⁷ UN, 2016: Why Geographical indications for least developed countries? UNCTAD Publications

the area. Patches of fertile red clay soil, in addition to river floodplains or damboes, provide sites more suited to agricultural production²⁸. The area is so far the only place known for pineapple production in Zambia and presents a good opportunity for communities in Mwinilunga District to benefit from pineapple production and GI registration for marketing purpose at local and international levels.

Another important potential GI is the cashew nut grown in western province of Zambia. The cashew grows in the arid regions of western province with its temperate kind of climate, with some dry seasons and short rain season. Rainfall is approximately 1000mm. The other potential GI is the rice which grows in the flood plains of the same region around Mongu district and surrounding areas. The two crops are of great significance in that they provide a great source of income to the growers. In addition, owing to food insecurity in the country, the two crops are a source of nutrition for many families of this particular region of the country. Overall, there is also great demand for these two crops from Zambia's neighbouring countries with the potential to become foreign exchange earners for the country. Others may include handcrafts and traditional crops which are specific to certain regions in countries such as Mango from Luapula and Luangwa river basins.

In terms of the legal framework, Zambia currently has no law on GI at the domestic level. However, Zambia is a member of the WTO and the TRIPS Agreement therefor applied from 1995. At the national level, the trademark law CAP 401²⁹ as provided for registration of Certification trademarks. According to section 42. (I), a Certification trademark is, a mark adapted in relation to any goods to

distinguish in the course of trade goods certified by any person in respect of origin, material, mode of manufacture, quality, accuracy or other characteristic from goods not so certified shall be registrable as a certification trademark in Part C of the register in respect of those goods in the name, as proprietor thereof, of that person: Provided that a mark shall not be so registrable in the name of a person who carries on a trade in goods of the kind certified.³⁰ Despite this provision, there is a need for the country to enact laws on GI, against the backdrop that all forms of trademark registration tend to create a monopoly for few individuals through whom the marks have been registered. A sui generis system for GI protection would enable the country to protect its various agricultural products and reap the social economic benefits. However, the good news is that the current Trademarks Bill of 2016, before parliament, has provided for protection of GIs³¹.

CASE STUDY ON MOZAMBIQUE

Mozambique is a member of WIPO, a member of the Paris Convention, a signatory of the Madrid Agreement and a WTO member.³¹ In terms of the GI regulatory framework, Decree 21/2009 by the government of Mozambique approved the Regulation of Appellations of Origin and Geographical Indications.³² The scope of application of the law is more extensive than the scope of the EU system (applicable to all agricultural and industrial goods).³³ The Industrial Property Institute is responsible for the registration of GIs.³⁴ Mozambique is also a member of the African Regional Intellectual Property Organization (ARIPO).

According to the recent Mozambican Industrial Property Code Decree No. 47/2015 of 31 December 2015³⁵, the

²⁸ I. Pesa, (2014) Moving along the roadside: a social history of Mwinilunga District, 1870s-1970s <https://openaccess.leidenuniv.nl/bitstream/handle/1887/28744/02.pdf?sequence=8>

²⁹ The Trade Marks Act (Chapter 401); version of 1994 as amended <http://41.77.4.165:6510/www.wipo.int/edocs/lexdocs/laws/en/zm/zm003en.pdf>

³⁰ <http://www.parliament.gov.zm/sites/default/files/documents/acts/Trade%20Marks%20Ac>

³¹ https://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2

³² https://au.int/sites/default/files/documents/36127-doc-au_gis_continental_strategy_enng_w

³³ <http://www.fao.org/faolex/country-profiles/general-profile/en/?iso3=MOZ>

³⁴ https://www.wipo.int/members/en/contact.jsp?country_id=125&type=ADMIN_IP

³⁵ Mozambique (2016). Industrial Property Code, Decree No. 47/2015 of 31 December 2015

right of ownership over a geographical indication or a designation of origin shall be acquired on registration in accordance with the provisions of the Industrial Property Code. Article 163, Section (2) of the Code states that, once registered, geographical indications and designations of origin become the common property of those who effectively reside or have their place of business in the locality, region or territory, and can be used interchangeably by those who carry out any characteristic productive activity in the area, subject to the consent of the registered owner.³⁶

Further, section (3) of the same Article states that, the exercise of the right does not depend on the importance of the operation, the nature of the products, nor an affiliation to any association and, consequently, the GI or designation of origin shall apply to all products that are characteristic of and originating in the locality, region or territory, in the usual and traditional conditions, or duly regulated.³⁷

According to Inventor international (2018) report, in terms of GI registration, Mozambique had recorded its first ever GI registration in 2018³⁸ (through the Registration of Tete goat meat.³⁹

Tete Goat Meat

The Mozambican goat market has recently obtained registration for the 'Tete goat' as a GI under the Industrial Property System in Mozambique. According to Moyo (2018), this is the first registered Mozambican GI and a milest one in the history of the nation.⁴⁰ The Tete GI registration is in relation to the unique Tete Goat meat products. Furthermore, Moyo (2018) states that the

Goats belong to the species *Capra aegagrus* or *Capra hircus*. The Goats are reared in extensive systems, according to traditional practices in the area.⁴¹ For example, feeding takes place on natural pastures, hay, standing stubble and straw.⁴² The flavour and juicy taste of Tete goat meat originates from grazing in natural pastures in the semi-arid region but also from the consumption of massaniqueira, massanica and malambe (baobab fruit), mainly in the dry season, which is the longest in the region, from April to November.⁴³ The fruits and leaves of massaniqueira and baobab are commonly consumed by goats and cattle.⁴⁴ Goats are reared in the Tete province and in adjacent areas with similar soil and climate conditions. The main source of goats sold in Tete City is the southern region of the Tete province⁴⁵.

The Agro-climatic conditions are prominently arid and semi-arid, with very hot and rainy summers and cool dry winters.⁴⁶ The spontaneous vegetation and natural pastures mainly consist of xerophytic flora (e.g. *Combretum* spp, *Colophospermum mopane*, *Adansonia digitata* (Baobab), *Heteropogon contortus*, *Aristida* spp. and *Acacia* spp) during the dry season⁴⁷.

The registered GI for Tete goat will bring in benefits to the communities and the province as a whole. For instance, according to UN (2016), the GI can be useful not only for exports of Tete goat meat to foreign markets but also to supply supermarkets in other domestic provinces.⁴⁸ For example, locally in Tete City, a registered GI will now imply quality improvement from goat rearing and processing to commercialization. Due to the GI, a

³⁶<http://www.inta.org/GlobalPortal/Pages/Profile.aspx?country=Mozambique>

³⁷<http://www.inta.org/GlobalPortal/Pages/Profile.aspx?country=Mozambique>

³⁸ Inventa International (2018) <https://inventa.com/en/pt/news/article/309/tete-goat-first-geographical-indication-of-mozambique>

³⁹ https://unctad.org/en/PublicationsLibrary/aldc2015d4_en.pdf

⁴⁰ <https://www.vonseidels.com/tete-goat-the-rise-of-gis-in-sub-saharan-africa/>

⁴¹ <https://www.intechopen.com/books/goat-science/goat-system-productions-advantages-and-d>

⁴²<https://inventa.com/en/news/article/309/tete-goat-first-geographical-indication-of-mozam>

⁴³ https://unctad.org/en/PublicationsLibrary/aldc2015d4_en.pdf
⁴⁴http://www.fao.org/ag/againfo/resources/en/publications/sector_briefs/lsb_MOZ.pdf

⁴⁵ UN, 2016: Why Geographical indications for least developed countries? UNCTAD Publications

⁴⁶https://www.researchgate.net/publication/23663923_Communal_goat_production_southern_Africa

⁴⁷ UN, 2016: Why Geographical indications for least developed countries? UNCTAD Publications

⁴⁸https://unctad.org/en/PublicationsLibrary/aldc2015d4_en.pdf

potential price increase can support local rural communities who currently consume cheaper goat meat sold in informal markets. But other markets for Tete goat meat may be exploited in other provinces and countries as well. Additionally, in Tete City, there is a well-organized municipal slaughterhouse that is willing to be a stakeholder under the GI registration⁴⁹.

White prawn

Another unique product with GI potential is the well-known white prawn from Mozambique which has peculiar organoleptic features, characterized by a distinctive flavour appreciated by consumers. The taste and the unique texture are because the prawns eat and grow in their natural habitat. With regard to organoleptic characteristics, the meat of the white prawn is compact and lean. The flavour is typical for marine prawns having a soft smell of fresh seaweed.⁵⁰ Because of the firm texture, it is difficult to take the meat out of the shell, and it has a higher yield of edible parts in comparison with freshwater prawns.⁵¹ Therefore, there is a close link between the geographical area and the mangrove ecosystem in which white prawn is fished along the coast, over a length of 1,200 km that covers an area of 400,000 ha. Of these, approximately 126,000 ha are geographically concentrated between Pebane and the Save River and between Quelimane and the Mocambo Bay⁵².

The extensive areas of mangroves associated with river bays are considered ecologically important productive areas due to the high amounts of nutrients that characterize these zones.⁵³ They have large natural nurseries for species typical to these environments such as fish. The white prawn from Mozambique (*P. indicus*) is fished in a geographical area with unique ecological conditions for the growth of post-larvae and juvenile

prawns. This environment provides ideal conditions for the protection of the prawn and holds large amounts of nutritious food. According to UN (2016), the white prawn is also drawn into this geographical fishing area because of a large river network discharging into the Indian Ocean, especially the two main rivers, Zambezi and Save, in the Sofala Bank region.⁵⁴ These form the only deltaic coasts of the country. Thus, the white prawn from Mozambique has a differentiated quality, an acknowledged reputation and is widely accepted in both domestic and international markets, and is preferred by consumers who distinguish its unique characteristics.

CONCLUSION

Geographical indications are vital for the economies of LDCs, as they can support the development of local international markets of local products. The countries should therefore formulate appropriate legislation to support the development of GI protected product value chains and enhance product competition in the global economy. Though some strides have been made with some LDCs establishing laws, there is more work to be done to raise awareness among the various stakeholders in the respective countries. For instance, Zambia currently has no specific laws on GI protection. The trademark law which is the closest alternative has provisions for collective marks and certification marks. However, this type of protection is limited in scope and has the disadvantage of excluding the majority in the case of collective marks which may belong to a small section of society. The trademark law as provided for in the TRIPS agreement also prevents marks which are protected as trademarks from GI registration. In the case of Mozambique, despite having legislation on GI protection through Decree 21/2009, the country has only managed to record one GI protection for Tete goats.

⁴⁹ UN, 2016: Why Geographical indications for least developed countries? UNCTAD Publications

⁵⁰ https://unctad.org/meetings/en/Presentation/aldc2014-12-16_White%20Prawns.pdf

⁵¹ https://wwf.panda.org/knowledge_hub/where_we_work/east_african_coast/mozambican_

⁵² UN, 2016: Why Geographical indications for least developed countries? UNCTAD Publications

⁵³ https://www.researchgate.net/publication/271510319_Mozambique_marine_ecosystem

⁵⁴

http://www.fao.org/fishery/docs/DOCUMENT/fcp/en/FI_CP_MZ.pdf

The researcher would like to recommend that deliberate programmes and institutions are put in place to promote and support implementation of GI systems where laws are readily available. Zambia is, however, also in the process of developing a legal framework on GI by incorporating a section on GI in the Trademark amendment bill of 2016, which is still before parliament for possible enactment into law. The responsibility lies with various governments in LDCs to take proactive steps and support the development of GI systems and facilitate registration of GI to contribute to social and economic development.

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GEOGRAPHICAL INDICATIONS AS A TOOL FOR ENHANCING ETHIOPIAN APICULTURE VALUECHAIN AND DEVELOPING THE HONEY MARKET AT DOMESTIC AND INTERNATIONAL LEVEL

Selam Gebrehiwot*

ABSTRACT

The world's concern towards the promotion and protection of intellectual property (IP) assets is increasing from time to time with the advancement of technology and cross boundary marketing systems. Developing countries are also adopting laws on IP and complying with international standards recognizing the role of IP in facilitating international trade and rural development. The scope of IP rights protection in Ethiopia is also growing to promote local products at international markets. Millions of Ethiopians' lives depend on the production and trade of multiple agricultural products. Beekeeping is among the integral income sources of households in the country. Ethiopia is the biggest honey producer in Africa and 10th in the world. However, it has not tapped its full potential in production and export of this commodity. It has a huge potential of serving its citizens and other countries with differentiated organic honey products. Currently poor quality and quantity of production has limited the country's benefit from the commodity. But the current attention employed by the government and engagement of private entities in the production and processing of honey is a good opportunity for the country to access international market and improve the lives of its citizens. Adding value to the product use through IP has a significant role in promoting the product. The newly introduced geographical indications (G) protection in the country's legal system can be a good mechanism for bringing such effect.

Key words: Apiculture, honey, geographical indications, value chain, rural development.

INTRODUCTION

Beekeeping has been an essential aspect of agriculture. It is adopted as a local development strategy by many countries for ensuring food security, economic

development and environmental sustainability.¹ Like the case in many developing countries, this sector plays an important role in Ethiopia's economy as well. The history of honey production and market in Ethiopia dates thousands of years back. Ethiopia is the 1st in Africa and 10th world largest honey producer. With around 10 million bee colonies, it is also the owner of the biggest bee colonies in Africa.² Beekeeping is practiced in many parts of the country with different tastes and colors of the honey depending on the environment...honey in Ethiopia it is dominantly produced through traditional techniques. The apiculture industry accommodates the lives of different groups of the society serving as a means of income mainly for women, the youth and unemployed people in the country.³

Despite the fact that the country has been practicing honey and beeswax production for very long, the sector has not been promoted as much as required. The sector is characterized by low production rate and poor-quality honey. The use of traditional techniques coupled with lack of skill on effective management of production and marketing strategy has been a factor for the production of honey with less quality and quantity adversely affecting the economic returns of farmers. Though consumers traditionally distinguish the source of the honey with their colors, the producers have not adopted skills in promoting their specialty products in the market. The market is typically characterized by no formal value chain and fixed actors. Producers are forced to sell their products to local wholesalers at lower prices and they are unable to easily access domestic market.⁴ Also in many

*Selam Gebrehiwot graduated with a law degree from Mekelle University in 2013. She obtained her Master's degree in taxation and Investment from Mekelle University in the year 2015. She has been working as a lecturer at Mekelle University since 2014. She was seconded to the Ethiopian Intellectual Property Office in August 2016 and worked there as a director of the IP development Directorate until August 2017. At present Selam is teaching IP in the undergraduate program at the University and her research interests are focused on IP for agricultural development.

¹ Atsbeha Hailemariam, Taye Tolemaria and Kebede Debele, 'Assessment of honey production system, constraints and opportunities in there selected Woredas of Tigray region, Ethiopia' (2015) 4(10) Basic Research Journals

<<http://www.basicresearchjournals.org>> accessed 27 March 2018, 305

² Haftu Kebede Sebeho, 'production and quality characteristics of Ethiopian honey: a review' (2015) 8(4) Academic Journal of Entomology 168, 169

³ Melaku Girma and others, 'Approaches, methods and processes for innovative apiculture development: Experiences from Ada'a-Liben Woreda Oromia Regional State, Ethiopia' (2008) Improving productivity and Market Success (IPMS) of Ethiopian Farmers Working paper 8 <www.ipms-ethiopia.org> accessed 27 March 2018

⁴ Ministry of Agriculture (MOA) and International Livestock Research Institute (ILRI), *Apiculture value chain vision and*

cases, the honey producers sell their products locally in traditional markets directly to users. This is mainly caused by lack of government or private actors engaging in the sector to create connection between the stakeholders. Such traditional marketing system and lack of government control gives rise to irresponsible use of the product and adulteration. This leads consumers to opt for cheapest honey without being familiarized with the specific sources and qualities. This may result in unsustainability of consumer preferences towards their specific products. It also limits the country's ability to produce with full potential and make it an export commodity as well as source of foreign currency.

Recently the government is taking actions by enacting laws, expansion of research and extension, inclusion of apiculture related courses in the curriculum and policies strategizing the apiculture industry in the way it enhances the lives of the actors and contributes for the overall economy of the country.⁵The engagement of private organizations in honey production and processing is also a recent phenomenon in Ethiopia. Different government agencies and international and local private bodies are taking part in value chain development activities by providing technical and financial assistance to the stakeholders.

The Ethiopian Intellectual Property Office (EIPO) which is entrusted with ensuring the legal protection of intellectual properties and maximizing its role in development,⁶ has reached an agreement to adopt a sui generis law on GIs. The Agence Française De Développement (AFD) under its Trade Capacity Building Program (PRCC) project showed an interest to approve a project for defining a legal framework on the protection of GIs in Ethiopia. A draft legislation has been prepared by EIPO and has been submitted for review to the relevant

government Organ. This action can be taken as a big shift for developing the agricultural sector and IP value addition to the country's export commodities. The draft law, which is prepared in accordance with international and regional laws on protection of GIs, is expected to regulate production and trading of agricultural products in Ethiopia by delimiting areas, setting labeling standards and introducing traceability mechanisms.

This paper specifically focuses on the need of taking this opportunity for enhancing the Ethiopian apiculture industry by using GIs to develop the domestic and international honey market. The government and non-governmental bodies' action towards an improved quality and quantity of production, supported by IP asset inclusion in marketing the product, has a potential to shift consumers' preferences towards Ethiopian honey. This paper argues that GIs are the relevant IP protection system suitable to promote and enhance Ethiopian apiculture industry. As showcased in cheese and wine products protected by GIs in Europe, protection of reputed indigenous products with GIs coupled with effective implementation and regulation of its production and marketing process has an economic, cultural and environmental significance. Ethiopian honey industry is one of the country's untapped industries with huge potential and unique taste and color qualifying it to be protected by GIs. Effective management of the GIs system in Ethiopia will contribute to support local producers of agricultural products by effectively linking the origin to the products and building a strong cooperation between stakeholders to maximize the economic and social returns.

The paper is divided in different parts. The first section discusses the existing facts related to honey production and export in Ethiopia followed by the second part

strategy for Ethiopia, (2013) Ethiopia Livestock Master Plan Background Paper 1

⁵ Negash Bekena and Juergen Greiling, 'Quality Focused Apiculture Sector Value Chain Development in Ethiopia' (2017) *A 7 Journal of Agricultural Science and Technology* 107

⁶ Proclamation no 320/2003, on Ethiopian Intellectual Property Office Establishment [2003],art 5(1)

discusses history of GIs and its role in promoting agricultural products. The third section focuses on the existing enabling policies and legal frameworks to implement the proposed law in Ethiopia. The fourth part highlights some of the challenges in developing the apiculture industry in Ethiopia. Finally, the fifth section analyzes the facts with the proposed solution stressing on how GIs will contribute in enhancing the apiculture industry and contribute to the economic and social development of the country.

ETHIOPIAN HONEY FACTS

Ethiopia's economy is mainly based on agriculture. According to the first Growth and Transformation Plan period (2010/11-2014/15) report, Agriculture contributed for 41.5% of the overall GDP of the country in 2009/2010 and 38% in 2014/2015. (GTP II, pp7). Ethiopian agricultural products which take the lead in the export include flower, fruits and vegetables, coffee, sesame and cereals.⁷ Agriculture still remains to be the backbone of the country's economy. It is recognized as a means to improve lives of smallholder farmers and creating jobs for youth farmers by linking them with private investors which can provide capital and technologies.⁸ The sector has a huge potential to create jobs for unemployed youth as well.⁹

The role of honey in improvement of the lives of many people, poverty reduction, uplifting economic return to a country and environmental conservation is recognized by many sectors in Ethiopia resulting in their engagement in the sector. It is considered as a commodity with big potential of pulling millions of poor farmers out of

poverty. Small holders improve their lives by deriving income from honey production and its byproducts such as beeswax, pollen, bee venom and bee colonies. Honey production is a preferable business for small holders because it requires little investment of capital and labor creating better market opportunities.¹⁰

Beekeeping is a longstanding practice in Ethiopia estimated to have started around the 3rd hundred AD. Significant numbers of societies have engaged in beekeeping in different regions of the country. Tigray, Oromia, Southern Nations, Nationalities and Peoples Regional State (SNNPR) and Amhara regions, are the main sources of honey and beeswax production in Ethiopia. More Specifically places such as Wollega, Sidamo, Jimma Gondar, Gojjam, Raya Azebo and Temben are the most popular sources.¹¹ In spite of this fact, honey, beeswax production and the apiculture sub-sector has not met the required level of production and quality standards.¹² Currently, around 2 million people have regularly based their livelihood on honey production.¹³ The country offers varieties of plants that serve as bees' forage. This has contributed for the country's leading production capacity and potential in the world, particularly in Africa. Ethiopia's ecological status with diversified and typical plant varieties and environment has contributed to achieving the highest bee colonies and honey and beeswax production in the continent.¹⁴ More than 7000 species of plants serving as bees' forage are estimated to be found in Ethiopia. These plants contribute for producing variety of honey with their own

⁷ Federal Democratic Republic of Ethiopia Growth and Transformation Plan II (2015/16-2019/20), 123, <<https://www.greengrowthknowledge.org/sites/default/files/downloads/policy-database/ETHIOPIA%29%20Growth%20and%20Transformation%20Plan%20II%2C%20Vol%20I.%20%20%282015%2C16-2019%2C20%29.pdf>> accessed June 2020

⁸ Ibid 82

⁹ Apitrade Africa, 'Ethiopian Youth to benefit from "young Entrepreneurs in Silk and Honey" project' (2016) 023 The African

Honey Magazine <www.apitradeafrica.org> accessed 25 April 2018

¹⁰ Yoshimasa Ito, 'Local Honey Production Activities and Their Significance for Local People: A Case of Mountain Forest Area of Southwestern Ethiopia' (2014) sup 48 African Study Monographs, 77

¹¹ Melaku (n3) 4

¹² Ministry of Agriculture and Rural Development (MOARD) : *Annual Reports Series* (2006)

¹³ Negash (n5)107

¹⁴ Atbeha (n1) 305

typical tastes. This potential has attracted many agencies to engage in the production and processing of honey.¹⁵

Ethiopia has produced 60.7 thousand tons of honey in the year 2014/15 and has a short-term plan to increase production to 123,900 tons by the end of the year 2019/2020,¹⁶ and 200,000 tons by 2025.¹⁷ This makes Ethiopia the leading honey producer in Africa accounting for 21.5% and 10th in the world accounting for 2.5% of the total production. The country's estimated potential of production is 550,000 tons annually, only 10% of which is exploited. Even though traditional hives and techniques are used, the sector records certain improvements from time to time with the engagement of many actors.¹⁸ About 90% of the honey produced is available in markets for income generation while the remaining 10% is consumed by the beekeeping households. The greatest percentage of the honey produced in the country is consumed at domestic markets, of which about 70% is used for making honey wine, known as 'Tej', locally, while the rest portion is used as table honey. Because of such consumption pattern, very little amount is exported. The export rate composes only 2% and this makes it hard to consider honey as an export commodity at present and the country is only the 45th largest exporter worldwide. The country has a plan to increase the amount of export which is about 400 tons to 2400 tons by 2025.¹⁹

The Ethiopian Growth and Transformation Plan II (2015-2020) emphasizes the need to maximize the country's export capacity by promoting effective honey production and marketing with an improved quality and quantity. The plan acknowledges the industry's role in creating job opportunities and tackling poverty. 374 million USD is planned to be collected from the export of meat and its by-products, honey and beeswax, processed fish, and

milk and milk products.²⁰ It is reported that 416.56 million USD were generated from the export of meat, milk and honey in the 1st Growth and Transformation Plan (GTP I) period, recording an improvement throughout the years.²¹

The apiculture industry and the products offered to international markets are bringing more economic gain to developing countries.²² However, the sector faces multiple challenges which negatively impact the amount and quality of production. Among the biggest challenges the Ethiopian honey production is struggling with is poor quality honey attributed to lack of modern technology and effective management of production and export.²³ Ethiopia is striving to develop the sector and share the benefits providing quality honey products to the international market. The Government of Ethiopia (GoE) is embarking on developing the sector through different activities which are supported by other private bodies with similar mission.

The global honey market in EU, USA and the Middle East is a huge opportunity for Ethiopian honey as the demand increases from time to time. The involvement of government and non-governmental bodies in distributing modern hives as well as providing technical knowhow to the producers and private bodies' engagement in the sector has contributed for the improvement of the industry. But still, the country is not much benefited from the commodity as much as its potential requires.²⁴ The Ethiopian apiculture industry calls for system intervention in ensuring best quality and making it an export commodity to meet its basic needs.²⁵ Undoubtedly, Ethiopia should exert extra effort to fully exploit its

¹⁵ Yoshimasa (n 10) 78

¹⁶ GTP II (n 7) 16

¹⁷ MoA (n4) 6

¹⁸ Ibid, 1

¹⁹ Ibid, 6

²⁰ GTP II (n12) 139

²¹ Ibid 39

²² Paulos Desalegn, 'Ethiopian Honey: Accessing International Markets with Inclusive Business and Sector Development' (2012), <www.snvworld.org/en/sectors/agriculture> accessed June 2018

²³ Atbeha (n 1) 168

²⁴ MOA (n 4) 2

²⁵ Paulos (n22) 2

production capacity and offer the world with organic honey.

Ethiopia has succeeded in qualifying for EU third country listing in 2008.²⁶ This has allowed the producers and traders whose market was highly limited to local and neighboring countries to consider better options. The export has significantly increased since the year 2010. Norway takes the biggest share in importing Ethiopian honey followed by neighboring countries Sudan and South Sudan.²⁷ This opportunity also encourages the youth to engage in traditional honey production, processing and export. This can also contribute for taking due attention on quality standards to get better market access by the government and stakeholders. This paper highlights the importance of availing means to consumers to verify sources by linking products with their geographical origin. It recommends adding IP value to the products and familiarizing consumers with Ethiopian specialty honey products worldwide.

GIS FOR AGRICULTURAL DEVELOPMENT

The experience of developed countries has proved the role of IP in enhancing one's economic development by regulating invention and technology transfer. IP assets have been used as marketing tools which has to be effectively utilized and administered as it determines the value of the goods and services they are embodied in.²⁸ Many developed and developing countries have become members to international agreements on IP and adopted domestic laws recognizing its role in realizing development.

Consumers' choices of goods are dependent on the quality and the reputation of the goods in reference to the place they originated from. They are becoming keener about the quality of agricultural products and geographical source as their awareness on food safety and health related matters increased.²⁹ Specifically, they take due attention to the sources and ways of production of agricultural goods. According to Article 22 of the TRIPs Agreement, Geographical indications are defined as indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.. GIs create a linkage between a product and an identified geographical location and set standards that are applicable in the production of that specific product. These laws give producers a right to prevent others from using the indication for the production and marketing of the product which does not follow such standards.³⁰

GIs' role on the realization of rural development and poverty reduction is subject to different arguments. The arguments for GIs stress on its role in promoting agricultural rural development by providing income and employment opportunity.³¹ Practical cases of products protected by GIs in countries such as Italy, France, Jamaica and India showcase the significant role of this products in the countries' economies and societies as their source of income as well as promoting their cultural and environmental values.³² GIs are considered as means of ensuring economic, cultural and environmental sustainability in many cases. It is justified as promoting

²⁶ Yoshimasa (n10)

²⁷ Final Report for WEEMA International, Improving household livelihoods with modern beekeeping and honey production in Ethiopia, (School of International and Public Affairs (SIPA) and WEEMA International, 2016) 17

²⁸ Getachew Mengiste, *Intellectual Property as a Policy Tool for Development: The Ethiopian Fine Coffee Designations Trademarking and Licensing Initiative Experience* (A case study commissioned by WIPO, World Intellectual Property Organization 2011) 7

²⁹ Cerkia Bramley, Estelle Biénabe and Johann Kirsten, *The economics of Geographical Indications: Towards A conceptual*

Framework for Geographical Indication Research in Developing Countries, (The economics of Intellectual Property, WIPO) 109

³⁰ World Intellectual Property Office (WIPO), *Intellectual Property for Agri-food Small and Medium Enterprises* (Guide, WIPO 2015) 155

³¹ Bilge Dogan and Ummuhan Gokovali, 'Geographical Indications: the aspect of rural development and marketing through the traditional products' (2012) 62 *Procedia: Social and Behavioral Sciences* <www.sciencedirect.com> accessed 30 may 2018, 762

³² Daniele Giovannucci and others, *Guide to Geographical Indications: Linking products and their origins*, (International Trade Center, 2009)

differentiated products which may bring in varied biodiversity by creating sustainable means of production.³³ Taking the argument that effective management and implementation promotes rural development and protection of GIs should extend to all food products; this paper analyzes how Ethiopia can promote its differentiated products by using GIs. On the other hand, others as opposed to GIs, see them as typical European system limiting local producers from freely using geographical terms and origin specific designations for their generic products.³⁴

GIs create a link between the name of the specific geographical origin and the quality of the product which in most cases bases itself on a reputation that already existed. Such marks give information to the consumer about the origin of the product that enables the consumer to choose based on the quality linked to the place. Using these indications has an impact on influencing economic return towards the producers of the reputed product.³⁵ GIs also play an important role in protecting cultural heritage, promoting local cultures and traditions, reducing rural poverty and ensuring environmental conservation sustainability.³⁶ Origin based products represent a particular product with its typical local identity as the protection by GI recognizes the link between that typicity and authenticity of the product with the indicated source. This is insurance to consumers that the product with that tag on it is actually the product that they preferred possessing the quality it is reputed for. This has a direct or indirect positive impact on the economic, social and environmental perspectives.³⁷ Unlike trademarks, which are used to distinguish goods or services owned by one enterprise from the other, GIs inform the user of origin of the products, production processes and expected quality

standard. Moreover, trademarks can be registered before the goods or services have got reputation while in cases of protection through GIs, reputation is a necessity. Trademarks which merely describe geographical origin of the good are not able to be registered unless consumers associate it as identifying the company or the producer with that specific place over time.³⁸

Protection of GIs dates back to the 18th Century where laws regulating fraudulent acts of producers were introduced to protect consumers. GI laws were originally adopted as system of tackling adulteration and fraudulent usage of indications practiced in the wine industry. In the 20th Century, the wine industry was challenged by multiple problems that resulted in European governments' action against it through formal delimitation of the wine growing areas. France adopted the first law in 1905 to combat fraudulent wine labeling by creating the French appellation of Origins system for wines, spirits, cheeses and other agricultural products. Two years after the European Union regulated GIs for agricultural products and foodstuffs in 1992, the GIs as IP rights were recognized by the TRIPs Agreement.³⁹

The GI protection system is originally a European system concerned with protecting economic benefits of producers and consumer protection. Such protection has been limited and mostly applicable for the protection of food wines, spirits and cheeses. However, such trend is changing and the scope is widening to cover the protection of agricultural food products. Darjeeling tea from India, Tequila from Mexico, Gruyère Cheese from Switzerland, Colombian Coffee and Tete Goat from Mozambique are some of the well-known GI protected goods in different parts of the world.⁴⁰ GIs give rise to the relationship between a place and quality of the product

³⁴ Rachael M. Williams, 'Do Geographical Indications promote sustainable rural development?' (2009) *Journal of Austrian Society of Agricultural Economics* 31

³⁵ *Ibid* 156

³⁶ Food and Agriculture Organization of the United Nations (FAO) and SINER-GI, *Linking People, Places and Products, (A guide for*

promoting quality linked to geographical origin and sustainable Geographical Indications, FAO and SINER-GI, 2009)

³⁷ *Ibid* 3

³⁸ Daniele (n26)

³⁹ WIPO (n24) 77

⁴⁰ *Ibid* 156

which may be a result of environmental or social factors. It institutionalizes the system by setting quality standards that have to be met and sanctions for misappropriation of the benefits through legal means.⁴¹ Thus, the already existing reputation is safeguarded by providing a legal framework for production and marketing.

ETHIOPIAN POLICY AND LEGAL SET UP ON APICULTURE DEVELOPMENT AND IP

The GoE has adopted a policy that promotes the improvement of the apiculture industry recognizing its potential to support the country's economy. Such action is also supported by research and extension projects. It has included the development of apiculture industry as one basic strategy for the overall development of the country in the 2nd GTP. Additionally, Ethiopia has adopted Proclamation no 660/2009 on Apiculture Development. The law has recognized the role of apicultural sector development in: the overall economic development of the country, reducing poverty rate by an increased production and environmental conservation.⁴²

There are different governmental and non-governmental institutions and associations which are actively engaged in the apiculture value chain development in the country. Among these are the Ethiopian Agricultural Transformation Agency, the Ethiopian Apiculture Board, the Netherlands Development Agency (SNV), Farm Africa, Slow Food Foundation and WEEMA International. These actors have actively supported the sector by raising awareness on effective harvesting skills, conducting research and extension programs, and boosted quality standards, creating market opportunities, value chain development and financial support to cooperatives. Public actors, such as state, regional and local governments, as well as other authorities and institutions representing the public interest, can play a particularly important role in the local development of origin-based products in order to enhance their positive contribution

to rural and sustainable development., they can provide an adequate legal and institutional framework enabling the recognition, regulation and the protection of collective property rights on GIs.

The GTP recognizes the role of developing agro-processing industries, such as honey processors, in maximizing the country's benefit from the sub-sector.⁴³ Building a system that links actors in the value chain such as beekeepers, retailers, tej brewers, processors and exporters, may bring an effective production and marketing system at domestic and international level. Ethiopia's action towards the adoption of laws on IP and institutional setup for the implementation has brought improvements in the area. Even though Ethiopia has not yet adopted a comprehensive national IP policy, it has recognized and protected some aspects of IP through issuing legislations. It has laws that govern patents, utility models and minor invention, copyrights, trademarks, plant varieties and protect against unfair competition.⁴⁴ But all aspects of IP have not been addressed. The country's involvement in international IP agreements is also very limited. Ethiopia is not a member to the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement, the Madrid convention or the Lisbon agreement, that obligate countries to recognize or protect GIs. It does not also have a sui generis law on GIs so far.

IP is not a well-developed and utilized subject matter in Ethiopia. Ethiopia has signed only two international agreements on IP which are the WIPO establishment convention and the Nairobi agreement on Olympic signs. Unlike the case in many countries, IP is not offered in higher education institutions as a separate subject of specialization. The country's limited membership in these agreements and understaffed institution with less qualified personnel has been a challenge for effective protection and enforcement of IP rights in Ethiopia. Both

⁴¹ Cerkia (n23) 110

⁴² Proclamation no 660/2009 on Apiculture Resources Development and Protection (2009) preamble

⁴³ GTP II, pp 138

⁴⁴ WIPO pub 1029, pp 18

developed and developing countries own IP assets but the management and effective utilization of it has created a difference in its economic returns.⁴⁵ The intangible assets enhance the value of the product they are embodied in. Despite the fact that Ethiopia produces and exports limited percentage of the potential production capacity, the sector shows improvement from time to time. The engagement of governmental and non-governmental entities in the sector has created a better production and market environment for the actors.

The Ethiopian Trademark Registration and Protection Proclamation No 501/2006 and the Trademark Registration and Protection Regulation No 273/2012 recognize protection of goods and services through trademark and collective trademarks. The EIPO registers domestic and international trademarks owned by individuals and entities as well as collective trademarks for products owned by associations. Ethiopia also has registered three coffee trademarks in more than 30 countries across the world. Some argue that the Ethiopian coffee products qualify for GI protection given the fact that the tastes and qualities of the coffee products are directly associated to the specific places they originated from as well as traditional practices and knowledge of the farmers. The three trademarks, i.e. Harar®, Yirgacheffe® and Sidamo® represent the name of the places the coffee grows in.⁴⁶ Recently, the EIPO and AFD have reached an agreement to define a domestic sui generis law on GIs and support the value chain. This project aspires to realize the recognition and protection of multiple agricultural products through this effective IP tool.

CHALLENGES IN EFFECTIVE DEVELOPMENT OF APICULTURE INDUSTRY

In general, Ethiopia's export market is characterized by price instability and fluctuations.⁴⁷ Such challenges extend to the honey sector as well. The Ethiopian apiculture industry faces multiple problems resulting in difficulties in introducing specialty products to the local and international consumers. The main problems include, low quality,⁴⁸ adulteration and mal-practices; climate change and others related to natural and man-made problems. These problems directly or indirectly affect the production and trading of honey products in Ethiopia.

The Ethiopian system fails to set up a standard on quality and other related matters on honey marketing at domestic or international level. There are multiple issues that need the attention of the government and actors in the value chain as to producing and trading honey with the required international quality standards. Honey marketing has different appearances in sale of the product in different parts of Ethiopia. There are significant changes in packaging, consumption patterns and preferences of consumers in rural urban parts of the country. The sector needs further improvements especially to get a better access of international market. There are actions taken by the government in setting quality standards but these guidelines are not effectively considered by the actors and enforced.⁴⁹

There are additional factors contributing for production of honey with poor quality. Beekeeping in Africa in general and in Ethiopia in particular is practiced by groups of the society who are poor and marginalized using low cost production mechanisms.⁵⁰ Financial limitations and

⁴⁵ Getachew (n 22) 10

⁴⁶ Mary O'Kiki, 'Lessons Learned from Ethiopia's Trademarking and Licensing Initiative: Is the European Union's Position on Geographical Indications Really Beneficial for Developing Nations?' (2009) 6(2) Loyola University Chicago International Law Review <<https://lawcommons.luc.edu/cgi/viewcontent.cgi?article=1044&context=luclir>> accessed June 2020

⁴⁷ Using traditional hives, use of excessive smoke for extracting the honey as well as traditional processing and packaging affect

the quality of the product. These factors also have an impact on limiting the quantity of production.

⁴⁹ WEEMA (n 27) 38

⁵⁰ United Nations Conference on Trade and Development, *Enabling small Commodity Producers in Developing Countries to reach Global Markets*, (Bees for Development, Issues paper constraints to African Honey trade, UNCTAD, 2006) 1

less access to credit services lead to consistently using traditional mechanisms of production. The smallholders may not be able to improve their quality and quantity due to such limitations. Both the government and other financial sectors must extend their credit services to producers, especially youth engaged in this sector. In this regard, GIs are the effective tools to tackle this challenge by creating a systematic link between stakeholders in the production and marketing sections to support the sector. Though GIs require huge investment in the process of linkage, labeling, verifying traceability and other aspects of it,⁵¹ its subsequent economic returns to the individual stakeholders and the country is significant.

Natural challenges related to global climate change may not be solved by introducing GIs system in Ethiopia but the other man-made problems can be mitigated by defining a legal framework and implementing the rules effectively.

OPPORTUNITIES FOR APICULTURE DEVELOPMENT THROUGH IP IN ETHIOPIA- GIS FOR ETHIOPIAN HONEY

The world community's demand towards honey increases through time as the production is affected by the environmental degradation and climatic change. This puts Ethiopia in better position to focus on improving quality and quantity of its honey which can be another export commodity that is a source of foreign exchange. Ethiopia owns honey with typical taste and flavors attributed to plants growing in different parts of the country. Similar to its coffee trademarking initiative which resulted in introducing Ethiopian coffee to its consumers throughout the world, Ethiopia should invest on improving its honey products and avail it to the international market. Learning from the experiences of coffee trademarking, protecting its honey products with a GI will provide stronger protection and create stronger chain of stakeholders in the industry.

Adulteration is among the main risks that the apiculture industry in Ethiopia is facing. The experience of associations which sell honey with higher adulteration rate tend to lack consistency in number of their consumers and their market is only limited to their co-op.⁵² Lack of quality control and traceability system and guidelines for selling honey in local market made the sellers act irresponsibly by diluting honey with odd substances and for honey harvested from other regions of the country.⁵³ These practices have an impact on confusing customers by affecting the quality of the reputed honey. Due to this fact the honey sector demands for a system with enforceable quality guidelines and standards for the sake of consumer protection. Both direct and indirect methods of adulteration are practiced in Ethiopia. The producers or processors add adulterant substances such as banana, sugar syrup, maize and wheat flour and sweet potato or feed the bees industrial sugars which results in inorganic honey production.⁵⁴ GIs are specifically designed to combat fraudulent acts of production and mal-practices such as adulteration in the trading by delimiting the areas of production and tracing the origin of the products

The recent initiative to adopt a law on GIs by the government of Ethiopia and its support by external donors marks a huge opportunity for the country to promote its specialty agricultural products in general and honey in particular. Given the huge potential in the sector and the existing challenges, adopting a consistent GIs system in the country can play a great role in improving the livelihoods of those in the value chain by further contributing to the country's economic returns. Implementation of a GI system in Ethiopia will have the effect of improving the current challenges by illusive traders.

As the country is introducing a new IP protection system, it is worth to identify products with bigger potentials.

⁵¹ Daniele (n26)

⁵² WEEMA (n 27) 68

⁵³ Ibid 38

⁵⁴ Haftu k (n 2)171

Following the four stages of developing a GI i.e. identification, qualification, remuneration and reproduction are worth to be noticed in implementing the system. The popular types of honey produced in Ethiopia including the Tigray white honey, Wenchi honey, Masha and Gojjamadot honey qualify for protection through GIs representing special tastes and colors related to their origin. The Tigray white honey is the most reputed and most refined variety which is preferred by domestic and international consumers. Its price goes up through time as consumers' demand is increasing. The bright white color and its intense flavor is attributed to the blossom of the labiates.⁵⁵ Moreover, the higher demand towards an organically produced honey possessing fair trade certificate has a tendency to attract more consumers and encourage private bodies to engage in the sector. Organic way of production of honey in Ethiopia makes it preferable over products produced elsewhere from GMOs.⁵⁶ The sector should emphasize on promoting such specialty honey products to maximize the benefits.

Taking all these opportunities into consideration, it is advisable that Ethiopia add IP value to its honey products. As the world's trend on trade is changing and the value of IP assets is rising, countries with specialty products are encouraged to identify their specialty products and promote them. Consumers tend to focus on reputed agricultural products which are easily identifiable in markets. For instance, EU honey consumers pay more to products indicating geographical source.⁵⁷

Ineffective legal setup for quality control as a challenge in Implementing GIs

Inefficiency in quality control systems and issues related to traceability may remain to be challenges in implementing the GI system in the sector. Additionally, lack of well-trained professionals at the implementing and enforcing organs may be a challenge in enforcing the

rights against free riders. Poorly equipped institutional setup may result in the scattering of obligations to different institutions which may take time to link them up. For example, the EIPO may need the support of the Ethiopian conformity assessment institution of the standards agency to assure the attainment of international quality standards to grant GIs. The nature of GIs demands the engagement of many actors as well as strong professional ethics and system. The current loose system in the protection and enforcement of IP rights in Ethiopia appears to be a big challenge in creating an effective regulatory framework. As the GI engages stakeholders with different roles, well equipped and staffed government and private actors are vital in the effective implementation. Establishing special implementing agencies and special tribunals handling cases specifically related to GIs with professionals on the area should be considered.

The existence of different associations such as The Ethiopian apiculture board, Honey and Beeswax Producers and Exporters Association and The Ethiopian beekeepers associations play a significant role in linking producers with local and international markets and defining quality control standards.⁵⁸ This also makes assessment and identification of actors in the value chain easier. Moreover, it eases formation of the Inter-professional bodies and communication within. Therefore, engaging those private bodies as well as governmental and non-governmental entities interested in the subject matter will have a great importance in facilitating and managing the system.

CONCLUSION

Ethiopia, as a home of various plant varieties which are suitable for honey production, has a big potential in sustaining its economy by exploiting its huge production potential. The apiculture sector has not been performing efficiently. But there are improvements in production and

⁵⁵ Weema (n 27) 8

⁵⁶ Yoshimasa (n 10) 77

⁵⁷ UNCTAD (n 39) 3

⁵⁸ MOA (n 4) 6

export quality and quantity. The role of the government, non-governmental and other private bodies is significant in such improvements. The new law on the protection of GIs on progress to be enacted can play a great role in adding intangible value on the product and keeping the quality of the reputed products. It also enables local and international consumers to recognize and define their preference towards the reputed honey products. Providing a GI system to the apiculture industry enable to identify the actors in the value chain and promote the sector by granting a right to take action against the free riders which confuse the consumers by selling unauthentic products using the geographical names of the origins of good honey. Issues of ineffective quality control system, availability of less qualified experts on IP and traceability may still be challenges in implementing GIs on the apiculture sector. But, given the increasing consumers' demand towards the existing blooming sector and engagement of different actors, the product can be more differentiated and promoted by implementing the GI framework.

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**THE ROLE OF INTELLECTUAL PROPERTY EDUCATION IN
ENHANCING THE QUALITY OF PHARMACEUTICAL
PATENTS: THE EGYPTIAN EXPERIENCE**

Eman S. Ibrahim*

ABSTRACT

Patents in the pharmaceutical field are of special significance. They could support innovation and incentivize research and development. However, there are often concerns that they could also hinder access to medicine. Therefore, pharmaceutical patents should be of high quality in terms of their ability to achieve their intended socioeconomic goals with limited negative impact. Despite the international interest in patent quality and the wide agreement on the need to improve it, there is much less agreement on what patent quality is. Patent quality can be closely linked to the compliance with the legal requirements for patent protection. Therefore, the quality of patent examination procedure has a great influence on patent quality. In absence of a clear patent policy or patent examination guidelines, it would be difficult to ensure the quality of the examination procedure and the granted patents in the pharmaceutical field. The role of intellectual property (IP) education of patent examiners in bridging this gap and enhancing the quality of patent examination procedure is examined. For this purpose, the Egyptian experience is presented and analyzed. IP education helps patent examiners to realize the impact of the quality of the work they perform and the patents they grant in their society. IP education ultimately contributes to enhancing the quality of patents granted in the pharmaceutical field.

Keywords: IP Education, Patent Quality, Pharmaceutical, Examination Procedure, Patent Examiner, Egypt

1. INTRODUCTION

One of the most important aims of the patent system is to encourage research and development (R&D) processes to satisfy society's various needs and to provide solutions for its problems in all technological fields.¹ The ultimate

goal is to achieve socioeconomic development. The main functions of the patent system are protection through the grant of exclusive rights, and information through the requirement of disclosure.² Both functions should work together to support innovation and this is particularly true for pharmaceutical innovation.

Pharmaceutical patents have special significance. They can be valuable tools to encourage pharmaceutical R&D. The exclusive rights granted to patent holders reward the effort, time and investments put in R&D, and incentivize further research. Public disclosure of patent information is important because information on previous inventions could serve as a starting point for future research.

However, despite the positive role that patents can play in supporting R&D, it is feared that granting too many patents on pharmaceuticals could lead to undesirable outcomes. The most prominent negative effects are, hindering access to medicine and blocking further research.³ Patents confer monopoly rights on their owners regardless of the possible consequences on human's right in access to medicine. When patients need a particular medication that is solely available from one source, and cannot afford it, this becomes a public health issue.⁴ In addition, overprotection of pharmaceutical research results by patent exclusive rights may stifle innovation instead of supporting it. Pharmaceutical innovation is a typical example of sequential innovation which depends to a large extent on previous technologies and research results.⁵

* Eman S. Ibrahim is a Senior Pharmaceutical Patent Examiner and the Vice President of the Egyptian Patent Office. She is an Intellectual Property Trainer and Researcher in the National Intellectual Property Academy of Egypt. Eman is a Tutor for WIPO Distance Learning Courses and Coach for WIPO IP for Youth and Teachers Blended Courses. She holds an Advanced Studies Diploma in Intellectual Property Law - Regional Institute of Intellectual Property, Helwan University, Egypt, the online WIPO - University of South Africa (UNISA) Intellectual Property Law Specialization Program Certificate, and the University of Wisconsin Madison's Professional Certificate in Online Education.

¹WIPO, 'Frequently Asked Questions: Patents' <https://www.wipo.int/patents/en/faq_patents.html> accessed 1 May 2019.

² WIPO, *WIPO Guide to Using Patent Information* (WIPO 2015) 4.

³ Carlos M Correa, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing' (2011) South Center Research Paper 41, 3 <https://www.southcentre.int/wp-content/uploads/2013/05/RP41_Pharmaceutical-Innovation_EN.pdf> accessed 19 April 2018.

⁴ Robert Pearl, 'Why Patent Protection in the Drug Industry is out of Control' (Forbes, 19 January 2017) <<https://www.forbes.com/sites/robertpearl/2017/01/19/why-patent-protection-in-the-drug-industry-is-out-of-control/#e6c702078ca9>> accessed 19 April 2018.

⁵ Kyle A Marchini, 'Patents and Innovation in the Pharmaceutical Industry' (2013) 4 Grove City College Journal of Law & Public Policy 47, 49.

The patent system should be efficiently used in the pharmaceutical field to achieve its intended purpose in encouraging innovation while taking into consideration the possible undesirable effects on access to medicine and access to knowledge. It is of utmost importance to devise a patent policy that aims to strike the right balance between patent holders' exclusive rights and public rights. This balance of rights and obligations is an important component of the TRIPS Agreement objectives of protection and enforcement of intellectual property rights (IPRs) in the contribution to the promotion of technological innovation and transfer of technology.⁶

Moreover, countries need to put in place systems which aim to ameliorate the possible negative effects of patents on medicines availability and affordability and on future pharmaceutical R&D. An important principle under the TRIPS Agreement is that World Trade Organization (WTO) members may adopt measures necessary to protect public health, to promote the public interest in sectors of vital importance to socio-economic and technological development, and to prevent the abuse of IPRs.⁷

Although legal control could be exercised to remedy some of the negative effects of excessive patent protection or abuse of patent exclusive rights in the pharmaceutical field, prevention is always better than cure. Patent rights should not be granted in the first place for inventions that do not merit such protection.⁸ Creation of unnecessary monopolies must be avoided as much as possible. It is therefore essential to ensure that pharmaceutical patents are of a proper 'quality'.

The issue of patent quality has lately attracted worldwide attention. However, despite the almost universal

agreement on the need to improve the quality of patents, there is much less agreement on what patent quality means. Patent offices bear the primary responsibility in ensuring that patents granted on pharmaceutical inventions are 'good' quality patents.⁹

Linking patent quality to the compliance with the legal requirements for patent protection makes the patent examination process a main determining factor.¹⁰ Patent examination process is performed by patent examiners having technical background and experience in patent search and examination.¹¹

Ideally, the examiners would be working according to a set of guidelines formulated in light of a national patent policy. However, in absence of such guidelines or a policy that defines their framework, maintaining high-quality examination procedure and granting high-quality patents would be a difficult task.

This paper highlights the important role that Intellectual Property (IP) education plays in improving the quality of patent examination and granted pharmaceutical patents. This role would be especially prominent when clear policy guidance is not available. In this regard, the experience of the pharmaceutical patent examiners in the Egyptian Patent Office (EGPO) is presented and discussed.

2. PATENTS IN THE PHARMACEUTICAL FIELD

It is not disputed that the pharmaceutical industry is one of the most important industries worldwide. It greatly affects human life and the quality of this life. This industry is particularly important for two reasons. The first is social since the provision of affordable high-quality medicines to the patients is a genuine human right. The second

⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS 1994) Art 7.

⁷ TRIPS 1994, Art 8 (1).

⁸ Carlos M Correa and Germán Velásquez, 'Access to Medicines: Experiences with Compulsory Licenses and Government Use – The Case of Hepatitis C' (2019) South Centre Research Paper 85, 14 <https://www.southcentre.int/wp-content/uploads/2019/04/RP85_Access-to-Medicines-Experiences-with-Compulsory-Licenses-and-Government-Use-The-Case-of-Hepatitis-C_EN.pdf> accessed 30 April 2019.

⁹ German Velasquez, 'Guidelines on Patentability and Access to Medicines' (2015) South Center Research Paper 61, 7

<https://www.southcentre.int/wp-content/uploads/2015/03/RP61_Guidelines-on-Patentability-and-A2M_EN.pdf> accessed 20 January 2018.

¹⁰ WHO, *The Role of Intellectual Property in Local Production in Developing Countries: Opportunities and Challenges* (WHO 2016) 11.

¹¹ WIPO, 'Alternatives in Patent Search and Examination' Policy Guide (WIPO 2014) 8 <https://www.wipo.int/edocs/pubdocs/en/wipo_pub_guide_patentsearch.pdf> accessed 1 May 2019.

reason is economic as this industry can largely contribute to the national economic growth and development.¹²

The pharmaceutical industry is often reported to be one that needs huge financial investments to cover R&D costs.¹³ Developing a new pharmaceutical product takes considerable time and effort, requires large investments and involves major risks. The process includes multiple stages; from the initial discovery and experimentation, through clinical testing and regulatory approval, to the final product development and launch into the market.¹⁴

The patent system has a very special significance in the pharmaceutical field. Both protection and information functions of the patent system work towards supporting innovation and ensuring the continuity of R&D activities.

A patent confers on its owner the right to exclude others from commercially exploiting the invention without the owner's authorization. Patents provide pharmaceutical companies with the opportunity to recoup their large R&D investments while protected from the competition of third parties who have not made those investments.¹⁵ Patents reward the effort, time and money put into R&D, and provide incentives for further innovation.¹⁶

Making the information disclosed in patent documents publicly available is equally important for pharmaceutical R&D. Pharmaceutical innovation relies heavily on the knowledge of preceding innovations and prior research

results.¹⁷ Information on existing inventions and previous R&D outcomes could be the basis for further research.

Effective utilization of the patent system could create an environment conducive to innovation. Such environment is crucial to develop new pharmaceutical products and to improve the existing ones. However, there are often concerns that granting unnecessarily high numbers of patents to protect pharmaceutical R&D results could lead to undesirable consequences. The most prominent negative outcomes in this regard are hindering access to medicines¹⁸ and blocking future research¹⁹.

A patent empowers its owner to exclude third parties from unauthorized production, use, sale, offering for sale or importation of the patented product. For a pharmaceutical product, that could cause serious problems when, for example, the patent owner sets an exorbitant price for the product, does not make the product available in the market at least in sufficient quantities, or refuses to license the patent despite offering reasonable terms. Such abusive practices might be controlled by drug pricing mechanisms²⁰, competition law²¹ and patent law²². However, the mere fact that a particular person or entity could have significant control over the availability and accessibility of an essential commodity like medicines remains a matter of concern.

Patents do not only allow companies to recoup their R&D costs: they also place the power to control medicine

¹² Dennis A Ostwald, Katharina Zubrzycki, Julian Knippel, 'Research Report: The Economic Footprint of the Pharmaceutical Industry' (International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), WiFor 2015) <https://www.ifpma.org/wp-content/uploads/2016/02/wifor_research-report_2015_web.pdf> accessed 5 June 2018.

¹³ 'Total Global Pharmaceutical Research and Development (R&D) Spending from 2008 to 2022 (in billion U.S. dollars)' Statista: The Statistics Portal <<https://www.statista.com/statistics/309466/global-r-and-d-expenditure-for-pharmaceuticals/>> accessed 5 June 2018.

¹⁴ Henry Grabowski, 'Patents and New Product Development in the Pharmaceutical and Biotechnology Industries' (2002) Working Paper, Duke University, Department of Economics, 4 <<http://public.econ.duke.edu/Papers/Other/Grabowski/Patents.pdf>> accessed 5 June 2018.

¹⁵ Ellen 't Hoen, 'Analysis: Medicines Patents, Access and Innovation' (Astrid Berner-Rodoreda, Maïke Lukow, Luise Steinwachs Eds, Bread for the World 2016) Analysis 58, 6

<https://www.brot-fuer-die-welt.de/fileadmin/mediapool/2_Downloads/Fachinformationen/Analyse/Analyse_58_Medicine_Patents.pdf> accessed 19 April 2018.

¹⁶ Grabowski (n 14).

¹⁷ Carlos M Correa, 'Ownership of knowledge — the role of patents in pharmaceutical R&D' (2004) 82(10), Bulletin of the World Health Organization 784, 785.

¹⁸ Carlos M Correa, 'Public Health and Intellectual Property Rights' (2002) 2(3) Global Society Policy, SAGE Publications 261, 262

<<http://journals.sagepub.com/doi/abs/10.1177/1468018102002030201>> accessed 18 February 2018.

¹⁹ Correa, 'Ownership of knowledge' (n 17).

²⁰ WHO, WIPO, WTO, *Promoting Access to Medical Technologies and Innovation - Intersections between public health, intellectual property and trade* (WHO, WIPO, WTO 2013) 157.

²¹ *ibid* 76.

²² *ibid* 61.

prices in the hands of those companies.²³ In the nineties, millions of AIDS patients in Africa died although antiretroviral medicines were already developed then. Patients did not have access to antiretroviral medicines as they were very expensive and hence not affordable. The pharmaceutical companies that had developed those medicines charged very high prices for them because they were protected by patent exclusive rights.²⁴

Pharmaceutical patents can be used to block generic competition.²⁵ Generic companies usually charge lower prices and thus facilitate access to medicines. In absence of generic competition, for instance, due to strategic patenting of minor modifications, prices would be higher and access to affordable medicines would be blocked.²⁶

Overprotection of pharmaceutical research outcomes by patents could impede rather than encourage innovation. While patents are aimed to incentivize their owners to continue innovation, their exclusionary nature could make it difficult for others to do the same. This would block or at least slow down follow-on innovation.²⁷ When a single medicine is protected by a bundle of patents²⁸ on the basic molecule, manufacturing processes, various derivatives and physical forms; further R&D on this medicine by third parties would be practically blocked.

Considering the above concerns, the patent system in the pharmaceutical field should strike the right balance between protecting the legitimate interests of innovators and incentivizing innovation on one hand and ensuring that the public at large can benefit from the fruits of this

innovation on the other.²⁹ In this regard, the strategic adoption and implementation of public health related patent flexibilities in international IP instruments plays a vital role. Pharmaceutical patents should be able to achieve its intended socioeconomic goals with minimum negative effects on access to medicine, generic competition and future innovation. Pharmaceutical patents should be high-quality patents.

3. THE CONCEPT OF PATENT QUALITY

There has been an increasing international interest in patent quality. It is seen as an essential component of the patent system that significantly impacts its ability to achieve its intended goals.³⁰ Therefore, patent quality has been a regular discussion topic in the sessions of the World Intellectual Property Organization (WIPO) Standing Committee on the Law of Patents (SCP).³¹ Both developed and developing countries are concerned with the issue and actively engaging in the discussions.³² However, despite the general agreement on the need to enhance the quality of patents, there is little consensus on the meaning or definition of the term 'patent quality'.

Without a clear and comprehensive definition of what constitutes patent quality, it would be difficult to conduct a fruitful discussion on whether there are patent quality issues and what can be done to fix them. Defining patent quality is a prerequisite to adopting the appropriate measures and policy changes to improve the quality of patents.

²³ Erica Penfold, 'Explainer: the problem drug patents pose for developing countries' (The CONVERSATION, 6 August 2015) <<https://theconversation.com/explainer-the-problem-drug-patents-pose-for-developing-countries-45667>> accessed 4 May 2018.

²⁴ Hanna Keppler, 'The Untold AIDS Story: How access to antiretroviral drugs was obstructed in Africa' (The EJBM Blog, 1 October 2013) <<https://theejbm.wordpress.com/2013/10/01/the-untold-aids-story-how-access-to-antiretroviral-drugs-was-obstructed-in-africa/>> accessed 11 May 2018.

²⁵ Correa, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing' (n 3).

²⁶ Correa, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing' (n 3) 5.

²⁷ Correa, 'Ownership of knowledge' (n 17) 786.

²⁸ WIPO Patent Landscape Report on Ritonavir (2011) showed that over than 800 patent have been filed to protect different aspects of Ritonavir (an antiretroviral drug for treatment of HIV infection and AIDS) including its variants, derivatives, combinations, methods of production and use <http://www.wipo.int/edocs/pubdocs/en/patents/946/wipo_p_ub_946.pdf> accessed 29 May 2018.

²⁹ Hoen (n 15).

³⁰ WIPO, 'Quality of Patents' <http://www.wipo.int/patents/en/topics/quality_patents.html> accessed 22 January 2018.

³¹ *ibid.*

³² WIPO Secretariat, 'Report on the International Patent System' (SCP/12/3 Rev2, WIPO Standing Committee on the Law of Patents, Twelfth Session, Geneva, June 2008) 56 <http://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2.pdf> accessed 22 January 2018.

There are two important questions to answer with respect to the issue of patent quality: how patent quality could be defined and measured? and why the quality of patents has received much attention lately?

The question of the definition of patent quality could be viewed from a technical, legal or economic perspective, or a combination thereof.³³ From a technical point of view, patent quality reflects the quality of the scientific content or technical information included in the patent application.³⁴ A high-quality patent would significantly contribute to the body of knowledge in the respective technological field. In this case, patent quality is seen as the quality of the described invention itself.

From a legal perspective, patent quality means validity. A patent of good quality would stand possible invalidation claims. The quality of patents in this regard is dependent on the degree of fulfillment of the legal requirements for patent protection under the respective patent law.

In respect of the economic value, patent quality can be linked to the market value of the patent or the profit it could generate when commercially exploited. The value of the patented technology and the ability of the patent to provide its owner with a competitive edge by excluding other market players are relevant aspects. Patent value could be linked to the quality of the underlying invention or the quality in terms of legal validity. However, at many occasions, patent value and patent quality are considered as two distinct concepts.³⁵

Patent quality could have various meanings to different stakeholders. Patent offices, courts, legal experts and patent agents are usually concerned with legal validity.³⁶ Technology experts and researchers focus on whether the underlying invention involves major technological advancement or minor improvement over the state of the art.³⁷ Policy makers and macroeconomic experts should link patent quality to the ability of patents to fulfill their main objectives in rewarding and incentivizing innovation while enabling the dissemination and diffusion of technological developments.³⁸

Equating the quality of a patent with its legal validity rather than the quality of the underlying invention or its market value is a common approach to patent quality.³⁹ The quality of patents is often measured in terms of satisfaction of the legal patentability standards. Another approach is to examine how those standards could be applied to ensure the grant of high-quality patents.⁴⁰ This requires identifying the parameters against which patent quality could be assessed. In light of those parameters, patent reforms should be more focused on the target of increasing the number of good quality patents rather than just increasing the number of legally valid patents⁴¹.

At this point, it is necessary to consider the meaning of patent quality from the perspective of patent offices. For this purpose, the ongoing discussions on patent quality in the framework of the WIPO SCP provide a useful insight.⁴² Both small offices with limited resources and larger offices with full search and examination capacities are concerned with the quality of the patents they grant.

³³ Alexandra Sklan, 'Patent Quality' (2014) 3(1) *Pharmaceutical Patent Analyst* 17 <<https://www.future-science.com/doi/full/10.4155/ppa.13.74>> accessed 22 January 2018.

³⁴ Justus Baron, Henry Delcamp 'Patent Quality and Value in Discrete and Cumulative Innovation' Working Paper (2010) CERNA WORKING PAPER No. 2010-07, 5 <<https://ssrn.com/abstract=1709999>> accessed 2 May 2019.

³⁵ R Polk Wagner, 'Understanding Patent-Quality Mechanisms' (2009) 157 *University of Pennsylvania Law Review* 2135, 2139-2140 <<https://ssrn.com/abstract=1452862>> accessed 18 February 2018.

³⁶ Mariagrazia Squicciarini, Hélène Dernis, Chiara Criscuolo, 'Measuring Patent Quality: Indicators of Technological and Economic Value' (2013) OECD Science, Technology and Industry Working Papers No 2013/03, OECD Publishing, 7

<<http://dx.doi.org/10.1787/5k4522wkw1r8-en>> accessed 18 May 2018.

³⁷ *ibid.*

³⁸ *ibid.*

³⁹ Bruce Berman, 'The puzzle that is patent quality' (2015) 4 *WIPO Magazine* 16 <http://www.wipo.int/export/sites/www/wipo_magazine/en/pdf/2015/wipo_pub_121_2015_04.pdf> accessed at 19 April 2018.

⁴⁰ Christi J Guerrini, 'Defining Patent Quality' (2014) 82(6) *Fordham Law Review* 3091, 3091 <<https://ir.lawnet.fordham.edu/flr/vol82/iss6/18/>> accessed 04 May 2018.

⁴¹ *ibid.*

⁴² WIPO, 'Quality of Patents' (n 30).

Small offices might not have the required infrastructure and well-trained examiners to conduct comprehensive search and examination.⁴³ Large offices with sufficient capabilities may have problems due to the pressure of increasing backlogs of unexamined applications.⁴⁴

At the sixteenth SCP session, the delegations of Canada and the United Kingdom proposed a work program on the quality of patents.⁴⁵ It indicated that patent offices need to adopt appropriate measures to ensure that the patents they grant meet the standards that achieve the patent system's economic and social policy objectives.⁴⁶

By the eighteenth session, it became clear that WIPO Member States have different definitions and diverse views on what constitutes patent quality.⁴⁷ Therefore, the two delegations proposed a questionnaire on quality of patents to explore the various definitions used within national and regional patent offices of Member States.⁴⁸

At the twenty-fourth session, the committee agreed that the Secretariat would circulate a draft questionnaire on the term 'Quality of Patents'.⁴⁹ Question 1 dealt with how each office understands the term 'quality of patents'.⁵⁰ The responses highlighted two main concepts. One is that the term relates to the quality of the patent itself. The other is that the term is understood in the context of patent grant procedure. Multiple responses referred to both concepts considering them as closely related.⁵¹

Most responses where patent quality was understood as the quality of the patent itself stated that a high-quality patent shall meet the requirements for patent protection under the applicable law.⁵² Those include the three patentability criteria (novelty, inventive step and industrial applicability), sufficiency of disclosure, and claims clarity and conciseness. More specifically, patent quality was linked to the compliance with patentability criteria. According to those responses, patents that meet the patentability criteria have a high presumption of validity and most probably would not be revoked if challenged. This was considered important to create legal certainty both for the patent holder and third parties.⁵³

With regard to the quality of the patent grant procedure, it has been seen as the process leading to the desired outcome of patent quality. Many responses indicated factors that would contribute to high-quality grant procedure. The factors included the quality of search and examination process and generated reports, procedure timeliness, availability of skilled and well-trained staff, communication with stakeholders and transparency.⁵⁴

Associating quality with the compliance with statutory requirements of patentability seems appropriate for two reasons.⁵⁵ First, the legal patent protection requirements are universal standards for patents. Second, legal validity is the key for legal stability and certainty which are

⁴³ WIPO Secretariat, 'Report on the International Patent System' (n 32) 54

⁴⁴ *ibid.* 55.

⁴⁵ WIPO Secretariat, 'Proposal from the Delegations of Canada and the United Kingdom' (SCP/16/5, WIPO Standing Committee on the Law of Patents, Sixteenth Session, Geneva, May 2011) <http://www.wipo.int/edocs/mdocs/scp/en/scp_16/scp_16_5.pdf> accessed 22 January 2018.

⁴⁶ *ibid.*

⁴⁷ WIPO Secretariat, 'Questionnaire on Quality of Patents: Proposal by the Delegations of Canada and the United Kingdom' (SCP/18/9, WIPO Standing Committee on the Law of Patents, Eighteenth Session, Geneva, May 2012) <http://www.wipo.int/edocs/mdocs/scp/en/scp_18/scp_18_9.pdf> <http://www.wipo.int/edocs/mdocs/scp/en/scp_17/scp_17_8.pdf> accessed 22 January 2018.

⁴⁸ *ibid.*

⁴⁹ WIPO Secretariat, 'Report adopted by the Standing Committee' (SCP/24/6, WIPO Standing Committee on the Law of Patents, Twenty Fourth Session, Geneva, June 2016) 81 <http://www.wipo.int/edocs/mdocs/mdocs/en/scp_24/scp_24

[6.pdfhttp://www.wipo.int/edocs/mdocs/scp/en/scp_17/scp_17_8.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_17/scp_17_8.pdf)> accessed 22 January 2018.

⁵⁰ WIPO Secretariat, 'Updated Responses to the Questionnaire on the Term "Quality of Patents" and Cooperation between Patent Offices in Search and Examination (Part 1)' (SCP/27/4 REV, WIPO Standing Committee on the Law of Patents, Twenty Seventh Session, Geneva, December 2017) <http://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_4_rev.pdf> accessed 22 January 2018.

⁵¹ *ibid.*

⁵² *ibid.*

⁵³ *ibid.*

⁵⁴ *ibid.*

⁵⁵ SONG Hefa, LI Zhenxing, 'Patent Quality and the Measuring Indicator System: Comparison among China Provinces and Key Countries' (2014) 4 <<https://www.semanticscholar.org/paper/Patent-quality-and-the-measuring-indicator-system%3A-Hefa-Zhenxing/7280dae19448d15018320e623c2009aa699746f8>> accessed 22 January 2018.

important for achieving the balance between the rights of the patent owner and the public.⁵⁶

While the legal requirements for patent protection are universal, their respective definitions and standards of application vary according to the law and practice in each country. Those requirements are usually assessed during patent examination in patent offices.

Low-quality examination procedure would negatively impact the quality of the granted patents. Patent examination could be considered of low quality when the legal patentability requirements are not adequately and comprehensively assessed by patent examiners. This could happen due to various reasons such as lack of the necessary resources, an insufficient number of qualified examiners, increased workload and backlogs, or even worse, a patent policy that encourages the grant of high numbers of patents regardless of their quality.

This leads to the question of why patent quality has surfaced as a topic that attracted worldwide attention in recent years. There has been a tremendous increase in patent filing and granting activities since the 1980s.⁵⁷ This has been accompanied by fears that it might hinder rather than encourage innovation.⁵⁸ While patents might create an environment supportive for innovation, the number of granted patents in a particular country or region cannot be used as a direct and reliable measure of the innovation level in that country or region.⁵⁹

The OECD composite patent quality index based on patents filed at the European Patent Office (EPO) suggests

that the increase in numbers of patent filings observed over the past two decades was accompanied by an average 20% decrease in patent quality.⁶⁰

There are two main contributing factors to the patent proliferation phenomenon reflected in the grant of high numbers of low-quality patents.⁶¹ First, large companies often follow extensive patenting strategies to sustain market monopoly and block competition from other enterprises especially the Small and Medium Enterprises (SMEs).⁶² Second, a number of patent offices around the world apply a relaxed approach for the assessment of patentability criteria.⁶³

Low-quality patents have the exact opposite effect to a well-functioning patent system. They create unnecessary monopolies, deter competition and burdensome businesses with high costs in the form of royalties paid to obtain licenses or litigation expenses for invalidation lawsuits.⁶⁴ They also negatively impact the scope of public domain. Knowledge which otherwise would be in the public domain will become the private property of patent owners. Access to such knowledge would require obtaining authorization and payment of royalties.⁶⁵

4. QUALITY OF PHARMACEUTICAL PATENTS

Pharmaceutical companies are keen to extensively acquire and enforce patent rights. The main reason they state is that developing new products involves major risks and substantial investments in R&D. However, there are only few patents covering truly new drug molecules.⁶⁶ Despite the exponential growth of the number of patents

⁵⁶ *ibid.*

⁵⁷ 'Proliferation of Patents' The Innovation Policy Platform <<http://www.innovationpolicyplatform.org/www.innovationpolicyplatform.org/content/proliferation-patents/index.html>> accessed 5 April 2021.

⁵⁸ *ibid.*

⁵⁹ Carlos M Correa, 'Tackling the Proliferation of Patents: How to Avoid Undue Limitations to Competition and The Public Domain' (2014) South Center Research Paper 52, 1 <https://www.southcentre.int/wp-content/uploads/2014/09/RP52_Tackling-the-Proliferation-of-Patents-rev_EN.pdf> accessed 20 January 2018.

⁶⁰ OECD, 'OECD Science, Technology and Industry Scoreboard 2011: Innovation and Growth in Knowledge Economies' (OECD 2011) 190 <[https://www.oecd-ilibrary.org/science-and-](https://www.oecd-ilibrary.org/science-and-technology/oecd-science-technology-and-industry-scoreboard-2011-sti-scoreboard-2011-en)

[technology/oecd-science-technology-and-industry-scoreboard-2011-sti-scoreboard-2011-en](https://www.oecd-ilibrary.org/science-and-technology/oecd-science-technology-and-industry-scoreboard-2011-sti-scoreboard-2011-en)> accessed 20 April 2018.

⁶¹ Carlos M Correa, 'Beyond 'Patent Quality': Basic Concepts of the Patent System Need to be Reviewed' (2012) Latin America in Movement Online <<https://www.alainet.org/es/node/159796>> accessed 22 January 2018.

⁶² *ibid.*

⁶³ *ibid.*

⁶⁴ Guerrini (n 40) 3093.

⁶⁵ WIPO Secretariat, 'Opposition Systems' (SCP/14/5, WIPO Standing Committee on the Law of Patents, Fourteenth Session, Geneva, January 2010) 5 <http://www.wipo.int/edocs/scp/en/scp_16/scp_16_ref_scp_14_5.pdf> accessed 22 January 2018.

⁶⁶ Correa, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing' (n 3) 4.

filed and granted in respect of pharmaceuticals,⁶⁷ the majority of those patents actually cover simple variations and trivial modifications of existing drug molecules.⁶⁸

Whereas developing new drug molecules would probably involve considerable efforts and entail varying levels of inventiveness, the techniques of making various physical forms and preparations of existing pharmaceutical compounds are often comprised within the general knowledge of a person skilled in the art.⁶⁹ Therefore, only few developments of the latter category could be seen as genuinely inventive in the pharmaceutical field in light of the state of the art.⁷⁰ In other words, it would be often difficult for such forms and preparations to pass the inventive step test as one of the patentability criteria.

Patent proliferation phenomenon is very prominent and has serious implications in the pharmaceutical field.⁷¹ The core problematic aspect of the proliferation of pharmaceutical patents is the low quality of those patents. According to the OECD composite patent quality index, the quality of pharmaceutical patents filed at the EPO was less than the average and less than the quality of patents in most of the other technological fields.⁷² Patent proliferation undermines rather than stimulates innovation and competition.⁷³

Various measures could be adopted to address patent proliferation and ameliorate its negative impact on public health and local generic manufacturing capacities.⁷⁴ However, the most efficient way is to avoid the grant of such high numbers of low-quality patents rather than trying to minimize their negative effects after being granted. This should ideally happen at the very first place

where patent applications are processed: the patent office.

One of the most important TRIPS flexibilities is the freedom left for WTO members in defining and setting the standards for application of each of the patentability criteria.⁷⁵ For example, different countries have different policy choices for the assessment of inventive step. This involves multiple factors such as the degree of progress over prior art and common general knowledge, and the definition of the person skilled in the art.⁷⁶

Countries often apply at least one of two approaches to implement the flexibility on the standards for applying the patentability criteria. The first approach deals with how the patentability criteria are defined in the respective national law and how it is interpreted by case law and practice.⁷⁷ An example is Section 3(d) of the Indian Patents Act 1970 (as amended in 2005) which does not consider as an invention the mere discovery of a new form of a known substance unless it provides significant difference in efficacy.

The second approach focuses on how patent examiners apply the patentability criteria. In this respect, and to ensure the quality of granted patents, some patent offices - as in Argentina - issued examination guidelines for patent applications in the pharmaceutical field.⁷⁸

In practice, patent offices in different countries have a range of perspectives on the various aspects involved in assessing the inventive step criterion. This was reflected in the series of studies on inventive step conducted within the framework of the WIPO SCP between 2015 and 2019 and covered, among other topics, the definition of the person skilled in the art, methodologies for inventive step

⁶⁷ Correa, 'Ownership of knowledge' (n 17) 784-785.

⁶⁸ Correa, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing' (n 3) 4.

⁶⁹ Chandra Mohan SB and others, 'Patents - An Important Tool for Pharmaceutical Industry' (2014) 2(2), *Research and Reviews: Journal of Pharmaceutics and Nanotechnology* 12, 14.

⁷⁰ *ibid.*

⁷¹ Correa, 'Tackling the Proliferation of Patents' (n 59) 2-3.

⁷² OECD (n 60).

⁷³ Correa, 'Beyond Patent Quality' (n 61).

⁷⁴ Correa, 'Tackling the Proliferation of Patents' (n 59) 3-21.

⁷⁵ WHO, *Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health* (WHO 2006) 51.

⁷⁶ WHO, WIPO, WTO, *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade*. (2nd edn, WHO, WIPO, WTO 2020) 70.

⁷⁷ *ibid.* 173.

⁷⁸ *ibid.*

evaluation and the level of the inventive step⁷⁹; common general knowledge: its combination with the state of the art⁸⁰, secondary indicia and problem invention⁸¹; and inventive step for inventions in the field of organic and inorganic chemistry, including pharmaceutical application.⁸²

Deciding on the appropriate level of patentability standards, particularly for the inventive step, involves multiple considerations: how to encourage innovation as an important goal for an effective patent system, how to avoid negative consequences on public health and access to medicines, and how to promote competition in the pharmaceutical market and build local pharmaceutical manufacturing capacity.⁸³ All these considerations have to be studied in light of the respective national context.

Countries can choose to apply rigorous standards for the assessment of patentability conditions to avoid granting patents on inventions that do not merit the protection.⁸⁴ Opting for high standards for patentability requirements would result in patents that are low in quantity but high in quality.⁸⁵ By utilizing such pre-grant flexibility, resorting to more cumbersome, lengthy and expensive post-grant flexibilities such as compulsory licensing and invalidation could be avoided.⁸⁶ Prevention is always better than cure.

When patent offices apply lax patentability standards, pharmaceutical companies would be encouraged to file high numbers of patent applications on several minor

modifications and trivial developments. The aim of those filings is to extend the length of the exclusivity beyond the 20-years patent protection period, a practice known as 'evergreening'⁸⁷. Although such patents are weak and not likely to withstand invalidation, they could be, and often are, strategically used by their holders to deter generic competition.⁸⁸ When generic companies are kept out of the market, drug prices increase and access to medicine is seriously hampered.

High-quality pharmaceutical patents result from high-quality examination procedure. Thus, the most important policy option in respect of the quality of pharmaceutical patents is the choice to apply rigorous standards for the assessment of patentability requirements.⁸⁹ This requires a diligent and thorough search and examination process.⁹⁰

The quality of the patent examination procedure, in turn, depends on a number of factors. First of all, a substantive examination system is a prerequisite. Obviously, patent offices that apply formal examination only do not check compliance with the patentability conditions let alone apply high standards to assess them.

Substantive examination requires a sufficient number of qualified patent examiners with solid background in pharmaceutical sciences besides being aware of the latest developments in the field.⁹¹ The examiners need also to

⁷⁹ WIPO Secretariat, 'Study on Inventive Step' (SCP/22/3 WIPO Standing Committee on the Law of Patents, Twenty-Second Session, Geneva, July 2015) <https://www.wipo.int/edocs/mdocs/scp/en/scp_22/scp_22_3.pdf> <https://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2.pdf> accessed 3 April 2021.

⁸⁰ WIPO Secretariat, 'Further Study on Inventive Step (PART I)' (SCP/28/4 WIPO Standing Committee on the Law of Patents, Twenty-Eighth Session, Geneva, July 2018) <https://www.wipo.int/edocs/mdocs/scp/en/scp_28/scp_28_4.pdf> <https://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2.pdf> accessed 3 April 2021.

⁸¹ WIPO Secretariat, 'Further Study on Inventive Step (PART II)' (SCP/29/4 WIPO Standing Committee on the Law of Patents, Twenty-Ninth Session, Geneva, December 2018) <https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_4.pdf> <https://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2.pdf> accessed 3 April 2021

⁸² WIPO Secretariat, 'Further Study on Inventive Step (PART III)' (SCP/30/4, WIPO Standing Committee on the Law of Patents,

Thirtieth Session, Geneva, June 2019) <https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_4.pdf> <https://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2.pdf> accessed 3 April 2021.

⁸³ Correa, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing' (n 3) 15-16.

⁸⁴ *ibid* 20-21.

⁸⁵ Chan Park, Achal Prabhala, Jonathan Berger, 'Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law' (UNDP 2013) 26.

⁸⁶ Correa, 'Beyond Patent Quality' (n 61).

⁸⁷ WHO, *Public Health, Innovation and Intellectual Property Rights* (n 75) 131.

⁸⁸ Correa, 'Ownership of knowledge' (n 17) 784.

⁸⁹ Correa, 'Tackling the Proliferation of Patents' (n 59) 3.

⁹⁰ *ibid*.

⁹¹ WIPO Secretariat, 'Report on the International Patent System' (n 32) 53.

have a good understanding of the applicable law especially the provisions on patentability requirements.⁹²

Another essential requirement for conducting the search is adequate access to a wide range of patent and non-patent databases.⁹³ It is important also to ensure that specialized and technology specific databases are available.⁹⁴ Other complementary yet influential factors include specialized training programs and access to search and examination products of other patent offices.

For optimum interaction between all of the mentioned factors, they need to be applied in light of a clear vision to the purpose of the patent examination procedure and a general framework for conducting such procedure. Ideally, there would be a clear national patent policy with certain components addressing the interplay between pharmaceutical patents and areas of public interest.

The patent office would then formulate guidelines for the examination of pharmaceutical patents in light of the national policy and aiming to achieve its objectives. In this ideal situation, patent examination procedure would be conducted in a manner consistent with the guidelines that emanate from the national patent policy.

Adopting pharmaceutical patent examination guidelines is highly important. The guidelines ensure the quality and consistency of the examination procedure. Applying the patentability requirements in the pharmaceutical field involves several issues and cases that are specific to this particular field. Those issues should be dealt with in sufficient details and with practical examples. Therefore, it would be more convenient and preferable to address

such issues in the examination guidelines rather than the provisions of the national patent law.⁹⁵

Recognizing the importance of examination guidelines, the World Health Organization (WHO) in cooperation with the International Centre for Trade and Sustainable Development (ICTSD) and the United Nations Conference on Trade and Development (UNCTAD) supported the development and publication of guidelines for the examination of pharmaceutical patents.⁹⁶ The aim was to help patent offices in developing their own guidelines by offering guidance on examination of multiple common categories of pharmaceutical patent claims.⁹⁷ As a later follow-up, the United Nations Development Program (UNDP) published guidelines for pharmaceutical patent examination taking into account the developments since the earlier guidelines.⁹⁸

A number of countries have indeed adopted patent laws or policies that define a framework for examination of pharmaceutical patents taking public health implications into consideration. Argentina and India are good examples.⁹⁹ Patent offices in those countries conduct rigorous patent examination and apply strict standards to assess the patentability requirements of pharmaceutical patents. They are practically combating the phenomenon of proliferation of low-quality pharmaceutical patents.¹⁰⁰

Without a clear patent policy or examination guidelines, there would be no guarantee of the quality of the examination procedure or the granted pharmaceutical patents. In absence of defined government policies, it would ultimately be the responsibility of patent offices or courts to develop and implement patent policies.¹⁰¹ Since

⁹² *ibid.*

⁹³ WIPO, *Guide to Technology Databases* (WIPO 2012) 4.

⁹⁴ *ibid.* 5.

⁹⁵ Carlos M Correa, *'Integrating Public Health Concerns into Patent Legislation in Developing Countries'* (South Center 2000) 51.

⁹⁶ Carlos M Correa, *'Guidelines for the examination of pharmaceutical patents: developing a public health perspective – A Working Paper'* (2007) ICTSD, WHO, UNCTAD <<http://apps.who.int/medicinedocs/en/d/Js21419en/>> accessed 19 January 2018.

⁹⁷ Velasquez, *'Guidelines on Patentability and Access to Medicines'* (n 9) 25.

⁹⁸ Carlos M Correa, *'Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective'* (UNDP 2016) 4.

⁹⁹ *ibid.* 11.

¹⁰⁰ Carlos M Correa, *'Patent Examination and Legal Fictions: How Rights are Created on Feet of Clay'* (2014) South Center Research Paper 58, 6 <https://www.southcentre.int/wp-content/uploads/2014/12/RP58_Patent-Examination-Legal-Fictions-rev2_EN.pdf> accessed 18 May 2018.

¹⁰¹ Carlos M Correa (Ed), *A Guide to Pharmaceutical Patents*, vol 1 (South Center 2008) xiv.

patent offices are the first stop for patent examination, they have to take the initiative to develop patent policies that support and do not run counter to health policies.¹⁰²

5. IP EDUCATION OF PATENT EXAMINERS AND THE QUALITY OF EXAMINATION PROCEDURE AND PHARMACEUTICAL PATENTS

Patent examiners are the first line of defense against the grant of low-quality patents. They are responsible for conducting high-quality patent search and examination. To efficiently perform this duty, they should be equipped not only with specialized technical knowledge in their respective technical fields but also with an in-depth understanding of the applicable law.¹⁰³

5.1 Importance of Legal Education of Patent Examiners

Pharmaceutical examiners have to understand the significance and implications of the quality of the search and examination work they perform and the patents they grant. They should realize their country's right to avail itself of the TRIPS pre-grant flexibility of defining and setting the standards for the patentability criteria. Patent examiners need to have a good grasp of the interpretation of the relevant legal provisions of their national law and the major international instruments, particularly the TRIPS Agreement.

The quality of patent examination can be seen in light of the examiner's ability to take the right decision whether to grant a patent in view of the applicable law and the appropriate standards for patentability requirements. In doing so, the examiner's decisions would be consistent with a court ruling that has involved a comprehensive review of the patent application¹⁰⁴ against law provisions

and their underlying purpose. Patent examiners should not only have sound knowledge and skill in the respective technical field but also knowledge of relevant court rulings and their legal bases.¹⁰⁵

Based on the above, patent examiners need to receive continued IP education. An increasing number of patent offices are becoming aware of the importance of legally educating their examiners. However, the form, scope and framework of such education or training may differ.

Training activities provided to the EPO examiners include legal and practical expertise. On top of training on how the patentability criteria are applied in practice, they also attend courses on European and international patent law and practice.¹⁰⁶

The patent branch of the Canadian Intellectual Property Office (CIPO) has created a patent examiner continuous training program.¹⁰⁷ IP related training is seen as the most important covering all the aspects that influence patent examination including jurisprudence. Training activities also cover patent law, appeal decisions and court cases.¹⁰⁸

One proposal to improve the quality of granted patents from the United States Patents and Trademarks Office (USPTO) was to standardize patent examiners training and qualifications.¹⁰⁹ It is based on the premise that the quality of patent examination could be improved when the examiners are required to undergo both legal and technical training.¹¹⁰ The proposal requires the examiners to pass the patent bar exam and complete a continuing legal education (CLE). This ensures that the examiner

¹⁰² Velasquez, 'Guidelines on Patentability and Access to Medicines' (n 9) 7.

¹⁰³ Fatima Beattie, 'Sharing expertise to boost patent quality' (2013) 5 WIPO Magazine 27 <http://www.wipo.int/export/sites/www/wipo_magazine/en/pdf/2013/wipo_pub_121_2013_05.pdf> accessed 22 January 2018.

¹⁰⁴ John L King, 'Patent Examination Procedures and Patent Quality' in National Research Council; Wesley M Cohen, Stephen A Merrill (Ed), *Patents in the Knowledge-Based Economy* (The National Academies Press 2003) 56.

¹⁰⁵ *ibid.*

¹⁰⁶ EPO, 'Patent examiner training' <https://jobs.epo.org/content/Training/?locale=en_GB> accessed 24 January 2018.

¹⁰⁷ Marc De Vleeschauwer, 'The Canadian Patent Examiner Continuous Training Program' (2014) 39 World Patent Information 73.

¹⁰⁸ *ibid.*

¹⁰⁹ H. Whei Hsueh, 'Standardizing Patent Examiner Training and Qualifications' (Berkeley Technology Law Journal, 11 April 2016) <<http://btli.org/2016/04/standardizing-patent-examiner-training-and-qualifications/>> accessed 19 April 2018.

¹¹⁰ *ibid.*

understands how patent law provisions are applied and interpreted in a similar manner to patent agents.¹¹¹

The National Center for Industrial Property Information and Training (INPIT) offers training for the Japanese Patent Office (JPO) examiners including highly specialized law courses.¹¹² IP education is offered to the Korean IP Office (KIPO) examiners including in-depth education on fundamental legislation and intensive training with case studies on patent law and patent litigation.¹¹³

The National Institute of IP Management (NIIPM) in India is in charge of examiners' training and education. Some programs aim to provide information on the latest global developments in IP.¹¹⁴ In 2012, an extensive training program was designed for the newly appointed patent examiners where the topics included introduction to IP, and administrative and constitutional law.¹¹⁵

IP knowledge can effectively increase the capacity of patent examiners in understanding and applying the relevant law provisions. In absence of policy guidance or examination guidelines, it would be the examiners' responsibility to evaluate various law interpretations and patentability standards. This is critical for pharmaceutical patent examiners as public interest and socioeconomic considerations strongly influence the choice to adopt the most appropriate interpretations and standards.

5.2 The Egyptian Experience in IP Education of Pharmaceutical Patent Examiners¹¹⁶

EGPO applies a substantive examination system. A patent application should be examined to ascertain that it satisfies the three patentability criteria and fulfills the requirements of unity of invention and disclosure.¹¹⁷

In January 2005, EGPO commenced the examination of patent applications related to pharmaceutical products which were kept -since January 1995- in the 'Mail Box'.¹¹⁸ There was only a few newly-hired pharmaceutical patent examiners with excellent background in pharmaceutical sciences but very little experience in patent examination. Pharmaceutical patent search and examination requires special skills and various resources which were not, at least adequately, available then. Some training programs were conducted, but they were not very specialized. In addition, access to field specific databases was limited.

Under such circumstances, the examiners had to rely, primarily, on the international search and preliminary examination reports issued by international authorities under the Patent Cooperation Treaty (PCT) system. It was therefore natural that patent examination reports prepared by the Egyptian examiners and issued by EGPO were highly influenced by those reports. In fact, the international reports had significantly contributed to the development and refinement of examination skills of the examiners. They contained rich technical arguments and information on the databases and search fields used.

Also, the pharmaceutical examiners often consulted EPO and USPTO websites to follow examination procedure and final decisions of the corresponding applications. As

¹¹¹ *ibid.*

¹¹² INPIT-JPO, 'Education' <<http://www.inpit.go.jp/english/educate/index.html>> accessed 24 January 2018.

¹¹³ KIPO, 'IP Education of Government Officials' <http://www.kipo.go.kr/kpo/user.tdf?a=user.english.html.HtmlApp&c=91003&catmenu=ek02_03_01> accessed 24 January 2018.

¹¹⁴ Rajiv Gandhi National Institute of Intellectual Property Management <<http://www.ipindia.nic.in/about-us-rg.htm>> accessed 14 June 2018.

¹¹⁵ Prashant Reddy, 'CGPDTM announces impressive training syllabus for new patent examiners' Spicy IP, 5 January 2012 <<https://spicyip.com/2012/01/cgpdmt-announces-impressive-training.html>> accessed 24 January 2018.

¹¹⁶ Interviews with the Pharmaceutical Patent Examination Department in EGPO (Cairo, Egypt, May 2018); Eman S Ibrahim,

'Inventive Step in Pharmaceutical Inventions and its Application Standard in Egypt' (Unpublished Advanced Studies Diploma Research Paper, Regional Institute of Intellectual Property, Faculty of Law, Helwan University, Egypt 2012).

¹¹⁷ Egyptian Law 82 on the Protection of Intellectual Property Rights 2002, Art 16.

¹¹⁸ Egypt has utilized the flexibility provided for in Art 65(4) of the TRIPS Agreement and postponed the examination of patent applications related to pharmaceutical chemical products filed starting from 1 January 1995. Those applications were kept at what was called "Mail Box". According to Art 43 of the Egyptian Law on Protection of Intellectual Property Rights 82 of 2002, patent applications related to pharmaceutical chemical products which were filed starting from 1 January 1995 were received and maintained pending their examination until 1 January 2005.

much as the Egyptian examiners were learning, their final decisions were also in line with the final decisions for the foreign corresponding applications. Consequently, most of the pharmaceutical patents in EGPO were granted with confidence that their counterparts had already been granted in major patent offices. This was the trend in the first few years after opening the 'Mail Box' in 2005.

As a result, many of the granted pharmaceutical patents covered very broad product claims, various physical forms and minor modifications of known compounds, and second medical uses.¹¹⁹ The Egyptian examiners did not realize the impact of importing lax patentability standards from the developed world. They could not foresee the serious consequences on public health, medicine affordability and local pharmaceutical industry.

In November 2006, EGPO issued a "Manual of Procedures for Examiners of the Egyptian Patent Office" in accordance with the provisions of the Egyptian Law on the Protection of Intellectual Property Rights 82 of 2002 and the Implementing Regulations. As indicated in its introduction, this manual was largely based on the PCT International Search and Preliminary Examination Guidelines (effective March 2004).¹²⁰

With time, the work in the pharmaceutical department began to take a different form. The number of examiners has increased. They started to accumulate experiences and access specialized databases. Various face-to-face and online courses were co-organized with WIPO and other patent offices. Instead of making individual decisions, the work became more collaborative. The continuous exchange of views and experiences has largely contributed to the consistency of the examination

process and issued reports which became more clear, precise and detailed.¹²¹

At that point, the examiners started to notice a certain pattern in pharmaceutical patent applications. Despite the ever-increasing numbers of the applications, only a small proportion thereof covered new chemical entities or significant advancements. The vast majority claimed different physical forms, formulations, combinations, methods of manufacture, or second uses of known drugs. They were based on common knowledge and widely used techniques in the pharmaceutical field.

However, the examiners' observations and discussions in this regard were limited. This was because of the lack of awareness of the implications of such a phenomenon let alone the need to take effective steps to deal with it. No policy guidance was available on how to deal with the mentioned cases of pharmaceutical patent claims. In addition, the manual of examination procedure did not deal specifically with any of those cases.

In October 2008, a number of the Egyptian pharmaceutical examiners participated in the workshop "Examination of Pharmaceutical Patent Applications: Developing a Public Health Perspective". The workshop was organized by UNDP and WHO for patent examiners and IP experts from African countries.¹²² It involved multiple in-depth technical and legal discussions on the standards for applying patentability requirements, especially the inventive step, to various cases of pharmaceutical patent claims. The discussions also dealt with evergreening of pharmaceutical patents and its impact on medicines availability and affordability and local generic manufacturing in developing countries.¹²³

¹¹⁹ Tahir Amin, 'Granted Pharmaceutical Patents in Egypt' Initiative for Medicines, Access and Knowledge (i-Mak) December 2011.

¹²⁰ EGPO, 'Manual of Procedures for Examiners of the Egyptian Patent Office' (November 2006).

¹²¹ Interview with Ms Mona S. Farag, Former Head of Pharmaceutical Examination Department in EGPO (Cairo, Egypt, 27 May 2018).

¹²² UNDP, WHO, 'Workshop on the Examination of Pharmaceutical Patents: Developing a Public Health Perspective'

Meeting Report, Cape Town - South Africa, 30-31 October 2008 <<http://www.undp.org/content/dam/aplaws/publication/en/publications/hiv-aids/meeting-report-from-undp-and-who-workshop-on-the-examination-of-pharmaceutical-patents-developing-a-public-health-perspective-/Patentability%20criteria%20meeting%20report%20Cape%20To wn.pdf>> accessed 22 January 2018.

¹²³ *ibid.*

The workshop was a great success. EGPO examiners were actively engaged sharing their experience and concerns. One important lesson to learn was on how to examine pharmaceutical patents taking public health objectives into consideration. According to the workshop report, the examiners have come to realize how the work they perform and the decisions they take could impact access to medicine, conceding that due to the special nature of their jobs they are responsible as guardians of public health.¹²⁴ The delegates returned to EGPO and started internal discussions on choosing the most appropriate standards for applying the patentability requirements in respect of pharmaceutical patents.¹²⁵

In April 2009, UNDP, WHO and ICTSD co-organized another workshop on the Examination of Pharmaceutical Patents from a Public Health Perspective for the benefit of examiners from patent offices in the Arab Region including EGPO.¹²⁶ The main objective was to discuss the appropriate guidelines for examining different types of pharmaceutical patent claims, concluding that such guidelines should ensure that public health concerns are considered while examining pharmaceutical patents.¹²⁷

After the two workshops, the pharmaceutical examiners worked together towards a common understanding on the optimum standards for assessing the patentability requirements. As a matter of fact, the twin workshops were the tipping point for a radical improvement in the manner that pharmaceutical patent applications were examined in EGPO. The pharmaceutical examiners decided to adopt high patentability standards, especially regarding the assessment of inventive step. They drafted template paragraphs, covering various categories of pharmaceutical patents, which could be customized and included in patent examination reports.¹²⁸ EGPO

pharmaceutical department has informally adopted the Guidelines for Examination of Pharmaceutical Patents developed by WHO, UNCTAD and ICTSD.¹²⁹

Examples of the adopted high standards for patentability criteria include: proper application of absolute novelty requirements and therefore not allowing selection inventions, and requiring a significant and unexpected / non-obvious degree of progress compared to prior art and common general knowledge to meet the inventive step criterion.¹³⁰

Since then, the quality of pharmaceutical examination procedure and issued reports in EGPO has increased.¹³¹ The decisions taken became independent of their foreign counterparts. Reports and decisions of other offices could be used only for general guidance. Only the inventions that involve a significant advancement would be allowed while conventional and trivial modifications would be rejected. The main goal was to ensure that only high-quality pharmaceutical patents are granted.

At this stage, it was clear for the pharmaceutical examiners how adopting the appropriate choice of the patentability standards would impact not only public health but also innovation and competition in the pharmaceutical field. Applying lower standards for assessing patentability could lead to a number of negative consequences. These include incentivizing minor rather than significant innovations resulting in the grant of unnecessarily high numbers of patents on secondary inventions that only block competition without a real innovative impact.¹³²

Pharmaceutical companies would not be motivated to spend money, effort and time on developing new chemical entities and truly innovative improvements on existing ones when they could easily obtain secondary

¹²⁴ *ibid.*

¹²⁵ Farag (n 121).

¹²⁶ UNDP, WHO, ICTSD, 'Examination of Pharmaceutical Patents from a Public Health Perspective' Meeting Report, Cairo - Egypt, 14-15 April 2009 <https://www.iprsonline.org/ictsdialogues/2009-04-14/2009-04-14_desc.html> accessed 22 January 2018.

¹²⁷ *ibid.*

¹²⁸ EGPO and Ibrahim (n 116).

¹²⁹ Velasquez, 'Guidelines on Patentability and Access to Medicines' (n 9) 28.

¹³⁰ EGPO and Ibrahim (n 116).

¹³¹ Farag (n 121).

¹³² Hyewon Ahn, *Second Generation Patents in Pharmaceutical Innovation* (Nomos Verlagsgesellschaft MbH 2014) 185 -187.

patents. In other words, low patentability standards would hinder innovation in the pharmaceutical field.¹³³

EGPO pharmaceutical examiners realized the positive impact of IP education on their work. Most of them attended multiple courses and pursued their studies in the field of IP. Currently, most of the pharmaceutical examiners in EGPO hold an Advanced Studies Diploma or LL.M in IP laws. Most of their IP Diploma research papers dealt with various aspects of the relationship between IPRs and pharmaceuticals.¹³⁴

In 2013, EGPO pharmaceutical department established an internal quality team to review the applications to be granted. This team is independent of the general quality committee reviewing samples of accepted and rejected applications in all technological fields.¹³⁵ The aim was to ensure the consistency of the examination procedure and that all the granted pharmaceutical patents are in compliance with the applied high patentability standards.

Today, EGPO pharmaceutical examiners exchange their experience with other patent offices through training programs and workshops on applying high patentability standards for pharmaceutical patents. In addition, about 30% of the trainers in the National IP Academy of Egypt are pharmaceutical patent examiners.¹³⁶

What has happened with EGPO pharmaceutical patent examiners between 2005 and today is mainly due to IP education. Pharmaceutical examiners realized the impact of their daily work on issues of public concern. Their perspective has changed influencing their choice of the examination standards they should apply. This affected their practice and inspired them to formulate their own examination guidelines. In absence of external policy guidance, IP education has enabled EGPO pharmaceutical

examiners to develop an internal policy that governs how pharmaceutical patents should be examined.

5.2.1 The Atazanavir and Sofosbuvir Cases in Egypt

The Atazanavir and Sofosbuvir patent applications are great practical examples to demonstrate the significant improvement in the quality of patent examination and granted pharmaceutical patents in Egypt.

Atazanavir is an antiretroviral agent for treatment and prevention of HIV/AIDS. Although the base compound itself was not patented in Egypt, a patent was granted in January 2008 covering its bisulfate salt and a formulation thereof. This patent was a barrier for local production of the medicine in Egypt until its expiry in January 2019.¹³⁷

In 2016, the International Treatment Preparedness Coalition ITPC-MENA requested that this patent be revoked for lack of novelty and inventive step. EGPO examiners issued a report confirming that the patent does not satisfy the patentability criteria.¹³⁸ Actually, if the application had been examined any time after mid-2009, it would be rejected by EGPO due to the application of rigorous patentability standards.

ITPC-MENA partnered with other NGOs to initiate court case procedure to revoke the patent in Egypt. However, in 2017 the patent owner announced the extension of its voluntary license on Atazanavir to 12 countries including Egypt. This would reduce the price and facilitate access in Egypt.¹³⁹ The Atazanavir patent required a lengthy and costly procedure to ameliorate its negative effects. A lot of money and effort could have been saved if the patent was not granted in the first instance.

Sofosbuvir is an antiviral medication for treatment of hepatitis C virus (HCV). Egypt has the highest prevalence of HCV infection in the world.¹⁴⁰ In 2014, the originator

¹³³ *ibid* 192.

¹³⁴ Interview with Professor Hossam El Saghir, Founder and Director of the Regional Institute of Intellectual Property, Helwan University (Cairo, Egypt, 30 May 2018).

¹³⁵ Interview with Mr Adel Oweida, Former Head of the EGPO (Cairo, Egypt, 30 May 2018).

¹³⁶ *ibid*.

¹³⁷ WHO, *The Role of Intellectual Property in Local Production in Developing Countries* (n 10) 10.

¹³⁸ Zakaria, 'A new victory for ITPC-MENA : Bristol-Myers Squibb extends its voluntary license on Atazanavir to Egypt' (International Treatment Preparedness Coalition ITPC-MENA, 25 July 2017) <<https://itpcmena.org/language/en/a-new-victory-for-itpc-mena-bristol-myers-squibb-extends-its-voluntary-license-on-atazanavir-to-egypt/>> accessed 1 February 2018.

¹³⁹ *ibid*.

¹⁴⁰ Fatma El Zanaty, Ann Way, 'Egypt Demographic and Health Survey 2008' Ministry of Health, El-Zanaty and Associates, and

company offered to supply the drug to Egypt at a price of US\$ 900 for a 12-week course of treatment which was only about 1% of the price in the United States.¹⁴¹ In the same year, EGPO rejected a key product by process patent application on Sofosbuvir¹⁴² as it did not meet EGPO strict standards of novelty and inventive step.

Rejecting this patent opened the door for several local companies to sell the drug in Egypt causing a significant price reduction.¹⁴³ A 28-day treatment has become available for about US\$ 51 enabling the treatment of hundreds of thousands of patients in Egypt.¹⁴⁴ Moreover, patients from other countries including developed countries are seeking treatment in Egypt.¹⁴⁵ A number of the corresponding granted patents were opposed in various developing and developed countries.¹⁴⁶

The Atazanavir and Sofosbuvir patents were low-quality pharmaceutical patents. Neither complied with the patentability requirements if applied properly. They did not provide significant contributions over the prior art. However, they would hinder access to medicine and generic competition.

The difference between how the two patent applications were examined in EGPO was mainly due to the difference in the level of IP knowledge of the pharmaceutical patent examiners. IP education has indeed played a pivotal role in improving the quality of the examination procedure and subsequently the quality of the granted patents in the pharmaceutical field.

6. CONCLUSION AND A WAY FORWARD

Quality is a key pillar of a well-functioning patent system that is able to achieve positive socioeconomic outcomes. This is especially true in the pharmaceutical field. Patent offices might have different perceptions of patent quality but most of them at least agree that the quality of the examination procedure is a very important factor.

Establishing an efficient patent search and examination system requires substantial skills and resources. Many small limited capacity patent offices, including in Africa and the Arab region, seek technical assistance from larger patent offices which are usually of developed countries. The assistance takes various forms, most often; the provision of training and the sharing of search and examination products and examination manuals.

The advanced infrastructure and technical capabilities of major patent offices usually impress the offices seeking assistance. This builds trust in the quality of search and examination procedure and granted patents in the major offices.¹⁴⁷ It is common to see the examination process in small patent offices performed under the same standards applied in the major offices. Similar reports and final decisions are issued. Practically speaking, the smaller offices become followers of the leader major offices.

This leader-follower approach is problematic. It assumes the examination procedure and granted patents of the leader offices to be always of high quality while this is not necessarily the case. Large patent offices might have their

Macro International (2009) 251-252
<<https://dhsprogram.com/pubs/pdf/fr220/fr220.pdf>> accessed 17 June 2018.

¹⁴¹ Maggie Fick, Ben Hirschler, 'Gilead offers Egypt new hepatitis C drug at 99 percent discount' (Reuters, 21 March 2014) <<https://www.reuters.com/article/us-hepatitis-egypt-gilead-sciences-idUSBREA2K1VF20140321>> accessed 17 June 2018.

¹⁴² WHO, 'Patent Situation of Key Products for Treatment of Hepatitis C: Sofosbuvir' Working Paper, Updated and revised version June 2016 <http://www.who.int/phi/implementation/ip_trade/sofosbuvir_report.pdf?ua=1> accessed 1 February 2018.

¹⁴³ Germán Velásquez, 'Access to Hepatitis C Treatment: A Global Problem' (2017) South Center Research Paper 77, 23 <https://www.southcentre.int/wp-content/uploads/2017/05/RP77_Access-to-Hepatitis-C-Treatment-A-Global-Problem_EN-2.pdf> accessed 17 June 2018.

¹⁴⁴ WHO, 'Global Report on Access to Hepatitis C Treatment: Focus on Overcoming Barriers' (2016) <<http://www.who.int/iris/handle/10665/250625>> accessed 17 June 2018.

¹⁴⁵ Carmen Paun, 'Another Reason to Visit Egypt: Europe's High Drug Prices' (Politico, 26 April 2018) <<https://www.politico.eu/article/egyptian-holiday-scheme-cashes-in-on-europes-high-drug-prices/>> accessed 17 June 2018.
¹⁴⁶ Patent Opposition Database, 'Sofosbuvir' <<https://www.patentoppositions.org/en/drugs/sofosbuvir>> accessed 17 June 2018.

¹⁴⁷ Peter Drahos, 'Trust me: Patent offices in developing countries' Working Paper (Centre for Governance of Knowledge and Development 2007) 17 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1028676> accessed 29 May 2018.

own patent quality issues.¹⁴⁸ In addition, there are many differences to be considered such as differences in relevant law provisions, public policies, local capacities, and socioeconomic situations. Importing patentability standards that are unfriendly to the prevailing national conditions must be avoided.¹⁴⁹

Ensuring high-quality examination in the pharmaceutical field requires an appropriate policy framework and examination guidelines. When they are not available, the role of patent examiners becomes more crucial. They need to be well-equipped with IP knowledge to be able to bridge the policy gap. They should also understand the implications of applying either lax or strict patentability standards for the public interest in their own countries.

The Egyptian experience showed how IP education has significantly changed the attitude of the pharmaceutical examiners towards low-quality patents. It helped them realize that rigorous examination of pharmaceutical patents is the right choice to protect public health.¹⁵⁰ They were able to formulate and implement examination guidelines and enhance the quality of examination and the granted pharmaceutical patents in Egypt.

Many developing countries populations suffer from the negative effects of the increasing numbers of low-quality pharmaceutical patents. Therefore, patent offices in the developing world should follow the example of Egypt and consider IP education as a main component of their examiners' qualifications.

IP education is an effective way to prevent the grant of low-quality patents by improving the quality of the examination procedure. Even when search and examination products of other offices are used, IP

education would enable the examiners to adapt and customize them to suit the locally applied standards.

It would also be advantageous for small patent offices to partner with patent offices in countries having similar socioeconomic conditions and public policies. Particularly important in respect of pharmaceutical patents is the cooperation with offices that have adopted strict patentability standards such as those of Argentina, Egypt and India.¹⁵¹ Cooperation activities may include training on examination practices and providing guidance on formulating examination guidelines.

IP education increases the capacity of patent examiners to protect public interest by defending against low-quality pharmaceutical patents.

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¹⁴⁸ See Kieren McCarthy, 'Patent quality has fallen, confirm Euro examiners' (The Register, 15 March 2018) <https://www.theregister.co.uk/2018/03/15/patent_quality_has_fallen_confirm_euro_examiners/> accessed 26 May 2018; Dugie Standeford, 'Despite Ongoing Efforts, USPTO Still Faces Patent Quality Issues' (Intellectual Property Watch, 19 June 2016) <<http://www.ip-watch.org/2016/09/16/despite-ongoing-efforts-uspto-still-faces-patent-quality-issues/>> accessed 26 May 2018.

¹⁴⁹ WHO, *The Role of Intellectual Property in Local Production in Developing Countries* (n 10) 11-12.

¹⁵⁰ Chloé Forette, 'Hepatitis C: Gilead Patent on Sofosbuvir Partially Maintained Following Mdm Patent Opposition' (hepCoalition, 5 October 2016) <<http://hepcoalition.org/news/press-releases/article/hepatitis-c-gilead-patent-on-sofosbuvir-partially-maintained-following-mdm>> accessed 19 April 2018.

¹⁵¹ Correa, 'Patent Examination and Legal Fictions' (n 100) 8.

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REGULATION OF BIOTECHNOLOGY IN UGANDA: A NECESSARY EVIL?

Anthony C.K. Kakooza*

ABSTRACT

Humankind has been feeding on biotech products, better known as genetically modified organisms (GMOs), for decades without paying keen attention to this reality. Innovation into biotech products was orchestrated, among other reasons, by growth in demand for food as well as harsh climatic conditions that negatively affected supply of agricultural products in the global market. When the presence of genetically modified agricultural products in the market place came to the surface, negative publicity outshined the benefits accredited to them. This fueled the overwhelmingly hostile knee-jerk reaction that the general public currently gives to GMOs. This article looks at the perceptions towards GMOs and how the negative misconceptions could easily derail us from enjoying the benefits that are imbedded within them and more particularly, addressing food security. In this paper, Uganda is used as a case study because of the wealth of research and development (R&D) into GMOs that have been conducted in Uganda over the years. The article argues for a renewed understanding of GMOs through robust dissemination of information and the need for effective regulation of their usage so as to ensure that mechanisms are diligently employed by the producers of GMOs to avoid the negative consequences accredited to them. The key objective should be on having a balance between rewarding innovation and satisfying consumer interests. On the whole, the article posits that the merits associated with GMOs outweigh the demerits and, as such, they should not be seen as a necessary evil, especially if their production and market placement are adequately regulated.

Key words: Biotechnology, Genetically Modified Organisms, Food Security

1. INTRODUCTION: FOUNDATIONAL ASPECTS TO THE ROOT PROBLEM

Uganda, like most Least Developed Countries (LDCs), is predominantly an agro-based economy. A wide variety of food crops are grown in Uganda and these are inclusive of

Maize (Corn), Millet, Sorghum, Rice, Cassava, Potatoes, Beans, Cow Peas, Soya Beans, Plantains and Coffee. However, according to the National Statistical Abstract of 2017, there was a marked decreased production in most crops between 2015 and 2016.¹ This is in spite of an ever increasing national population which currently stands at approximately 44 million people.²

The decrease in food production juxtaposed with an increase in population is widely spread out in sub-Saharan Africa. The Academy of Science of South Africa released a study report on the 'Regulation of Agricultural GM Technology in Africa'.³ In this report, it states that "according to the UN Food and Agriculture Organisation's (FAO) State of Food and Agriculture 2010-2011, sub-Saharan Africa:

- Is home to 26 percent of the world's undernourished population;
- Has the highest number of countries experiencing food emergencies due, in part, to climate extremes such as drought and exacerbated by civil unrest;
- Experienced increased food imports during the first half of this decade; and
- Is very vulnerable to global food price increases."

This therefore portrays a reality of an increase in demand for food while at the same time, there is also a decrease in food production to satisfy the market. Food security is therefore at the peripheral of the socio-economic development of agro-based economies such as those in sub-Saharan Africa.

* **Dr. Anthony Conrad K. Kakooza** is an enrolled Advocate in Uganda and Partner as well as Head of the Intellectual Property Unit in the law firm of M/s Byenkya, Kihika & Co. Advocates. He also lectures Intellectual Property law in Makerere University and Uganda Christian University. He is a Visiting Professor in Intellectual Property Law (Traditional Knowledge and Folklore) at the University of Illinois and Cornell University (U.S.A) as well as Masaryk University, Brno (Czech Republic). The law in this paper is stated as it stood on 1st July 2018.

¹ Uganda Bureau of Statistics: *2017 Statistical Abstract* at p. 61. See: [https://www.ubos.org/wp-](https://www.ubos.org/wp-content/uploads/publications/03_20182017_Statistical_Abstract.pdf)

[content/uploads/publications/03_20182017_Statistical_Abstract.pdf](https://www.ubos.org/wp-content/uploads/publications/03_20182017_Statistical_Abstract.pdf) (Accessed December 19, 2017)

² See: <http://www.worldometers.info/world-population/uganda-population/> (Accessed June 10, 2018)

³ Academy of Science of South Africa (ASSAF), Regulation of Agricultural GM Technology in Africa – Mobilizing Science and Science Academies for Policymaking, November 2012. See: <https://www.assaf.org.za/files/2012/11/K-9610-ASSAF-GMO-Report-Dev-V8-LR.pdf> (accessed March 1, 2018)

2. WHAT IS FOOD SECURITY?

Numerous definitions have come out with attempts at describing the concept of Food Security. This article, however, borrows from the understanding of Food Security proposed by the FAO in stating that food security is attained “when all people, at all times, have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life.”⁴ The focus of this article is to address the issue as to whether agro-biotechnology contributes towards food security as a supplement for - or beyond - the conventional methods of farming.

The new trend towards changing the traditional farming methods started in the 1960s in an era dubbed as the “Green Revolution”.⁵ This era witnessed increased investments in the agricultural sector and was marked by development and distribution of new high yielding food varieties mainly wheat and rice⁶.

Biotechnology in the food industry thus emerged as one of the solutions in addressing the problem of decreasing food production in an ever increasing market base. As highlighted below, biotechnology is not only meant to address the increasing demand for food, but also address the challenges impending adequate supply of food, such as climatic conditions and plant disease.

3. WHAT IS BIOTECHNOLOGY?

Biotechnology is the use of living organisms and molecular biology to produce healthcare-related products and therapeutics or to run processes such as

DNA fingerprinting.⁷ This paper is particular focused on agricultural biotechnology as an offshoot of biotechnology that pertains to plants. Professor Chidi Oguamanam has described agricultural biotechnology as “. . . a subset of biotechnology steeped in diverse techniques for manipulating genetic materials of living organisms and for exploring and exploiting the complex chemistry of biological systems for food production and other agro-industrial ends”.⁸

4. IS BIOTECHNOLOGY EVIL?

The response to this question, particularly with regard to agricultural biotechnology, is dependent on the perspectives of the stakeholders in the food industry. These perspectives are presented as follows:

- a) Agricultural researchers and Research & Development (R&D) firms

Bongo Adi argues that “Agricultural biotechnology has the potential to increase the productivity and adaptability of crops, diversify the variety of agricultural crops and enhance the nutritional value of food to combat the perennial problems of poverty, malnutrition, food insecurity and diseases”.⁹ In the same vein, Paragraph 2 of the Memorandum to Uganda’s National Biotechnology and Biosafety Bill,¹⁰ defends the need for modern biotechnology as an aspect that will create “enormous opportunities for modernization of agriculture, protection of the environment, enhance public health and industrialization.” Ugandan researchers in Agro-biotechnology have also come

⁴ World Food Summit, Nov. 13-17, 1996, *Rome Declaration on World Food Security: World Food Summit Plan of Action*, 1, WFS 96/REP, available at

http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/003/w3613e/w3613e00.htm cited in Chidi Oguamanam, *Agro-Biodiversity and Food Security: Biotechnology and Traditional Agricultural Practices at the periphery of International Intellectual Property regime complex*, 2007 Mich. St. L. Rev. 215, at p. 230.

⁵ Douglas Gollin et al, *Two blades of Grass: The Impact of the Green Revolution*, National Bureau of Economic Research (NBER) Working Paper Series, 2018 No. 24744 (https://www.nber.org/system/files/working_papers/w24744/w24744.pdf) (Accessed May 2, 2021)

⁶ Bongo Adi, *Intellectual Property Rights in Biotechnology and the fate of poor farmers’ Agriculture*; A version of this paper was submitted to the United Nations University International Courses (International Trade and Dispute Settlement) in 2000. See: <https://onlinelibrary.wiley.com/doi/abs/10.1111/i.1422-2213.2006.00270.x> (Accessed March 3, 2018)

⁷ See: <https://www.investopedia.com/terms/b/biotechnology.asp> (Accessed May 2, 2021)

⁸ Chidi Oguamanam Fn 5 supra, at p 222

⁹ Ibid, fn 7 supra at p. 2

¹⁰ The National Biotechnology and Biosafety Bill, No. 18 of 2012

out strongly in favour of the proposed legislation.¹¹ Dr. Denis Kyetere, the Executive Director of the African Agricultural Technology Foundation (AATF) opines that, on account of the proposed regulation of biotechnology, Uganda now stands out as a leader in advanced agricultural research on the Continent and other nations will be watching how it utilizes a legal framework for advancing better crop technologies¹².

Needless to say, Agro-tech researchers are cognizant of the benefits that accrue from modern agro-biotechnology. They view regulation of this industry as an approval stamp that will gradually change the mindset of GMO pessimists and bring the general populace into understanding and embracing the benefits accruing from the use of agro-biotechnology in the food industry.¹³ Gilbert Gumisiriza, an Agricultural Research Analyst, dismisses anti-GMO activism as a manipulation of the human mind by a cult movement committed to agricultural stagnation in vulnerable developing countries.¹⁴

This assertion may be justified from the perspective of those knowledgeable about the benefits to be obtained from the use of agro-biotechnology but one also need to appreciate the concerns of others hesitant to embrace the use or generation of GMOs, especially local farming communities as highlighted below.

b) Local farming communities

Most local farming communities, particularly in least developed economies like that of Uganda, find it difficult to adapt to the systems of modern farming and plant breeding that define agro-biotechnology. Professor Graham Dutfield points out two key reasons for this: (1) Subsistence farmers from developing countries, to a large extent, obtain seeds from their own farms or from neighbours; and (2) local farmers often perform breeding within their own fields in order to develop varieties that are compliant with their own local conditions.¹⁵

This goes to show that agricultural practices from local farming communities are at cross-roads with those of modern agro-biotechnology. It is the considered view of this author that modern agro-biotechnology appears to be more focused in providing solutions for a larger market as well as addressing large scale challenges. It is, as such, individualistic and – to a certain extent – commercially-focused, as it inevitably requires some form of legal protection for the innovations involved – an aspect that is covered later in this article. Agricultural practices of local farming communities, on the other hand, are mainly subsistence in nature and thus primarily concerned with satisfying the needs of the nuclear family for another day and, at most, borrow a few ideas from neighbours within the local proximity if any farming challenges arise. It is thus a practice that relies heavily on Traditional Knowledge (TK) and communal rights¹⁶.

Bongo Adi, describes this juxtaposition succinctly by stating that: “Farmers’ seeds were now declared

¹¹Peter Wamboga-Mugirya, *Uganda’s agriculture sector welcomes new GMO crop law*, , Cornell Alliance for Science blog, November 29, 2017, <https://allianceforscience.cornell.edu/blog/2017/11/ugandas-agriculture-sector-welcomes-new-gmo-crop-law/> (accessed March 3, 2018)

¹² *ibid*

¹³ Peter Wamboga-Mugirya, *Uganda Scientist dismisses anti-GMO activism as bio-hegemony cult*, Cornell Alliance for Science blog <https://allianceforscience.cornell.edu/blog/2018/03/ugandan-scientist-anti-gmo-activism-cult/> (Accessed March 5, 2018)

¹⁴ *ibid*

¹⁵ Graham Dutfield, *Social and Economic Consequences of Genetic Use Restriction Technologies in Developing Countries*, pp.293-303 at p. 294, in Jay P. Kesan (Ed.), *Agricultural Biotechnology and Intellectual Property: Seeds of Change*, CAB International, 2007

¹⁶ Food and Agriculture Organization (FAO): Agricultural practices and extension services, Chapter 6 in ‘Guidelines on Spate Irrigation’, see: <http://www.fao.org/3/i1680e/i1680e02.pdf> (Accessed May 2, 2021)

“primitive cultivators” and “land races”, suggesting no intellectual work had gone into their evolutions. The Green Revolution varieties were on the other hand, referred to as, “elite”, “modern” and “miracle”.¹⁷ Citing Shiva, he goes on to add that local farming communities in developing countries consider community seeds as sacred and a free gift of nature which should not be commercialized.¹⁸

Local farmers are also part of the same consumers of agricultural products mainly due to the fact that the primary beneficiaries of their services are their own families. As such, apart from the conflicting paradigm showing the current parallel focus towards agricultural practices, as consumers, there is also generally a negative reaction towards GMOs.¹⁹

c) Consumers of agricultural products

The interests of consumers and their appreciation towards agro-biotechnology, focuses on two major aspects: food safety and liability for product deficiency. As expounded upon in detail below, there are global concerns that GMO products are carcinogenic and that GMO seeds (such as terminator seeds) have negative effects on the Soil, especially in preventing other seeds from being placed in the same soil components.²⁰ Where such fears arise, the follow-up issue is then whether the R&D firms and corporate institutes that rely on and utilize GMOs can be held liable for negative effects upon local farmers and those that consume GMO products.

In an online article, Canary Mugume - an investigative journalist - shares his experience in having undertaken an investigation into whether there are

any GMO products in the Ugandan market.²¹ He purchased several brands of cereal from a local supermarket and was intrigued at establishing that the labelling on the boxes of cereal highlighted the fact that they were produced by GMOs.²² He proceeded to carry out investigations into product liability in case of deficiencies in the product. On inquiry with the Uganda National Bureau of Standards (UNBS) – the National Regulatory Body that oversees adequate standardization of products and services in the country – he was informed that UNBS does not have any specific standards for GMO products because it does not standardize technology.²³ UNBS emphasized to him, however, that under UNBS’ supervision, all products (whether GMOs or not) are expected to meet the quality and safety parameters set by the National Authority.²⁴ Ironically, this contradicts the earlier denial from UNBS on standardizing technology because it reflects the fact that UNBS recognizes its mandate in looking into the quality and safety of GMO products that are in the Ugandan market.

Needless to mention, however, that Canary Mugume’s experiences are reflective of the fact that GMO products are already in the Ugandan market and that there are consumer concerns, legitimate or not, over the safety of such products and establishing liability over unsafe products. In addressing these concerns, the Biotechnology and Biosafety Bill provides for the establishment of an Institutional Biosafety Committee to, among others, monitor effective research into, as well as output of GMOs ;²⁵ submission of Risk and Safety Assessment Reports by GMO manufacturers;²⁶ product liability in terms of offences and penalties, related to general

¹⁷ Ibid, fn 7 supra at p. 3

¹⁸ Ibid, fn 7 supra at p. 19, citing Shiva, V.: 1996, ‘*The Seeds of our Future*’ Development Journal 4.

¹⁹ GMOs – Top five concerns for family farmers, See: <https://www.farmaid.org/issues/gmos/gmos-top-5-concerns-for-family-farmers/> (Accessed May 2, 2021)

²¹ Canary Mugume, The dark secrets behind the GMOs war in Uganda, <http://nilepost.co.ug/2018/05/22/the-dark-secrets-behind-the-gmos-war-in-uganda/> (accessed 28 June 2018)

²² Id.

²³ Id.

²⁴ Id.

²⁵ Clause 14.

²⁶ Clause 29.

release of GMOs without approval, failure to disclose important information related to GMOs, or furnishing of false information.²⁷ On failure to disclose information, it is not clear whether such provision also addresses the issue of food package labelling, which is given top most consideration within international best practices related to safety standards in biotechnology.

The short fall in this particular respect of product liability, is therefore generally to the effect that the Bill is silent on the likely repercussions upon GMO producers in the event that it is established that a consumer has suffered upon the consumption or utilization of a GMO product.

It is nonetheless a buildup of consumer concerns that is transferred towards political leaders and Governments to work out a solution towards the question of GMO usage as seen below.

d) Politicians and government perceptions

Professor Jay Kesan cites political demonstrations that began in Europe in the early 2000s against importation of GMOs and the low acceptance levels towards GMOs which culminated into the introduction of government standards on food-labelling in Europe and Japan.²⁸ This was to the effect that food items must have labels indicating how much of the ingredients are GM²⁹.

It is generally highlighted that the major concern, especially from Europe and Japan, is that genetic engineering has an overall negative effect of reducing plants, animals and micro-organisms to “mere commercial commodities bereft of any sacred character”.³⁰ This resonates with the previously

highlighted conflict with regard to the notion that the general characteristic of African agricultural practices is that they are communal in nature and based on family survival rather than individualism and profit generation. It is nonetheless important to appreciate that the introduction of agro-biotechnology will continuously shift agricultural practices from what has been termed as land-based farming to “transdisciplinary convergences in therapeutics, pharmaceuticals, chemicals, and marketing in complex industrial and political economics of globalization”³¹.

On the face of the Ugandan “GMO” Bill, considering that it is a 2012 draft regulation, it is apparent that the Ugandan government has played ping pong to passing legislation on safe production and utilization of biotechnology in the country. In a 2004 study report, it was reported that the consensus among Ugandan government officials was that the Country should invest in GMO technologies as well as encourage importation and application of GMOs³².

However, on fast tracking into 2018, there is hardly any progress made towards regulation of this nascent industrial development. The Bill, in spite of its limited shortfalls highlighted within this article, was shelved in the Ugandan Parliament for a good number of years and then hurriedly debated and passed in October of 2017 by the Parliament of Uganda. However, although the President had initially expressed frustration at the delay in Parliament’s debates over the Bill, when it was taken to him for signing into law, he out-rightly rejected the Bill in its current form and sent it back to

²⁷ Clause 37.

²⁸ Jay Kesan, *Seeds of Change: A Link among the Legal, Economic and Agricultural Biotechnology Communities*, in Jay P. Kesan (Ed.), *Agricultural Biotechnology and Intellectual Property: Seeds of Change*, *ibid*, fn 16 supra at p. xx.

²⁹ *Id*.

³⁰ Bongo Adi, fn 7 supra at p. 4, Citing Persley, G.J.: 2000, *Promethean Science, Chapt. Agricultural Biotechnology and the Poor: Promethean Science*, Washington, D.C.; CGIAR

³¹ Chidi Oguamanam, fn 5 supra at p. 222

³² Ronald Naluwairo and Godber Tumushabe, *Uganda’s position on GMOs: Whose Position? Reflections on Uganda’s Policy Making Process on GMOs*, ACODE Policy Briefing Paper No. 5, 2004

Parliament for further scrutiny.³³ The President's objection towards signing the Bill into law was generally premised on the reasoning that: the Bill talks of giving monopoly of patent rights and forgets about communities that developed original material; there should be no cross-pollination between GMOs and indigenous seeds; there should be clear labelling of GMO products; and the consumer must be protected from harmful GMOs.³⁴

The issue of fair and equitable sharing of benefits with local farmers is of paramount importance in least developed economies like Uganda where agrobiotechnology favors Patent rights of breeders over and above the rights of local farmers. However, the Bill, in its current form, has no specific mention of granting monopoly of patent rights, an issue which is addressed later on in this article. As for the other concerns from the President which are pointed out above, although as aforementioned, the Bill is not clear as to whether provision of information or the lack thereof, involves labelling of GMO products, it can be argued that cross pollination is unconsciously covered under the provision which makes it an offence to engage in GMOs without obtaining the necessary approval (clause 37). Consumer protection against harmful GMOs is generally the objective of the Bill. It would therefore be incomprehensible for the President not to sign the Bill into law on the basis that this principle was lacking in the Bill. The first paragraph under the Memorandum of the Bill clearly highlights the objective of ensuring that consumers of biotechnology receive a product that has gone

through all the necessary safety standards. It stipulates thus:

"The Object of this Bill is to provide a regulatory framework that facilitates the safe development and application of biotechnology;

...

to provide mechanism[s][sic] to regulate research, development and general release of genetically modified organisms and for related matters."³⁵

It is therefore apparent that on most of the issues raised by the President in objecting to signing the Bill into law, he was ill-advised. This paints a hazy picture in the regulation of biotechnology in Uganda based on mistrust and political uncertainty which, subsequent to the passing of the National Biotechnology Policy in 2009, has only reflected government inaction in following up with the necessary regulation.

Such inaction on the part of the government of Uganda, is fueled by assumed risks and negative perceptions towards the use of GMOs and the corporations that produce them. The most common of these perceptions are expounded upon as follows:

a) Considered carcinogenic

It is a general belief that agricultural products that are prepared for human consumption should be naturally grown. This therefore makes it difficult to appreciate the possibility of using artificial techniques in the use of living organisms to produce agricultural or animal products, which ironically, have been in consumption across the globe for decades. It is on the basis of the idea that GMOs cannot possibly hold the same health benefits

³³ See: Ivan Okuda, *Museveni declines to sign GMO bill into law*, Daily Monitor Newspaper, December 28 2017 <http://www.monitor.co.ug/News/National/Museveni-declines-to-sign-GMO-bill-into-law/688334-4243964-wfynm9z/index.html> (accessed March 19, 2018)

³⁴ Ibid, also see: Report of the Committee on Science, Technology and Innovation on a Bill for an Act entitled The Biosafety Act, 2017

³⁵ Republic of Uganda: The National Biotechnology and Biosafety Bill, No. 18 of 2012, See: http://mediad.publicbroadcasting.net/p/kwmu/files/201610/biotechnology_biosafety_bill_2012_3.pdf (Accessed May 2, 2021)

derived from naturally grown crops, that assumptions are created to the effect that GMOs can lead to non-communicable diseases such as cancer.³⁶

As earlier on mentioned in the first part of this article, Gilbert Gumisiriza asserts that the labelling of GMO products as health hazards is actually a manipulation of the mind.³⁷ Indeed, this fact came true through a revelation that ActionAid Uganda (AA Uganda), a Civil Society Organization, had falsely and with intent, painted a wrong picture about GMO crops by spreading false propaganda to Ugandan farmers about GMOs. ActionAid Uganda had been telling farmers that GMOs can cause cancer and it relied on false reports from various scientists.³⁸ These Scientists later disassociated themselves from such reports and categorically stated that there has so far not been any scientific research connecting GMOs to negative health effects.³⁹ ActionAid UK (the parent Organization of AA Uganda) also responded by denouncing AA Uganda in making a false report and added that “all AA chapters have been explicitly instructed not to claim ill health effects from GM crops, that AA Uganda has apologized and withdrawn its claims⁴⁰.

As such, the belief that GMOs cause cancer is a mind manipulation that has – so far- not been supported by any concrete evidence.

b) Un-natural

Biotechnology is the opposite of natural. Researchers, working in labs, use genetic engineering to produce a new form of plants with a

specific purpose in mind. Professor Graham Dutfield argues that although terminator technology⁴¹ – an aspect of genetic engineering in Agro-biotechnology – can boost further investment in agricultural biotechnology, it also has a down side. Adoption of terminator technology can weaken natural plant breeding efforts globally by reducing the variety of germplasm available and gradually marginalize traditional farming practices, such as seed sharing by modern practices of multi-national corporations.⁴²

However, although GMOs are unnatural, the focus should be on the desired end for which they are created. When you have an unnatural outcome which, nonetheless benefits the consumer, then that is a big plus for the product. This includes using technology to increase productivity and adaptability of crops to ecological hazards.

Part V of the Biotechnology and Biosafety Bill caters for situations in which the use of biotechnology can create potential harm to the environment. It provides to the effect that the entity that is found culpable of causing such harm to the environment is given an order by a Government regulatory authority to restore the environment to the state it was in before the damage.⁴³

No guarantee can be given, however, that there can be sufficient environmental restoration subsequent to damage caused by terminator technology. A reasonable way forward, therefore, is to ensure that research activities that potentially have adverse negative effects on the environment, albeit also

³⁶ Touyz L. Z. (2013). *Genetically modified foods, cancer, and diet: myths and reality*. *Current oncology (Toronto, Ont.)*, 20(2), e59–e61. <https://doi.org/10.3747/co.20.1283> (Accessed May 2, 2021)

³⁷ Ibid, fn 12, supra

³⁸ ActionAid International, *ActionAid CE’s Response to INGO Accountability Charter Independent Panel Feedback*, July, 30 2015 at p. 8, see: <https://accountablenow.org/wp-content/uploads/2017/01/ActionAid-CE-response-to-Independent-Panel-Feedback-Report-2013-July-2015.pdf> (accessed June 20, 2018)

³⁹ Ibid

⁴⁰ Id.

⁴¹ Terminator Technology is a technique for genetically altering a plant so that the seeds it produces are sterile. See Crouch, M.L.: 1998, *How the Terminator Terminates*, Washington, D.C. The Edmonds Institute., <http://www.indiana.edu/people/terminator.html>. Cited in Bongo Adi, fn 7 supra. Also See fn 16 supra at pp. 293-294

⁴² Graham Dutfield, fn 16 supra at pp. 293-294

⁴³ See supra fn 36

presenting some benefits towards food security, should be conducted in isolated premises or green houses with guaranteed seclusion and controlled exposure to the environment. Such an approach would thus preserve traditional subsistence farming practices keeping them safe from potential dangers that may follow from agro-biotechnology and at the same time keep the door open for local farmers to utilize such technology from an excluded zone if they so wish.

c) Linked to the “Evil Corporation”

The so-called “Evil Corporation” in this context, is the U.S based Monsanto Corporation that deals in Agribusiness.⁴⁴ Although Monsanto was established in 1901 as a producer of saccharin, a synthetic sweetener, it gradually moved into raw materials; then into chemical production.⁴⁵ In the late 1970s Howard Schneiderman, joined Monsanto and became its Senior Vice President for R&D.⁴⁶ He was credited for building up Monsanto’s dominance in Agro biotechnology.⁴⁷

Over the years, Monsanto was seen as a devourer of smaller farming entities which gave it a competitive edge in the agribusiness with the ability to influence direction of such business in developed countries.⁴⁸ For instance, towards the end of 1998, Monsanto controlled 86% of the US Cotton seed market.⁴⁹ It later on divested some of these interests in response to regulatory conditions that would enable it acquire other smaller stakeholders in the industry.⁵⁰ Nonetheless, within the same period of the late 1990’s Monsanto made significant acquisitions of shares in Seed companies across the globe which

enabled it to generate access to the gene-market (plant breeding, seed testing, seed multiplication and distribution operations) in 51 countries.⁵¹

This buildup of a global domineering position in the seed manufacturing biotech industry positioned Monsanto as a Corporate entity that was perceived to edge out competition and traditional farming mechanisms (such as farm-saved seeds) that were seen to offer any resistance or competition (however small) to its modern farming mechanisms.⁵²

This has thus created the discernment of Monsanto as the evil corporation, albeit the positive attributes that are highlighted in the next part of this paper.

d) Cultural Perceptions

The cultural perceptions towards GMOs are, to one extent, tied to the aforementioned belief that GMOs spread incommunicable diseases like cancer.⁵³ Other perceptions that are mainly specific to developing economies like Uganda, hold the view that Traditional Knowledge practices relating to the agricultural industry should also be given credence in how we relate with GMOs. The argument in this respect is that the production of GMOs borrows heavily from TK to create a product worthy of patenting as an individual right within the mind-set of developed countries.⁵⁴ But to the local farming communities in developing countries, on the other hand, they are not compensated for the contributions they make towards the fruition of such product. In their understanding, the GMO is derived from a product that they have been enjoying under a common right. The commodification and valuation of the new product within a market with restrictions

⁴⁴ As of June 7, 2018, Monsanto was acquired by German – based Corporate entity known as Bayer for 62 Billion U.S Dollars. See: <https://monsanto.com/news-releases/bayer-closes-monsanto-acquisition/> (Accessed June 28, 2018)

⁴⁵ Dorothy Leonard-Barton and Gary Pisano, *Monsanto’s March into Biotechnology* (A) See Teaching note on: <https://hbr.org/product/monsantos-march-into-biotechnology-a/690009-PDF-ENG> (Accessed June 29, 2018)

⁴⁶ Id.

⁴⁷ Id.

⁴⁸ Id

⁴⁹ Id.

⁵⁰ Ibid, fn 7 supra at p. 12.

⁵¹ Ibid, at p. 15

⁵² Supra, note 46

⁵³ Supra, note 37

⁵⁴ Ibid fn 29 supra at p. xix

on usage and purchase, creates an element of bio piracy⁵⁵. The response argument in this line should therefore look more towards a strong access and benefit sharing mechanism within the legal system.

e) Selfish interests of profit motivation

Slightly over ten years ago, the value of global mergers and acquisitions passed the two trillion US Dollar mark – a total of 2.4 trillion USD.⁵⁶ Daniel Vasella, at the time a CEO of Novartis⁵⁷, stated that the real motive in such direction was that “ the common denominator of our business is biology. . .The research and technology is applied to discover, develop and sell products that have an effect on biological systems, be they human beings, plants or animals.”⁵⁸ The trend towards mergers and acquisitions has been on the increase since 1995.

This makes business sense largely because the transformation in the way large corporate entities look at Agriculture, is now towards businesses involving constant innovations and thus creation of monopolies in IP. The more innovations they own, the broader the IP portfolio and thus more profits made at the end of the day. For instance, between 1995 and 1997, Monsanto which was focused on the Seed and Agriculture industry, had a transaction value worth U.S 8 Billion dollars, while Bayer – a German Biotech Corporation, had a transaction value of U.S 1.2 Billion dollars within the same time period. First forward roughly 21 years later and in June 2018, Bayer fully acquired all the stakes in Monsanto at slightly over U.S 62 Billion dollars⁵⁹ and has intentions to drop the Monsanto name entirely. It goes without mention as to what this will mean in terms of future profits in Agro-biotechnology for the Bayer Corporation.

However, Jay Kesan warns that the profit generating objective and sharing of benefits that may be subjected towards benefiting local farming communities, is

hampered by heavy regulation on the part of developing economies. This, in turn, discourages foreign investors in such markets.⁶⁰ As more countries pursue regulation of biotechnology practices, such regulation should balance out the interests of stakeholders as opposed to focusing more on protecting domestic interests. The latter approach may erode the various parties from achieving their intended objectives.

Needless to state that the pursuit of profits is natural in businesses, and corporations engaged in the Agro-technology business cannot be seen to shy away from displaying it. Criticism on this particular issue should be on a case by case basis following particular considerations of a focus on profits being seen to overshadow the safety of consumers of GMOs. However, government regulation of such businesses in matters related to taxation and conformity to business and consumer risks standards should be practical and should, as well, be seen to conform to international best practices that encourage safe business practices and growth of the industry.

Regulation that is seen to create a balance in effective R&D of Biotech products on the one hand, and consumer protection on the other hand, is of the essence. This is in light of the potential benefits that accrue from GMOs. In cognizance of all the criticism that has been levelled against GMOs, they do have quite a number of benefits derived from them.

For instance, although Monsanto has been portrayed as “the evil corporation”, it rolled out a humanitarian cause for the benefit of specific African countries, Uganda inclusive. In March 2008, Monsanto entered into a partnership with various African researchers working with funding from the Bill and Melinda Gates Foundation as well as the Howard Buffet Foundation. Under this partnership, Monsanto donated some of its genetic “markers” and other breeding resources to research

⁵⁵ Id

⁵⁶ Id

⁵⁷ Novartis International AG is a Swiss multinational pharmaceutical company based in Basel, Switzerland.

⁵⁸ Ibid, fn 7 supra at p. 10

⁵⁹ Ibid fn 45 supra

⁶⁰ Ibid fn 16 supra at p. xxi

institutes in Uganda, Kenya, Mozambique, South Africa and Tanzania⁶¹.

By way of emphasis, agro-biotech research targets global challenges affecting agricultural production such as drought which negatively affects crop yield in many African agro-based economies like Uganda. The Monsanto project is therefore enabling farmers to acquire better knowledge on the proper use of fertilizers and land management. The research involves “experimenting with a number of gene combinations to stimulate greater photosynthesis, improve root structures, and enhance other characteristics so the transgenic corn can yield more kernels with less water.”⁶²

It therefore follows that the highlighted benefits of GMOs are as follows⁶³:

- a) Reducing crop production costs and increasing yield;
- b) Reducing toxic chemicals in the environment by reducing need for pesticides;
- c) Environmental monitoring and remediation;
- d) Plant-based biopharmaceuticals.

Gilbert Gumisiriza, a Ugandan biosafety regulator, also articulates a clear summary of GMO benefits by stating that GM Technology focuses on the “need and mandate to save plants from ferocious pests, virulent diseases and adverse climate change impacts, while improving their ability to perform in nitrogen depleted soils without the use of synthetic fertilizers.”⁶⁴

GMO researchers therefore have consumer interests in mind while undertaking biotech R&D. Regulation of Agro-biotechnology in Uganda thus serves the purpose of ensuring that the research and output of such practice is well coordinated by government agencies with full

participation and benefit-sharing coming in from local farming communities. This is on the basis of their strong impact on the economy.

As aforementioned, several African countries, alongside Uganda, have been carrying out research into GMOs over the years.⁶⁵ These too, recognize the need for such R&D of Agro-biotechnology to be backed up by adequate regulation. As of late 2011, fourteen African countries had full regulations on GMOs: Burkina Faso, Cameroon, Ethiopia, Kenya, Mali, Mozambique, Malawi, Mauritius, Namibia, Senegal, Tanzania, Togo, Zambia and Zimbabwe.⁶⁶

5. IS THE NATIONAL BIOTECHNOLOGY AND BIOSAFETY BILL ALIGNED WITH INTERNATIONAL INSTRUMENTS?

Uganda is signatory to a number of International Instruments that are of relevance in conducting research and utilization of biotechnology. These are discussed below:

- a) The TRIPS Agreement

Uganda is a founder member of the World Trade Organization (WTO) which was established in 1995. On that basis, Uganda is obligated to domesticate the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which is an international legal agreement between all the member nations of the WTO. Article 27.3(b) of the TRIPS agreement provides that member states can exclude from patentability plants and animals but not micro-organisms and “essentially biological processes for the production of plants”. Under the same provision, member states can effectively protect new plant varieties either by patents or a sui generis system or by any combination thereof. In response thereof, in 2014, the Ugandan Parliament

⁶¹ Carey Gillam, *Special Report: Food – Is Monsanto the answer or the problem*, <https://reliefweb.int/report/uganda/special-report-food-monsanto-answer-or-problem> (accessed June 29, 2018)

⁶² Op cit.

⁶³ Jay Kesan, *GMOs: Policy, Law & Regulation* (presentation), citing: Om V. Singh et al., *Genetically Modified Crops: Success,*

Safety Assessment, and Public Concern, 71 *Appl. Microbiology & Biotechnology* 598-607 (Apr. 2006).

⁶⁴ Ibid supra fn 14

⁶⁵ The other countries are inclusive of Egypt, Kenya, South Africa, Morocco, Nigeria, Tunisia and Cameroon. See: Jay Kesan, *Agricultural Biotechnology and Intellectual Property: Seeds of Change*, fn 16 supra at p. xx.

⁶⁶ Ibid

enacted the Plant Variety Protection Act as a sui generis legislation providing for the promotion of development of new plant varieties and their protection.

The long title to the National Biotechnology and Biosafety Bill, on the other hand, does not mention the word “protection” at all. The focus of this Bill, as reiterated, is more towards facilitating safe development and application of modern biotechnology. It can be claimed therefore that following the guidance of Article 27.3(b) of the TRIPS Agreement, Ugandan legislation gives plant breeders and biochemists the option to either apply for protection of their agro-biotechnology under the Plant Variety Protection Act or for the grant of a Patent under the Industrial Property Act.⁶⁷ The latter legislation provides for the protection of Patents, Utility models and Industrial Designs in Uganda. Section 13 of the Industry Property Act excludes Plant Varieties from Patent protection, however, one should also take note of the stipulation in 27.3(b) of TRIPS providing for “. . . the protection of plant varieties either by patents or by an effective sui generis system **or by any combination thereof**” (emphasis mine). This can also be read in line with the 1980 US Supreme Court decision in **Diamond v Chakrabarty**⁶⁸ in which it was decided that biological organisms, traits and genes may be eligible subject matter for utility patent protection. The authorities therefore back the claim in this article to the effect that biotechnology in Uganda can be protected either as Plant Varieties or as Patents.

b) The Convention on Biological Diversity and its Protocols

Uganda is a party to the 1992 Convention on Biological Diversity (CBD). The Convention provides for conservation and sustainable use of biological diversity and involvement of local communities in the sharing of benefits arising from their utilization. Of particular significance is the **Cartagena Protocol on Biosafety of the Convention**. This Biosafety Protocol concerns protection of biological diversity from the likelihood of risks posed by living modified organisms resulting from modern biotechnology. Article 2.1 of the Cartagena Protocol requires member states to “take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.”⁶⁹ The Protocol entered into force in Uganda on September 11, 2003.⁷⁰

The Ugandan proposed legislation adheres to its obligations under the Protocol by designating the Uganda National Council for Science and Technology (UNCST) as the competent authority with powers to oversee the development and use of biotechnology including approving research, development and use of GMOs; ensuring safety of biotechnology to human health and the environment during development, testing and usage; promoting awareness of biotechnology and biosafety activities and research.⁷¹

Another significant instrument under the CBD is the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization. This Protocol aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable manner. Uganda

⁶⁷ Act. No. 3 of 2014.

⁶⁸ *Diamond, Commissioner of Patents and Trademarks v Chakrabarty* (U.S 1980) 447 U.S. 303 (more) 100 S. Ct. 2204; 65 L. Ed. 2d 144

⁶⁹ See: Cartagena Protocol on Biosafety to the Convention on Biological Diversity, <https://bch.cbd.int/protocol/> (Accessed July 2, 2018)

⁷⁰ Op cit.

⁷¹ Clause 7 of the National Biotechnology and Biosafety Bill, No. 18 of 2012

ratified it on 25th June 2014 and it entered into force on 12 October 2014.⁷²

Although, as discussed above, the Ugandan Bill is skewed towards effective research and development of biotechnology, it is inevitable that the outcome of this research can be subjected to IP protection either as Patents or as Plant Varieties. The concern, therefore is that protective restrictions emanating from usage of GMOs such as the saving, sharing and multiplication of seeds, are likely to conflict with the traditional farming mechanisms of local farming communities which are communal in nature. A related concern is the cost for IP protection of agro products which is considered out of reach for most local Ugandan farmers. As such, implementation of the Bill needs to take into account such concerns, especially considering that Uganda, as a signatory to the Nagoya Protocol, is expected to fulfill its obligations relating to access, fair and equitable sharing of benefits in GMOs.

6. CONCLUSION:

The National Biotechnology and Biosafety Bill is ultimately about food safety. It addresses the fact that in the current trend of the global economy coupled with market demands, communities need alternatives to tackle rising challenges in Agricultural production and, as such, the use of biotechnology is a solution that cannot be avoided. The regulation is thus meant to dispel all negativity surrounding GMOs by focusing on effective research and guaranteed food security. Although just like any other legislation, it is not perfect in its stipulations, especially with regard to public participation and awareness-building, there is nothing evil about defending GMOs through regulation. It is, as such, a necessary legislation to have in the strengthening of the country's Agro-based economy.

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⁷² See: Nagoya Protocol on Access and Benefit-sharing, <https://www.cbd.int/abs/> (accessed July 2, 2018)

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IP AND ACCESS TO MEDICAL DEVICES IN NIGERIA: CHALLENGES AND THE LEGAL PERSPECTIVE

Temitope O. Oloko*

ABSTRACT

While access to essential medicines is a major problem for public health in Nigeria, the country confronts other significant health care problems stemming from access to other areas of medical technology, which have received less attention in the scholarly literature. Medical devices play an essential role in health care, from screening to diagnosis and treatment. Outdated medical devices and insufficient medical equipment and supplies, and lack of access to high-quality, safe and appropriate priority medical devices greatly impair health services. Addressing these shortcomings will likely require a tailored and focused approach to developing a technology transfer strategy including appropriate measures within the intellectual property system as shaped by the WTO TRIPS Agreement. As a potential contribution to future work on developing such an approach to leveraging access to these vital technologies, this article reviews the legal and policy background, and then provides a case study of priority medical devices related to the diagnosis and treatment of cancer in 13 hospitals in Lagos with consideration of availability, affordability, accessibility, appropriateness, quality and age.

Keywords: Access to Medical Devices, Public Health, Technology transfer

1. INTRODUCTION

Generally, intellectual property (IP) denotes a class of legal regimes with distinct degrees of rights of ownership

over different forms of intangible subject matter.¹ In principle, intellectual activity in the field of industry, science or art attracts legal protection.² The common categories of rights included within the general term 'intellectual property' are patents, trademarks, copyright, trade names, and indications of origin.³ Patents today are associated with economic, health, cultural and social conditions prevailing in a country. There is no doubt that patents have assisted in national development and have created benefits for humanity. Inventions have played an important part in human development and have contributed to social and economic welfare. However, patent protection in relation to public health has been extensively debated over the last 20 years due to assertions that patents constitute a barrier to access to medicines in developing countries.⁴

Public health concerns have led to the only multilateral reconsideration made so far to the World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property Rights⁵. The Doha Declaration on Public Health⁶ addressed important points of principle at the highest political level, and led to the only amendment so far applied to the TRIPS Agreement, in the form of a Special Compulsory Licensing System to give vulnerable countries a new avenue for access to medicines.⁷ Even though there is a provision for regular review of the TRIPS Agreement,⁸ and an annual review of the Special Compulsory Licensing System, developing countries and non-governmental organisations assert that the TRIPS Agreement and in particular its patent provisions, represent a barrier to effective access to medicines.⁹ The

* Masters in Law (University of Lagos), Master in Law in Intellectual Property and Commerce and Technology (Franklin Pierce Law Center Concord, New Hampshire USA), Doctor of Law – LL.D (University of Pretoria South Africa). Currently lectures as Senior Lecturer in the faculty of law Lagos State University in Intellectual Property, Law of Trust and Contracts

¹Peter Drahos, 'The Universality of Intellectual Property Rights: Origins and Development' p. 1 www.wipo.int/edocs/mdocs/tk/en/.../wipo_unhchr_ip_pnl_98_1.doc accessed 02 February 2018; see also Paul Craig and Grainne de Burca, *EU Law Text, Cases and Materials* Oxford University Press 5th ed 2011 p. 5.

² Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to p. 21- 28 www.unsgaccessmeds.org/final-report/ accessed 02 February 2018.

³Craig and Grainne de Burca p. 5; A striking feature of intellectual property is that, despite its early historical links to the idea of monopoly and privilege, the scope of its subject matter continues to expand. See also Drahos p. 1; Intellectual property rights are also among the most controversial forms of trade and business regulation in the global economy. See Keith E. Markus *Introduction. The*

WTO, Intellectual Property Rights and the Knowledge Economy, in Keith Markus (ed) *Critical Perspective on the Global Trading System and the WTO* Elgar Cheltenham 2004 p. 34.

⁴ Sampat B N Academic Patents and Access to Medicines in Developing Countries. (2009) *American Journal of Public Health*, 99, 9-17.

⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organisation (WTO Agreement) Annex 1C ('TRIPS Agreement')

⁶ The 4th WTO Ministerial meeting at Doha, Qatar adopted, on the 14 November 2001, a Declaration on the TRIPS Agreement and Public Health ('Doha Declaration').

⁷ See Article 31bis of the Revised TRIPS Agreement

⁸ See Article 71 TRIPS Agreement.

⁹ Frederick M. Abbott, 'The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference' (October 2001). *FSU College of Law, Public Law Working Paper No. 36 and QUNO Occasional Paper No. 7* available at SSRN: <http://ssrn.com/abstract=285934> or <http://dx.doi.org/10.2139/ssrn.285934> accessed 05 February 2018; see also Zita Lazzarini, 'Making Access to Pharmaceuticals a Reality: Legal Options under TRIPS and the

Doha Declaration was conceived mainly as a result of apprehensions about the likely impact of the TRIPS Agreement on access to medicines.¹⁰

Yet access to essential medicines is not the only problem faced in relation to public health. Over the years the issue of access to medicines has continued to dominate the discussion in relation to public health care and despite this, the needs of the poorest countries are still not met.¹¹ This has led to the examination of other areas such as access to medical devices. The current debate is on affordable health care which include access to medicines, medical care and medical devices. The lack of access to high-quality, safe, and appropriate, priority medical devices¹² which have an essential role to play, from screening to diagnosis and treatment,¹³ may lead to an effective deprivation or deterioration of health services.

Accordingly, the World Health Assembly passed its first resolution on Health Technologies¹⁴ in May 2007.¹⁵ The resolution was based on a project called Priority Medical Devices (PMD) which was launched by the WHO at the request of the Government of the Netherlands through the Ministry of Health, Welfare and Sports to identify inequalities in the available preventive, diagnostic, therapeutic and assistive medical devices in the market by determining whether the needs of health care providers and end-users throughout the world are being met and if not, to propose remedies to resolve the inadequacies or shortcomings.¹⁶

Case of Brazil' 6 *Yale Human Rights & Development Law Journal* 2003 pp 103-138.

¹⁰The Doha Declaration explained available at http://www.wto.org/english/tratop_e/dda_e/dohaexplaine_d_e.htm#trips accessed 07 February 2018.

¹¹ Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to p. 21- 28 www.unsaccessmeds.org/final-report/ accessed 02 February 2018

¹²Medical device is defined as "An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means."

¹³WHO, Medical Devices, Priority medical devices available at http://www.who.int/medical_devices/access/en/ accessed 12 March 2018.

¹⁴This term refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life. It is used interchangeably with 'health care technology'. Resolution WHA60.29. Health Technologies. In: Sixtieth World Health Assembly. Geneva, 23 May 2007. Available at http://www.who.int/medical_devices/resolution_wha60_29

2. RESEARCH PROBLEM

The health care sector challenge is enormous and not limited to the lack of access to medical devices. The medical system in Nigeria is largely underdeveloped and lacks modern healthcare devices, infrastructure and facilities. With the population of Nigeria growing astronomically and currently put at 180 million, it is glaring that access to required medical devices is in short fall and practically supplied by imports while new innovations in medical devices are largely unavailable.¹⁷ This has led to lack of proper diagnosis, treatment and preventive intervention culminating in countless deaths and a surge in medical tourism which costs Nigeria over \$1bn annually.¹⁸ The fact that there are negligible innovations in the country also creates a gap in easy access to medical devices and this was aptly captured in the recent Global Innovation Index which ranked Nigeria ranked 119 out of 127 countries worldwide.¹⁹ This in essence reveals that there is no capacity to develop medical devices or to maintain and repair biomedical devices in the country.²⁰

Available statistics show that cancer is the second leading cause of death globally, killing 8.8 million persons in 2015 worldwide, meaning nearly 1 in 6 deaths is caused by cancer. In Nigeria, 100,000 cases of cancer are diagnosed every year and about 80,000 people die yearly as a result of the same, meaning 4 in every 5 people die of cancer. This seems outrageous but is not farfetched as Nigeria currently has only 9 Radiotherapy Centers. The

[-en1.pdf](#) accessed 12 March 2018. See also WHO, Local Production and Technology Transfer to Increase Access to Medical Devices Addressing the barriers and challenges in low- and middle-income countries 2012 available at http://www.who.int/medical_devices/1240EHT_final.pdf accessed 16 March 2018.

¹⁵WHO Sixtieth World Health Assembly Health Technologies WHA60.29 available at http://www.who.int/medical_devices/resolution_wha60_29_en1.pdf accessed 12 March 2018.

¹⁶WHO. Medical Devices, Priority medical devices.

¹⁷2016 ITA Top Markets Report Medical Devices Country Case Study https://www.trade.gov/topmarkets/pdf/Medical_Devices_Nigeria.pdf accessed 02 February 2018.

¹⁸Omatseye C. Nigeria loses \$1bn annually to medical tourism Vanguard 23 August 2017 <https://www.vanguardngr.com/2017/08/nigeria-loses-1bn-annually-medical-tourism-omatseye/> accessed 02 March 2018.

¹⁹Global Innovation Index 2017 https://www.globalinnovationindex.org/UploadedFiles/Indepths/Files/Indepths_9db22f7962064f1282db29c9aec30365.PDF accessed 05 March 2018.

²⁰Towards improving access to medical devices through local production Phase II Report of a case study in four sub-Saharan countries

available of devices is way below the WHO requirement of 1 radiotherapy machine per 1 million population²¹ and grossly inadequate for a population of 180 million.

DEFINITION OF TERMS

Public Health: public or privately organised measures used to prevent disease, promote health, and prolong life among people generally with the aim of offering people healthy living conditions as well as the eradication of disease.²²

Harmonized definition of “medical device”: any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical or diagnostic purposes by means of *in vitro*
- examination of specimens derived from the human body;

and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.²³

Medical Device: any instrument, apparatus or contrivance (including components, parts and accessories thereof) manufactured, sold or advertised for internal or external use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or in animal²⁴

Access to Medical Devices: defined in terms of the various factors that determine the extent of a patient’s access to medical devices and services. These factors include the availability, affordability, accessibility, appropriateness, acceptability and quality of the medical device.

Medical Products covers pharmaceuticals, vaccines and diagnostics but does not include medical devices and other health services.

The following are six crucial components to improve access to medical devices²⁵

Availability: when a medical device can be found on the medical device market; it may also mean whether medical devices are physically available at health care facilities and are usable by medical providers to treat patients.

Affordability: the extent to which the intended clients of a health service or product can pay for its utilization.

Accessibility: people’s ability to obtain the technology and use it appropriately when needed; it may also refer to whether households or individuals are geographically able to reach health care facilities that offer necessary medical devices for a specific health condition.

Appropriateness: medical methods, procedures, techniques and equipment that are scientifically valid, adapted to local needs, acceptable to both patients and health care personnel, and that can be utilized with resources the community or country can afford; appropriateness should include the consideration of available infrastructure and human and financial requirements.

Acceptability: households’ or individuals’ attitudes and expectations towards the use of medical devices, specifically whether those devices are socially and culturally appropriate to meet local demands.

²¹ Adeyanju Adekunle Joseph. Radiotherapy Technical Challenges In Nigeria, LUTH.

²² WHO, Public health, available at

<http://www.who.int/trade/glossary/story076/en/#> accessed 16 March 2013.

²³ Global Harmonization Task Force, Information Document Concerning the Definition of the Term “Medical Device” GHTF/SG1/N29R16:2005

www.imdrf.org/.../ghtf/.../sg1/.../ghtf-sg1-n29r16-2005-definition-medical-device-05... accessed 02 April 2018

²⁴ Section 13 Food, Drugs and Related Products Act 1993 Cap F33 LFN 2004.

²⁵ Local Production and Technology Transfer to Increase Access to Medical Devices Addressing the barriers and challenges in low- and middle-income countries 2012 http://www.who.int/medical_devices/1240EHT_final.pdf 17 April 2018;

Quality: whether the medical devices found in health care facilities and used by medical providers meet regulatory standards for effective and safe use.

Age: how long the device has been in use in the facility.

LITERATURE REVIEW

Innovation and research and development are fundamental to strategic and sustainable growth. Innovation cuts across the boundaries of various subjects and disciplines and is essential for the development of knowledge and technology. Scientific innovation and commercial innovation create competitive advantage that is vital for economic development.²⁶

Almost 25 years into the TRIPS Agreement regime, questions are still being raised in relation to innovation and R&D with reference to the effects of patents. Do patent rights impede innovation and research, or does patenting encourage research and development? Patent rights are given as a result of R&D carried out in a particular field that results in an innovation. Without R&D, there can be no innovation that leads to an invention and, thus, there would be no patent right. Whether the knowledge of the grant of a patent inspires R&D or if the target of R&D and the entire patent system is based on mere economics has been subject to significant debate. Patent protection and economic incentives play a role in innovation²⁷ although the statement is supported by little empirical evidence.²⁸

Torrance and Tomlinson, using a multi-user interactive simulation of patent and non-patent systems (PatentSim) compare the rates of innovation, productivity and societal utility. The study showed that patent protection did not spur innovation.²⁹ On the other hand, Moser, using nineteenth-century exhibition data to determine the effects of patent laws on innovation, resolved that weak patent laws encourage innovation where effective

alternative methods of protection exist and concludes that patent laws chart the course of innovative production.³⁰

In terms of the level of patent protection in Nigeria, there may be a correlation with the study that claims that patents do not stimulate innovation and R&D.³¹ Since 1970, the Nigeria Patent and Designs Act (PDA) has provided a term of protection for 20 years and allows products and process patents with little examination yet, there are not many registered patents, both locally and by foreign applicants.³² Therefore, stronger patent protection alone does not stimulate innovation and R&D, other variables still need to be taken into consideration.

Strong patent protection may not necessarily lead to increased innovation and R&D. Thus, according to Boschiero, in practice the exclusive right in patents operates as a commercial tool coupled with the erosion of the balance of the public interest and patent holder's right, with the society shifting towards possessive mechanism for proprietary benefit as opposed to the general good.³³ The exercise of maximum patent right, however, may create a strangle-hold on people's lives as a result of their inability to acquire the necessary knowledge to use such technologies or products. Especially, in relation to innovations in the treatment of diseases that require medical devices that are necessary for preventive, diagnostic, therapeutic and assistive treatment. If these devices are beyond the reach of people who need them, then innovation fails to have a positive impact on society. Innovation and health care go hand in hand, the improvement of health care is mainly dependent on advancement in technology. Diaconu *et al.* while examining the procurement process of medical devices in low and middle incomes countries, notes that the lack of basic medical devices seriously compromises the provision

²⁶ Sadi Koray Demircan. The Role of R&D and Innovation in Us Economy as a Benchmark for Turkish Economy the Eli Broad College of Business Michigan State University available at http://www.ekonomi.gov.tr/upload/bf09ae98-d8d3-8566-520b0d124e5614d/koray_demircan.pdf accessed 23 April 2018.

²⁷ Petra Moser, How Do Patent Laws Influence Innovation? Evidence from Nineteenth-Century World Fairs Working Paper 9909 National Bureau of Economic Research <http://www.nber.org/papers/w9909>; Organisation for Economic Co-Operation and Development (OECD) Patents and Innovation: Trends and Policy Challenges p.1 available at <http://www.oecd.org/science/sci-tech/24508541.pdf> accessed 21 May 2018.

²⁸ Andrew W. Torrance & Bill Tomlinson, Patents and the Regress of Useful Arts, Colum. Sci. & Tech. L. Rev. 10 (2009) 130-168 p.130.

²⁹ Andrew W. Torrance & Bill Tomlinson, Patents and the Regress of Useful Arts, 10 Colum. Sci. & Tech. L. Rev. 4 (2009) 130-168 p.131.

³⁰ Petra Moser, 'How Do Patent Laws Influence Innovation? Evidence from Nineteenth-Century World Fairs' National Bureau of Economic Research Working Paper No. 9909 2003 available at <http://www.nber.org/papers/w9909> accessed 21 May 2018.

³¹ Andrew W. Torrance & Bill Tomlinson, 'Patents and the Regress of Useful Arts', (2009) Columbia Science and Technology Law Review 10 130-168 p.130.

³² Get statistic on current patent application.

³³ Nerina Boschiero Intellectual property rights and public health: an impediment to access to medicines and health technology innovation? https://www.statoeche.it/images/uploads/articoli_pdf/Boschiero.2_Intellectual.pdf accessed 09 April 2018.

of health care services.³⁴ Not only is there a dearth of medical devices; access to new innovations is not available and this was evident in the visits to various hospitals.

It is against this broad background that the present paper analyses the specific situation confronting Nigeria's serious, systemic access issues. A survey of the availability of certain key technologies in Nigeria may contribute an empirical foundation for further work on shaping and implementing appropriate policy initiatives to address these challenges, including considering specific measures for local innovation, technology transfer and the application of IP measures towards these ends.

NATIONAL REGULATIONS ON MEDICAL DEVICES

The Federal Ministry of Health (FMOH) is the supervising ministry for all Federal health institutions and it is responsible for all health-related policy formulation. The National Agency for Food and Drug Administration and Control (NAFDAC) is an agency under the FMOH which regulates food, drugs and related products which include medical devices in Nigeria.³⁵ NAFDAC operates through the legislation which prohibits manufacturing, importing, exporting, advertising, selling or distribution of medical devices in Nigeria without registration in accordance with the provisions of the Act or Regulations.³⁶

For registration, a medical device must meet the prescribed standards for quality, safety and efficacy. Registration may be cancelled if the medical device is unsuitable for what it is intended.³⁷ In addition, the agency provides registration guidelines for imported medical devices.³⁸ Other regulatory agencies, such as the Standard Organisation of Nigeria (SON), Bureau of Public Procurement (BPP) and Nigeria Nuclear Regulatory

Authority (NNRA), may also be involved in ensuring conformity with expected quality and safety standards.

Following their registration, access to medical devices is an important component of the right to health. Although the Nigerian Constitution does not expressly provide for the right to health care, it is presumed that under section 17(3) (d)³⁹ claim can be laid to such right. The right to health - like all human rights - is indivisible, universal, interdependent and interrelated. Mark and Bendent are of the view that access to medicines and devices finds a foothold in the right to health and they further state that it can be affirmed as human rights based on the right to health set out in the International Covenant on Economic Social and Cultural Rights.⁴⁰

Registration of medical devices under this regulation is a prerequisite for their intended use in Nigeria, but it does not in itself ensure or improve access to medical devices that are important for public health needs. There is still a need for policy analysis, technical assistance and capacity-building at the national level focussed on leveraging improved actual access to these technologies.

TECHNOLOGY TRANSFER

The developed countries were offered technology transfer as an incentive during the negotiation of the TRIPS Agreement⁴¹ in maintaining the protection of IP rights in developing and least-developed countries (LDCs).⁴² The expectation of developing countries was that stronger IP protection would encourage technology transfer, but this perception has shifted dramatically.⁴³

According to the United Nations Conference on Trade and Development (UNCTAD): 'technology transfer is the process by which commercial technology is disseminated'.⁴⁴ Access to the right technology is vital to

³⁴ Karin Diaconu, Yen-Fu Chen, Semira Manaseki-Holland, Carole Cummins and Richard Lilford, 'Medical Device Procurement In Low- And Middle-Income Settings: Protocol For A Systematic Review', *Systematicreviewsjournal.Biomedcentral.Com/Articles/10.1186/2046-4053-3-118* Accessed 09 April 2018.

³⁵ Section 1 Food, Drugs and Related Products Cap F33 LFN 2004.

³⁶ Ibid.

³⁷ Ibid.

³⁸ NAFDAC/RR/007/00 <http://www.nafdac.gov.ng/index.php/guidelines/medical-devices-guidelines> accessed 19 April 2018.

³⁹ Chapter II 1999 Constitution of the Federal Republic of Nigeria.

⁴⁰ Stephen P Marks and Adrianna L Benedict Access to Medical Products, Vaccines and Medical Technologies in Jose M Zuniga, Stephen P Marks and Lawrence O Gostin (ed) *Advancing Human Right to Health*, Oxford University Press, 2013, pp. 305-324.

⁴¹ Tú Thanh Nguyễn Competition Law, Technology Transfer and the TRIPS Agreement: Implications for Developing Countries Edward Elgar Cheltenham 2010 p. 29-30; see also Poku Adusei 'Regulatory Diversity as Key to the 'Myth' of Drug Patenting in sub-Saharan Africa' (2010) 54 *Journal of African Law* 26-27.

⁴² WTO Technology transfer http://www.wto.org/english/tratop_e/trips_e/techtransfer_e.htm accessed 19 April 2018.

⁴³ Tana Pistorius 'The Impact of Intellectual Property Law and Policy on Sustainable Development' 32 (2007), *South African Yearbook of International Law* 376-395 p.381; See also Du Plessis 'Perspectives from a 33 developing country' Extraordinary Session I: IP and the global economy AIPPI Lisbon (Exco Meeting) (17 21 June 2002): http://www.aippi.org/reports/Vortrag_DuPlessis.pdf accessed 19 April 2018.

⁴⁴ United Nations Conference on Trade and Development (UNCTAD) Series on issues in international investment agreements UNCTAD/ITE/IIT/28

the growth of any nation. Correa has noted that the North-South technological gap is widening and there has been no increase in technology transfer to the developing countries. Instead he observes, big companies are forming 'strategic alliances'⁴⁵ which increase their dominance in the generation and use of technology⁴⁶ whereas developing countries are still struggling to obtain technology transfer that enhances economic development. It has been observed that technology transfer is a major global economy challenge⁴⁷ and economic advancement will be realised only if ideas, experience and practice are borrowed from more advanced countries.⁴⁸

Unlike the specific steps taken in relation to public health, which arose as a result of protest that the TRIPS Agreement impeded access to essential medicines, an expectation of transfer of technology was in the TRIPS Agreement from its entry into force.⁴⁹ The promotion of technology transfer is said to be an important objective of the TRIPS Agreement; however, it acts only as a platform and does not actually transfer technology from developed to developing countries.⁵⁰ That said, Article 66.2 of the TRIPS Agreement does require developed country WTO Members to "provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base".⁵¹

Technology transfer is vital for developing a strong technological base necessary for economic growth. Access

to technology transfer has been underscored as an approach of achieving indigenous inventiveness.⁵² For this reason, NOTAP is significant, as it renders services which include preparation of technology transfer agreements, IP right promotion and provision of state of the art technological information, commercialisation of R&D results, research-industry linkage, monitoring, consultancy and extension services and technology advisory services.⁵³ Technology transfer will be one of the ways to ensure access to medical devices needed for diagnosis and treatment as this would assist patients to enjoy better health care provision. This article therefore reviews the current situation in Nigeria, and in particular considers critical unmet needs, as a potential contribution to further consideration of suitable technology transfer strategies tailored to this field.

METHODOLOGY

This study employed both a situation analysis based on a literature review of available relevant research, survey, data, statistical analyses as well as a questionnaire-based survey research strategy and it is purely descriptive in nature. Current information relating to healthcare in Nigeria is extracted from various analysis done by the WHO and by other scholars. Data on access to medical devices in 12 tertiary hospitals in Lagos⁵⁴ was used as a pilot to collect through questionnaire developed for that purpose. The questionnaire is based on the WHO list of PMD for cancer management⁵⁵ which was collated as part of a medical device technical series. This study gives an overview of access to priority medical devices ranging

<http://unctad.org/en/Docs/psiteiid28.en.pdf> accessed 19 April 2018.

⁴⁵ For example, Ranbaxy Laboratories (a leading Indian pharmaceutical company) and Bayer AG, (a German pharmaceutical company) for the development of a new generation of antibiotics called ciprofloxacin. See also UNCTAD/UNDP, Transfer of Technology for Successful Integration into the Global Economy UNCTAD/ITE/IPC/2003/6 p.18 available at http://unctad.org/en/Docs/iteipc20036_en.pdf accessed 20 October 2013.

⁴⁶ Carlos M. Correa Review of the TRIPS Agreement: Fostering the Transfer of Technology to Developing Countries, TWN Trade & Development Series 13 p.21- 22; The Journal of World Intellectual Property (Vol. 2, No. 6), <http://www.twinside.org.sg/title2/t&d/tnd13.pdf> accessed 19 April 2018.

⁴⁷ David B. Audretsch, Erik E. Lehmann, Albert N. Link, Alexander Starnecker (eds) (introduction) Technology Transfer in a Global Economy Springer Group 2012 p. 2.

⁴⁸ UNCTAD/UNDP, Transfer of Technology for Successful Integration into the Global Economy UNCTAD/ITE/IPC/2003/6 p.6 http://unctad.org/en/Docs/iteipc20036_en.pdf accessed 24 April 2018.

⁴⁹ Article 7 TRIPS Agreement.

⁵⁰ Tú Thanh Nguyễn Competition Law, Technology Transfer and the TRIPS Agreement: Implications for Developing Countries Edward Elgar Cheltenham 2010 p. 29-30.

⁵¹ Implementation of this provision is surveyed in Watal, Jayashree; Caminero, Leticia (2017), Least-developed countries, transfer of technology and the TRIPS Agreement, WTO Staff Working Paper, No. ERSD-2018-01, World Trade Organization (WTO), Geneva, <http://dx.doi.org/10.30875/412bee53-en>

⁵² Adejoke Oyewunmi, The Patent System and Transfer of Technology in Nigeria Olanrewaju Fagbaohun and Bambo Adewopo (ed.). *Developments and Reform, Nigeria's Commercial Law s Essays in honour of Chief Dr Chris Ogunbanjo* The Law Center LASU Lagos, 1998, 78-92 p.79.

⁵³ NOTAP website <http://notap.gov.ng/content/technology-transfers> accessed 09 September 2013.

⁵⁴ This is because Lagos is cosmopolitan and people from every state in Nigeria empty themselves there.

⁵⁵ WHO list of Priority Medical Devices for cancer management

www.who.int/medical_devices/publications/priority_med...cancer_management/en/ accessed 15 April 2018.

from consumables to routine medical equipment and devices which are typically considered essential for the prevention, diagnosis and treatment of cancer. The questionnaire was structured and defined in the format of close-ended questions or statements represented with medical devices or apparatuses.

The article gives a summary of the regulation that is of significance to MD. The study draws together materials regarded as priority medical devices in cancer management. To determine each question, under each construct there is a set of six kinds of measurement scales, viz. availability, affordability, accessibility, appropriateness, quality and age of the device with different response categories to verify access to MD. The response categories with their respective codes of each of the measurement scales are given as follows:

Availability: 1: yes; 2: no

Affordability: 1: not at all; 2: low extent; 3: some extent

Accessibility: 1: not at all; 2: low extent; 3: some extent

Appropriate: 1: 0–25% (low); 2: 26–50% (medium); 3: 51–75%; (high); 4: 76–100% (optimal).

Quality of MD: 1: low; 2: medium; 3: high

Age: 1: < 1 year; 2: 1–5 years; 3: 6–10 years

Out of thirteen questionnaires administered to the selected medical centres in Lagos State (South-West of Nigeria), twelve were filled and returned while one was returned but not filled. This was the questionnaire sent to Badagry general hospital. Thus, it was excluded from this analysis. Since the nature of the study is descriptive, frequency tables were prepared showing the numbers and percentages of responses.

DESCRIPTIVE ANALYSIS

The frequency distribution of each kind of device with respect to its availability, affordability, accessibility, appropriateness, quality and age is discussed below, with reference to the tables of data provided at the end of this article.

CANCER MEDICAL DEVICES

Table 1 presents the descriptive frequency distribution of responses on the items for *General Medical devices for Clinical Assessment and Minor Procedures*. Of the twelve medical centres surveyed, item 1 (Aneroid sphygmomanometer Stethoscope) is available in 11 (92%) centres and 1 centre (8%) lacks it. 5 (42%) respondents indicated that the item is affordable to low extent while 6 respondents indicated that it is affordable to a large extent. Accessibility is low in 7 (58%) centres and

substantial in 4 (33%). Its appropriateness is considered moderate, high and optimal in 5 (42%) centres, 5 (42%) centres and 1 centre respectively. Its quality is low in 6 (50%) centres and high in 4 (33%). The age of the device in 1 (8%) is less than 1 year, while in 1 centre (8%) and 8 (67%) centres, its age falls within the ranges 1–5 years and 6–10 years respectively.

Item 1 (Thermometer) is available in 11 (92%) of the surveyed centres and not in the remaining one. It is not affordable in 1 centre, affordable in 3 (25%) centres to a low extent while it is affordable to large extent in 7 (58%) centres. Accessibility in 6 (50%) centres is low while in 5 (42%) centres accessibility is substantial. The appropriateness of the device is moderate in 4 (33%) centres, high in 5 (42%) centres and optimal in 2 (17%) centres. The device is of low, medium and high quality in 4 (33%) centres, 1 centre (8%) and 5 (42%) centres respectively. The device is less than 1 year old in 1 (8%) between 1–5 years and 6–10 years in 1 centre (8%) and 8 (67%) respectively.

Examination table resuscitation trolley

Examination table resuscitation trolley equipped, with medicines and defibrillator fixed examination/treatment light is available in 11 (92%) of the centres surveyed and is not available in 1. The device is not affordable in 1 centre, affordable in 4 (33%) to a low extent and to large extent in 6 (50%) centres. Accessibility is low in 8 (67%) centres, and substantial in 3 (25%). Appropriateness is moderate in 4 (33%) centres, high in 5 (42%) centres and optimal in 2 (17%). In 6 (50%) centres, 1 centre (8%) and 3 (25%) centres, the devices are of low, medium and high quality respectively. The age of the device in 2 (17%) centres is less than 1 year and between 1–5 years in 8 (67%).

Pulse oximeter

A pulse oximeter is available in 9 (75%) of the centres surveyed. It is affordable in 3 (25%) centres to a low extent and affordable to large extent in 7 (58%) centres. The accessibility is low in 6 (50%) centres and substantial in 4 (33%). Appropriateness of the device is moderate in 3 (25%) centres, high in 5 (42%) and optimal in 2 (17%). In 4 (33%) centres, 3 (25%) centres and 2 (17%) centres, the device is of low, medium and high quality respectively. The device less than 1 year old in 1 centre, and between 1–5 and 6–10 years in 2 (17%) and 6 (50%) centres respectively.

Electrocardiography system

An electrocardiography system is available in 10 (83%) centres while it is not available in 2 (17%) centres. The device is affordable in 4 (33%) centres to a low extent while it is affordable to large extent in 6 (50%) centres. The level of accessibility in 7 (58%) centres is low, while in 3

(25%) centres there is a substantial (to some extent) level of accessibility. The appropriateness of the device in 4 (33%) centres, 3 (25%) centres and 3 (25%) centres falls within the ranges 26% – 50%, 51% – 75% and 76% – 100% respectively. In 5 (42%) centres, 2 (25%) centres and 2 (17%) centres, the device are of low, medium and high quality respectively. The ages of the device in 2 (17%) centres and 7 (58%) centres, the ages of the device are within the ranges 1–5 years and 6–10 years respectively.

Colposcopy

Table 2 presents the descriptive frequency distribution of the respondents' responses to the item for *Colposcopy*. This item is available in 2 (17%) of the 12 surveyed centres while 10 (83%) centres do not possess such item. 17% of respondents indicated that the affordability of the item is low in their centres while others could not respond to this measure. Only two respondents indicated the level of accessibility: in one there is a low level of accessibility while in the other there is a substantial level. The appropriateness of the device in 2 (17%) centres falls within 76% – 100%. Only two respondents indicated the quality and age of the device. In each case, the devices are of low and high quality respectively while the age of the device are within the range 1–5 years and 6–10 years respectively.

Cryotherapy

Table 3 presents the descriptive frequency distribution of the respondents' responses to the item for *Cryotherapy*. Of the twelve medical centres surveyed, item 1 (Cryosurgery unit) is available in 2 (17%) centres while 10 (83.3%) centre do not possess it. Two respondents indicated that affordability is low in their centres while others could not respond. Only 2 respondents indicated the level of accessibility, which is low both cases. The appropriateness of the device in 2 centres falls within 76% – 100%. Only two respondents indicated the quality and age of the device: in both cases, the devices are of high quality and the device falls within the range 6–10 years.

Endocervical curettage

Table 4 presents the descriptive frequency distribution of the respondents' responses to the items for *Endocervical curettage ECC*. Of the twelve medical centres surveyed, items 1 and 2 (Cryosurgery unit and Endocervical curettage) are available in 11 (92%) and 2 (17%) centres respectively while the remainder lack this item. Both items are affordable to a low extent while only item 2 (Endocervical curettage) is affordable to a large extent in just one centre. Both items are accessible to some extent in 1 centre (8%) and in 2 (17%) centres respectively. The device is optimally and highly appropriate in 1 and 2 centres respectively. They are of high quality in just 1

centre, each while endocervical curettage (item 2) has a medium quality in 1 centre. The age of each of the devices falls within 1–5 years in only 1 centre while the age of Endocervical curettage (item 2) falls within the range of 6–10 years in just one centre.

Electrocautery system electrode for LEEP

Table 5 presents the descriptive frequency distribution of the respondents' responses to the item (Electrocautery system electrode for LEEP) for *Large loop excision of transformation zone (LEEP/LLETZ) - Electrosurgical unit*. Of the twelve medical centres surveyed, item 1 (Electrocautery system electrode for LEEP) is available in 2 (17%) centres while 10 (83.3%) centres lack this item. Two respondents reported low affordability in their centres while others could not respond. Two respondents indicated that accessibility was low. Appropriateness was high in 1 centre and optimal in one other centre. The devices are of low and high quality in two centres while device is newer than 1 year in one centre and between 1–5 years in another.

Papanicolaou Test

Table 6 presents the descriptive frequency distribution of the respondents' responses to the item (Vaginal speculum, reusable) for Papanicolaou Test. The table depicts that out of the twelve medical centres surveyed, item 1 (Vaginal speculum, reusable) is available in 11 (92%) centres while 1 centre lacks this item. 6 (50%) respondents indicated that the item is affordable to a low extent while 3 (25%) respondents indicated that it is affordable to large extent. Accessibility is low in 7 (58%) centres and substantial in 2 (17%) centres. The appropriateness of the device in 6 (50%), 2 (17%) and 1 centres is medium, high and optimal respectively. The devices are of low, medium and high quality in 6, 1 and 2 centres respectively. The device is between 1–5 years in 2 centres and between 6-10 years in 7 (58%) centres.

MEDICAL IMAGING & NUCLEAR MEDICINE (IMAGING DEVICES)

Table 7 presents the frequency distribution of the respondents' responses to the items 1 to 5 for *All Cancers*. Of the centres surveyed, item 1 (Ultrasound scan preferably with capacity for colour Doppler imaging system and accessories X-ray imaging) is available in 2 (17%) centres and not the remainder (83.3%). The device is not affordable at all in 1 centre and affordable to a low extent in 1 other. It is accessible to some extent in 2 centres. It is optimally appropriate in 2 (17%) centres. The device is of medium and high quality in just 1 centre in both cases. The device's age falls within 1–5 years in 1 centre and 5 – 10 years in the other.

Item 2 (CT scan) is available in 3 (25%) centres while the device is not available in the remaining 9. It is not affordable at all in 1 centre and only affordable to a low extent in 2 centres. The device is not accessible at all in 1 centre and accessible to a low extent in 2 centres. It is highly appropriate in 1 centre and optimally in one other. The age of the device (item 2) falls within the range 5 – 10 years in 1 centre (8%).

MRI Scan

Item 4 (MRI scan: Magnetic Resonance Imaging (MRI) Scan) is available in 1 centre (8%) surveyed and not in the remaining 11. The device is affordable and accessible to a large extent in the centre where it is optimally appropriate. The device is of high quality and its age falls within the range 5 – 10 years.

Item 4 (Biopsy procedures) is available in 1 centre and not in the remaining 11. In that centre, it is affordable at a low level and only moderately accessible, despite its optimal appropriateness. The device is of high quality and its age falls within the range 5 – 10 years.

Fluoroscopic scanning

Item 5 (Fluoroscopic scanning for image guided procedures Image guided procedures to place catheter for chemotherapy) is available in 2 (17%) centres and not in the remaining 10. Its affordability is low in 1 centre and moderate in the other. The device is accessible to some extent in 2 (17%) centres. The device is optimally appropriate and one and highly in the other. Its quality is medium quality in 1 centre and high quality in the other. The device is between 1–5 years old in 1 centre and 5 – 10 years in the other.

Breast Cancer

Table 8 presents the frequency distribution of the respondents' responses to the items 1, 2, 3, 4 and 5 for *Breast Cancers*. Item 1 (Mammographic X-ray system) is available in 4 (33%) centres and not in the other 8. The item is affordable to low extent in three centres. Accessibility is low in 1 medical centre. Three report appropriateness as medium, high and optimal in their centres, where it is of low, medium and high quality respectively. The age of the device in 2 (17%) centres falls within 1–5 years while in 1 (8%) it falls within the range 6–10 years.

Mammographic stereotactic biopsy

Of the twelve medical centres surveyed, item 1 (Mammographic stereotactic biopsy system) is available in only 2 (17%) centres and is lacking in the remaining 10. It was reported as of low affordability, low accessibility, low

quality but high appropriateness and recent age in one centre.

Ultrasound scan

Ultrasound scan is available in 3 (25%) centres and not the remaining 9 (75%). The device is unaffordable in 1 centre and affordable to a low extent in 2 others. It is inaccessible in 1 centre (8%) and accessible to a low extent in 2 others. The device is highly and optimally appropriate in two separate centres, of high quality in 2 centres, and with an age in the range 6–10 years in 1 centre.

Breast Tomosynthesis

All 12 respondents indicated that item 5 (Breast Tomosynthesis) is not available in all.

Cervical Cancer

Table 4 presents the descriptive frequency distribution of the respondents' responses to the items for *Cervical Cancer*. Of the twelve medical centres surveyed, items 1 and 2 (Ultrasound scan TVUS (transvaginal ultrasound scan) and Image guided procedures to place catheter for chemotherapy) are available in 3 (25%) centres and 1 centre (8%) respectively while 9 (75%) centres and 11 (92%) centres do not possess such item respectively. Both items are affordable to a low extent in 2 (17%) centres and 1 centre (8%) respectively while item 1 (Ultrasound scan TVUS (transvaginal ultrasound scan) is affordable to a large extent in 1 centre (8%)., both items are accessible to a low extent in 2 (17%) centres and 1 centre (8%) respectively while item 1 (Ultrasound scan TVUS (transvaginal ultrasound scan) is accessible to a large extent in 1 centre (8%). The appropriateness of both devices fall within 26% – 50% in 1 centre (8%) and 1 (17%) centre respectively, item 1 is appropriate within the range 26% – 50% in 1 centre (8%) as well as appropriate within 76% – 100% in 1 centre (8%). Also, each of the two devices are of low quality in just 1 centre (8%) and 1 (8%)centre respectively while item 1 has a medium quality in 2 (17%) centres. The age of each of the devices falls within 1–5 years in only 1 centre (8%) each while the age of Endocervical curettage (item 2) fall within the range of 6–10 years in just one centre.

TRUS (transrectal ultrasound scan) for leukaemia

Table 10 presents the frequency distribution of the respondents' responses to the item (TRUS (transrectal ultrasound scan) Image guided procedures to place catheter for chemotherapy) for *Leukaemia*. The table depicts that out of the twelve medical centres surveyed, the item (Ultrasound scan CT scan) is available in 2 (17%) centres while the device is not available in 10 (83.3%) centres., the device is affordable to a low extent in 2 (17%) centres. The device is accessible to low extent in 1 centre

(8%) while it is accessible to some extent in 1 centre (8%). The appropriateness of the device is high in 1 centre (8%) and optimal in another. In 2 (17%) centres, the device is of high quality. The age of device the ages fall within the range 5 – 10 years in 2 (17%) centres.

Ultrasound scan CT scan for leukaemia

Table 11 presents the frequency distribution of the respondents' responses to the item (Ultrasound scan CT scan) for *Leukaemia*. The table depicts that out of the twelve medical centres surveyed, the item (Ultrasound scan CT scan) is available in 3 (25%) centres while the device is not available in 9 (75%) centres. , 2 (17%) respondents indicated that the item is affordable to low extent in their respective centres while it is affordable to some extent in 1 centre (8%). The device is accessible to some extent in 3 (25%) centres. The appropriateness of the device falls within 51% – 75% in 1 centre (8%) while it falls within the range 76% – 100% in 2 (17%) centres. In 2 (17%) centres, the device is of medium quality while it is of high quality in 1 (8%). As indicated by 1 respondent, the age of the device 1 centre (8%) falls within 1–5 years while the ages fall within the range 5 – 10 years in 2 (17%) centres.

TRUS for prostate cancer

Table 12 above presents the frequency distribution of the respondents' responses to the item (TRUS (transrectal ultrasound scan)-guided prostate biopsy) for *Prostate cancer*. The table depicts that out of the twelve medical centres surveyed, the item (transrectal ultrasound scan)-guided prostate biopsy) is available in 3 (25%) centres while the device is not available in 9 (75%) centres. , 1 (8%) respondent indicated that the item is affordable to low extent in his/her centre while it is affordable to some extent in 1 centre (8%). The level of accessibility in 1 (25%) of the medical centres is of low extent while it is accessible to some extent in 1 (8%). The appropriateness of the device falls within 51% – 75% in 1 centre (8%) while it falls within the range 76% – 100% in 1 centre (8%). In 2 different centres, the device is of medium and high quality respectively. As indicated by 2 respondents, the ages of the device in 2 (17%) centres fall within 1–5 years.

PROCEDURES

Mammographic X-ray

Table 13 presents the frequency distribution of the respondents' responses to the item (Mammographic X-ray system) for Mammography. Item 1 (Mammographic X-ray system) is available in only 4 (33%) centres. 3 (25%) respondents indicated that the item is affordable to low extent in their respective centres. The level of accessibility in 1 (25%) of the medical centre of low extent while to

some extent, the device is available. In 3 different centres, the device is of low, medium and high quality respectively. As indicated by 2 respondents, the ages of the device in 2 (17%) centres fall within 1–5 years while in 1 (8%) fall within the range 6–10 years.

Mammographic stereotactic biopsy system

Table 14 presents the descriptive frequency distribution of the respondents' responses to the item (Mammographic stereotactic biopsy system) for *Stereotactic guided Core Needle Biopsy of Primary Tumor or Metastatic Lesions*. Of the twelve medical centres surveyed, item 1 (Mammographic stereotactic biopsy system) is available in 2 (17%) centres while 10 (83.3%) centre do not possess such item. , only one respondents indicated that the affordability of the item is low in the centre while others could not respond to this measure. , only 1 (8%) respondent indicated the level of accessibility is of low level in the centre. The level of appropriateness of the device in 1 centre (8%) falls within 51% – 75%. Also, exactly one respondent indicated that the quality of the device is of low in the centre and likewise just one respondent indicated that the age of the device is less than 1year in the centre.

Biopsy gun

The biopsy gun (ultrasound probe or transducer/Linear array) for Ultrasound Guided Biopsy of Regional Lymph and Sentinel Nodes (FNA) is unavailable in all the centres surveyed.

Fine Needle Aspiration

The item single use devices/ disposables/medical Supplies for Fine Needle Aspiration (FNA) is available in only 4 (33%) centres. It was affordable to a low extent in 1 centre and to a large extent in 2, accessible at a low level in 3 centres, highly appropriate in 1 centre and optimally appropriate in 2. The ages in three centres range between less than one year, 1–5 years and 6–10 years respectively.

CONCLUSION

It can be inferred from the analysis that some of the apparatuses or devices required for diagnoses or treatments of certain illnesses such as cancer etc. are available in a few medical centres in Lagos State (the South-western geopolitical zone of Nigeria) with respect to certain levels of accessibility and appropriateness. Apparatuses or devices such as aneroid sphygmomanometer stethoscopes, thermometers, examination tables, resuscitation trolleys, and defibrillators. Fixed examination/treatment lights, pulse oximeters, electrocardiography systems, colposcopes and vaginal speculums are available in at least 75% of the surveyed centres. Comparatively, apparatuses or devices

such as cryosurgery units, endocervical curettes, electrocautery systems, ultrasound scans, CT scan, biopsy procedures, mammographic X-ray systems, mammography stereotactic-guided core needle biopsy of primary tumour or metastatic lesions, ultrasound scan TVUS (transvaginal ultrasound scan), image-guided procedures are available in at most 33.3% of the surveyed medical centres.

On the contrary, breast tomosynthesis biopsy guns are not available in all the surveyed medical centres while only one of the surveyed medical centres has magnetic resonance imaging (MRI) System in Lagos State. Clearly there is a problem of access to these medical devices.

In addition to the conclusion based on the questionnaire, in most of the hospitals the ratio of patients per device is high leading to overuse of these devices, with frequent breakdowns leaving the patients with no options. This survey therefore suggests that further work should be done on improved clinical evaluation and investigation for medical devices as a crucial opportunity to improve the rules about the conduct of clinical investigations and the collection of clinical data for medical devices.

There are numerous challenges and systemic issues which are attached to the lack of access to medical devices that should also be considered in the development of an overarching policy for enhanced access: these include power failures, environment, policy, safety, product development and technology transfer, maintenance and preventive maintenance and training.

The health care situation in Nigeria is in a state of emergency and there is need to overcome the barriers to accessing medical devices. There is also a need to improve, promote, and accelerate the transfer of technology between developed and developing countries through cooperation and coherence at the international level (promoting access) and the adoption of a holistic approach by government policy makers, healthcare providers, researchers to create an efficient, effective regulatory system tuned to the realities of the Nigerian situation. This article has mapped out in concrete terms the nature of the challenge and the needs to be practically addressed through such an approach.

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WHO, Public health,

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TABLES

Source throughout: Field survey, 2018

CANCER MEDICAL DEVICES

Table 1: General Medical devices for Clinical Assessment and Minor Procedures

	Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
		1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
1	Aneroid sphygmomanometer Stethoscope	11	1	-	5	6	-	7	4	-	5	5	1	6	-	4	1	1	8
2	Thermometer	11	1	1	3	7	-	6	5	-	4	5	2	4	1	5	1	1	8
3	Examination table Resuscitation trolley	11	1	1	4	6	-	8	3	-	4	5	2	6	1	3	2	8	-
4	Pulse oximeter	9	3	-	3	7	-	6	4	-	3	5	2	4	3	2	1	2	6
5	Electrocardiography system	10	2	-	4	6	-	7	3	-	4	3	3	5	2	2	-	2	7

Table 2: Colposcopy

Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
	1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
Colposcope	2	10	-	2	-		1	1	-	-	-	2	-	1	1	-	1	1

Table 3: Cryotherapy

Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
	1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3

Cryosurgery unit	2	10	-	1	1		2	-	-	-	-	2	-	-	2	-	-	2
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Table 4: Endocervical curettage ECC

	Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
		1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
1	Colposcope	11	1	-	1	-	-	-	1	-	-	-	1	-	-	1	-	1	-
2	Endocervical curette	2	10	-	1	1	-	-	2	-	-	-	2	-	1	1	-	1	1

Table 5: Large loop excision of transformation zone (LEEP/LLETZ) - Electrosurgical unit

Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
	1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
Electrocautery system electrode for LEEP	2	10	-	1	1	-	-	2	-	-	1	1	-	1	1	1	1	-

Table 6: Papanicolaou Test (Pap smear)

Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age			
	1		2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
Vaginal speculum, reusable	11		1	-	6	3	-	7	2	-	6	2	1	6	1	2	-	2	7

MEDICAL IMAGING & NUCLEAR MEDICINE (IMAGING DEVICES)

Table 7: All Cancers

	Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
		1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
1	Ultrasound scan preferably with capacity for colour Doppler imaging system and accessories X-ray imaging	2	10	1	1	-	-	-	2	-	-	-	2	-	1	1	-	1	1
2	CT scan	3	9	1	2	-	1	2	-	-	-	1	1	-	-	2	-	-	1
3	MRI scan: Magnetic Resonance Imaging (MRI) System (1.5 T)	1	11	-	-	1	-	-	1	-	-	-	1	-	-	1	-	-	1
4	Biopsy procedures (including stereotactic biopsy)	1	11	-	1	-	-	-	1	-	-	1	-	-	-	1	-	-	1
5	Fluoroscopic scanning for image guided procedures Image guided procedures to place catheter for chemotherapy	2	10	-	1	1	-	-	2	-	-	1	1	-	1	1	-	1	1

Table 8: Breast Cancer

	Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age					
		1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3			
1	Mammographic X-ray system	4	8	-	3	-	-	1	2	-	1	1	1	1	1	1	1	-	2			
2	Mammography Stereotactic-guided core needle biopsy of primary tumour or metastatic lesions	2	10	-	1	-	-	1	-	-	1	-	-	1	-	-	1	-	-	1	-	-
3	Ultrasound scan	3	9	1	2	-	1	2	-	-	-	1	1	-	-	2	-	-	1			
4	Ultrasound guided biopsy of regional lymph and sentinel nodes	1	11	1	-	-	-	1	-	-	1	-	-	1	-	-	-	-	-	1		
5	Breast Tomosynthesis	12	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Table 9: Cervical Cancer

	Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age				
		1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3		
1	Ultrasound scan TVUS (transvaginal ultrasound scan)	3	9	-	2	1	-	2	1	-	1	1	1	1	2	-	-	2	1		
2	Image guided procedures to place catheter for chemotherapy.	1	11	-	1	-	-	1	-	-	1	-	-	1	-	-	-	-	1		

Table 10: Colorectal Cancer

Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
	1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
TRUS (transrectal ultrasound scan) - Image guided procedures to place catheter for chemotherapy.	2	10	-	2	-	-	1	1	-	-	1	1	-	-	2	-	2	-

Table 11: Leukaemia

Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
	1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
Ultrasound scan - CT scan	3	9	-	2	1	-	-	3	-	-	1	2	-	2	1	-	1	2

Table 12: Prostate cancer

	Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
		1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
1	TRUS (transrectal ultrasound scan)-guided prostate biopsy	3	9	-	1	1	-	1	1	-	-	1	1	-	1	1	-	2	-

PROCEDURES

Table 13: Mammography

	Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age			
		1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3	
1	Mammographic X-ray system	4	8	-	3	-	-	1	2	-	1	1	1	1	1	1	1	-	2	1

Table 14: Stereotactic guided Core Needle Biopsy of Primary Tumour or Metastatic Lesions

Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
	1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
Mammographic stereotactic biopsy system	2	10	-	1	-	-	1	-	-	1	-	-	1	-	-	1	-	-

Table 15: Ultrasound Guided Biopsy of Regional Lymph and Sentinel Nodes

	Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age			
		1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3	
1	Biopsy gun (Ultrasound probe or transducer/Linear array)	12	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Table 16: Fine Needle Aspiration (FNA)

Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
	1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
Single use devices/ disposables/medical supplies	4	8	-	1	2	-	-	3	-	-	1	2	-	-	3	1	1	1

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