



WIPO-WTO COLLOQUIUM PAPERS

RESEARCH PAPERS FROM THE WIPO-WTO COLLOQUIUM
FOR TEACHERS OF INTELLECTUAL PROPERTY LAW 2014



WTO OMC





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FOR TEACHERS OF INTELLECTUAL PROPERTY LAW**

Compiled by the WIPO Academy and the WTO Intellectual Property Division

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The views and opinions expressed in the collection of papers from the WIPO-WTO Colloquium of Teachers of Intellectual Property (2014) are those of the authors. They do not necessarily reflect the positions of the organizations cooperating on this project. In particular, no views or legal analysis included in these papers should be attributed to WIPO or the WTO, or to their respective Secretariats.

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FOREWORD



Mr Francis Gurry



Mr Roberto Azevêdo

This volume is the fifth in a series of annual publications from the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO). Prepared by the WIPO-WTO Colloquium for Teachers of Intellectual Property, this collection of academic papers represents an important contribution to international scholarship in the field of intellectual property (IP). Today we witness ever increasing, more diverse forms of international interaction on IP, yet equally we see growing attention to differing national policy needs and social and developmental priorities in this field. The *Colloquium Papers* series highlights the importance of fostering scholarship in emerging IP jurisdictions, harvesting the insights from policy and academic debates from across the globe, and promoting mutual learning through the sharing of research and scholarship on a broader geographical base.

For over a decade, the annual WIPO-WTO Colloquium itself has played a central role in the joint capacity building programmes of WIPO and the WTO. This cooperation seeks to enrich dialogue on IP issues and to address the developmental and wider policy considerations that form an integral part of IP law and policy today. The Colloquium responds to the recognition that developmental benefits from the IP system can only be reaped through skilled adaptation to national circumstances and judicious use by informed practitioners. Equally, effective policy development at the national level needs increasingly to draw upon skilled, informed and sophisticated policy analysis. The Colloquium bolsters the capacity of those best placed to ensure truly sustainable, long-term benefits from the adept use of the IP system – those who teach the IP practitioners of the future, and those who conduct research on IP law and policy.

The programme has produced more than 260 alumni. This is a diverse and active network of highly engaged teachers and researchers, which reaches across the developing world. Whilst this network is the principal focus of the programme, it also includes a number of developed countries. It is heartening to see the contributions of these scholars in many avenues – through their academic publications, through their active participation in national and international policy debates, through their own teaching and through their contribution to capacity building in the developing world.

We see the *Colloquium Papers* – an edited, peer-reviewed academic journal – as epitomizing the trend towards more diverse and yet more rigorous capacity building in IP law and policy. The five publications issued since 2010 draw together the participants' original insights into current IP issues in their countries, and give greater substance to the network of mutual learning and intellectual exchanges that characterize the Colloquium programme.

The latest publication, a selection of papers from the 2014 Colloquium, covers an impressive range of IP subject matter, including patents, copyright and trademarks. The papers discuss policy issues, including IP protection of traditional knowledge and biodiversity, and IP and public health, all of which are vital to the development of IP systems in developing countries. This publication series may now be presented as a significant academic journal with unique coverage of IP law and policy focussed on emerging IP jurisdictions.

In today's changing global economy, IP significantly influences the everyday lives of all citizens around the world. An international IP system that can adjust to the shifting global economic landscape, while also stimulating innovation and furthering development, demands the understanding, participation and cooperation of all peoples across the societal spectrum. Initiatives such as the Colloquium play an important role in building capacity, raising awareness, and engaging all societies that are affected by the evolution of the international IP system.

We congratulate the contributing scholars for their first rate research, and we thank the Editorial Board – a highly distinguished group of senior IP scholars – for their invaluable support and engagement, which has helped establish the *Papers* as a credible academic publication. We should also record our appreciation for the work of our colleagues in the WIPO Academy and the WTO IP Division in organizing the Colloquium and facilitating the publication. Finally, we commend the *Colloquium Papers* as an important source for academic research to what we trust will be a wide and ever more diverse readership.



Francis Gurry
Director General
World Intellectual Property
Organization



Roberto Azevêdo
Director-General
World Trade Organization

PREFACE

This volume is the fifth in the series of academic papers resulting from the WIPO-WTO Colloquium: it serves as a tangible reminder of the vitality and richness of collaboration between the two organizations as they mark 20 years of cooperation following the conclusion of a bilateral agreement in 1995, shortly after the WTO was established. The content of this journal, representing emerging scholarship from across the developing world, encapsulates much that is challenging, significant and fascinating in the field of intellectual property (IP) today, and underscores why this bilateral cooperation is as valuable as ever.

Always with a strong international dimension, the IP system is undergoing an unprecedented phase of globalization and a building of international institutions, bringing with it a deepened understanding of the centrality of a balanced and effective IP system in economic and social development. Yet this same period has precipitated an intensive, wide-ranging process of inquiry about how to adapt and apply IP principles to ensure economic growth, sound public policy, and sustainable development in diverse settings across the globe, recognizing the diversity of economic, social and technological settings, national developmental priorities, and legal and commercial systems.

Intellectual property is seemingly ubiquitous in contemporary life, but its role and impact are both highly diverse and in need of careful analysis and informed debate. An IP dimension is present in many challenging public policy issues today. For instance, we see growing attention to its role in promoting public health, addressing climate change, and achieving food security, as well as its interaction with human rights and social and economic development. Intellectual property has been the subject of complex, multifaceted debates at the multilateral, regional and national levels over the rights of indigenous people, the conservation of biodiversity, the ethics and use of genetic resources, Internet governance, climate change technology, and access to education and medicine. And behind these debates lies an essential question: how to come to grips with the significant responsibility of IP systems in the current world economy, in international trade, and in national policy environment: how should IP systems be designed or adapted to promote economic development, stimulate innovation, and disseminate knowledge in a manner that balances the rights of all stakeholders?

The contemporary field of IP is therefore characterized by profound and searching debates on questions of essential public policy; an approach to policy-making that emphasizes empirical research, theoretical clarity, and achieves coherence with other areas of law; and the harvesting of practical experience from an ever widening base of national IP systems and participants in the policy and practice of IP. It is, therefore, a field in need of a deeper and wider research effort; sophisticated, informed and carefully tailored approaches to education and practical capacity building; and, above all, dialogue and debate founded on a richer base of information, theoretical understanding, practical experience, and knowledge of its implications in other areas of law and policy.

Both WIPO and the WTO have been called upon to play a role in strengthening capacity to deal with the intellectual challenges of these policy debates. This increasing diversity of demand for capacity-building support has had a profound impact on programme design and delivery. The WIPO Academy has developed a wide range of specialist courses and training activities to respond to this evolving pattern of demand, and to reach out to and support an ever widening range of stakeholders.

The WTO IP Division continues to broaden and tailor its technical cooperation and policy support activities, developing a wider engagement with current international issues and with a broader base of stakeholders, exemplified by work on public health issues. But none of these outcomes can be possible without partnerships – the sharing of ideas, pooling of resources, and coordination of practical activities – so that the necessary wide range of experience and expertise can be drawn on to meet diverse needs.

Both the WIPO Academy and the WTO Intellectual Property Division therefore enjoy many valuable partnerships as a central strategy in ensuring programme delivery. The Colloquium has exemplified and promoted current trends in technical assistance and capacity building: it builds upon and extends an existing partnership between WIPO and the WTO; it responds to the need for stronger, broader dialogue and a greater involvement of voices from all perspectives in contemporary debates; it recognizes the central role of indigenous capacity building and of the key contribution of IP teachers and researchers as the mainstay of sustainable development of the necessary IP expertise in developing countries; it transcends traditional boundaries between regions and between 'north' and 'south' to allow fruitful discourse on the future of IP systems. Most importantly, it recognizes the importance of extending beyond an educational function to one of bringing together a diverse group with the aim of reviving and refreshing dialogues on IP and its cognate fields.

The Colloquium has, in particular, laid emphasis on the role of participants as active players, as informed, stimulating teachers and researchers who bring to the two-week dialogue as much as they take away from it. Past feedback from participants stressed the need to capture, in more permanent form, the many insights gleaned from these few days of intensive, vigorous discussion. Participating teachers and researchers expressed important new ideas and insights to global debates that could enrich and inform the exchange among policymakers, the academic community, and the public at large.

These thoughts, guided very much by the participating teachers and researchers themselves, are what gave rise to the present publication, which is in a way a tribute to the intellectual energy and curiosity of the many alumni of the past Colloquia, with whom we continue to enjoy a range of partnerships and dialogue.

WIPO and the WTO both host numerous meetings every year, in Geneva and in many locations elsewhere, and under numerous headings: committees, seminars, workshops, roundtables, symposia, and so on. But amidst all this activity, the idea of a 'colloquium' has a special ring to it – for the WIPO-WTO Colloquium, it connotes a spirit of academic enquiry, a search for new ideas and new ways of analysing IP and related fields, through open debate, rigorous research, and new ways of communicating the complexities of IP law, practice and policy. We trust that this publication will bring to a wider community of researchers, policymakers and teachers some of the colloquium spirit that we have valued so much in this unique programme.

All of us who have participated in the Colloquium have benefited from the hard work and dedication of many colleagues within WIPO and the WTO Secretariat – notably, the WIPO Academy and the WTO Intellectual Property Division. All have contributed valuably to the design and delivery of this programme, and their spirit of collegiality makes a demanding programme also a pleasurable one.

We owe a particular debt of gratitude to the Editorial Board and the editors of the *Colloquium Papers*: 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 from across the developing world. Finally, we record our deep appreciation for the contributions made by individual scholars to this, and the preceding, volumes – we have come to know and respect their contributions to policy and legal scholarship, and we are sure that this active, informed and thoughtful participation in many of the key public policy debates of today will continue, exemplifying the important public service role performed by the scholarly community today.



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1 INTERACTION BETWEEN PATENT PROTECTION AND ACCESS TO ESSENTIAL MEDICINES - THE POTENTIAL CONFLICT BETWEEN RIGHTS TO HEALTH AND PROPERTY RIGHTS

Dr Gustavo Schötz*

ABSTRACT

In many human rights treaties and national constitutions, health and property rights are considered fundamental rights. As a manifestation of such rights, access to essential medicines must be taken into consideration, along with the right of the patentee who generated them. As there is no express hierarchy of such rights, it is necessary to seek to harmonize them with the aim of achieving two objectives: (1) health protection; and (2) new and better medicines for the treatment of diseases. This article will analyse several approaches pursued in different jurisdictions and recommend the best approach for achieving these objectives. Among possible solutions, it will adhere to the 'essential content of rights'.

Keywords: *Patents, essential medicines, compulsory licence, principle of proportionality, and rule of law*

I. INTRODUCTION

The issue to be addressed in this article is complex. The intention is to provide grounds for a fair and balanced solution to the potential conflict which may arise from the interaction between patents and access to essential medicines.¹ This article seeks to demarcate the content of each of those rights, highlight the circumstances under which a conflict may arise, and address the proportionality judgment as a proposed solution. It briefly structures the main premises and conclusions and considers the Brazil case in further detail. Ultimately, it advocates

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¹ Frederick M Abbot, 'Intellectual Property and Public Health: Meeting the Challenge of Sustainability' (2011) Global Health Programme, Working Paper n 7 (The Graduate Institute, Geneva, Global Health Programme) 7; Alynna C Smith, 'Intellectual Property Rights and the Right to Health: Considering the Case of Access to Medicines' in Christian Lenk, Nils Hoppe and Roberto Andorno (eds), *Ethics and Law of Intellectual Property. Current Problems in Politics, Science and Technology* (Ashgate 2009) 47 at 62.

harmonization of rights that is very close to the principle of proportionality.

The issue is part of a more extensive debate. For many years in the academic world there have been strong adherents in favour of the coexistence of intellectual property and human rights.² Two perspectives have existed side by side: on the one hand, some academics advocate a conflicting coexistence, which emphasizes the negative impacts of intellectual property on rights such as freedom of speech, health, safety or education; on the other hand, others are proponents of a model that establishes an equilibrium or synchronized coexistence between both types of rights. In my view, the latter perspective will gain more relevance in the coming years.

Far from formulating a complete conclusion, the analysis in this article must be supplemented with additional issues related to this subject, such as the effectiveness of the patents system as an instrument of innovation, the political and economic management and distribution of expenses in those countries that require such medicines, the global allocation of funds in science and technology, and the functioning of the sanitary system as a whole. Additionally, particular consideration must be given to the cost-effectiveness ratio of treatments, the interaction between innovation, intellectual property, and sanitary regulation, and the effectiveness of local and international court systems. Any change in the above elements or subsystems will have a bearing on the solution to either the problem as a whole or a specific case, respectively.

Then, when reflecting on a specific instance, a resolution system of the apparent dispute must be applied. The author of this article stresses the idea of 'apparent' as he asserts that rights are inherently complementary or collaborative among themselves. The reasonableness analysis is the best system to achieve a harmonization of rights. Far from a theoretical or abstract proposal, the factual assumption must be analysed. These are the grounds upon which a specific case should be approached, such as the compulsory licence for Efavirenz, which was ordered by the Brazilian Government.

II. SETTING OUT THE PROBLEM - PREMISES AND KEY FACTORS

The following are some basic premises upon which this article relies:

² Willem Grosheide, *Intellectual Property and Human Rights. A Paradox* (CIER-Edward Elgar Publishing Limited 2010).

(a) Health and life are fundamental rights entrenched in constitutions and international human rights treaties.³

(b) Intellectual property has been recognized in international instruments and is also included in fundamental rights and guarantees. In some cases, recognition is specific and in others it is achieved by integrating property or estates.

(c) Occasionally, these two rights seem to be incompatible and there appears to be potential conflict between health and medical patents, whenever the availability of some medicine should be scarce due to an exclusive right or an extremely high price, thus rendering that medicine unaffordable.

(d) A solution-oriented method or system should be established by taking into consideration that the potential conflict between fundamental rights will be equally present in other ambits, aside from intellectual property rights.⁴

(e) A generic solution method should be established in national and international environments by considering that the potential conflict is equally present in other areas of intellectual property rights: copyright and the right to education, intellectual property rights and freedom of speech, patents and farmers' rights, freedom of speech and trademarks, copyright and consumers' rights, etc.⁵

(f) Consequently, the method or system could be similar to that utilized to resolve other conflicts between fundamental rights.

In keeping with this simplified reasoning, it is also worth noting the existence of a common good pertaining to the international community consisting of patients, medical doctors, sanitary agents, not-for-profit organizations, inventors and researchers,

governments, and manufacturers of generic drugs.⁶ The premises to be verified in that regard are:

(a) It can be established that both the health and creativity of all members of the community are basic human goods, in the sense that all members can have their own stake in them, with no regard to the extent to which those goods are used and enjoyed individually, regardless of their actual concrete existence here and now.⁷

(b) Human goods, as desirable values and grounded on the human condition, give rise to natural rights.⁸

(c) Members of the community have common shared interests. Thus, in both a national and international community, we believe that all members are entitled to life and health. That is why the common good will always be the driving force of any community, and the community as a whole will have its own common good.⁹

(d) In order to move on from this level of generality to operative conclusions, the relations, aims and property of that community, in particular, must be detailed.

(e) In the case under analysis, it is possible to note that there is an international community of patients and inventors in need of each other.

⁶ Holger Hestermeyer, *Human Rights and the WTO – The Case of Patents and Access to Medicines* (Oxford University Press 2007). Common good can be sustained beyond conflicts of interests among the parties involved. As stated by Abbot, 'There is an inherent logic in the position of the OECD governments and originator companies, and there is a reasonable justification for developing countries and their local industries to oppose that logic. The consequence is a continuing struggle for an equilibrium point at which the originator multinational companies are earning an adequate return on investment, while developing countries have access to medicines at prices that are reasonably affordable.' Frederick M Abbot, 'Intellectual Property and Public Health – Meeting the Challenge of Sustainability' 14.

⁷ John Finnis, *Natural Law and Natural Rights* (Clarendon Press Oxford 1980) Chs 1-2.

⁸ Javier Hervada, *Introducción crítica al derecho natural* (Universidad de Piura 1ª Ed Peruana 1999).

⁹ The common good of a community, in particular, is outlined in TRIPS Article 7:

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.

³ The terms 'fundamental rights', 'constitutional guarantees' or 'human rights' are not equivalents. They are to be distinguished based on the theoretical background supporting them, their field of application, and their effectiveness. However, I will refer to them interchangeably in this paper.

⁴ Virgilio Afonso da Silva, 'Comparing the Incommensurable: Constitutional Principles, Balancing and Rational Decision' (2011) Vol 31 n 2 OJLS 273, 274.

⁵ Jakob Cornides, 'Human Rights and Intellectual Property – Conflict or Convergence?' (2004), *Journal of World Intellectual Property* 7.2, 135.

The following, therefore, contain some general propositions that will both activate consensus and serve as a starting point to seek a solution for the potential conflict:

- (a) A patient's health through access to medicines is a positive thing that is suitable for every human being.
- (b) Access to medicines must be prioritized.
- (c) Diseases or death that may be attributed to limited access to required medicines must be avoided.
- (d) The supply of medicine to a patient in need is a valuable action.
- (e) The search for new and better medicines must be promoted.
- (f) Those who benefit society with better medicines, through their effort or investment, deserve an award.
- (g) Those who have invested time, effort and capital to obtain new property cannot be deprived of such property without fair compensation.

Broadly speaking, it could be asserted that there are no clashes, but rather the common good is manifested through coexisting and complementary rights. In all societies, the authority exercises distribution of common goods and assigns rights through norms, some of which are principles and others are rules. The former are deontological judgments, lacking the required precision to command, prohibit, or allow the conduct of agents with respect to others. That is the reason why principles will then have to be established by enacting proper rules assigning specific rights to their beneficiaries, including provisions as to who has the duty to give certain objects to others or else refrain from engaging in certain conduct.

Consequently, rights must be enunciated by specifying three concepts: an obligee, a beneficiary, and the action that must be undertaken, prohibited, or allowed.¹⁰ To understand the full right to health or how the right to patents is made effective, the provisions of international treaties or national laws are to be observed. If there is no consistency between enunciations and normative purposes, or in the absence of regulations that attribute rights or

impose duties, there needs to be a mechanism to remedy such a defect or omission in the legal regime.

Therefore, Article 8 from the TRIPS Agreement stipulates the following:

Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

However, the wording of the Article does not allow inferring what those necessary measurements are or what is compatible with the TRIPS Agreement.

The same applies to paragraph (1) of Section 25 of the Universal Declaration of Human Rights:

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services.

Similarly, the Constitution of the World Health Organization (WHO), enacted in 1946, stipulates the following:

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

These principles lead to natural questions: are these rights negative or affirmative rights, that is to say, is a specific conduct required or is it aimed at preventing interferences? Against whom can these rights be enforced? Are there affirmative conducts demanded, and if so, what are they?

In order to address these questions, some key notions must be established. First, it must be made clear that the State is the first passive subject in the obligation derived from right to health. As the patient is a member of a community, the community must ensure the right to life and health of each and all of its members. It is only indirectly that such an obligation affects individuals, either arising out of a contract with the patient (social security), or from a

¹⁰ This is the overall conception of Hohfeld's rights. WN Hohfeld, *Fundamental Legal Conceptions* (New Haven 1919).

delegation of a duty made primarily upon an organized community.¹¹

Consequently, pharmaceutical companies are not the subjects bound to fulfil the duty derived from the right to medicine. Their duty is to make medicines available in terms of quantity and quality, and to ensure that they are otherwise harmless and meet statutory requirements, which may include a duty to refrain from setting abusive prices.

The right of the patent holder, as already stated, is also considered a fundamental right. In other words, the same right is asserted in Article 17 of the Universal Declaration of Human Rights:

(1) Everyone has the right to own property alone, as well as in association with others [and] (2) [n]o one shall be arbitrarily deprived of his property.

Additionally, Article 27, paragraph (2) states:

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.

These rights were subsequently embodied in the International Covenant on Economic, Social and Cultural Rights:

¹¹ Even though the existence of a global community can be considered, and even if patients can be treated as its members, such community is not bound to ensure the right to health. An ethical mandate does not entail, per se, sufficient grounds to a claim under the law. That is the reason why the main player under a duty to provide health is still the state, this being conceived as a community to which the patient belongs. With regard to the existence of a global community but with obligations at a national level, Taubman's words are particularly useful:

This is because the extent to which the 'world's welfare' is influenced by international IP standards ultimately can only depend on choices and actions taken at the municipal level, under domestic laws and legal measures that apply and operationalize more abstract and remote international standards, and in so doing mediate and interpret them, in such a way that either delivers or denies the 'articulated standard of welfare.' Antony S Taubman, 'TRIPS Jurisprudence in the Balance: Between the Realist Defence of Policy Space and a Shared Utilitarian Ethic,' in Christian Lenk, Nils Hoppe and Roberto Andorno (eds), *Ethics and Law of Intellectual Property. Current Problems in Politics, Science and Technology* (Ashgate 2009) 117.

The States Parties to the present Covenant recognize the right of everyone:

(a) [t]o take part in cultural life; (b) [t]o enjoy the benefits of scientific progress and its applications; [and] (c) [t]o benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

These rights, stated in the form of principles—not rules—must be harmonized with others. In this sense, Article XIII of the American Declaration of the Rights and Duties of Man establishes:

[r]ights to the [b]enefits of [c]ulture: [e]very person has the right to take part in the cultural life of the community, to enjoy the arts, and to participate in the benefits that result from intellectual progress, especially scientific discoveries.

He likewise has the right to the protection of his moral and material interests as regards his inventions or any literary, scientific or artistic works of which he is the author.'

From the perspective of a patent as a proprietary right, some key aspects have to be determined. Is intellectual property a human right? Do all intellectual property rights have the same hierarchy or rank? Is the right to patent a human right? Can they be considered absolute rights, even to the detriment of other needs in society? Can a company be a holder of human rights? Are pharmaceutical companies holders of human rights?

We can also establish that property, being in itself a right, is subjected to the restrictions imposed at the time it is granted and those derived by applicable legal rules. In my view, then, the right to property would not be affected if the patent is not granted by virtue of legislation that was duly enacted and does not result from arbitrariness. Still, a human right to property (or a fundamental guarantee) could be invoked if a patent holder is unjustly deprived of his own property or full enjoyment of that property, or, if the patent is not granted, because of an arbitrary decision.

These premises are applied to medical patents. This is mainly because investment in research and development with a view to future returns generates an expectation to earn compensation. Undoubtedly in all legal systems such investment is property. And

this is because it is largely the way in which our global society has decided to assign resources to award innovation in medicine. Such pressures apply with more force in the scientific and industrial sectors because the market failures in the generation of information are much more evident. Rapid and easy imitation of products is not comparable to the extensive, costly, and high risk activity involved in researching new products and launching them on the market for the first time.

III. SOLUTIONS AVAILABLE

The attempt to solve the potential conflicts between fundamental rights is not new. In some countries, rights or privileged freedoms are ordered into a hierarchy. Other countries, in turn, resort to a balancing test. Some legal experts and courts favour the application of the theory of external limits.

In European case law, the proportionality principle, which originated in the German Federal Court, is utilized.¹² These are all methods that intend to achieve objectivity or rationality in a decision that resolves conflicting rights, values or principles. The intention is to safeguard the rule of law and the principle of due process.¹³

Undoubtedly, this type of mechanism must be applied to the conflict to which we have referred. Some authors even consider that the so-called three-step rule test is a concrete application of the proportionality principle to the conflicts involved in intellectual property rights.¹⁴

As part of this search, the author is more in favour of the solution provided by legal experts on the essential content of rights.¹⁵ This involves, first of all,

¹² Tor-Inge Harbo, 'The Function of the Proportionality Principle in EU Law' (2010) *European Law Journal* Vol 16 n 2, 158.

¹³ Laurence R Helfer, 'The New Innovation Frontier? Intellectual Property and the European Courts of Human Rights' in Paul LC Torremans (ed) *Intellectual Property and Human Rights* (Kluwer Law International 2nd Edition 2008) 25.

¹⁴ Christophe Geiger, 'The Constitutional Dimension of Intellectual Property' in Paul LC Torremans (ed) *Intellectual Property and Human Rights* (Kluwer Law International 2nd Edition 2008) 101 at 131; see also H Grosse Ruse-Khan 'Proportionality and Balancing within the Objectives for Intellectual Property Protection' 161.

¹⁵ In this respect, see Fernando Toller, 'Resolución de los conflictos entre derechos fundamentales, una metodología de interpretación constitucional alternativa a la Jerarquización y el Balancing Test' in Eduardo Ferrer MacGregor (ed) *Interpretación Constitucional Vol II* (Editorial Porrúa 2005) 1199. See also Pedro Serna Bermúdez and Fernando Toller, *La interpretación constitucional de los*

demarcating the material and formal aspect of each right. Then, an assessment on the facts must be undertaken, so as to determine which right is at stake in the case under analysis. This amounts to analysing each situation individually. Just like the case of the proportionality principle and the reasonableness judgment, the specific case must always be borne in mind. Thus, it will be necessary to determine at least the following elements of each right at stake:

(a) For what purpose or purposes may the State suspend or else limit the right of the patent holder and the right of the owner to uncontestedly preserve their proprietary interests or receive the payment requested?

(b) Who is the holder of each right (the clash will be between the government, which wants to favour a group of patients and the holder of the essential medicine)?

(c) Who must observe or enforce such right, or, who is the subject under duty to fulfil certain conducts in relation to the other subject and vice versa?

(d) What are the sense, scope, and conditions for the exercise of each of those rights, including time and other circumstances and conditions for its enforcement?

(e) Under what conditions does the holder of the intellectual property right lose entitlement thereof, and what are the conditions for the lawful exercise of each of those rights through the causes of action stated in the claim?

(f) What are the powers and faculties enjoyed by the holder in case of infringement by the subject under a duty to comply with the State, and in case of breach by the government, what are the powers of the patent holder?

(g) Finally, which freedoms and rights are to be enjoyed by the patent holder claiming such right?

derechos fundamentales: una alternativa a los conflictos de derechos (La Ley 2000); Juan Cianciardo, 'El ejercicio regular de los derechos: análisis y crítica del conflictivismo' (Ad-hoc 2007); Juan Cianciardo, *El principio de razonabilidad: del debido proceso sustantivo al moderno juicio de proporcionalidad* 2a. ed. (Ábaco 2009); Juan Cianciardo, *Principio de proporcionalidad y concepto de derecho: una aproximación desde las tesis del positivismo jurídico* (Ad-Hoc 2009).

These questions emerge when a rule is being challenged, be it specific or hypothetical. As an illustration, a hypothetical rule could be: 'Given the scarcity of necessary doses to suit the needs of a population, and as it is a patented drug and with no therapeutical substitute, the State shall apply a compulsory licence, by allowing third party suppliers to ease the required production, thereby disregarding the patent or paying a royalty.' If that were the rule, where there is a possible factual occurrence and a legal consequence arising therefrom, the judge should consider the following:

- (a) Does the rule have a constitutionally socially relevant purpose?
- (b) Is there an adequate relationship between means and the purpose sought?
- (c) Are these prescriptions necessarily required?
- (d) Is there a reasonable proportion between the results and the impediments reached through such prescriptions?
- (e) Is the essential content of the right respected?
- (f) Is the content included within the reasonable functioning sphere of such right?

The hypothetical rule presented is therefore precise, but drafted in an abstract sense. However, specific cases naturally go hand in hand with their own exclusive facts. The aim is to analyse a solution of justice for the event occurring here and now, and this includes adjectival circumstances and the procedures sought. The rule created herein will be contrasted systematically with the whole legal regime, including international treaties subscribed by the State, the relevant constitution, and constitutional guarantees, statutory rules, etc.

Thus, the rule must make provisions for a country in particular, the precise pathology, the alternative methods, the substitute products, the functioning of the sanitary system of that specific community, the price within a contained economic system, the number of affected patients, the specific epidemic situation, etc. If justice, in its typical sense, consists of giving each his due, we must specify what we mean by 'each' i.e. who is the one that gives, and who receives? And further, what is given and received, and what is actually 'due'?

One way of illustrating the application of the essential content of rights could be the case of compulsory licences granted in accordance with TRIPS Article 3 or pursuant to paragraph 6 of the

subsequent Declaration on the TRIPS Agreement and Public Health. This article will analyse cases in which a compulsory licence is a solution in keeping with the standards for a case in particular, as explained above.¹⁶

IV. COMPULSORY LICENCES

In this final section, the author attempts to apply the concepts formerly outlined in a case of compulsory licence that occurred in Brazil. The case of compulsory licence was selected, for it consists of a device designed in such a way that the rights of the patent holder can be suspended in the event of an emergency, consistent with the needs of the population.¹⁷

The relevance of this case is rooted in the peculiar situation encountered in Brazil. On the one hand, this is a country with a remarkable level of economic development and a large population. On the other, it has its own capacity for the production of medicines and a well defined position in international forums, where intellectual property is negotiated.¹⁸

During the 1980s and 1990s, several social organizations, including groups representing persons infected with HIV, based their petitions on the Constitution to claim free access to retroviral medicine. They also claimed these had to be produced by the state. As part of their claim, they

¹⁶ Nuno Pires de Carvalho has, so far, concluded that a mistake has been made in granting compulsory licences, either because of the reasons given, or because of the low compensation established or the failure to specify a beneficiary. Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights* 3rd Edn (Kluwer Law International 2010) 227, 425, 426.

¹⁷ Under Article 31 of the TRIPS Agreement and the Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001. For an analysis of the background of this Declaration, as stipulated in Javier Nuñez, 'Acuerdo sobre los ADPIC y Salud Pública. Evolución de la cuestión en la Organización Mundial de Comercio y la posición asumida por la República Argentina en las negociaciones' in Gustavo Schötz (ed.), *Patentes y Medicinas Esenciales* (Heliasta 2013).

¹⁸ These characteristics are the main sources of concern for multinational companies, especially when the need for compulsory licences emerges. 'Despite the way this issue has been featured in the press, the drug companies are not worried about a poor country overriding patents to meet an internal public health emergency. The concern is over the potential to legalize intellectual property theft in places such as India and Brazil, where low-cost manufacturers would exploit wider latitude to produce knock-off drugs for export.' Sidney Taurel, 'The Campaign against Innovation' in Michael A Santoro and Thomas M Gorrie (eds), *Ethics and the Pharmaceutical Industry* (Cambridge University Press 2005), 326, 327.

contended that compulsory licences had to be applied, if necessary, by limiting the rights of pharmaceutical companies in relation to certain products.¹⁹

Efavirenz, under the trade name Stocrin®, is an antiretroviral (ARV) drug produced by Merck, Sharp & Dohme (MSD), for the treatment of HIV, which facilitates once daily dosing. In 2003 the Ministry of Health of Brazil began negotiations with the laboratories aimed at obtaining better prices. During a specific phase of the negotiation process, the Ministry of Health of Brazil threatened to implement compulsory licences for Merck's ARV. The compulsory licence granting process was activated after the medicine was declared of public interest. MSD had a seven-day term to make a pronouncement, after which it made an offer of US\$ 1.10 per pill. The offer was rejected by the government, which granted the compulsory Efavirenz licence. An initial term of five years was established, which could in turn be extended for an additional five years.

Royalties were fixed at 1.5 per cent over the prices to be paid by the Ministry of Health of Brazil to importers or local manufacturers. Medicines subject to compulsory licences cannot be traded, but only purchased and distributed by the Ministry of Health of Brazil for the sanitary assistance of populations infected with HIV/AIDS.²⁰ As stipulated by such

¹⁹ The strategy of compulsory licences in Brazil is strengthened by the capacity that the country has to produce a generic drug, thus creating a run on the resources that poorer countries may have access to, and which exclusively depend on imports. As stated by Laurence R Hefner and Graeme W Austen in *Human Rights and Intellectual Property: Mapping the Global Interface* 130-131. Also in WCV Rodrigues and O Soler, 'Licença compulsória do efavirenz no Brasil em 2007: contextualização' (2009) *Rev Panam Salud Publica* 26(6) 553. Aspects of the political debate can be found in W Flanagan and G Whiteman, 'AIDS is Not a Business – Study in Global Corporate Responsibility – Securing Access to Low-Cost HIV Medicines' 70.

²⁰ The Executive Order allows both local manufacturing and imports from countries with no patent protection. Those in favour of the decision considered that innovation would not be affected, since sales of developing countries only account for 11 per cent of worldwide sales of pharmaceutical companies, and Latin America only accounts for 4 per cent of such sales. It is estimated that companies will not refrain from investing due to losing part of their sales in these markets. But it is also true that Brazil represents one of the ten major countries worldwide in the field of medicines, as stated in Gabriela Costa Chaves, 'Perguntas e respostas sobre o licenciamento compulsório do medicamento Efavirenz no Brasil' (2007) *Associação Brasileira Interdisciplinar de AIDS (ABIA)* paragraph 12; Fernando Lopes Ferraz Elias, 'Patente de medicamento: a questão do licenciamento compulsório do Efavirenz'

provisions, at least one of the following necessary conditions for the grant of a compulsory licence would have to be met: abuse, public necessity or national emergency.²¹

The other aspect to be considered is the time period: this must be precise and appropriate for the circumstances of a given case. Granting a compulsory licence until the termination of the patent implies depriving it of its content, as stipulated in Articles 31(a) and (c) of the TRIPS Agreement.

In the case under analysis, the time period was five years, which was later extended for an additional five-year period. Besides, as the government delivered the medicine under a compulsory licence scheme to the entire population, the market for such medicine ceases to exist for the patent holder.

In the reasonableness judgment, a question arises first whether the political measure of the Brazilian Government fulfilled a constitutional and socially relevant purpose. This was undoubtedly the case, as it is necessary to cater for the health of the population affected.

Then, the political decision is also appropriate when it comes to the ratio between means and the purpose sought, as the purpose originally envisaged by the governor or legislator is achieved. Indeed, by achieving a reduction of prices there are more chances to achieve the universal treatment of affected patients.

http://www.cedin.com.br/revistaeletronica/volume4/arguivos_pdf/sumario/art_v4_XII.pdf

²¹ In all cases in which a compulsory licence was granted, the parties first had to attempt to obtain a voluntary licence (Section 31 of the TRIPS Agreement). This requirement was apparently met by the Brazilian Government, which made a specific petition: the price paid by Thailand. According to Pires de Carvalho, the Brazilian Government indicated that the licence was granted by virtue of its public and non-commercial use. In truth, the requirement would have sufficed, so as to avoid preliminary negotiations (TRIPS Article 31.(b)). The Government received an offer by MSD that it approved. Pires de Carvalho, *The TRIPS Regime of Patent Rights*, 445. The Brazilian policy brought about significant changes in access to retrovirals. Savings are said to amount to US\$400 million a year, through a reduction of prices. This information is provided by Sigrid Sterckx, 'Lack of Access to Essential Drugs: a Story of Continuing Global Failure, with Particular Attention to the Role of Patents' in Christian Lenk, Nils Hoppe and Roberto Andorno (eds), *Ethics and Law of Intellectual Property - Current Problems in Politics, Science and Technology* (Ashgate 2009) 175, 177.

Third, it must be verified whether those prescriptions are necessarily required or not, and whether those are the only method available to such an end. The answer is not so simple in this case. The state has undertaken to provide a system-wide sanitary coverage. To this end, estimates need to be made in keeping with the budget and resources available. Considering the terms under which the government sets out the requirement, there are apparently no resources for the purchase of medicines, when, in fact, the core of the argument concerns the savings obtained. The situation of Brazil seems to be totally different from that of African countries, or even the case of Thailand, a country chosen as a benchmark by the Ministry of Health of Brazil.

Ultimately, the means utilized should be the one that least undermines the rights of other players involved and is the least detrimental. This last aspect is not easy to evaluate in a litigation process. The way a government administers its resources is not subject to revision by the courts. In developing countries where there is a significant need for education, security, health, housing and the like, health expenses compete against the appropriation of resources. In poorer countries, the combination of needs and interests will be a different one. After all, priorities are not to be ascertained by judges, as the task of distribution is not inherent to them, but to the other powers of the State.²²

The work that is within the scope of the judge or court is to ensure that there is no infringement of a right that was originally granted. In that case, the right of a patent holder to receive compensation is contested.²³ In this respect, the author's opinion is

²² The appropriation of resources is a very complex task. Budgetary allocations must be jointly conducted by the executive and judicial branches. It is not an action that, in principle, should be in the hands of the judiciary. Still, if a right has been granted, and a budgetary allocation is required for its exercise or enjoyment, a judge can step in to enforce such performance against other branches of government, either individually or collectively. Such was the holding of the Argentine Supreme Court in *Hospital Británico de Buenos Aires c/ Estado Nacional (Ministerio de Salud y Acción Social)*. 13/03/2001. Fallos 324:754. See also 300:1282; 301:771; 251:53; 'Ramos, Marta Roxana y otros c/ Buenos Aires, Provincia de y otros s/ amparo' 12/03/2002, Fallos 325:396.

²³ Although Flanagan and Whiteman state that granting the compulsory licence was due to the abuse on the part of MSD, I have not found any debate or grounds being raised by the Brazilian Government to support such a position. According to Flanagan and Whiteman in 'AIDS is Not a Business: A Study in Global Corporate Responsibility – Securing Access to Low-cost HIV Medications' (2007) in *Journal of Business Ethics* 73: 65, what was actually being challenged here is a 'necessary' savings to suit customers'

negative. Saving is not a sufficient motive to violate a right. Invoking necessity is simply not enough; rather, a well grounded argument process is required.²⁴

The fourth question that arises is whether the decision is proportionate, that is, whether there is a sound balance between the results derived from the prescription and the impediments thereby obtained. In this respect, the aim is to determine whether this is the best solution, rather than the only one. The intended purpose is assisting a universe of patients who are under the wing of the State. What is being prevented is profiting from the patent in an economic sense, except for the limited royalty earned by the compulsory licence. MSD is prevented from selling its product directly. If the government catered for the needs of all the population for free, there would be no market available, whatever the price may be.²⁵

needs. Such was the action undertaken by the Ministry of Health, when considering that the success of the anti-AIDS campaign had many advantages from the point of view of low morbidity of patients. Further, the overall outcome has been a positive economic result. As stated in the Commission on Intellectual Property Rights (CIPR), *Integrating Intellectual Property Rights and Development Policy* (London 2002 <<http://www.iprcommission.org>>), 42:

So, although the NSAP is expensive, the costs avoided due to reduced illness, hospitalization and other impacts of HIV/AIDS are beginning to balance the budget. The MHB estimates that in 2001, the final cost of NSAP, incorporating reduced morbidity expenditure, was negative.

²⁴ The professional literature that usually justifies the application of a compulsory licence focusses on the lack of economic capacity to assist patients, as stated in Hestermeyer, *Human Rights and the WTO – The Case of Patents and Access to Medicines*, 138. That was not the case in Brazil. Comparing the prices of generic drugs with the original drugs, without considering the cost of development and without assuming the external nature of the research, is a clearly insufficient comparison and derived from a political discourse. The other aspect to be considered is the distinction between discretionary powers and arbitrariness, but that topic goes beyond the purpose of this paper.

²⁵ In the absence of sales, the 1.5 per cent royalty is not proportionate. There is a wide gap between the usual maximum royalty for voluntary licences in this field, which is closer to 15 per cent and the government proposal. The parties could have also raised the issue of calculating the royalty. By considering the few existing cases of compulsory licences, 1.5 per cent is too low and does not meet the standard of TRIPS Article 31(h), which stipulates that the 'economic value of the authorization' must be considered. See Hestermeyer, *Human Rights and the WTO – The Case of Patents and Access to Medicines*, 247.

The fifth aspect to be addressed is whether the political measure respects the essential content of the right. In that case, the intellectual property of the patent holder is at stake. Although compulsory licences potentially limit the right of the holder to commence operations, a fair compensation must be awarded.

Lastly, it is worth asking whether the measure is to be included within the reasonable operative sphere of such right. This refers to the right of the government to claim a given price or else allow for the manufacturing or importation by third parties that can meet this budgetary demand. The government's duty to provide free assistance to patients is not being challenged, but achieving the goals of the sanitary policy does ultimately affect the right to property. Needless to say, the state has its own discretionary margin. The problem lies in finding the limit without allowing for arbitrariness.

Ultimately, after applying a reasonableness analysis, the author's opinion is negative. The lack of an appropriate procedure and the reduced amount of the royalty are at the core of the discussion. Even more debatable and which typically belongs to the sovereign political power of Brazil, is the allocation of resources to health, particularly AIDS drugs, against hundreds of budgetary options for the distribution of honours, rank and wealth.

V. CONCLUSION: THE THREE-STEP RULE AS A MANIFESTATION OF THE ESSENTIAL CONTENT OF RIGHTS

The proportionality test that the author applied to the Efavirenz case, is generally thought to be made up of three steps:

- (a) The adaptation of the means chosen for the accomplishment of the aims sought;
- (b) the necessity to resort to these means for achieving the goal (i.e. ensuring that there are no other means conducive to that end and which may be less detrimental to potentially affected constitutional principles; and
- (c) the proportionality - in a strict sense - between the means and ends and that the principle satisfied by meeting such end will not sacrifice more important constitutional principles.

Both compulsory licences granted under Article 30 and other measures adopted by virtue of Article 8 of the TRIPS Agreement must be analysed as particular applications of the three-step rule or application of the proportionality judgment to the specific

problem.²⁶ As a conclusion, the author considers that, in the current state of economy of knowledge and productive and sanitary systems, patents are necessary for the better health of the population. However, it is evident that, given emergency situations, or in the absence of a market, patents can make it difficult to access medicines that derive from a system of global innovation. The absence of a market is particularly relevant in communities unable to afford those medicines, either during a specific crisis, or as a result of an endemic problem, particularly when incomes of the population to which medicines are addressed are recurrently low. The situation is more serious and its solution is not an easy one, especially when needed medicines are still being developed for diseases that currently have no cure. In the absence of a future market, the necessary investments are scarce to find a cure.

Compulsory licences imply a waiver to patents, at least during the persistence of a crisis. As this is a mechanism laid down in international agreements and local legislations, a solution derived from consensus can be found there, which may amount to the harmonization so vigorously intended. Although cases of application of the proportionality principle have not emerged so far, this would be the mechanism that should enable us to verify whether the compulsory licence has achieved a balance of rights in a given case. For that purpose, a case-by-case analysis must be undertaken, in order to determine whether the premises for regulation are present and whether fair compensation is provided.

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²⁶ Helfer, 'Intellectual Property and the European Court of Human Rights' 73.

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2 DEFICIENCIES OF EXISTING SYSTEMS FOR THE TAKEDOWN OF COPYRIGHT INFRINGING CONTENT HOSTED ON THE INTERNET IN BOSNIA AND HERZEGOVINA AND PROPOSED SOLUTION

Haris Hasić*

ABSTRACT

The growth of the Internet increases the likelihood of copyright infringement online. Copyright holders need a quick and efficient mechanism for taking down infringing content. In Bosnia and Herzegovina (B&H) there is no such suitable mechanism. This article reviews and finds the existing B&H mechanisms deficient. The first method, petitioning the infringer, is based on voluntary cooperation by the infringer and is thus not practicable. Petitioning the courts is unsuitable because the B&H court system is complicated for the average person, overburdened with cases, unacceptably slow to process claims when time is essential, and the judges do not possess sufficient knowledge and experience in intellectual property cases. Petitioning the Internet Host Service Providers (IHSPs) is not suitable because, though ideally placed to help, the IHSPs are shielded by broad and confusing safe harbour provisions and, due to legal uncertainty, do little, which aids their customer (the infringer). This article also examines the EU and US takedown mechanisms and finds that, due to an inherent bias either toward the alleged infringer or toward the copyright holder, both are prone to uncertainty and widespread abuse. The article suggests that such abuse could be avoided by introducing a neutral intermediary. For B&H that intermediary should be the Institute for Intellectual Property of B&H. Some of the advantages of this proposed system are impartiality, legal certainty, advisory capacity and centralization, among others.

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Keywords: *copyright infringement, Internet, hosting, notice and takedown, intermediary, Institute*

I. INTRODUCTION

The Internet is an ever more prominent medium of social exchange and social expression in B&H¹ and in the world.² The Internet is evolving such that posting content is easier for the average user.³ This facilitates the posting of copyright infringing content as well. At the same time, effective methods of removing infringing content from the Internet, as this article will demonstrate, do not exist, at least not in B&H.

It is incumbent on the developing nations to ensure that copyright is sufficiently protected on the Internet to stimulate the flourishing of creative expression on this medium, which can be an important part of prosperity.

One instance of copyright infringing content placed on the Internet can be accessed by countless users, who, in turn, can make countless reproductions of the work in any part of the world, significantly reducing the economic value of the existing right and work. Thus, from the perspective of the right holder, the first priority must be to remove the infringing content as expeditiously as possible. Once, and only once, the infringing content is removed from the Internet can the copyright holder pursue sanctions through the existing enforcement mechanisms.

As this article will demonstrate, a copyright holder in B&H does not have any such mechanism that will consistently ensure the timely taking down of copyright infringing content hosted on the Internet.

The first part of the article will review what options the copyright holder does have at his or her disposal in B&H. The second part will review existing notice and takedown mechanisms in the European Union and the United States. The third part will suggest a solution by using the Institute for Intellectual Property of B&H as an intermediary in the takedown process.

¹ In 2000 only 1.1 per cent of B&H's population had access to the Internet, while that number was 67.9 per cent in 2013. Source: World Bank <<http://data.worldbank.org/indicator/IT.NET.USER.P2>> accessed 29 October 2014.

² World growth of the number of Internet users from 2000 to 2014 was 676.3 per cent. Source: Internet World Stats, 'Internet Usage Statistics, The Internet Big Picture, World Internet Users and Population Stats' <<http://www.internetworldstats.com/stats.htm>> accessed 30 October 2014.

³ See Organization for Economic Cooperation and Development, Participative Web: User-Created Content (Directorate For Science, Technology and Industry Committee for Information, Computer and Communications Policy Working Party on the Information Economy DSTI/ICCP/IE(2006)7/FINAL 2007).

II. MECHANISMS CURRENTLY AVAILABLE IN BOSNIA AND HERZEGOVINA FOR REMOVING COPYRIGHT INFRINGING CONTENT HOSTED ON THE INTERNET

When copyright infringing content is hosted on the Internet, the copyright holder can:

- (a) Petition the infringer;
- (b) petition the courts; or
- (c) petition the Internet host service provider (IHSP).

A. PETITIONING THE INFRINGER

A prudent first step for the copyright holder is to petition the infringer to remove copyright infringing content that he or she has placed on the Internet. While this is not mandated by any statute in B&H, it stands to reason that at least some of the copyright infringement might have been committed as an accident or out of ignorance. Lack of knowledge and understanding of copyright rules is a significant problem in B&H.⁴ In cases of accident or misunderstanding, a simple notice to the infringer would most likely result in the removal of infringing content without the need to involve any other, more formal takedown mechanisms.

However, as compliance is strictly voluntary, the infringer can refuse to cooperate or even ignore the petition altogether. Still, any takedown method should require the copyright holder to make a good faith⁵ effort to petition the infringer prior and as a precursor to taking any other steps.

⁴ This problem is pervasive in all segments of society. As this paper will show it is also present in the courts and also in other intellectual property enforcement institutions. It is probable that this lack of knowledge can be attributed to two primary causes: (1) intellectual property is not considered particularly valuable or important by the society as a whole due to cultural and pragmatic reasons; and (2) there is very little intellectual property education and awareness at the university level and almost no formal intellectual property education at elementary and high school levels. Piracy and counterfeiting are rampant and accepted. Further research into the causes of this problem is both beyond the purview of this paper and warranted on a much more extensive level.

⁵ The term 'good faith effort' is being used as a legal standard that would need to be ascertained in every particular case. It should, however, include an effort to contact the infringer and to offer a reasonable deadline to remove the content. Because of the frantic nature of the

B. PETITIONING THE COURTS

B&H does not have specialized intellectual property courts. In the Federation of Bosnia and Herzegovina⁶, all copyright claims are processed by the business law division of municipal courts of general jurisdiction. B&H courts are not well suited for removing copyright infringing content from the Internet expeditiously, for the following reasons:

- (a) The average person cannot understand or use the courts or legal system in general;
- (b) the courts are overburdened,
- (c) judicial relief is unacceptably slow; and
- (d) the judges lack knowledge and understanding of intellectual property law.

(i) DIFFICULTY IN USING THE COURTS FOR THE AVERAGE USER

Given its peculiar nature as the by-product of a peace agreement and its varied formative legal ideologies, the Bosnian legal system is difficult to understand and use, even for legal professionals. Furthermore, in order to petition the courts for judicial relief, the copyright holder must first discover the identity of the infringer. Because infringement takes place on the Internet, the identity of the infringer can be nearly impossible to ascertain for an average citizen. If the identity of the infringer is known, the suit must be filed in the court where the infringer has his or her permanent residence. The suit must fulfil certain formal requirements.⁷ The copyright holder must also indicate the value of the claim, which is particularly difficult for online copyright infringement cases. The copyright holder must then pay filing fees on the amount being sought upfront, at the time of filing. The processing of intellectual property cases can be very expensive and time intensive.⁸ Understandably, given the

Internet, a reasonable deadline would be, for example, one working day or even potentially shorter.

⁶ B&H consists of the Federation of Bosnia and Herzegovina, Republic Srpska and Brčko District. The Federation of Bosnia and Herzegovina only has courts of general jurisdiction. Republic Srpska has specialized business law courts but no intellectual property courts.

⁷ If a case does not fulfil these requirements, the suit will be returned to the petitioner, resulting in the loss of valuable time.

⁸ In one notable yet relatively straightforward copyright case (not involving online infringement) the ratio of reward to court costs was 1:13, and it took 3.5 years to resolve the case.

urgent nature of such lawsuits, it can be difficult for the average person to handle the claim properly.

(ii) THE OVERWHELMING BACKLOG OF CASES

At the end of 2013, there were 20,120 unresolved cases at the business law divisions of the courts of the Federation of Bosnia and Herzegovina.⁹ As of 30 September 2014, the Sarajevo Municipal Court¹⁰ business law division alone had 2,409 unresolved cases¹¹ involving business trespass, business property law, business contract law or intellectual property protection. There are ten judges in the business law division.¹² The average caseload for the business law division for 2013 was 289 cases per judge.¹³

(iii) THE TIME IT TAKES TO RECEIVE JUDICIAL RELIEF

For the Sarajevo Municipal Court the 'optimal'¹⁴ timeline for resolving intellectual property cases is 210 days.¹⁵ For the purposes of removing content from the Internet this time frame is unacceptable. The fastest a case can be resolved by law is 90 days.¹⁶ This too is problematic, and neither time frame is realistic. The more realistic 'predicted' timeline for resolving a case is 912 days.¹⁷ The

average age of such pending cases is 400 days.¹⁸ From January to September 2014, 176 cases took more than 912 days to resolve.¹⁹

Under Article 160 of the Copyright and Related Rights Law of B&H²⁰, the copyright holder can ask the courts to issue a provisional measure. For copyright holders to succeed, they must prove a series of claims, including that:

- They are the copyright holder;
- a danger exists that enforcing the claim could be made impossible;
- the provisional measure is necessary to prevent the occurrence of damage; and
- the copyright holder would recompense the alleged infringers if the claim is unfounded.

It is a very legally technical rule. However, no court has issued this provisional remedy in the four years it has been available to the courts.²¹

(iv) LACK OF KNOWLEDGE AND UNDERSTANDING OF INTELLECTUAL PROPERTY CASES BY THE JUDGES

It is difficult to measure actual knowledge and understanding of the principles of intellectual property of judges. However, circumstantial evidence shows that the lack of knowledge and understanding of intellectual property on the part of judges is a real problem. In 2010 B&H adopted a set of eight new laws protecting intellectual property, notably different from the previous laws. Their understanding requires careful study. It is doubtful that given the caseloads, such careful study is being carried out by the judges. Especially as intellectual property cases are not that prominent or frequent in Bosnian courts.²² For that purpose, the Centres for

of optimal and predictable deadlines) issued by the Court Case Management System on 20 October 2014 at 14:57:36.

¹⁸ Ibid.

¹⁹ Ibid.

²⁰ Zakon o autorskim i srodnim pravima Bosne i Hercegovine (Službeni glasnik Bosne i Hercegovine 63/10).

²¹ Proving status as the copyright holder requires the issuance of a certificate by the Institute for Intellectual Property of Bosnia and Herzegovina, which can take up to 30 days. An additional 30 days must be given for processing the claim, according to private conversations with some of the judges.

²² In private conversations with the authors, judges admit that they see on average one intellectual property case a year. Only one judge admitted to seeing several intellectual

⁹ High Judicial and Prosecutorial Council of B&H, 'Visoko sudsko i tužilačko vijeće za Bosnu i Hercegovinu Godišnji izvještaj za 2013. Godinu' (Yearly report for the year 2013) <http://www.hjpc.ba/intro/gizvijestaj/pdf/VSTV_GI_2013_3_0042014.pdf> accessed 27 October 2014.

¹⁰ This is the largest municipal court in the Federation of B&H (FB&H). It is indicative of all the courts in FB&H.

¹¹ Sarajevo Municipal Court, 'Izveštaj o poštivanju optimalnih i predvidivih rokova' (Report on the Application of Optimal and Predictable deadlines) issued by the Court Case Management System on 20 October 2014.

¹² Sarajevo Municipal Court, 'Bulletin of the Sarajevo Municipal Court' (March 2014 Issue n 25) 32.

¹³ Ibid.

¹⁴ The courts of B&H have a two-tier system for deadlines to resolve pending cases. The first tier is the optimal deadline. This represents the number of days the law says this case must be resolved in. There are no sanctions for breaching this deadline. The second tier is the expected deadline. This is a more realistic expectation for how many days it actually will take to resolve the case, as calculated by the Court itself on the basis of the current caseload and on several other factors including past performance.

¹⁵ Sarajevo Municipal Court, 'Izveštaj o poštivanju optimalnih i predvidivih rokova' (Report on the application of optimal and predictable deadlines) issued by the Court Case Management System on 20 October 2014 at 14:57:36.

¹⁶ Zakon o parničnom postupku Federacije Bosne i Hercegovine (Law of Civil Procedure) (Službene novine Federacije Bosne i Hercegovine 53/03, 73/05, 19/06).

¹⁷ Sarajevo Municipal Court, 'Izveštaj o poštivanju optimalnih i predvidivih rokova' (Report on the application

Education of Judges and Prosecutors of both the Federation of Bosnia and Herzegovina and the Republic Srpska commissioned a guide for judges on intellectual property.²³ Yet, the guide is rife with errors, omissions, and misunderstandings.

One such error is demonstrative. On pages 21, 286, and 289, it is stated that Articles 120, 121, 122, 123, and 124 of the Copyright and Related Rights Law relate to criminal sanctions for copyright infringement. Articles 120, 121, 122, 123, and 124 of the Copyright and Related Rights Law instead relate to the related rights of the performer.²⁴ The courts in B&H are not an effective means of removing copyright infringing content from the Internet, at least not in a timely manner.

C. PETITIONING THE IHSP

In order for content to be hosted on the Internet, the infringer will most likely²⁵ use the services of a third party - an Internet hosting service provider (IHSP).²⁶ While the identity of the infringer can be hard, if not impossible, to ascertain in most cases, that is not the case with an IHSP. They are required by law²⁷ to make their contact information easily available. Its role as an intermediary in the infringement of copyright and this ease in

property cases a year. Additionally an examination of the Court Case Management System has revealed that currently there is less than a dozen pending intellectual property cases.

²³ Centres for Education of Judges and Prosecutors of the Federation of Bosnia and Herzegovina and Republic Srpska, 'Priručnik iz oblasti intelektualnog vlasništva za sudije' Bosnia and Herzegovina 2013

<http://www.fbih.cest.gov.ba/images/stories/dokcentra/prirucnik_iv.pdf> accessed 27 October 2014.

²⁴ The right of Remuneration for Private Use, Remuneration for Public Communication and Rental of the Fixation of Performance, Presumed Transfer to a Film Producer, Use of Performance for the Completion of an Audiovisual Work and Performance Given within the Scope of Employment respectively.

²⁵ It is possible that the infringer will use his or her own server to host content on the Internet. In those instances, the infringer will not be using the services of an IHSP for hosting, but will be using mere conduit and caching services from an IHSP, both of which do not fall under the purview of this paper.

²⁶ An Internet Hosting Service Provider for the purposes of this work will be defined as any entity that offers services directly resulting in a copyright infringing work being hosted on the Internet. For purposes of clarification, hosting is essentially providing space to store content on the Internet that can then be accessed by others.

²⁷ Article 15 of the Zakon o elektronskom pravnom i poslovnom prometu (Law on the Electronic Legal and Business Transactions) (Službeni glasnik Bosne i Hercegovine 88/07).

identification make the IHSP ideal for removing infringing content from the Internet. This was recognized by both governments²⁸ and researchers.²⁹

In B&H, IHSPs are shielded from liability for, among other things, copyright infringement for hosting infringing content. Pursuant to the provisions of Article 26 of the Law on the Electronic Legal and Business Transactions, no liability exists provided that five conditions are met:

- (a) That the IHSP itself did not post the infringing material;³⁰
- (b) that the IHSP does not have reliable cognition of the infringement;
- (c) that the IHSP is not familiar with any facts or circumstances from which the infringement is obvious;
- (d) that the IHSP begins the process of removing or disabling access to the infringing material in question as soon as the IHSP is informed or receives cognition of infringement; and
- (e) that the service user is not subordinated or under the supervision of the IHSP.

Article 26 does not provide, *per se*, a concrete set of steps that must be followed in order for the copyright holder to petition the IHSP to take down copyright infringing content. Rather, it provides the IHSP with a safe harbour from prosecution for hosting infringing content if it removes such content upon learning of its infringing nature. If the IHSP does not act to remove content upon gaining reliable cognition or upon being presented with facts or circumstances from which infringement is obvious, the IHSP becomes liable for copyright infringement.

²⁸ Recital 59 of the Directive (EC) 29/2001 on the harmonization of certain aspects of copyright and related rights in the information society (Infosoc directive) [2001] OJ L167/10: In the digital environment, in particular, the services of intermediaries may increasingly be used by third parties for infringing activities. In many cases such intermediaries are best placed to bring such infringing activities to an end.

²⁹ For one such example see J de Beer and CD Clemmer, 'Global Trends in Copyright Enforcement: A Non-Neutral Role for Network Intermediaries?' (2009) <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1529722> accessed 28 October 2014.

³⁰ This eliminates all those possible instances where the infringer is itself the IHSP.

It is uncertain what exactly constitutes reliable cognition or what is to be taken as facts or circumstances from which the infringement is obvious. No case has addressed this issue. Additionally, no legislative or administrative guidance on interpreting these provisions exists. This results in a high degree of legal uncertainty, which favours the infringer.

In straightforward cases³¹, a petition to the IHSP will most likely result in the removal of the content. If the slightest doubt exists, however, the IHSP can always claim that it did not have reliable cognition, or that there was uncertainty, which made infringement non-obvious. With that, it can be assumed that the IHSP will be biased in favour of the service user. Unless it is compelled, the IHSP will most likely err in favour of its user and direct the copyright holder to seek judicial relief. It seems clear that the IHSP, and not the infringer, should remove the infringing content from the Internet. However, the existing rules are biased in favour of the IHSP and the infringer.

III. COMPARATIVE LAW APPROACHES FOR TAKING DOWN COPYRIGHT INFRINGING CONTENT HOSTED ON THE INTERNET

In B&H the copyright holder does not have an effective method available to remove infringing content from the Internet in a timely manner. A working system must be implemented if B&H wants to reap the benefits of creative endeavours.

In order to determine what system B&H should implement, this article examines two of the most prominent approaches, the EU and the US takedown mechanisms.

A. EU TAKEDOWN MECHANISM

Acquis communautaire³² does not have a specific takedown mechanism for removing copyright infringing content from the Internet. It has a 'horizontal approach to Internet service liability'³³, as found in the EU Electronic Commerce Directive.³⁴

³¹ If, for example it is blatantly obvious from the work itself who the author is or if the infringer makes it obvious that the right holder is someone else.

³² The combined body of European Union Law.

³³ P Baistrocchi, Liability of Intermediary Service Providers in the EU Directive on Electronic Commerce, 19 Santa Clara High Tech LJ 111 (2002) available at: <http://digitalcommons.law.scu.edu/chtli/vol19/iss1/3> accessed 29 October 2014 117.

³⁴ Directive (EC) 31/2001 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce) [2000] OJ L 178/1.

Article 26 of the Law on Electronic Legal and Business Transactions of B&H adopts³⁵ Article 14 of the EU Directive on electronic commerce. B&H essentially copied the EU rules, but poorly.³⁶

Though there is some guidance for the interpretation of Article 14 by the European Court of Justice³⁷, the EU model encourages self-regulation on the part of the IHSPs.³⁸ This self-regulation to date has failed to produce an effective system. It introduces uncertainty on the part of all actors, and, as was seen in Bosnia, uncertainty tends to favour the infringer. In practice a multitude of often vary different procedures exist and it is not easy, either for intermediary service providers or for victims of illegal content, to determine which one applies and in what way.³⁹ Problems with the Article 14 mechanism were evident in the results of the public consultation that was conducted in 2010.⁴⁰ This was echoed by the researchers⁴¹ and by judges.⁴²

³⁵ B&H is not a member of the European Union and thus does not have the obligation to adopt EU directives, but it does so with the aim of joining the European Union.

³⁶ There is a tendency in B&H to adopt legislation without understanding it or without adapting it, where possible, to the needs and peculiarities of the Bosnian legal system. There is also a tendency to create translation errors in the adoptions. In this instance, where Article 14 of the Directive uses the standard of 'actual knowledge' which should have been translated as 'stvarno znanje' the translated term used is 'pouzdana saznanje' which translates as 'reliable cognition', thus potentially making the *acquis* incompatible with B&H law and hence defeating the purpose of the transposition and depriving itself of EU legal experience on this matter.

³⁷ See for instance Case C-324/09 *L'Oréal v eBay* [2011] 2011 I-0601; recital 49 of the Directive on electronic commerce; recital 29 of the Directive (EC) 48/2004 on the enforcement of intellectual property rights [2004] OJ L 195/16; recital 52 of the Infoc directive.

³⁸ See recital 49 of the Directive on electronic commerce.

³⁹ European Commission, Online Services, Including e-Commerce in the Single Market (Commission staff working document SEC (2011) 1641 final 2012) 25.

⁴⁰ European Commission, Summary of the results of the Public Consultation on the future of electronic commerce in the Internal Market and the implementation of the Directive on electronic commerce (2000/31/EC) available at http://ec.europa.eu/internal_market/consultations/docs/2010/e-commerce/summary_report_en.pdf accessed 29 October 2014 ch 5; European Commission, *E-commerce Action Plan 2012-2015 State of play 2013* (Commission staff working document SWD (2013) 153 final) 17: 'In particular they considered that there is too much regulatory fragmentation and legal uncertainty, growing costs due to inefficiencies, too many instances of too slow action against illegal content and instances of action against legal content.'

⁴¹ For one example see T Verbiest and others, 'Study on the Liability of Internet Intermediaries' (European Commission

As a result, the European Commission has decided to work on improving the Article 15 takedown mechanism.⁴³ The EU system for taking down infringing content is itself deeply flawed and in need of an overhaul.

B. US TAKEDOWN MECHANISM

Unlike the European Union, the United States has opted for a vertical approach⁴⁴ to IHSP liability and adopted a separate and special notice and takedown regime in Section 512⁴⁵ of the United States Copyright Act of 1976.⁴⁶ It sets out a clear notice and takedown procedure for the copyright holder to use upon discovery of infringing content being hosted on

the Internet, that if followed by the IHSP, creates a safe harbour from secondary liability for the IHSP.⁴⁷

Some have credited Section 512 as making the modern Internet possible.⁴⁸ In October 2014 Google alone received requests for the removal of 35,436,492 URLs.⁴⁹ For Google, use of notice and takedown requests has been on a constant and sometimes exponential rise.⁵⁰ However, the US Section 512 system is flawed in that copyright holders⁵¹ can exploit it for non-valid copyright reasons and for reasons other than copyright protection.⁵² This trend is expected to continue as

Markt/2006/09/E Service Contract ETD/2006/IM/EZ/69) [2007] available at http://ec.europa.eu/internal_market/e-commerce/docs/study/liability/final_report_en.pdf 14,15; See, in particular:

Providers as technical intermediaries, cannot always handle and assess complex legal matters. Whilst in some cases it might be easy to assess the illegality of contents or activities, such as those dealing with pedophilia, it is quite hard, even for lawyers, to tell if a trademark or a copyright has been infringed.' (p 14)

And also see: '... if providers are to act upon mere notifications there could be potential abuse by fictitious 'victims' seeking to hamper competitor or adversary.' (p 15).

⁴² *Cartier v B Sky B* [2014] EWHC 3354 (Ch) [199] – [204].

⁴³ European Commission, E-commerce Action Plan 2012-2015 State of Play 2013 (Commission staff working document SWD (2013) 153 final) ch 3.1.

⁴⁴ P Baistrocchi, Liability of Intermediary Service Providers in the EU Directive on Electronic Commerce, 19 Santa Clara High Tech LJ 111 (2002) available at: <http://digitalcommons.law.scu.edu/chtli/vol19/iss1/3> accessed 29 October 2014 117.

⁴⁵ Adopted as Online Copyright Infringement Liability Limitation Act (Official title: To amend title 17, United States Code, to implement the World Intellectual Property Organization Copyright Treaty and Performances and Phonograms Treaty, and for other purposes, as part of the Digital Millennium Copyright Act), came into force on 28 October 1998, part of the Digital Millennium Copyright Act (Official title: To amend title 17, United States Code, to implement the World Intellectual Property Organization Copyright Treaty and Performances and Phonograms Treaty, and for other purposes) or Digital Millennium Copyright Act, 17 U.S.C. § 512.

⁴⁶ Official title: An Act for the general revision of the Copyright Law, title 17 of the United States Code, and for other purposes, effective as of 1 January 1978.

⁴⁷ For more see CR Gellis, *Navigating the DMCA* 1 August 2012) Internet Law for the Business Lawyer 2nd Ed ABA Publishing 2012 available at SSRN <http://ssrn.com/abstract=2191013> accessed 29 October 2014 and CR Gellis, *2013 State of the Law Regarding Internet Intermediary Liability for User-Generated Content* (1 November 2013) available at SSRN <http://ssrn.com/abstract=2388943> or <http://dx.doi.org/10.2139/ssrn.2388943> accessed 29 October 2014; See also E Lee, *Decoding the DMCA Safe Harbours* (27 January 2009) Columbia Journal of Law and the Arts Forthcoming available at SSRN <http://ssrn.com/abstract=1333709> or <http://dx.doi.org/10.2139/ssrn.1333709> accessed 29 October 2014.

⁴⁸ David Kravets, '10 Years Later, Misunderstood DMCA is the Law That Saved the Web' (Wired, 27 October 2008) <http://www.wired.com/2008/10/ten-years-later/> accessed 29 October 2014, in particular 'Blogs, search engines, e-commerce sites, video and social-networking portals are thriving today thanks in large part to the notice-and-takedown regime ushered in by the much-maligned copyright overhaul.'

⁴⁹ Google, 'Transparency Report'

http://www.google.com/transparencyreport/removals/copyright/?hl=en_US accessed 29 October 2014.

⁵⁰ Google, 'How Google Fights Piracy' (September 2013) <https://docs.google.com/a/pfk.edu.ba/file/d/0BwxyRPFduTN2dVFqYml5UENueUE/edit> accessed 29 October 2014.

⁵¹ JM Urban L Quilter, 'Efficient Process or Chilling Effects'? Takedown Notices under Section 512 of the Digital Millennium Copyright Act Summary Report' <https://images.chillingeffects.org/Urban-Quilter-512-summary.pdf> accessed 29 October 2014. For full report see JM Urban and L Quilter, 'Efficient Process or "Chilling Effects"? Takedown Notices Under Section 512 of the Digital Millennium Copyright Act' (23 May 2006) Santa Clara Computer and High Technology Law Journal Vol 22 p 621, 2006 available at SSRN <http://ssrn.com/abstract=2210935> accessed 29 October 2014.

⁵² Some of these abuses are so egregious that some websites have Takedown Notice Hall of Shames, such as Electronic Frontier Foundation, 'Takedown Hall of Shame' <https://www.eff.org/takedowns> accessed 29 October 2014 and Wordpress, 'Hall of Shame' <http://transparency.automattic.com/tag/hall-of-shame/> accessed 29 October 2014; Ernesto, 'Google Discarded 21,000,000 Takedown Requests in 2013' (Torrentfreak 27

some copyright holders admit to using automated systems to send notice and takedown requests.⁵³ Widespread abuse of the Section 512 mechanism has led to the formation of the Chilling Effects website for the monitoring of notice and takedown requests.⁵⁴ Copyright holders are not fully satisfied with the existing system either.⁵⁵ Both the EU and US systems have significant problems. Thus they cannot be recommended for use, as in B&H.

IV. INSTITUTE FOR INTELLECTUAL PROPERTY OF BOSNIA AND HERZEGOVINA AS INTERMEDIARY

The EU system creates uncertainty and favours the infringer, while the US system favours the copyright holder. Both are open to abuse due to a distinct lack of review and oversight by a neutral third party. For B&H that intermediary could and should be the Institute for Intellectual Property of Bosnia and Herzegovina (The Institute). The Institute⁵⁶ is a special industrial property service within the

December 2013) <<https://torrentfreak.com/google-discarded-21000000-takedown-requests-in-2013-131227/>> accessed 29 October 2014; Google, 'Transparency Report: Government removal requests continue to rise' (Official Blog, 19 December 2014)

<<http://googleblog.blogspot.com/2013/12/transparency-report-government-removal.html>> accessed 29 October 2014 'Over the past four years, one worrying trend has remained consistent: governments continue to ask us to remove political content.'

⁵³ Mitch Stoltz, 'In Hotfile Docs, Warner Hid References to "Robots" And Its Deliberate Abuse of Takedowns' (Electronic Frontiers Foundation Deeplinks Blog 9 October 2014) <<https://www.eff.org/deeplinks/2014/10/hotfile-docs-warner-hid-references-robots-and-its-deliberate-abuse-takedowns>> accessed 29 October 2014.

⁵⁴ Berkman Centre for Internet and Society at Harvard, 'About Us' <<https://www.chillingeffects.org/pages/about/>> accessed 29 October 2014.

⁵⁵ See S Aistars, 'Statement for the Record of Sandra Aistars, Chief Executive Officer, Copyright Alliance, Section 512 of Title 17 before the Judiciary Committee's Subcommittee on Courts, Intellectual Property and the Internet' (Copyright Alliance 13 March 2014)

<https://copyrightalliance.org/2014/03/statement_copyright_alliance_ceo_sandra_aistars_committee_judiciary_subcommittee_courts> accessed 29 October 2014, in particular: 'It is incontrovertible that roughly fifteen years after its passage, the DMCA is not working as intended either for the authors and owners of copyrighted works who rely on its notice and takedown and repeat infringer provisions to reduce infringement of their works, nor for the website operators who must respond to the notices sent. When authors are forced to send upwards of 20 million notices a month to a single company— often concerning the same works and the same infringers—something is amiss.'

⁵⁶ Founded by the Zakon o osnivanju Instituta za intelektualno vlasništvo Bosne i Hercegovine (Službeni glasnik BiH 43/04) (Law Establishing the Institute for Intellectual Property of Bosnia and Herzegovina).

meaning of Article 12 of the Paris Convention⁵⁷ for B&H and the central B&H administrative institution for intellectual property.⁵⁸

A. REASONS FOR USING THE INSTITUTE AS AN INTERMEDIARY

As a government institution, the Institute would be neither prejudiced toward the interests of the copyright holder, nor have a particular reason to favour the alleged infringer. Furthermore the Institute would consider the interests of the IHSP, the interests of legitimate users and the society as a whole. The Institute is tasked with observing and ensuring the balance of rights and interests inherent in intellectual property law. Thus the Institute would be a neutral filter, allowing only those notices based on law, while at the same time bringing certainty to the proceedings.

Lack of knowledge and understanding of copyright law is a significant problem in the process of removing infringing material.⁵⁹ The Institute, on the other hand, understands copyright law. It drafted the Copyright and Related Rights Law of B&H⁶⁰ and has direct jurisdiction in matters of copyright.

The Institute centralizes and focusses the activity of taking down copyright infringing content from the Internet. This centralization brings several benefits to the process: increased coordination with IHSPs, other enforcement bodies, right holder associations, user associations, the judiciary and other significant entities in various activities; and the ability to maintain a database of repeat offenders and all notices and takedowns, akin to the Chilling Effects website, but potentially with a fuller dataset⁶¹, open to research and analysis, with appropriate safeguards.⁶²

⁵⁷ Paris Convention for the Protection of Industrial Property (as amended in 1979).

⁵⁸ Institute for Intellectual property of Bosnia and Herzegovina, 'Jurisdiction' (14 June 2011) <<http://www.ipr.gov.ba/en/o-nama-en/nadleznost-en.html>> accessed 30 October 2014 based on Article 7 of BH Institute Law.

⁵⁹ See Section 2.1.

⁶⁰ Ibid.

⁶¹ Chilling Effects does not receive all notice and takedown requests and participation is voluntary.

⁶² One of the criticisms of Chilling Effects is that it could potentially be used to find and use infringing content. See S Aistars, 'Statement for the Record of Sandra Aistars, Chief Executive Officer, Copyright Alliance, Section 512 of Title 17 Before the Judiciary Committee's Subcommittee on Courts, Intellectual Property and the Internet' (Copyright Alliance 13 March 2014)

The Institute's official governmental role benefits the process. It is staffed by highly qualified government officials who are well versed in the nuances of the legal system of B&H. All actions of the Institute are transparent because citizens have a guaranteed freedom to access information about it. Additionally, the Institute is subject to constitutional checks and balances, making abuse of the process unlikely. A mechanism exists to address such abuse as well.

The Institute could advise the copyright holder prior to filing the takedown notice about his or her rights, the limitation of such rights, and what steps to take. After filing, the Institute can advise IHSPs and alleged infringers of their rights and any possible defences. If the copyright infringing content is hosted in a different country, the Institute would be ideally suited to understand that country's takedown procedures and navigate intergovernmental cooperation. The Institute could also advise the copyright holder on issues pertaining to the lawsuit and subsequent trial, and advise⁶³ the IHSP on what evidence to preserve and in what way.

Being an intermediary would be a potential source of revenue for the Institute and the budget of B&H in the form of fees paid for services rendered.

B. THE PROPOSED TAKEDOWN PROCEDURE WITH THE INSTITUTE AS INTERMEDIARY

Bosnia and Herzegovina should introduce a concrete takedown procedure⁶⁴ for removing copyright infringing content from the Internet with the option⁶⁵ for the copyright holder to use the Institute as an intermediary.

The copyright holder should always initiate the procedure.⁶⁶ Upon discovering infringement of copyright protected material hosted on the Internet, the copyright holder should make a good faith effort to petition the infringer and, in straightforward cases

where there is no likelihood of confusion⁶⁷, the IHSP.⁶⁸ If the petition does not work, the copyright holder should submit the takedown notice to the Institute. It would be the duty of the copyright holder to present all the procedurally mandated information for the processing of the notice and to pay a reasonably small fee.

A special department would be created within the Institute to deal with the takedown requests. Upon receipt of the takedown request, the Institute would review the notice. Only those notices with an actual basis in the rules of Copyright law would be allowed to proceed to the next stage. By reviewing the notice, the Institute would be able to filter abuses and bad faith notices. A system would need to be in place to sanction bad faith abuses.⁶⁹

If the takedown notice is warranted, the Institute would notify the IHSP and request removal. This notification would, beyond a doubt, represent reasonable cognition under Article 26 of the Law on Electronic Legal and Business Transactions. Depending on the review and the nature of the problem, the Institute would give a short, reasonable deadline for compliance.⁷⁰ The Institute would instruct the IHSP to preserve certain evidence for use in a court of law. If the IHSP fails to comply, the Institute would advise the copyright holder on further legal remedies against the infringer and, due to its secondary liability, the IHSP. The Institute could also notify relevant regulatory bodies of the lack of cooperation on the part of the IHSP. If the IHSP complies, the infringing content is taken down and the Institute would advise the copyright holder on potential legal remedies against the infringer.

The Institute is not usurping the courts here, but its actions might actually reduce the burden on the courts. Any and all pre-existing legal measures are still available to their respective parties. Additionally there exists further judicial and administrative oversight of the work of the Institute.

<https://copyrightalliance.org/2014/03/statement_copyright_alliance_ceo_sandra_aistars_committee_judiciary_subcommittee_courts> accessed 29 October 2014.

⁶³ Such as advising the copyright holder on the nuances of the law and on best practices.

⁶⁴ With elements similar to the 17 U.S.C. § 512.

⁶⁵ The copyright holder would not be mandated to use the Institute as an intermediary. The copyright holder merely would have the option of either using the existing systems or asking the Institute to be the intermediary in the takedown process.

⁶⁶ The Institute should never have to be tasked with monitoring for copyright infringement. This is not in line with the private civil right nature of copyright. It is a task much better suited for commercial ventures.

⁶⁷ For instance if the name of the author is visible in the work, pursuant to Article 10 of the Copyright and Related Rights Law, or if it is abundantly and undoubtedly clear from the circumstances that the content being hosted is infringing material.

⁶⁸ In those cases, the IHSP would have to report the takedown request to the Institute for reasons of inclusion in the official database.

⁶⁹ Perhaps a register similar to the one of the infringers, a monetary fee, automatic dismissal of takedown notices for a period of time, or a combination of all of these.

⁷⁰ One business day seems reasonable, though it could be shorter.

C. SCALABILITY PROBLEM WITH USING THE INSTITUTE AS AN INTERMEDIARY

The biggest potential problem with using the Institute as an intermediary may be the issue of scaling. Could the system process ever increasing numbers of takedown requests?

The true scope of the need for a takedown procedure in B&H is not known as of yet.⁷¹ It is reasonable to conclude that the number of the requests will grow. This system might not be ideal for large countries or for developed nations. It would be worth researching if some parts of the system might be used to augment and improve existing systems and in what ways. It might be worth researching whether private venture intermediaries could be used to augment takedown mechanisms, but the focus would have to be on mechanisms for ensuring impartiality and transparency.

V. CONCLUSION

When a copyright holder discovers copyright protected content hosted on the Internet without his or her approval, the primary concern is to remove such infringing content as quickly as possible. If copyright law is to remain relevant in the digital age, it must provide the copyright holder with an effective and expeditious mechanism for taking down all infringing instances of copyright protected works.

Bosnia and Herzegovina does not have such mechanisms. Petitioning the infringer is not likely to bring about the desired outcome. The courts are particularly complicated to use, overburdened with cases, take far too long, and are inadequately knowledgeable of intellectual property matters to be of use. The IHSPs are ideally suited, being the intermediaries between the infringer and the rest of the world and technical enablers of the infringement itself, but the current system does not compel them to act and so the system and the IHSP conspire to aid the infringers through inaction or inadequate action.

Both the EU and US takedown systems have deep flaws related to their bias in favour of either the infringer or the copyright holder. One method to remove bias is to introduce an impartial third party to mediate the takedown process. For B&H such an intermediary should be the Institute. It would be

⁷¹ Research has failed to yield one such example of a request for removal under the current regime. This however cannot be taken as indicative. The author has had need of such a system several times already this year as have friends and acquaintances, who all find the current system unusable.

impartial, knowledgeable, centralized, and governmentally sectioned, as well as a source of revenue. The potential problem with using the Institute is the issue of scalability and lack of experience with such a practice.

Even if the proposed solution proves to be unworkable, one thing remains certain, that is, if copyright is to remain relevant in the digital age it must adapt and find ways to protect the inherent balance of the interests of all parties involved.

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3 PROTECTION AND REGULATION OF HIGHLY RENOWNED TRADEMARKS - A BRIEF OVERVIEW OF RECENT DEVELOPMENTS IN BRAZILIAN TRADEMARK LAW

DR ENZO BAIOCCHI*

ABSTRACT

This article analyses Brazilian legislation for protecting and regulating highly renowned trademarks in Brazil ('*marcas de alto renome*'). It aims to examine the problems arising from the interpretation and enforcement of Brazilian Intellectual Property Law and the latest Brazilian Patent and Trademark Office Resolution. It will then demonstrate possible legislative solutions that may be implemented to bring about improved and more effective protection and regulation of this special type of trademark in Brazil.

Keywords: *Brazilian trademark law, highly renowned trademarks, protection and regulation*

I. INTRODUCTION

The age of the global market economy and the information society has brought with it the increased potential for the infringement of intellectual property rights, especially in the field of trademark law. It has also led to a paradigm shift in the protection and enforcement instruments worldwide. Whilst more attention should be given to the protection and enforcement of intellectual property, there must be an equal balance of the interests of trademark owners, competitors, and consumers.¹

Protection against misappropriation and interference in the distinctive character of highly renowned trademarks is one of the basic components of any modern trademark law system. This is particularly true in the case of extended trademark protection for dissimilar goods or

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¹ See Enzo Baiocchi, *Der Schutz Bekannter Marken unter besonderer Berücksichtigung der zivilrechtlichen Sanktionen* (Carl Heymanns 2012) 441; Mônica C R Morgado, *Marcas de Alto Renome* (Juruá 2013) 63.

services, where it can be assumed that the goodwill and distinctiveness of a trademark are not only worthy of protection, but also especially vulnerable.

Indeed, this shows that highly renowned trademarks do not just play a special role in the 'classic' market economies of industrialized countries. They are developing an increased economic and legal importance, particularly in emerging markets such as the so-called 'BRIC' group of countries to which Brazil belongs. Special protection for highly renowned trademarks has now acquired even more legal and economic relevance in Brazil as a result of the substantial legal problems arising from the 2014 FIFA World Cup and 2016 Olympic Games, including trademark piracy and infringement, misrepresentation, and especially ambush marketing.²

This brief study will analyse the protection and regulation of highly renowned trademarks ('*marcas de alto renome*') in Brazil, provided by Article 125 of the Brazilian Industrial Property Law (BIPL) and Brazilian Patent and Trademark Office (BPTO) Resolution No. 107 dated 19 August 2013, as well as the problems arising from their interpretation and enforcement.³ This analysis will provide possible legislative solutions that may be implemented, in order to achieve improved and effective protection and regulation of this special kind of trademark protection, looking to other trademark law systems worldwide for comparison.

² See recent cases, for instance, *CBF v Retrô Mania* 3 July 2014 (3rd Commercial Court of First Instance, Court of Justice of Rio de Janeiro, Lawsuit No. 0218287-34.2014.8.19.0001); *CBF v Johnson & Johnson* 13 June 2014 (5th Commercial Court of First Instance, Court of Justice of Rio de Janeiro, Lawsuit No. 0198416-18.2014.8.19.0001); *CBF v Technos* 26 June 2013 (4th Commercial Court of First Instance, Court of Justice of Rio de Janeiro, Lawsuit No. 0217328-97.2013.8.19.0001); *CBF v Coca-Cola* 7 June 2011 (Court of Justice of Rio de Janeiro, Lawsuit No. 0383190-62.2009.8.190001); *CBF v CEF* 30 November 2010 (35th Federal Trial Court of the Second Federal Circuit, Rio de Janeiro, Lawsuit No. 2010. 02.01.007712-2). For court decisions, see José CT Soares, *Marcas notoriamente conhecidas – marcas de alto renome vs. diluição* (Lumen Juris 2010) 81.

³ According to the scope and page limit of this brief essay, a historical retrospective of Brazilian industrial property laws and trademark law doctrine in connection with the protection of famous and highly renowned trademarks will not be included. For a complete overview, see Morgado (n 2) 125; E Baiocchi, 'A proteção à marca de alto renome no Brasil', in DB Barbosa and K Grau-Kuntz (eds), *Ensaio sobre o direito imaterial – estudos dedicados a Newton Silveira* (Lumen Juris 2009) 231; Denis B Barbosa, *Proteção das Marcas* (Lumen Juris 2008) 131; Maitê C F Moro, *Direito de Marcas* (Revista dos Tribunais, 2003) 77, among others.

II. PROTECTION AND REGULATION

A. LEGAL THEORIES AND DEFINITIONS UNDER BRAZILIAN TRADEMARK LAW

Law No. 9279 of 14 May 1996 (BIPL)⁴ does not provide a definition for highly renowned trademarks ('marca de alto renome'). BIPL Article 125 states briefly that 'A trademark which is registered in Brazil and considered as highly renowned will be guaranteed special protection, in all fields of activity.' That Article is now regulated by BPTO Resolution No. 107/2013, the main provisions of which are set out below.

According to the BPTO, a sign is considered to be a highly renowned trademark, when its performance in distinguishing goods or services and its symbolic efficiency, expand beyond its original scope, thus exceeding the principle of speciality in trademark law, which looks to distinctiveness, recognition by a large portion of the public, quality, reputation and prestige, and its capacity to attract consumers as a result of its mere presence.⁵

Unlike in Europe (for instance in England, France, and Germany) and the United States, Brazilian legal literature and jurisprudence have not developed and do not advocate any special doctrine for the protection of highly renowned trademarks. Therefore, the country does not necessarily have a standard legal justification or theory for this special kind of trademark protection. On the contrary, an analysis of legal texts shows that many of the country's lawyers, judges, and scholars import foreign trademark theories such as dilution, passing off, parasitic competition, unjust enrichment, etc. and quote them indistinctly within the national legal context, without referring sometimes to the particularities of case law or the specific legal requirements of the relevant foreign theory.

Furthermore, national literature and jurisprudence both refer to positive reputation, prestige, and goodwill as attributes of so-called 'marcas de alto renome'. These expressions highlight the distinctive features of the sign, which appears as a 'symbol of quality' and whose economic and commercial value deserves special legal protection per se.⁶

⁴ English version available at: <<http://www.inpi.gov.br/images/stories/Lei9279-ingles.pdf>> accessed 31 October 2014.

⁵ Article 1 BPTO Resolution No. 107 of 19 August 2013 <http://www.inpi.gov.br/portal/artigo/resolucao_pr_n_107_2013> accessed 31 October 2014; see also Maria AC Rodrigues, 'Parecer INPI/PROC/DICONS no 054/2002, de 09/10/2002' (2004) 72 Revista da ABPI 3, 15.

⁶ Daniela A Levigard and Nilson F Silva, 'A proteção das marcas de alto renome no Brasil' (2007) 86 Revista da ABPI 41, 52.

B. LEGAL PROTECTION ACCORDING TO BRAZILIAN INTELLECTUAL PROPERTY LAW

It is worth clarifying at the very beginning that the special protection set out in BIPL Article 125 differs from that in Article 6*bis* of the Paris Convention (implemented in BIPL Article 126) and TRIPS Article 16.3, as both of these relate to the protection of well known trademarks.⁷ In addition, the previous legal provision concerning the protection of notorious trademarks ('marca notória'), in accordance with Article 67 of the former Brazilian Industrial Property Act, Law No. 5772 of 21 December 1971, abrogated by Law No. 9279 of 14 May 1996), differs. As demonstrated below, BIPL Article 125 introduced a new legal concept to Brazilian trademark law - the 'marca de alto renome'—especially with regard to the legal requirements related to its practical implementation, which is completely different to what was until then common practice in Brazilian trademark law.

As mentioned above, BIPL does not define what should be considered a 'marca de alto renome'. BIPL Article 125 states only that 'special protection' in all fields of activity will be guaranteed to trademarks registered in Brazil and considered to be highly renowned. It acts as an exception to the principle of specialization in Trademark Law (in other words, it is a type of extended protection for non-similar goods or services).

BIPL Article 125 is general and not a self-applicable legal clause, as it only provides two legal requirements for special protection to be granted: (i) the trademark must be registered in Brazil; and (ii) the trademark must be considered to be highly reputed (highly renowned). In other words, special protection is granted, regardless of the possibility of confusion as to the origin of goods and services or even damage to a trademark's good reputation.

Based on the legal definition provided in Article 1.1 of BPTO Resolution No. 107/2013, BIPL Article 125 provides special protection against third party attempts to register any sign that imitates or copies any highly renowned trademark (albeit when there are no similarities between goods or services), in order to curb the chances of diluting its distinctive character. It can be assumed that it provides at least

⁷ Regarding the non-implementation of TRIPS Article 16.3 in Brazilian Trademark Law, see E Baiocchi, 'A proteção à marca notoriamente conhecida fora do campo de semelhança entre produtos e serviços: a (não) aplicação do art. 16.3 do TRIPS no Brasil' (2009) 102 RABPI 3; E Baiocchi, 'Considerazioni sulla tutela allargata del marchio notoriamente conosciuto ai sensi dell'art. 16.3 TRIPS: uno studio dalla prospettiva del diritto dei marchi brasiliano' (2011) 3 RDI 130.

some indirect protection against dilution and undue exploitation of goodwill (parasitic exploitation).

Considering the lack of other legal requirements, BIPL Article 125 represents not only absolute and objective special trademark protection for dissimilar goods and services, but also the problem of interpretation and the insurmountable obstacle of its enforcement by trademark owners, as its wording is vague. As mentioned above, it is a general clause and is not self-applicable.

C. LEGAL REGULATION AND IMPLEMENTATION ACCORDING TO BPTO

BPTO Resolution No. 107 was published on 19 August 2013, to regulate the administrative procedures for the implementation of BIPL Article 125. This resolution is the most recent in a sequence of administrative provisions enacted by the BPTO regarding this matter and facilitates the process used to obtain recognition of high reputation status for registered trademarks in Brazil.

The first Resolution - No. 110 - was published in 2004 (almost seven years after BIPL Article 125 came into effect in May 1997), and since then a total of four resolutions have been published containing different approaches to the implementation of this article.⁸

According to Articles 1.2 and 2 of Resolution 107/2013, the recognition of a trademark's high reputation status is a separate initial step (by means of an 'autonomous procedure') for the application of special protection through BIPL Article 125 and is therefore no longer bound to any incidental procedure (i.e. it is no longer necessary to request special protection and high reputation status via an opposition or administrative nullity procedure).⁹ In other words, from now on, trademark owners may invoke the protection of BIPL Article 125 at any time during the validity of the trademark.

⁸ BPTO Resolutions No. 110 of 2004, No. 121 of 2005, No. 23 of 2013 and most recently No. 107 of 2013, which supersedes all previous resolutions and came into effect according to its Article 16.

⁹ In this regard and in comparison with previous resolutions, Resolution No. 107/2013 represents a paradigm shift concerning the exact moment to request special protection through BIPL Article 125. Under Resolution No. 110/2004, special protection could be requested only in two situations (i.e., incidentally in the course of an administrative procedure): (i) as a defence in an opposition against a third party trademark applications (within 60 days from the publication of the application in the Official Gazette); or (ii) as a defence in the request for an administrative nullity process against the grant of a third party trademark registration (within 180 days from the date of grant), according to BIPL Articles 158 and 169, respectively.

Furthermore, as stated in Articles 3 and 4, the proof of alleged high reputation status depends on the assessment of three fundamental requirements:

- The recognition of the trademark by a wide proportion of the general public¹⁰ (as demonstrated by opinion polls, market surveys or any other capable means, such as media plans, materials and articles in the general media);
- the quality, reputation and prestige that the public associates with the trademark and its goods or services (proved with trademark image surveys on a national scale); and
- the degree of distinctiveness and uniqueness of the sign.

In addition to evidence of the above, trademark owners should also consider the following elements in establishing the trademark's high reputation status¹¹:

- (a) The duration of the effective use of the trademark in the Brazilian market and, where applicable, in the international market;
- (b) the profile and proportion of actual or potential consumers/users of the products or services associated with the trademark, and the proportion of actual or potential consumers/users of other market segments that immediately and spontaneously identify the products or services associated with the trademark;
- (c) the profile and proportion of actual or potential consumers/users of the products or services associated with the trademark, and the proportion of actual or potential consumers/users of other market segments that immediately and

¹⁰ In this regard see the answer of the Brazilian Group on 19 April 2013 to the AIPPI Question Q234 'Relevant public for determining the degree of recognition of famous marks, well-known marks and marks with reputation' <<https://www.aippi.org/download/.../GR234brazil.pdf>> accessed 31 October 2014.

¹¹ Although the list provided in Article 4.4 of Resolution 107/2013 is quite long, it is not exhaustive. Therefore, other evidence may be presented by trademark owners in order to back up their arguments (e.g. the date the trademark was first used in Brazil and the length of effective promotion of the trademark in Brazil and other countries, mentioned in the first resolution – No. 110/2004). In comparison with former BPTO resolutions 110/2004, 121/2005 and 23/2013, the list provided in Article 4.4 of Resolution 107/2013 introduces slight changes and new elements that can be used to establish the trademark's high reputation status.

spontaneously recognize the trademark as a result of its tradition and rating in the market;

(d) the methods for commercializing the trademark in Brazil;

(e) the geographic extent of effective commercialization of the trademark in Brazil, and in other countries, where applicable;

(f) the recognition of a highly renowned trademark shall be requested by the trademark owner to means of promoting the trademark in Brazil and in other countries, where applicable;

(g) the amount of investment in advertising of the trademark in the Brazilian media in the last five years;

(h) the amount of product sales or service profits in the last five years;

(i) the economic value of the trademark as an asset of the company;

(j) the profile and number of people affected by the media through which the trademark owner advertises the trademark in Brazil;

(k) the information providing evidence that the distinctive character of the trademark's reputation has been diluted or parasitically exploited by third parties;

(l) the information providing identification of consumers/users with the trademark's values; and

(m) the information providing the degree of consumer/user trust towards the trademark.

The recognition of a highly renowned trademark shall be requested by the trademark owner to the BPTO through a specific petition with attached supporting documentation, as specified in Articles 3 and 4 of Resolution 107/2013, listed above. The requests are examined by a special commission using a specific application sheet and upon payment of a fee (which amounts to about US\$17,000)¹² during the term of registration. The special commission is composed of staff members from the BPTO's Trademark Department, who are selected by the president of the BPTO.

¹² Ordinance No. 27 of 6 February 2014, of the Ministry of Development, Industry and Foreign Trade (*Diário Oficial da União* 7 February 2014, No. 27, Section 1, 66): electronic applications registered on the INPI's website will be charged at R\$37,500.00, and requests on paper at R\$41,300.00 (Brazilian Reals).

In cases where the special commission recognizes the trademark's high reputation status, this is registered and published in the BPTO magazine and database. In other words, the trademark is then officially considered to be a 'marca de alto renome'.¹³ Any challenges to a trademark's high reputation status and its protection provided by BIPL Article 125 filed in petitions (such as oppositions or nullity procedures) do not oblige or require any comment from the BPTO. Therefore, since the implementation of Resolution 107/2013, the filing of special applications and procedures for the prior recognition of high reputation status is now mandatory.

According to BIPL Article 125 and Article 8 of Resolution 107/2013, the recognition of a trademark's high reputation status affords it special protection in all market segments (i.e. protection for non-similar goods and services) for a ten-year period. In practical terms, such recognition results in the potential denial of trademark applications and the nullity of previous trademark registrations involving similar trademarks. However, this special protection will cease or will no longer be guaranteed in cases of (i) extinction of the trademark's registration;¹⁴ or (ii) revision or cancellation of the trademark's recognized high reputation status applied by any third party, according to Article 10 of Resolution 107/2013.

III. A CONCISE CRITICAL ANALYSIS OF THE PROTECTION AND REGULATION OF HIGHLY RENOWNED TRADEMARKS IN BRAZIL

While Article 67 of the revoked Brazilian Intellectual Property Act of 1971 regulated the former 'marca notória', Article 125 of the Brazilian Intellectual Property Law of 1996 introduced the new legal concept of 'marcas de alto renome'. As already stated above, these represent two different types of special trademark protection. On the one hand, one could argue that BIPL Article 125 constitutes special trademark protection for dissimilar goods and

¹³ The BPTO's trademark online database with a list of all of the trademarks with highly renowned status that have been granted and that are still in force is available at: <http://www.inpi.gov.br/portal/artigo/busca_marcas> accessed 31 October 2014. There are also separate lists for FIFA's highly renowned trademarks, which were granted based on Article 3 of Law No. 12,663 of 5 June 2012 ('World Cup Law'); however, the effects of these recognitions are valid only until 31 December 2014.

¹⁴ According to BIPL Article 142, registration of the trademark shall be extinguished: (i) upon expiration of its term; (ii) upon the trademark owner's renunciation, either partially or in full, of the products or services associated with the trademark; (iii) upon forfeiture request by a third party; or (iv) upon non-compliance with the provisions of Article 217 (obligation to maintain a Brazilian attorney by persons domiciled abroad).

services as regulated in Article 67. On the other hand, the new protection regime is now much stronger and objective, as it is now largely based on clear legal requirements.

One of the major difficulties is the implementation of BIPL Article 125. No further legal conditions are required besides registration and the consideration of high reputation status. In other words, special protection can be guaranteed for all registered signs, in all fields of activity, **if they are considered to have a high reputation status in Brazil**. Therefore, BIPL Article 125 does not provide the legal requirements for a sign to be considered a highly reputed trademark, nor does it define the relevant Brazilian authority (BPTO, Judiciary, or otherwise) responsible for investigating the conditions necessary for the granting of special legal protection requested by the trademark owner.

It would be reasonable to suggest that BIPL Article 125 has opened up a 'Pandora's Box' for Brazilian trademark law and praxis. Given the lack of more specific legal requirements, the practical enforcement of BIPL Article 125 has been - since the very beginning - quite difficult, not only for trademark owners, but also for judges and BPTO trademark staff. In other words, BIPL Article 125 has brought with it a high level of legal uncertainty and chaos.

Despite the fact that it was clear from the outset that more precise regulation of BIPL Article 125 was necessary, the Brazilian Government took too long to respond. The very first BPTO Resolution (No. 110/2004) came into force almost eight years after the publication of BIPL in 1996. Consequently, Brazilian trademark law has recently witnessed judicial battles for the recognition and regulation of trademark reputations. In addition to the considerable number of lawsuits filed before the federal courts for the judicial recognition of the high reputation status¹⁵ of trademarks, the Brazilian PTO has made many attempts to regulate the implementation of BIPL Article 125.

¹⁵ Considering that BIPL Article 125 does not define the relevant authority in Brazil to recognize high reputation status of trademarks (BPTO, Judiciary, or other government entity), several trademark owners filed lawsuits in early 2000 requesting the special protection provided by BIPL Article 125. Many of these succeeded at that time, but now they are no longer in force (Marcelo MA Goyanes and Gustavo B Birenbaum, 'Marcas de alto renome e notoriamente conhecidas: cabimento de ação declaratória para a obtenção da proteção prevista na Lei No. 9.279/96' (2005) 75 Revista da ABPI 51; Gabriel F Leonardos and Rafael L Amaral, 'Marcas de alto renome, o artigo 16.3 do TRIPS e as ações declaratórias' (2005) 70 Revista da ABPI 57).

Although trademark owners held very high expectations regarding the BPTO's position and regulation in this regard, many class associations and intellectual property attorneys have heavily criticized its provisions. Previous BPTO Resolutions - Nos. 110/2004, 121/2005, and 23/2013 - were not well received by the entities representing intellectual property officers and agents. Many aspects, including the time taken to recognize and declare the trademark's reputation (until then limited to an argument of defence in opposition and nullity action procedures before the BPTO), the term provided for submitting all of the necessary proof and documentation and the five-year protection period were considered too short. The lack of clarity as to whether the reputation of the trademark can be granted ex officio by the BPTO was criticized. The approval and publication by the BIPL of four resolutions in less than ten years demonstrate how difficult it was (and probably still is) to solve the problem of interpretation and implementation of BIPL Article 125 in practice.

Indeed, it is difficult to comply with such a wide range of viewpoints as to what a highly reputed trademark is or should be, on the one hand, and to deal with differing interests and claims from trademark owners and their intellectual property agents¹⁶ on the other hand, while striking a balance with public interest (e.g. government policies in the field of trademark law such as consumer and competition law). In Resolution No. 107/2013, as analysed above in Section II.B., the BPTO seems to have conceded defeat and recognized the previous resolution's imperfections, while taking into consideration the concerns of trademark owners and their agents. This introduced some substantial changes such as a separate initial procedure for the recognition of the trademark's high reputation status and the extension of the protection period from five to ten years.

IV. POSSIBLE INTERNATIONAL INPUTS: SUPPORT FROM COMPARATIVE PRIVATE LAW

For decades, the special protection of highly renowned trademarks against misappropriation and interference in their distinctive character has constituted one of the basic components of any modern trademark law system. Deeper analysis in terms of comparative private law may identify many national trademark systems and international rules that regulate this particular situation in a better and more effective manner than BIPL No. 9.279/1996.¹⁷

¹⁶ Some of these claims and concerns are summarized in Resolution No. 60 of 21 October 2004, of the Brazilian Intellectual Property Association (ABPI)

<<http://www.abpi.org.br>> accessed 31 October 2014.

¹⁷ See E Baiocchi (n 2) 441.

In this regard, both the Brazilian Government and Parliament should learn from the experience gained by other countries and consider improving the wording of BIPL Article 125, particularly to include more precise and clear legal requirements to guarantee the legal certainty in this field of trademark law. In order to achieve this goal, some good examples of international provisions exist: Articles 4.4.a and 5.2 of EU Trademark Directive 2008/95/EC, former 89/104/EEC; Article 9.6 of the Protocol on Harmonization of Intellectual Property Norms (South Africa), and Article 2.g of Paraguayan Trademark Law, Law No. 1.294/1998), as well as WIPO Joint Recommendations and Resolutions concerning the protection of well-known trademarks, particularly WKM/CE/I/3, WIPO-doc. A/34/13, and WIPO-doc. 833(E), Article 4.1,b, No. i, ii, and iii.

V. FINAL REMARKS AND CONCLUSION

Despite the enormous commitment of the BPTO to restore trademark owners' and attorneys' faith in applying for the special protection provided by BIPL Article 125 through administrative resolutions, there is still a high degree of legal uncertainty surrounding the effective protection of highly renowned trademarks in Brazil. BPTO Resolution No. 107/2013 has been welcomed, but fails to provide a permanent solution.

As long as there are no clear and precise legal requirements anchored firmly in BIPL Article 125, this special kind of trademark protection will remain tied to restrictions within the current political and economic climate. Resolutions are changing on a constant basis (four have already been published) due to pressure from lobbying groups and other political interests, or due to the inadequacy and inconsistencies associated with the substantial number of legal conditions and proof required for recognition of high reputation status.

Therefore, instead of regulating the interpretation and implementation of BIPL Article 125 through administrative resolutions, legislative changes are necessary.¹⁸ As demonstrated above, the current wording of BIPL Article 125 encompasses a general clause and foresees absolute protection, which leads not only to legal uncertainty, but also to competition issues (market restraint), especially when considering the practical consequences of this legal

provision (trademark protection for all fields of activity, i.e. for non-similar goods and services). Considering the wide range of economic interests involved in this particular field of private law, changing the status quo will require both political will and a major undertaking.

This brief study shows that the protection of highly renowned trademarks in Brazil is quite different, not only from those adopted by other countries in Europe and South America, but also from Brazil's own trademark law tradition. The option of BIPL Article 125 to acquire objective and absolute protection (regardless of the possibility of confusion as to the origin of goods and services or damage to the trademark's reputation) was perhaps an audacious path for the Trademark Law of 1996 to take. However, instead of providing benefits, it has led to many concerns.

Finally, it is important to highlight that beyond any discussion of changes to the current wording of BIPL Article 125, it is also necessary to clarify that this legal provision must always be interpreted and applied on a strict basis. A highly renowned trademark should only be protected in cases where both signs are identical, or at least very similar to each other, thus considering the possibility of confusion as to the origin of goods and services or even damage to a trademark's high reputation.

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¹⁸ Bill of Law No. 4.890/2009, which encompasses some legal requirements that are already regulated in BPTO Resolution No. 107/2013, is still undergoing analysis by the Brazilian Congress.

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4 THE THIRD REVISION OF CHINESE TRADEMARK LAW AND ITS IMPACT ON FOREIGN COMPANIES

Dr Zhang Weijun*

ABSTRACT

Comprehensive modifications of the enforcement of Chinese trademark law have been made in the recent third revision of the People's Republic of China's Trademark Law. This revision not only provides more effective protection of the exclusive right to use a trademark, but also represents a significant improvement of the Chinese legal trademark system, establishing a fair and competitive market order that will contribute to a more inviting legal environment for foreign companies.

Keywords: Chinese Trademark Law, trademark, bad-faith trademark registration, trademark infringement, foreign company

I. INTRODUCTION

On 30 August 2013, the Decision on Revising the Trademark Law of the People's Republic of China¹ (the 'Decision on the Third Revision') was adopted at the Fourth Meeting of the Standing Committee of the Twelfth National People's Congress. The Third Amendment of Trademark Law of the People's Republic of China (the 'Third Amendment')² will come into effect on 1 May 2014. This is another substantive revision of China's Trademark Law in the wake of the Second Amendment of 2001. This article

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¹ Decision of the Standing Committee of the National People's Congress on Revising the Trademark Law of the People's Republic of China (promulgated by Order No. 6 of the President of the People's Republic of China, 30 August 2013, effective 1 May 2014), translated in Westlaw China (accessed 15 October 2013).

² The Third Amendment of Trademark Law of the People's Republic of China (amended according to the Decision on Revising the Trademark Law of the People's Republic of China, effective 1 May 2014), the English version is available in Westlaw China (accessed 15 October 2013).

provides a historical overview of the third revision, and discusses the revised contents and potential problems in the enforcement of the Third Amendment. It also puts forward proposals for the effective protection of the exclusive rights of trademarks owned by foreign enterprises.

II. BACKGROUND, PROCESS AND FEATURES OF THE THIRD AMENDMENT

The initial Trademark Law of the People's Republic of China³ is the first legislation on intellectual property rights since China launched its economic reforms and opening-up policy in the 1980s. On 1 March 1983, legal protection for the exclusive right to the use of a trademark was initiated in China.⁴ Thereafter, China was a signatory to the Paris Convention for the Protection of Industrial Property in 1985 and the Madrid Agreement Concerning the International Registration of Marks in 1989. In order to make it consistent with international practices and to meet the needs of the development of the market economy, in 1993⁵ the Trademark Law was amended for the first time.⁶ In 2001, the Trademark Law⁷ was again significantly revised with a view to fulfilling the requirements of accession to the World Trade

³ Shang biao fa [Trademark Law 商标法] (adopted at the 24th Meeting of the Standing Committee of the Fifth National People's Congress, 23 August 1982, effective 1 March 1983), 1982 Standing Comm. Nat'l People's Cong. Gaz. 3 (P.R.C.). Available at: http://www.npc.gov.cn/wxzl/gongbao/2000-12/05/content_5001321.htm (last visited 15 October 2013).

⁴ Ren Zhonglin [任中林], Guan yu Zhonghua Renmin Gongheguo Shang biao faxiuzheng an cao an de shuoming [Explanation on the Draft of the Trademark Law of the People's Republic of China. 关于《中华人民共和国商标法》(草案)的说明], 1982 Standing Committee of the National People's Congress Gaz. 3 (People's Republic of China). Available at: http://www.legalinfo.gov.cn/zt/2005-01/19/content_183660.htm (accessed 15 October 2013).

⁵ The First Amendment of the Trademark Law of the People's Republic of China (adopted at the 30th meeting of the Standing Committee of the Seventh National People's Congress, 22 February 1993), the English version is available at: http://www.wipo.int/wipolex/en/text.jsp?file_id=181327 (accessed 15 October 2013).

⁶ Liu Minxue [刘敏学], Guan yu Zhonghua Renmin Gongheguo Shang biao faxiuzheng an cao an de shuoming [Explanation on the Draft of the Trademark Law of the People's Republic of China. 关于《中华人民共和国商标法》(草案)的说明], 1993 Standing Committee of the National People's Congress Gaz. 1 (People's Republic of China). Available at: http://www.npc.gov.cn/wxzl/gongbao/1992-12/22/content_1481237.htm (accessed 15 October 2013).

⁷ The Second Amendment of the Trademark Law of the People's Republic of China (adopted at the 24th meeting of the Standing Committee of the Ninth National People's Congress, 27 October 2001) is the existing Trademark Law, the English version is available at: http://www.wipo.int/wipolex/en/text.jsp?file_id=131395 (accessed 15 October 2013).

Organization (WTO) and further strengthening its trademark protection.⁸

Considering that the Second Amendment of the Trademark Law was to a great extent merely filling the gap toward the Trade-Related Aspects of Intellectual Property Rights Agreement (the 'TRIPS Agreement'), some practical problems with respect to trademark registration and protection in China were still left unsolved, such as the inconvenience of the application procedure for trademark registration, the time-consuming and complicated opposition procedure, difficulties in preventing bad-faith registration, bad-faith opposition and other unfaithful actions.⁹ Thus, in 2003, the State Administration for Industry and Commerce of China (the 'SAIC') officially launched the third revision of the Trademark Law. After more than ten modifications, the initial Amendment Draft of the Trademark Law was finalized by SAIC and submitted to the State Council for approval on 18 November 2009.¹⁰ On 1 September 2011, the Legislative Affairs Office of the State Council circulated the Amendment Draft of the Trademark Law to seek public opinion¹¹, upon which the Amendment of the Trademark Law (the 'Draft Amendment') was based and passed after discussion at the executive meetings of the State Council on 31 October 2012. On 24 December 2012, the Standing Committee of the National People's Congress undertook the first review of said Amendment Draft¹², which was circulated thereafter again for public opinion,¹³ and

⁸Wang Zhongfu

[王众孚], Guan yu Zhonghua Renmin Gongheguo Shang biao faxiuzheng an cao an de shuoming [Explanation of the Draft of the Trademark Law of the People's Republic of China].

关于《中华人民共和国商标法》(草案)的说明, 2001 Standing Committee of the National People's Congress Gaz. 7. Available at: <http://www.npc.gov.cn/wxzl/gongbao/2001-12/06/content_5280833.htm>

⁹ See Li Jibin [李吉斌] (24 December 2012), Shang biao faxiuzheng an cao an shou ci beitiqingshenyi [The draft of the Trademark Law amendment is submitted for review for the first time 商标法修正案草案首次被提请审议], available at:

<http://www.npc.gov.cn/huiyi/cwh/1130/2012-12/25/content_1748210.htm>

¹⁰ The unpublished Amendment Draft by SAIC for Approval of the State Council contains a total of 79 articles. The Explanation on the Amendment Draft for Approval of the State Council by SAIC is also unpublished. (18 November 2009).

¹¹ The Amendment Draft for Public Comments published by the Legislative Affairs Office of the State Council on 1 September 2011 contains a total of 75 articles, available at: <http://www.gov.cn/gzdt/2011-9/02/content_1939013.htm>

¹² Idem *supra* note 9.

¹³ The Amendment of the Trademark Law of the People's Republic of China (Draft) and the Explanation of the Amendment of the Trademark Law of the People's Republic of China (Draft), announced by the National People's

on 27 June 2013, the second review of the Amendment Draft was undertaken, with revision of several points based on feedback from the public on the previous version.¹⁴ After the third review by the Standing Committee of the National People's Congress, the Decision on Revising the Trademark Law of the China was finally adopted and promulgated on 30 August 2013.¹⁵

After nearly ten years of intense debate and repeated discussion, the third revision of the Trademark Law was concluded. Overall, this modification of the Trademark law bears the following features:

- First, the process of this revision is transparent and open. It is unusual in the legislative history of China that the Amendment Draft was published for comments not only by the State Council, but also by the National People's Congress. Public opinions have been taken into consideration to a great extent during this revision. For instance, the rule that forbids the use of the wording of 'well-known trademark' in the advertising and packaging of goods was adopted into the revision at the last minute¹⁶, as suggested by the public, especially with the strong support by the trademark law professionals.¹⁷ This regulation is meant to

Congress for Public Opinion on 28 December 2012, the English version is available in Westlaw China (accessed 15 October 2013).

¹⁴See Shang biao faxiugaijinruershen [The revision of the Trademark Law is undergoing its second review 商标法修改进入二审], Ren min ribao [People's Daily 人民日报], (28 June 2013), available at: <http://www.npc.gov.cn/huiyi/lftz/sbfxzczt/2013-06/28/content_1799396.htm> (accessed 15 October 2013).

¹⁵ Id. *supra* note 1.

¹⁶ After the first review of the Trademark Law draft by the Standing committee of the National People's Congress, the following proposals have been put forwarded by some members of the NPC Standing Committee, local governments, relevant departments and enterprises: (1) the connotation of the well known trademark should be further clarified; (2) the provisions on the authorities in charge of recognizing the well known status and how to recognize the status should be specified according to the 'individual judgement, passive protection' principle; and (3) taking the well known trademark as a means of advertisement should be explicitly forbidden, so as to prevent the consumer from being misled. These proposals are aimed at the abnormal use of the well known trademark as an honorary title, which is pervasive in China and has led to some problems in practice.

¹⁷ For instance, Dong Baolin [董葆霖], Guanyu Shang biao fa di shi san tiao di shisitiaoxiugai de yijian [Opinion on modification of Articles 13 and 14 of the Trademark Law 关于商标法第十三条、第十四条修改意见], available at: <http://blog.sina.com.cn/s/blog_9b45f8da01016guy.html> (accessed 15 October 2013). Mr Dong is the chief of the

address the phenomenon in China that the wording of 'well-known trademark' is often misused as an honour for goods, or a means of advertising in practice, and therefore deviates from the essential purpose of the institution.

- Second, this revision is an active amendment based on the actual, domestic needs of China. As mentioned before, the First Amendment of the Trademark Law in 1993 and the Second Amendment in 2001 largely contributed to China's accession to the WTO and the international pressure, especially from developed countries like the United States, for the purpose of passively meeting the requirements of international agreements such as the Paris Convention and the TRIPS Agreement. However, rather than focus on international treaties that China has joined, the Third Amendment focusses further on China's actual domestic needs.¹⁸

Finally, this revision seeks to resolve practical enforcement of trademark protection, in particular by making the trademark registration process more convenient for the applicant, regulating the application and use of trademarks, and safeguarding the market order of fair competition through strengthening protection of the exclusive right to the use of a trademark and other legitimate interests of the trademark owner.¹⁹

III. THE CONTENTS AND CONTROVERSY OF THE THIRD AMENDMENT

A. PREVENTING BAD-FAITH TRADEMARK REGISTRATION AND PROTECTING PRIOR USE OF THE TRADEMARK

As China's trademark registration system originally adopted the 'first to file' principle, the interests of prior rights holders have been more or less overlooked. Consequently, it is very common in trademark disputes where companies have rushed to register a trademark that is already in use by others, and some trademark applications infringe upon others' existing prior rights (e.g. trademark applications using the names of athletes like Yao Ming or Michael Jordan etc.). Such unfair competition behaviours are harmful to market-oriented values and should therefore be prohibited.

expert committee of China's Trademark Association and former director of the Legal Affairs Department of China's Trademark Office.

¹⁸ *Idem supra* note 6.

¹⁹ *Idem*.

The Second Amendment of the Trademark Law of 2001 has sought to prohibit trademark applications made in bad faith, such as providing protection for well-known trademarks by preventing others from applying for registration or using another's well-known trademark.²⁰ According to Article 6 of the Paris Convention, the agent or representative of the person who is the proprietor of a trademark is forbidden to apply for the registration of the mark in his own name or to use the mark, without such proprietor's authorization.²¹ Additionally, no applicant for trademark application may infringe upon another person's existing prior rights, nor may he, by illegitimate means, rush to register a trademark that is already in use by another person and has certain influence.²² Nonetheless, applications that are made in violation of the good faith principle and trademark registrations by illegitimate means still abound. Thus, during the third revision of the Trademark Law, preventing violations of the good-faith principal was regarded as essential²³, and was one of the bases for further improvement.

(i) INCORPORATION OF THE GOOD FAITH PRINCIPLE

Article 7 of the new Trademark Law clearly defines the principle of good faith as a dominating principle in the application for trademark registration and the use of trademarks, namely, that this principle shall be observed in the application for trademark registration and in the use of trademarks.²⁴ This serves to deter preemptive registrations in bad faith of trademarks, which are already in use by others.

(ii) STRENGTHENED PROTECTION OF WELL KNOWN TRADEMARKS

During the Chinese enforcement of the protection of well-known trademarks, the understanding of the well-known trademark shifted away from being understood as an honorary title of the goods, and the requirements to earn the title were enhanced. This, in turn, eased the preemptive registration of others' well-known trademark by illegitimate means, as it became more difficult to claim protection of well-known trademarks. For instance, a Chinese company in Jiangsu, DER International Home Furnishing Co. Ltd, applied for a 'BMW' trademark for class 19 goods of the classification of the goods on floorboards in 2003. The German BMW Co. Ltd.

²⁰ Article 13 of the existing Trademark Law.

²¹ Article 15 of the existing Trademark Law.

²² Article 31 of the existing Trademark Law.

²³ *Id. supra* note 13.

²⁴ Article 7 paragraph 1 of the new Trademark Law provides: The principle of good faith shall be observed in the application for trademark registration and in the use of trademarks.

trademark which is, in fact, well known by the relevant public.

(iii) PROHIBITION OF PREEMPTIVE REGISTRATION OF THE TRADEMARK IN PRIOR USE BY BUSINESS PARTNERS

Considering the reality of increasing bad-faith registrations of others' trademarks in China and the requirement of Article 6 of the Paris Convention, the Second Amendment of the Trademark Law of 2001 provided that, where an agent or representative, without authorization of the client seeks to register in its own name the client's trademark and the client objects, the trademark shall not be registered and its use shall be prohibited.³³ As the wording of 'agent or representative' was simply copied from the Paris Convention without sufficiently considering the meaning of the terms in the context of the Chinese legal system, the explanation of the terms 'agent or representative' was rather debatable after the announcement of the Second Amendment of the Trademark Law.³⁴ Some believe that 'agent' stands for trademark agents who are entrusted to deal with application affairs for trademark registration and 'representative' stands for the person who represents the enterprise to deal with trademark registration applications and other matters.³⁵ While some understand 'agent or representative' as the subjects that include not only the entities mentioned above, but also the business agencies and representatives for the company such as distributors or officers³⁶, others consider it as incompatible with the Paris Convention to limit 'agent' merely to 'trademark agents' and consider that the 'agent or representative', pursuant to the Paris Convention, should refer to all agencies in other countries that are entitled to sell the products in their countries in which the registered trademark of the proprietor is used.

Such controversy has a direct influence on legal practice. On 3 April 2006, the decision of the Beijing

Higher People's Court (Decision No. [(2006) Xing ZhongZi No. 9]) defined the wording 'agent', pursuant to Article 15 of the contemporary Trademark law, only as 'trademark agent' and dismissed the review decision of the TRAB and the ruling of the court of first impression. Thereafter, the Supreme People's Court brought up the case directly and held in its decision (Decision No.:[(2007) Xing Ti Zi No.]) that in conforming with the authoritative explanation to the Paris Convention, the common practice in the member states, and the usual enforcement of relevant administrative laws of China, the terms 'agent or representative' in Article 6^{septies} of the Paris Convention should be defined broadly as agents or representatives who are in special sales relationships with the proprietor of the trademark, including exclusive distributors and general agents. In considering the legislative history, the legislative intent of the Trademark Law, and the provisions of the Paris Convention and judicial explanations, the Supreme People's Court of China held that the term 'agent' of Article 15 of the Trademark Law refers broadly, not only to the trademark agents who are entrusted by applicants for trademark registration to deal with trademark affairs within the scope of their authorization, but also to the agencies who are in special sales representative relationships with the proprietor of the trademark, including exclusive sellers and general agencies.³⁷

Although agents in special sales relationships with the proprietor of the trademark were explicitly included in the definition of 'agent or representative' pursuant to Article 15 of the existing Trademark Law, there are still certain malicious registrations by parties who do not have a sales representative relationship, yet share other business cooperative relationships with the proprietor of trademark. Thus, the Third Amendment adds supplementary provisions to Article 15 of the existing Trademark Law:

an application for registering a trademark for the same or similar goods shall not be approved if the trademark under application is identical with or similar to an unregistered trademark already used by another party; the applicant clearly knows the existence of the trademark of such another party due to contractual, business or other relationships with the latter, other than

³³ Article 15 of the existing Trademark Law.

³⁴ Wu Xinhua [吴新华], Shang biao ping shenyushijian de jian nan dui jie [Difficult adapting trademark examinations to practice 商标评审与实践的艰难对接], Zhongguozhishichanquanbao [China Intellectual Property News], 28 January 2007, available at: <http://blog.sina.com.cn/s/blog_4aa52ecd010007nd.html> (accessed 15 October 2013).

³⁵ Xinchangbiaofajieshiyuzaozuoshiwu [Interpretation and practice of new Trademark Law 新商标法释解与操作实务], at 44-48 (Hu Jihua, et al ed. [扈纪华等编], Zhongguoshang ye chu ban she, 2001).

³⁶ ZhonghuaRenminGongheguoshangbiaofashiyi [Interpretation of the Trademark Law of the People's Republic of China 中华人民共和国商标法释义], at 42-44 (XuYulin, et al.ed [徐玉麟等编], Zhongguofazhichu ban she, 2002).

³⁷ Ma Dongxiao [马东晓], Yi ci buche di di fan zheng -- jian ping shangbiaofa di shiwutiao'dai li ren'degainian [A not complete correction -- comment on the concept of 'agent' in Article 15 of the Trademark Law 一次不彻底地反正——兼评商标法第十五条'代理人'的概念], available at: <<http://cpfd.cnki.com.cn/Article/CPFDTOTAL-ZHQL200910001035.htm>> (accessed 15 October 2013).

those prescribed in the preceding paragraph; and such another party raises objections to the applicant's trademark registration application'.³⁸

In this way, the malicious preemptive registrations for the trademark of clients or business partners by the relevant parties could be effectively prohibited for those who are trademark agents, representatives entrusted with dealing with trademark registration affairs, goods distributor agencies and any other parties who are in a commercial cooperative relationship with the owner of the trademark.

It is worth noting that Article 15 paragraph 2 of the new Trademark Law adds two more requirements: first, the applicant for trademark registration must clearly know the existence of the trademark of another party due to contractual, business or other relationships with the latter; second, the unregistered trademark must 'have already been used' by said other party. It is still unclear whether the 'prior use' is restricted to the area within China or not.

It remains an open question as to whether a foreign company may raise an objection to an application for trademark registration, whose trademark is only used outside China and the goods for which the trademark is used have not been sold on the Chinese market or promoted commercially. It remains to be seen which provision is applicable in cases where a sales agent improperly registers the trademark owned by his principal.³⁹ In accordance with the decision of the Supreme People's Court, the sales agencies are clearly covered by Article 15 paragraph 1 of the Trademark Law. However the newly added provision of Article 15 paragraph 2 seems to touch upon the nature of the relationship between sales agencies and principals.

(iv) PRIOR USE RIGHTS DEFENCE

Although the Chinese Trademark Law observes the 'first to file' principle for trademark registration applications, an overemphasis of this principle would promote the unfaithful application for trademark registrations. Therefore, the existing Trademark Law states:

No applicant for trademark application may infringe upon another person's existing prior rights, nor may he, by illegitimate means, rush

to register a trademark that is already in use by another person and has certain influence.⁴⁰

The Third Amendment keeps this provision (as Article 32) and adds Article 15 paragraph 2 prohibiting preemptive registration of a trademark by an applicant who knows clearly that the said trademark is already used by his business partners.

The determination of 'illegitimate means' lies largely in the subjective status of the applicant. However, it is always difficult in practice to prove that the trademark applicant had or should have had the knowledge of the prior use by a prior user and it is therefore difficult to stop such behaviour by requesting the TRAB to declare the trademark invalid. Consequently, it is obviously unfair and improper if the holder of the exclusive right to use the trademark may prohibit prior users from continuing to use the trademark, which is now in use by him.

Accordingly, the Third Amendment of the Trademark Law takes the position in Article 59 paragraph 3:

where, before a trademark registrant applies for registration of the relevant trademark, another party has used ahead of the trademark registrant a trademark that is of certain influence and is identical with or similar to the registered trademark on the same or similar goods, the holder of the exclusive right to use the registered trademark shall have no right to prohibit the said party from continuing to use the trademark within the original scope of use, but may require the latter to add suitable logos for distinguishing purposes.

The 'continue to use' right is restricted according to this provision within the original scope of prior use, but which at the same time could be understood in practice differently. The following issues still need to be clarified in the enforcement of the Trademark Law by implementing rules or judicial practice: above all, how to define the geographical area of the use (especially with respect to subsidiaries within the original geographical area of the use). Furthermore, are there any limitations to the quantity and scale of the products and is it possible to expand the scale of operation within the original geographical area of the use? Additionally, is it beyond the original scope of use where the goods are circulated in the market outside the original geographical area of the use because of an operator other than prior user?

³⁸ Article 15 paragraph 2 of the new Trademark Law.

³⁹ Article 15 paragraph 1 or Article 15 paragraph 2 of the Trademark Law.

⁴⁰ Article 31 of the existing Trademark Law.

(v) TRADEMARK AGENCIES' ENHANCED DUTY OF GOOD FAITH

A trademark agency is a profession in which trademark representative organizations provide trademark-related agency services based on legal knowledge and experience. The quality of the service and the standards of professional morality concern both the interests of the principal and the trademark registration application, as well as the quality and effectiveness of the Trademark Office. Therefore, the regulations regarding trademark agency have been strengthened by this trademark law revision. For one thing, the interests of principals are protected. In addition to the regulation pursuant to Article 15 paragraph 1 of the existing Trademark Law mentioned above, prohibiting the agent and representative from registering in his own name the trademark of the principal without authorization, Article 19 paragraph 1 of the new Trademark Law states.

Trademark agencies shall observe the principle of good faith, apply for trademark registration or handle other trademark-related matters according to the entrustment of principals, and keep confidential the principals' trade secrets that come to their knowledge during the agency process.

In addition, Article 19 paragraph 4 of the Trademark Law states:

A trademark agency shall not apply for registration of trademarks other than the trademark for its agency services.

Violation of this rule subjects the trademark agency to administrative penalties.⁴¹

For another, the preemptive trademark registration for the principals by illegitimate means should be prohibited. As mentioned above, both Articles 15 and 32 of the new Trademark Law provide prohibition against preemptive registration of a trademark that is already in use by others. To

⁴¹ Article 68 paragraph 1 of the new Trademark Law provides:

A trademark agency that commits any of the following shall be ordered to make correction within the prescribed time period by the relevant administration for industry and commerce, be given a warning, and be subject to a fine of not less than CNY 10,000 but not more than CNY 100,000; its primary person-in-charge subject to direct liabilities and other personnel subject to direct liabilities shall be given a warning and be subject to a fine of not less than CNY 5,000, but not more than CNY 50,000 ... (3) violation Paragraph 3 or Paragraph 4 of Article 19 of this Law ...

prevent such preemptive registration more effectively, Article 19 paragraph 3 of the new Trademark Law adds:

A trademark agency shall not accept the entrustment of a principal if it knows or should have known that the trademark entrusted by the principal for registration application falls under any of the circumstances prescribed by Article 15 and Article 32 of this Law.

By violating this rule, the trademark agency might be ordered to make a correction, be given a warning or even be subject to a fine or other administrative punishments.⁴² However, this rule demands, in essence, that the trademark agencies carry the burden of examining whether the entrustment of their principals is a preemptive registration in bad faith, which in turn subjects the trademark agency to potentially heightened liabilities. Furthermore, it is not easy to determine whether the trademark agency knows or should have known the circumstances of the subjective stand of the principals. Hence, the feasibility of this rule in practice is still under observation.

B. REINFORCING THE ENFORCEMENT OF THE EXCLUSIVE RIGHT TO USE THE REGISTERED TRADEMARK

On 10 November 2001, the WTO Fourth Ministerial Conference approved China's accession to the WTO, which indicated that the Chinese intellectual property legislation had, in principle, complied with the minimum requirements of the TRIPS Agreement, as well as other pertinent international conventions. Even so, the effective enforcement of these intellectual property legislations in China where, as a developing country, piracy and counterfeiting are pervasive, has always been a challenging problem.⁴³ For this reason, intensifying efforts to crack down on counterfeits is a crucial task in the third revision of the Trademark Law.⁴⁴ In doing so, the adopted Third Amendment of Trademark Law has improved the remedies for trademark infringement in the following aspects:

⁴² *Idem*.

⁴³ For instance, on 10 April 2007, the United States requested consultations with China concerning certain measures pertaining to the protection and enforcement of intellectual property rights in China. See Dispute DS362, China — Measures Affecting the Protection and Enforcement of Intellectual Property Rights, available at: http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds362_e.htm (accessed 15 October 2013).

⁴⁴ *Idem supra* note 10, 13.

(i) ADMINISTRATIVE MEASURES

In the process of the enforcement of intellectual property rights, the system of administrative enforcement of law has been established by the Chinese Government with Chinese characteristics. In the event of infringement of the exclusive right to use a registered trademark, any entity may request the administrative department of industry and commerce to handle the matter. When the department is of the opinion that an infringement has been established, it orders the infringer to cease infringing upon that right immediately, and it will confiscate and destroy the infringing goods and instruments specially used to manufacture the said goods and counterfeit the representations of the registered trademark. It may also impose a fine.⁴⁵ The administrative enforcement of law is indeed beneficial to the effective protection of trademarks.

Based on Article 52 of the existing Regulations for the Implementation of the Trademark Law, the amount of a fine imposed on an act infringing the exclusive right to use a registered trademark shall not be more than three times the volume of the illegal business revenue. If it is impossible to calculate the volume of the illegal business revenue, the amount of the fine shall not be more than CNY 100,000. To increase deterrence, the administrative penalties are enhanced further in the Third Amendment of the Trademark Law:

- Where the infringer has gained CNY 50,000 or more of illegal business revenue, a fine of up to five times the illegal business revenue may be imposed thereon; or
- where the infringer has no illegal business revenue or has gained less than CNY 50,000 of illegal business revenue, a fine of up to CNY 250,000 may be imposed.
- in addition, the infringer shall be subject to heavier punishments if he has committed a trademark infringement on two or more occasions within five years or for other cases of a more serious nature.⁴⁶

(ii) IN RESPECT OF CIVIL REMEDIES

In compliance with Article 45 of the TRIPS Agreement⁴⁷, the existing Trademark Law adopts the

⁴⁵ Article 53 paragraph 1, 2 of the existing Trademark Law; Article 51 of Regulations for the Implementation of the Trademark Law.

⁴⁶ Article 60 paragraph 2 of the existing Trademark Law.

⁴⁷ Article 45 of the TRIPS Agreement:

1. The judicial authorities shall have the authority to order the infringer to pay the right holder damages

'compensatory principle' in determining the damages for trademark infringement and sets forth three calculation methods including:

- (a) the amount of the profits that the infringer has achieved due to the infringement during the period of the infringement;
- (b) the amount of the losses that the infringer has suffered due to the infringement during the said period, including any reasonable expenses the infringer has paid in its effort to put an end to the infringement (e.g. attorney fees); and
- (c) if the infringer's profits and actual losses of the infringer are difficult to prove, the damages shall not be more than CNY 500,000, based on the circumstances of the infringement (the so-called 'statutory damages').⁴⁸

Given the incompleteness of account books and difficulties in evidence collection, the infringer is often unable to prove effectively the actual losses he suffered from the infringement or the infringer's profits. Consequently, instead of proving the actual losses or the infringer's profits, infringing parties in many cases claim some portion of the statutory damages directly.⁴⁹ It is worth noting that the statutory damages approach does not possess any punitive characteristics by itself. Instead, this calculation method is an approach, with which a judge could base its determination of the amount of the damage award, within the allowed scope, by reference to the circumstances of the infringement and which still follows compensatory principles. However, when the statutory damages method is applied for determining the statutory damages, there is always a lack of sufficient evidence or even no evidence to support the final determination of

adequate to compensate for the injury the right holder has suffered because of an infringement of that person's intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.

2. The judicial authorities shall also have the authority to order the infringer to pay the right holder expenses, which may include appropriate attorney's fees. In appropriate cases, Members may authorize the judicial authorities to order recovery of profits and/or payment of pre-established damages even where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity.

⁴⁸ Article 56 of the existing Trademark Law.

⁴⁹ Zhishichanquanqinquanru he suan sun haipeichang [How to calculate the damages for IP infringement? 知识产权侵权如何算损害赔偿?], Zhongguozhishichanquanbao [China Intellectual Property News 中国知识产权报] (10 December 2009), available at: <<http://www.cipnews.com.cn/showArticle.asp?articleid=14435>> (accessed 15 October 2013).

damages.⁵⁰ In order to solve the problem, the Third Amendment has attempted to improve the trademark infringement damages system through the following two methods:

(a) RAISING THE CEILING OF THE STATUTORY DAMAGES

In the latest revision of the Chinese Patent Law, the upper limit of statutory damages awards was raised from CNY 500,000 to CNY 1 million.⁵¹ Consequently, in the early versions of the drafts for the Third Amendment of the Trademark Law, the scope of statutory damages had always been confined within the sum of CNY 1 million.⁵² In the Amendment Draft for the second review of the Congress in June 2013, the upper limit of the statutory damages was revised to CNY 2 million⁵³ and this has been unexpectedly raised once again to CNY 3 million in the final adopted Amendment, with the intention of furthering the crackdown on the trademark infringements.⁵⁴

This modification has given the courts more discretion in determining the statutory damages awards. However, as mentioned before, the amount of the statutory damages could by no means be decided by the court arbitrarily and is still subjected to the circumstances of the infringement and the compensatory principle. In practice, although the upper limit of the statutory damages is CNY 500,000, the courts can still determine an amount of damages in excess of the said upper limit on the basis of a comprehensive consideration of all the evidence in the case, where the exact amount of the damage caused by the infringement or profits generated by such infringement is difficult to prove, but there is competent evidence that the aforementioned amount is apparently higher than the maximum amount of the statutory damages as provided by

⁵⁰ *Idem*. The opinion quoted is by Chen Jinchuan, the presiding judge of the IP tribunal of Beijing Higher People's Court.

⁵¹ Article 65 paragraph 2 of the Chinese Patent Law provides:

If the losses of the patentee, profits of the infringer, or royalties of the patent cannot be easily determined, the people's court may, on the basis of the factors such as the type of patent right, nature of the infringement, and severity of the case, determine the amount of damages within the range from CNY 10,000 to CNY 1,000,000.

The existing Patent Law of the People's Republic of China (as amended up to the Decision 'Regarding the revision of the Patent Law of the People's Republic of China on 27 December 2008) is available at:

<http://www.wipo.int/wipolex/en/details.jsp?id=5484> (accessed 15 October 2013).

⁵² *Idem supra* note 10, 11 and 13.

⁵³ *Idem supra* note 14.

⁵⁴ *Idem supra* note 34.

law.⁵⁵ Therefore, it remains to be seen whether the increased maximum amount of statutory damages could bring about an increase in the amount of damages awarded in practice.

(b) IMPOSING PUNITIVE DAMAGES UPON MALICIOUS INFRINGEMENT

Whether punitive damages should be incorporated into the Amendment was one of the hot issues during the third revision. The Amendment Draft announced by the State Council⁵⁶ did not contain a provision concerning punitive damages. However, just one year later, this provision appeared in the Amendment Draft announced by the National People's Congress⁵⁷ which provides:

Where an infringer maliciously infringes upon another party's exclusive right to use a trademark and falls under grave circumstances, the amount of damages may be determined as not less than one time but not more than three times as the amount determined according to the foregoing methods.

The Explanation on the Amendment Draft provides the following rationale: 'In light of the phenomenon that the right holders usually incur high costs in protecting their rights and the loss outweighs the gain for them, the Draft adopts the system of punitive damages.'⁵⁸

This provision has finally been adopted in the new Trademark Law.⁵⁹ However, the argument

⁵⁵ Supreme People's Court Opinion on Certain Issues with Respect to Intellectual Property Judicial Adjudication under the Current Economic Situation, as promulgated by the Supreme People's Court on 29 April 2009 (hereinafter: SPC Opinion on IP Issues under Current Situation). The English version is available at Westlaw China (last visited 15 October 2013).

Section 16 thereof provides:

Where it is difficult to prove the loss caused or profits made but there is competent evidence that the aforementioned amount is apparently higher than the maximum amount of the statutory damages as provided by law, the court shall, on the basis of a comprehensive consideration of the actual case situation, determine a compensation amount greater than the statutory maximum...'

⁵⁶ *Idem supra* note 11.

⁵⁷ *Idem supra* note 13.

⁵⁸ *Idem*.

⁵⁹ Article 63 paragraph 1 of the new Trademark Law provides:

The amount of damages for infringement on the exclusive right to use a trademark shall be determined according to the actual loss suffered by the right holder as a result of the infringement or may be determined according

mentioned in the Amendment Draft is neither reasonable nor logical. First, the purpose provided is merely to offset the loss suffered by the right holders and the cost of safeguarding the right. The necessity of adding the punitive damages system in the Third Amendment is quite questionable, since the existing law has already provided remedial means in light of the compensatory principle, under which the loss and the expenses of infringed parties shall be comprehensively and sufficiently compensated by damages awards.

Moreover, the grounds for low damages awards in Chinese judicial practice do not lie in the imperfection of the substantive law with regard to damages, but in the difficulties in determining the amount of the actual losses and the infringer's profits due to the infringement. Surprisingly, the calculation of the amount of the punitive damages again happens to depend upon the confirmed amount of the actual losses or the infringer's profits. Considering the reality that the compensation for damages in most intellectual property cases in China is decided based on the statutory damages, even if the rule of punitive damages is set forth in the revision, its enforceability and practical effects are still extremely questionable.

In addition, as to the two preconditions for punitive damages—'subjective malice' and 'infringement of a serious nature'—there is still a lack of clarity with regard to the definitions. Whether 'malice' can be interpreted as knowingly infringing another's registered trademark and whether an 'act of infringement with malice' already indicates that such infringement itself is also an 'infringement of a serious nature', need to be clarified by future judicial interpretation.

Last but not least, there is the consideration that in addition to the severe punitive damages institution, administrative penalties shall also be imposed upon the infringer accordingly. If all these punitive measures were to be stringently enforced in reality, the penalties the infringing party may assume are excessively high.

to the profits gained by the infringer from the infringement if the actual loss is difficult to determine, or may be reasonably determined by reference to the multiples of the trademark royalties if both the loss of the right holder and the profits of the infringer are difficult to determine. Where an infringer maliciously infringes upon another party's exclusive right to use a trademark and falls under grave circumstances, the amount of damages may be determined as not less than one time but not more than three times the amount determined according to the foregoing methods.¹

(iii) BURDEN OF PROOF

Similar to Article 7 of the Directive 2004/48/EC on the enforcement of intellectual property rights ('Enforcement Directive'), Article 58 of the existing Chinese Trademark Law provides measures of evidence preservation. However, where the documents related to the infringing acts are mainly under the control of the infringer, the measures of evidence preservation are not able to ensure the acquisition of such evidences. Thus, by reference to Article 6 of the Enforcement Directive, Article 63 paragraph 2 of the new Trademark Law adds measures that entitle the People's Court to order the infringer to submit such related evidences:

(a) First, in the scenario where the right holder has duly discharged its obligation of burden of proof, but the account books and documents related to the infringing acts are mainly controlled by the infringer, the relevant People's Court may, for the purposes of determining the amount of damages, order the infringer to submit said account books and documents.

(b) Thereafter, provided the infringer fails to submit the account books and documents or submits false materials, the People's Court may determine the amount of damages by reference to the claims of the right holder and the evidence provided by the rights holder.⁶⁰ Thus, where the infringer refuses to provide evidence, the People's Court may infer the amount of profits gained by the infringer based on the evidence submitted by the right holder. Such a method has already been applied in some Chinese courts' decisions⁶¹; however, according to the

⁶⁰ Article 63 paragraph 2 of the new Trademark Law provides:

Where the right holder has duly discharged its obligation of burden of proof, but the account books and materials related to the infringing acts are mainly controlled by the infringer, the relevant people's court may, for the purpose of determining the amount of damages, order the infringer to submit account books and materials related to the infringing acts. Where the infringer fails to provide such account books and materials or provides false account books and materials, the people's court may render a judgment on the amount of damages by reference to the claims of the right holder and the evidence furnished thereby.

⁶¹ For example, *CHINT Group Co. Ltd v Schneider Electric* (Tianjin) for infringement of a small circuit breaker utility model patent, Decision of Wenzhou Intermediate Court 3rd Civil Tribunal (IP) first instance No. 135 (2006). The court decided on 26 September 2007 as follows: since the Schneider company refused to provide its cost accounts, its profit ratio from selling the infringing products was unable to be calculated directly. For this reason, this court regards the average operating profit ratio of Schneider's wholesale products as the operating profit ratio in calculating

opinion of the Supreme People's Court, where the infringer refuses to provide evidence under his control without reasonable excuse, the amount of the infringer's profits may be assumed by reference to the claim of the right holder, only if the claims are supported by reasonable evidences or grounds and the amount of profits is reasonably appropriate and persuasive enough.⁶² In contrast with this opinion, the relevant provision of the new Trademark Law is more favourable to the infringed party.

(iv) DETERMINATION OF TRADEMARK INFRINGEMENT

Under Article 52 of the current Trademark Law, using a trademark that is identical with or similar to the registered trademark of the same or similar goods without permission of the owner of the registered trademark, constitutes an infringement of the exclusive rights to the use of a registered trademark.

With regard to this point, some hold that causing public confusion is a necessary precondition to constituting a trademark infringement: Under this argument, using the same trademark which is identical with the registered trademark for the same goods does not constitute an infringement, so long as no public confusion is actually caused. For example, with respect to trademark infringement disputes over products of original equipment manufacture (OEM) no infringement is established, since the OEM products are entirely exported, and hence it is impossible for the domestic customers in China to confuse and mistake the origin of the goods.⁶³

Scheider's profits in the infringing products. The court judgement is available at: <http://www.zscf.com/shownews.asp?id=1283> (last visited 15 October 2013).

⁶² Section 16 of the SPC Opinion on IP Issues under Current Situation provides:

In determining the amount of the profits caused by infringement on the basis of the claims of the claimant and the fact that the defendant refuses to provide evidences in its possession without any valid reasons, the court shall have sound base or ground, and the amount so determined shall be reasonable and fully persuasive.

⁶³ In the case of *Shanghai Shenda Audio Electronics Ltd. v. Jiulide Electronics (Shanghai) Ltd.*, Decision of the Shanghai High Court 3rd Civil Tribunal (IP) final No. 65 (2009), the Court found that the OEM products were entirely exported to the United States and therefore only the US market and American consumers were involved. In other words, without any sales of such OEM products in the Chinese market, it was impossible for the relevant consumers in China to be confused. As a result, the acts of the Jiulide Company did not constitute trademark infringement.

However, based on the Interpretation of the Supreme People's Court, 'being liable to cause the relevant public to confuse the source of goods' is only one of the requirements in determining the similarity of trademarks.⁶⁴ That is to say, the likelihood of confusion is only a consideration when determining the similarity of trademark, but not for the case of identical trademarks. The likelihood of confusion is also not required to constitute a trademark infringement. This holding is not created by the Chinese People's Court originally. Early in the First Council Directive relating to Trademarks Directive 89/104/EEC, the two scenarios were clearly distinguished, providing that the protection of a registered trademark is absolute in the case of identity between the mark and the sign on the same goods or services, whereas it is only persuasive in the context of similarity in relation to the likelihood of confusion.⁶⁵

⁶⁴ Interpretation on the Application of Law in the Trial of Civil Trademark Dispute Cases (promulgated by the Supreme People's Court on 12 October 2002 and effective 16 October 2002). The English version is available at: http://www.wipo.int/wipolex/fr/text.jsp?file_id=194263 (last visited 15 October 2013).

Article 9 paragraph 2 thereof provides:

The phrase 'trademark that is similar' under Item (1) of Article 52 of the Trademark Law means where the suspected infringing trademark is compared with the plaintiff's registered trademark and the font, pronunciation or meaning of the words or the composition or colouring of the device are similar, or the overall structure of its combined main elements is similar, or where its three-dimensional shape and combination of colours are similar thereby easily leading the relevant public to mistake the source of the products or to believe that their source has a certain connection to products using the plaintiff's registered trademark.

⁶⁵ First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trademarks. Official Journal L 040, 11/02/1989 P. 0001 – 0007, available at:

<<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0104:en:HTML>>

Paragraph 10 of the Recital provides: Whereas the protection afforded by the registered trade mark, the function of which is in particular to guarantee the trade mark as an indication of origin, is absolute in the case of identity between the mark and the sign and goods or services; whereas it is indispensable to give an interpretation of the concept of similarity in relation to the likelihood of confusion.

Article 5 of the Directive provides:

1. The registered trade mark shall confer on the proprietor exclusive rights therein. The proprietor shall be entitled to prevent all third parties not having his consent from using in the course of trade:

That is why Article 57 of the new Trademark Law⁶⁶ further clarifies that in an instance of 'using a trademark that is identical with a registered trademark on the same goods', 'the likelihood of confusion' is not a necessary consideration; only in a case of using a trademark that is similar to a registered trademark on the same goods, or using a trademark that is identical with or similar to the registered trademark on similar goods', the likelihood of confusion is taken into account. This distinction is helpful to correct the misinterpretation by courts of the relationship between trademark infringement and the likelihood of confusion.

Further, there is no regulation concerning contributory infringement in the existing Trademark Law, in spite of the provision under Article 50 No. 2 of the Regulations for the Implementation of the Trademark Law, which states that intentionally providing facilities such as storage, transport, mailing, concealing, etc. for the purpose of infringing another person's exclusive right to use a registered trademark shall constitute an infringement on the exclusive right to use a registered trademark referred to in Article 52 (5) of the Trademark Law.⁶⁷ This provision has been adopted in the new Trademark Law, which states that 'intentionally providing convenience for the purpose of infringing another person's exclusive right to use a registered trademark and facilitating others to commit trademark infringement' shall be deemed as infringement on the exclusive right to use a registered trademark⁶⁸, in which the facilities

(a) any sign which is identical with the trade mark in relation to goods or services which are identical with those for which the trade mark is registered;

(b) any sign where, because of its identity with, or similarity to, the trade mark and the identity or similarity of the goods or services covered by the trade mark and the sign, there exists a likelihood of confusion on the part of the public, which includes the likelihood of association between the sign and the trade mark.

⁶⁶ Article 57 (1) (2) of the new Trademark Law provides: 'Any of the following acts shall be deemed infringement of the exclusive right to use a registered trademark: (1) Using a trademark that is identical with a registered trademark on the same goods without the licensing of the registrant of the registered trademark; (2) Using a trademark that is similar to a registered trademark on the same goods, or using a trademark that is identical with or similar to the registered trademark on similar goods without the licensing of the registrant of the registered trademark, which is likely to cause confusion...'

⁶⁷ *Id. supra* note 27.

⁶⁸ Article 57 (6) of the new Trademark Law provides:

Any of the following acts shall be deemed infringement of the exclusive right to use a registered trademark: ... (6) Providing, intentionally, convenience for activities infringing upon others' exclusive right of trademark use, and facilitating others to

measures are not enumerated in details anymore and thus various acts which facilitate the infringement can be included as contributory infringement.

C. STRENGTHENING THE OBLIGATION TO USE REGISTERED TRADEMARKS

The protection of the exclusive right to use a trademark by the Chinese Trademark Law is primarily based on registration. However, the actual use of a registered trademark is required as well. Under Article 44 of the existing Trademark Law, where a trademark user ceases the use of the registered trademark for three consecutive years, the Trademark Office shall order him to rectify the situation within a time limit or revoke the registered trademark. The third revision of Trademark Law makes further stricter requirements thereon.

First, provided that a trademark user ceases the use of the registered trademark for three consecutive years (rather providing an option to rectify the situation within a time limit) the registered trademark shall be directly revoked according to the new Trademark Law.⁶⁹

Second, limitations are imposed on the amount of damages for the infringement upon a registered trademark that has never been used by its holder. In 2009, the Supreme People's Court expressed an opinion that:

where a registered trademark for which protection is applied for has not been put into commercial use, ... in determining the damages, the court, as a general rule, shall take into account the fact that the trademark concerned has not been put into commercial use and shall not determine the amount of damages in light of the profit by the alleged infringing party, if there is no actual loss or other damage incurred in addition to the reasonable expenses for safeguarding the trademark right; where a trademark has been out of use for three consecutive years, as provided in the Trademark Law, the court may

commit infringement on the exclusive right of trademark use; ...'.

⁶⁹ Article 49 paragraph 2 of the new Trademark Law provides:

Where a registered trademark ... **has not been in use for three consecutive years without justification**, any entity or individual may apply to the Trademark Office for **cancellation of the registered trademark.**' (emphasis added).

reject the claim for damages by the right holder of such trademark.⁷⁰

The Third Amendment of the Trademark Law adopted this opinion, and provides that:

where the holder of the exclusive right to use a registered trademark claims for damages, and the alleged infringer counterclaims that the said holder has never used the registered trademark, the relevant people's court may require the holder to furnish evidence of its actual use of the registered trademark in the previous three years. The alleged infringer shall not be liable for damages compensation if the said holder is neither able to prove its actual use of the registered trademark for the previous three years, nor able to prove other losses suffered as a result of the infringement.⁷¹

Unlike the opinion of the Supreme People's Court, two preconditions must be simultaneously met to apply this provision: first, that the holder of a registered trademark is unable to prove actual use of the registered trademark during the three years 'prior to the lawsuit'; and second, that the holder is unable to prove 'other losses' suffered from the infringement. In other words, so long as a trademark right holder proves actual use of the registered trademark or the existence of other losses (for instance, losses of goodwill, etc.), he is still entitled to claim for damages.

This provision, however, begs the question of if the right holder fails to prove actual use of the trademark in the past three years (i.e. no actual loss), but does have evidence for the 'other losses', shall the alleged infringer take responsibilities to compensate the loss? If so, can the amount of damages be calculated based on the infringer's profit, the reasonable royalty, or the approach of statutory damages?

The terms of 'non-use of the registered trademark for the previous three years' are not clearly defined by this provision. Literally speaking, the word 'previous' is next to the action of the 'counterclaim,' and thus the 'previous' here means previous to the counterclaim of the infringer. However, this rule shall not apply, provided that the holder of the exclusive right to use a registered trademark had never used the trademark prior to the infringing acts or the actual use did occur, but only after the infringing acts happened or after the lawsuit was

brought to the court. Thus, considering that the civil liabilities shall be directed toward encouraging the use of trademarks, revitalizing trademark resources and preventing the use of registered trademark improperly and opportunistically⁷², it is reasonable to interpret 'non-use for the previous three years' as 'non-use of the registered trademark for three years prior to the infringing acts'.

IV. IMPACT OF THE THIRD REVISION OF THE TRADEMARK LAW OF THE PEOPLE'S REPUBLIC OF CHINA ON FOREIGN COMPANIES

In summary, comprehensive modifications dealing with the main issues in the enforcement of the Chinese trademark system have been made in the Third Amendment of the Trademark Law of the People's Republic of China, particularly with respect to facilitating the application for trademark registration and maintenance of a registered trademark for Chinese and foreign companies, simplifying the procedure for opposition to trademark registration, prohibiting bad-faith registration of the trademark in prior use by others, strengthening protection of the rights of trademark, and emphasizing the obligation of actual use of a registered trademark. Though there are still provisions and terms needed to enhance and further clarify this law, generally speaking, this revision of the Trademark Law further improves the legal trademark system in China, affords more effective protections of the exclusive right to use a trademark owned by Chinese and foreign companies, and establishes a fair and competitive market order. Overall, this sets up a good legal environment for foreign companies to protect their legitimate trademark rights and to enjoy fair competition in the business market of China.

Still, there are certain considerations that should be mentioned for foreign companies:

A. REGISTERING TRADEMARKS IN TIME IN CHINA

The potential of the Chinese market is being explored continuously as the market economy further develops. Any foreign company that wishes to explore the Chinese market and share benefits from the increase of the Chinese economy should pay attention to the application for trademark registration in China before entering the Chinese market.

As the existing Trademark Law adheres to the 'first to file' principle (though the Third Amendment also highlights the importance of prohibition of malicious preemptive registration of trademark, which is in

⁷⁰Section 7 of the SPC Opinion on IP Issues under Current Situation.

⁷¹Article 64 paragraph 1 of the new Trademark Law.

⁷²Section 7 of the SPC Opinion on IP Issues under Current Situation.

prior use of another person and the maintenance of fair competitive market order), it remains difficult for foreign companies to protect their legitimate interests effectively in practice through these legal institutions. For instance, because of the territorial limits of the protection of the intellectual property rights, a trademark sign which is well known abroad is not necessarily well recognized in China. If the sign has been registered as a trademark in the Chinese Trademark Office before other companies, its registration may not necessarily be cancelled on the grounds of conflicting with a well-known trademark. This becomes a hurdle for further exploitation of Chinese markets. Additionally, when some foreign companies assign Chinese agents as distributors to sell their goods, neither the company nor the distributor may have registered the trademark in China in time, nor have made an agreement with the agents regarding the use of the trademark. Some foreign companies may even lose their trademark rights, since no response and effective measures have been given after the agencies registered their trademarks without authorization.

Taking the trademark infringement dispute *Beijing Dewei Trading Co., Ltd. v Longyan Wanda Trade Co., Ltd.* as an example, the Dewei Trading Company imported and distributed Einsiedler Beer produced by the German Einsiedler Brewery as a long-term business, using the trademark '艾斯特' (Ai Si Te), the Chinese transliteration of 'Einsiedler' on a particular series of beers. In 2002, the Dewei Trading Company applied successfully to register the combination mark of Chinese characters, a head portrait of an old man and the German letters 'Einsiedler' on the goods in class No. 32 'beer.'

Figure 4.2: The combination trademark '艾斯特 Einsiedler' registered by Dewei

Detail information of Trademark					
Registration No./ Application No.	1804026	International Classification No.	32	Application Date	2001-06-22
Name of Registrant (Chinese)	北京德威威基啤酒销售有限公司		Address of Registrant(Chinese)	北京市丰台区天坛东路72号万福大厦518室	
Name of Registrant (English)			Address of Registrant(English)		
Trademark Image			List of Goods/Services	啤酒; Refer to details ...	Similar Group 3201
No. of Preliminary Publication Trademark Gazette	826	No. of Registration Publication Trademark Gazette	838		
Date of Preliminary Publication	2002-04-07		Date of Registration Publication	2002-07-07	
Effective Period of Exclusive Right	07/07/2012 - 07/06/2022		Year		

In 2008, the Longyan Wanda Trade Company imported products from the Einsiedler Brewery through a German distributor, the packaging of

which used the trademark of the German letters 'Einsiedler,' combined with the head portrait of the old man. Meanwhile the food labels were marked with 'Einsiedler country lager', 'Einsiedler black beer', and 'Einsiedler bock beer'. The Longyan Wanda Trade Company also used the brand 'Einsiedler' for online sales and promotion. The Court ultimately determined that the Longyan Wanda Trade Company infringed upon the exclusive right to use the registered trademark of the Dewei Trading Company and should cease the infringing acts immediately.⁷³

When the German Einsiedler Brewery first came to China, the trademarks in use were not promptly registered. Even after these trademarks were registered by the agencies or representatives, they did not exercise the right of cancellation in time. Although Article 41 of the existing trademark provides the remedies that the owner of the registered trademark or any interested party may, within five years from the date the trademark is registered, request that the TRAB make a ruling to cancel the trademark, the German Einsiedler Brewery apparently missed the five-year time limit and its sales of beer in China have been placed under control of its agency—the Dewei Trading Company only.

B. IMPORTANCE OF REGISTERING TRADEMARKS IN CHINESE CHARACTERS

It is essential for foreign companies to apply to register in China their already existing trademarks in their native language. However, it is of even more importance to register the Chinese translations of these trademarks in China to adapt to the specialty of the Chinese market and the customs of Chinese consumers, who prefer to pay close attention to and remember the trademarks in Chinese. Certain foreign companies choose to register fancy and catchy Chinese names as trademarks, such as '宝马' [Bao Ma] for BMW or '奔驰' [Ben Chi] for Mercedes-Benz, which have contributed largely to their business success in China. Without the prompt registration of the marks, whose pronunciations are similar to the transliteration of foreign registered trademarks (or if the Chinese translation has already been registered by other companies in China), foreign companies risk extreme passive effects of further business development in China.

One lesson is from a French wine company called CASTEL FRERES SAS, whose enterprise name 'CASTEL'

⁷³ *Beijing Dewei Trading Co., Ltd. v Longyan Wanda Trading Co., Ltd.* See details of the decision of Beijing Second Intermediate People's Court [(2008) Min Zhong Zi No. 17428, available at: <http://www.law-lib.com/cpws/cpws_view.asp?id=200401247449> (last visited 15 October 2013).

is similar to the Chinese pronunciation of a trademark '卡斯特'(Ka Si Te) registered in China owned by another company (which also sells foreign wines). Though the French company once intended to request cancellation of the registered Chinese trademark on the ground that the trademark 'CASTEL' is a well-known trademark in France, the claim was rejected by the court. Catering to the preference of the Chinese public, the French company also indicated the Chinese characters '卡斯特' [Ka Si Te] on the wine bottles sold in the Chinese market. Being sued for infringement, the French company was subject to significant damages (up to CNY 33,700,000).⁷⁴

In 1991, Nike applied to the Trademark Office of China to register the trademark 'Michael Jordan' in English. However, it did not apply to register the trademark in the form of Chinese characters in time. Only in 2008 did it apply for registration of the trademark '迈克尔·乔丹' [Mai KeEr-Qiao Dan] (the Chinese transliteration of Michael Jordan). The application with the Chinese characters was rejected in the review process because the Fujian Qiaodan Sports Goods Co., Ltd. had already registered a series of trademarks relating to the sports star in various forms, including:

The combination trademark '乔丹QIAODAN', with an image of a baseball athlete, registered in 1997.



The trademark, including the image of a basketball athlete, registered in 1999;



The '乔丹' trademark in Chinese characters registered in 2000

⁷⁴人民网: '卡斯特'商标纠纷一审判决, 法方被判罚3373万元, 2012年4月10日
<<http://wz.people.com.cn/n/2012/0410/c184386-16926546.html>>



Though this Chinese company was sued by Michael Jordan for infringement, the '乔丹' trademark has been actually used in the Chinese market for a very long time, and its cancellation would have been very difficult.

C. ACTIVELY LOGGING EVIDENCE AS A REQUISITE TO OBTAIN ADEQUATE COMPENSATION

Some foreign companies complain about the low amount of damages for intellectual property infringement awarded by Chinese courts. However, the true reasons are not rooted in the substantive legal regulations of intellectual property itself, but instead have to do with the difficulties in obtaining sufficient evidence to support a high damages award. In China, many companies do not have a complete and orderly system for financial accounting, nor is there a creditable system of intangible assets evaluation, which all increase the difficulties of obtaining the relevant evidence. Nonetheless, adequate damages can still be rewarded, if the party involved is able to furnish adequate and effective evidences.

In the case of *BMW Germany v Guangzhou Century Baochi Garment Industrial*, the evidence submitted by BMW was more than sufficient to prove the subjective bad-faith of the infringer, the seriousness of the infringement, the publicity of the BMW trademark, along with the fact that the infringer's profits and the reasonable expenses BMW paid to cease the infringing acts are more than CNY 2,000,000. To protect the legitimate interests of the right holder, increase the price the infringer has to pay and reduce the costs for the right enforcement, the court fully supported all the BMW company's claims for monetary relief in the amount of CNY 2,000,000, which exceeds the monetary limit of up to CNY 500,000 for damage under the existing Trademark Law.⁷⁵

This revision of the Trademark Law imposes a punitive damages system upon malicious trademark infringement. If foreign companies are able to

⁷⁵Zhang Xuesong [张雪松] etc., Beijing shifayuan 2012 nian zhishichanquan susong shi da an li [2012 top ten IP cases of Beijing People's Court
北京市法院2012年知识产权诉讼十大案例], available at: <<http://bjgy.chinacourt.org/article/detail/2013/03/id/931715.shtml>> (last visited 15 October 2013).

present evidence of the actual losses suffered from infringement, the current situation of the unsatisfied amount of damages awards would effectively be changed.

Appendix

Legal Grounds for Opposition and Declaration of Invalidity

Who may raise opposition	Who may seek a declaration of invalidity	Related provisions	Legal grounds
Any person (Article 33 of the new Trademark Law)	Any unit or individual (any person) (Article 44 paragraph 1 of the new Trademark Law)	Article 10	Signs, which may not be used as trademarks
		Article 11	Signs, which may not be registered as trademarks because of lacking distinctiveness
		Article 12	The shape of the mark only represents the nature of the product, or its shape is required for achieving a technological result, or its shape adds substantial value to the product.
A holder of prior rights or an interested party (Article 33 of the new Trademark Law)	A holder of prior rights or an interested party (Article 45 paragraph 1 of the new Trademark Law)	Article 13 paragraphs 2 and 3	Reproduction, imitation or translation of another's well-known trademark
		Article 15	Agents or representatives acting outside the scope of their authority; or, applications seeking protection for trademarks in use by an entity with a contractual, business or other relationship with the applicant.
		Article 16 paragraph 1	A trademark contains a geographical indication of goods and the goods are not from the region indicated therein.
		Article 30	A trademark is identical with or similar to another trademark that has been registered or approved after the preliminary examination.
		Article 31	A trademark is identical with or similar to another trademark, the application for which was filed first.
		Article 32	the application infringes upon another person's existing prior rights or the applicant, by illegitimate means, rushes to register a trademark that is already used by another party and has certain influence

5 PROTECTION OF TRADITIONAL KNOWLEDGE AND BIODIVERSITY THROUGH A HIGHER PROTECTION OF GEOGRAPHICAL INDICATIONS: A REVIEW OF COLOMBIA'S POSITION AT THE WTO

Dr Carolina Vásquez-Arango*

ABSTRACT

This article examines two crucial issues for Colombia concerning the amendment of the WTO TRIPS Agreement. Colombia supports the establishment of an obligation to disclose information related to the origin of genetic resources and traditional knowledge when filing a patent claim. This reflects Colombia's interest in ensuring the protection of biodiversity and traditional knowledge. Moreover, Colombia supports the proposal to extend to other products the higher protection given to wine and spirits under Article 23 of the TRIPS Agreement. The second section focusses on the lack of a WIPO or WTO international binding instrument aimed at protecting the natural resources and traditional knowledge of developing countries. It highlights the advantages of protecting plant varieties, biodiversity and traditional knowledge of local communities and indigenous peoples by geographical indications (GIs). The third section reviews the products that have been granted GI protection in the Colombian intellectual property system. Given the diversity of products that could benefit from GI recognition in Colombia, the fourth section focusses on the arguments in favour of extending the protection given to wines and spirits to other goods. Finally, some conclusions are proposed regarding the potential of GIs to contribute to the progress of rural areas in most developing countries. Geographical indications are described as mechanisms that are likely to be easily implemented in the developing world through public policies at the local and national government levels.

Key words: *Geographical indications (GIs), Traditional Knowledge (TK), biodiversity, plant varieties, development, Colombia*

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I. INTRODUCTION

One of the crucial issues for Colombia regarding the amendment of the TRIPS Agreement is the extension of the protection given to wine and spirits under Article 23 to other products. For Colombia there are other concerns such as the relationship between pharmaceutical patents and public health; the requirement for patent applicants to disclose information about the origin of genetic resources or traditional knowledge used in their inventions; and the protection of traditional knowledge and folklore.

In this respect, Colombia was a co-sponsor of documents IP/C/W/474¹ and TN/C/W/52² as part of the WTO Doha Round Negotiations. Colombia believes that an international binding instrument under the WIPO and WTO is required, in order to protect biodiversity and traditional knowledge. This explains why Colombia is in favour of the obligation to disclose information related to the origin of genetic resources and traditional knowledge used when filing a patent claim. Furthermore, Colombia is a staunch advocate of extending the higher protection given to wines and spirits under the TRIPS Agreement to other products, as an absolute necessity for developing countries.

Colombia provides protection for a variety of manufactured and agricultural products through denominations of origin (DOs), and has also sought to obtain the same treatment for its goods in other markets. For instance, in 2007, *Café de Colombia* was the first non-European product to obtain recognition as a protected geographic indication (PGI) in the European Union.

This article is in favour of GI protection of possessions frequently present in developing countries, such as the makings (known as traditional knowledge) of indigenous peoples and local communities, and biodiversity. Despite their use to protect mainly foodstuffs, GIs are described among intellectual property authors as an appropriate mechanism under current international intellectual property laws for protecting traditional knowledge and biodiversity.

¹WTO Doha Work Programme – The Outstanding Implementation Issue on the Relationship between the TRIPS Agreement and the Convention on Biological Diversity - Communication from Brazil, China, Colombia, Cuba, India, Pakistan, Peru, Thailand and Tanzania. Revised Documents WT/GC/W/564/Rev.2 TN/C/W/41/Rev.2 IP/C/W/474 dated 5 July 2006.

²WTO Trade Negotiations Committee – Draft Modalities for TRIPS-Related Issues - Communication from Albania, Brazil, China, Colombia, Ecuador, the European Communities, Iceland, India, Indonesia, the Kyrgyz Republic, Liechtenstein, the Former Yugoslav Republic of Macedonia, Pakistan, Peru, Sri Lanka, Switzerland, Thailand, Turkey, the ACP Group and the African Group. Document TN/C/W/52 dated 19 July 2008.

To this end, the second section of this article focusses on the lack of an international binding instrument to protect the natural resources and traditional knowledge of developing countries. This section also discusses the advantages of protecting plant varieties, biodiversity and traditional knowledge-based products of local communities and indigenous peoples by GIs.

The third section focusses on the instruments for granting GIs in Colombia and the goods that have been protected under the Colombian intellectual property system. Given the diversity of products that could obtain GI recognition in Colombia, the fourth section of this article focusses on the extension to other goods of the protection provided in the TRIPS Agreement to wines and spirits.

Finally, the article concludes that GIs can indeed contribute to the economic progress of poor areas in most developing countries. The article regards GIs as an effective mechanism for enhancing development around the globe if implemented through public policies at the local and national government levels. Developing countries should therefore continue lobbying for TRIPS Agreement protections that grant to all goods the same protection given to wines and spirits, in order to protect intellectual creations which are currently unprotected.

II. ADVANTAGES OF PROTECTING PLANT VARIETIES, TRADITIONAL KNOWLEDGE AND BIODIVERSITY THROUGH GEOGRAPHICAL INDICATIONS

No international binding instrument provides protection for plant varieties, traditional knowledge and biodiversity. Such goods are of considerable importance for developing countries. Despite the efforts from the developing world in international forums such as the Convention on Biological Diversity and in international organizations, including the WTO, WIPO, WHO, FAO, UNESCO and UNCTAD³, an international legal instrument has yet to be developed. Consequently, we need to consider the advantages of other intellectual property rights such as GIs in ensuring protection of these makings and goods.

The proposal described above has been called into question. There are indeed drawbacks to GIs and they are not suitable to protect all plant varieties and

traditional knowledge expressions such as folklore and medical procedures.

A. PLANT VARIETIES

Plant varieties are currently protected by plant breeders' rights under the International Convention for the Protection of New Varieties of Plants 1978 and 1991 (UPOV Conventions). Plant varieties can also be protected by patents under the TRIPS Agreement.

One of the problems with these rights is that they are not conceived to protect plant varieties created through artisanal breeding techniques. Plant varieties produced by most indigenous peoples and local communities within the developing world do not qualify for patents or plant breeders' rights. Plant breeders' rights and patents benefit big corporations that develop new plant varieties through biotechnology or costly genetic engineering processes.

Whereas plant breeders' rights and patents over plants provide protection for their right holders by limiting the breeder's exemption and the farmer's privilege under UPOV 1991⁴, plant varieties developed by indigenous and local farmers remain unprotected. This trend towards enhancing protection generates other problems, as pointed out by Mohammad Towhidul Islam⁵, such as increased farming costs.

In order to reduce starvation and extreme poverty among indigenous and traditional farmers, an adequate tool needs to be developed that will enable them to continue producing plant varieties and growing crops according to their own traditional methods.

In order to obtain new varieties adaptable to their environment and needs, these traditional methods involve collective work, rather than individual research. This has been well illustrated by Salazar, Louwaars and Visser, who argue that traditional farmer-breeders 'provide material to their communities and often need the involvement of their fellow farmers since they do not possess sufficient land and time to manage the trials on their own farm'.⁶

³ Carlos Correa and others, 'Chapter 4 Traditional Knowledge and Geographical Indications' in 'Integrating Intellectual Property Rights and Development Policy: Report of the Commission on Intellectual Property Rights' (3rd edn, Commission on Intellectual Property Rights 2003) 75.

⁴ Laurence R Helfer, 'Intellectual Property Rights in Plant Varieties. International Legal Regimes and Policy Options for National Governments' (FAO 2004) 28.

⁵ Mohammad Towhidul Islam, 'Protection of Public Interests through a Human Rights Framework in the TRIPS Agreement: Realities and Challenges' (2009) 4 *Journal of Intellectual Property Law and Practice* 579.

⁶ Rene Salazar, Niels P Louwaars and Bert Visser, 'Protecting Farmers' New Varieties: New Approaches to Rights on

Moreover, Helfer calls attention to the inconvenience of utilizing seeds developed and commercialized by new plant breeders, instead of the plant varieties produced by traditional methods. Whereas, the former has uniform genetic characteristics and could have adverse effects on the biodiversity of most developing countries, the latter is suitable for local growing conditions.⁷

Governments have the obligation to guarantee the rights of its less favoured groups. Geographical indications are presented as an alternative due to the advantages they offer, given the lack of mechanisms for protecting plant varieties obtained through traditional breeding techniques developed by indigenous peoples and local communities, which are transmitted from generation to generation as traditional knowledge. For instance, Dagne discusses the suitability of GIs for protecting traditional knowledge-based agricultural products (TKBAPs)⁸, which lack the novelty requirement needed for protection as plant breeders' rights under the 1978 and 1991 UPOV Conventions, and also for obtaining a patent under the TRIPS Agreement.⁹

Geographical indications could serve to protect plant varieties improved through time on the basis of traditional knowledge which become nationally or even internationally known due to their special qualities or reputation, and could be associated with a specific community or indigenous people or a geographical location. Even though GIs might not be an ideal tool to protect plant varieties, they could be useful until an appropriate scheme is established in the international arena. In this regard, GI protection is comparable to the suggestion made by Salazar, Louwaars and Visser, for the establishment of an alternative system that focusses on recognition and protection, rather than property.¹⁰

Collective Innovations in Plant Genetic Resources' (2006) CAPRI Working Paper #45 18-19.

⁷ Helfer (n 5) 16.

⁸ This author states that 'the expression "Traditional Knowledge-based agricultural products"' (TKBAPS) refers to the resources among indigenous people and local communities engaged in agricultural production who utilize traditional means of production.' Teshager Worku Dagne, 'Harnessing the Development Potential of Geographical Indications for Traditional Knowledge-Based Agricultural Products' (2010) 5 Journal of Intellectual Property Law and Practice 441- 42.

⁹ Ibid 447; Helfer (n 5) 26-27, 71.

¹⁰ These authors called this alternative scheme of protection 'origin recognition rights', based on the principle of declaration of origin and farmers' registers. Salazar, Louwaars and Visser (n 7) 25.

B. TRADITIONAL KNOWLEDGE

Given that GIs protect goods, they are not adequate to protect processes, techniques or cultural expressions such as dances and poetry. However, many of the forms in which traditional knowledge is expressed are goods such as plant varieties, food products, and handicrafts. Considering their characteristics, these forms of traditional knowledge could well be protected by GIs,

As mentioned above, GIs are helpful in protecting plant varieties such as TKBAPs. In addition, governments often protect handicrafts and artistic creations of indigenous peoples through GIs. For instance, Colombia has granted protection, under appellations of origin (AOs), to several products manufactured by indigenous communities, including ceramic works and sewing¹¹; likewise, India has granted protection to cultural products such as saris, the traditional dress used by Hindu women.¹²

Geographical indications serve to protect the creations of indigenous peoples and local communities based on traditional knowledge, because they do not confer a monopolistic right to an individual; instead, they confer a collective right that could benefit an entire population. Therefore GIs constitute an intellectual property right that is perfectly adaptable to the particularities of indigenous communities, since most of them consider that all their assets belong to the group as a whole¹³, or even go further by denying any form of private property, including the collective one.

Additionally, GIs do not grant a time limitation. The protection lasts while the special characteristics associated with the product subsist. For this reason and those listed above, GIs are well suited to protect TKBAPs and artisanal works, so long as these goods preserve the quality and reputation associated with them, as required in most GI systems.

C. BIODIVERSITY

There are some plants and natural resources that are original and exclusive to a country or region. These natural resources can be distinguished from other similar products by particular characteristics that make them more appreciated and valuable. Consequently, it can be said that these biodiversity products, characterized by their 'uniqueness',

¹¹ Superintendencia de Industria y Comercio, 'Productos con Denominación de Origen'

<<http://www.sic.gov.co/drupal/productos-con-denominacion-de-origen>> accessed 10 June 2014. The appellations of origin in Colombia will be enumerated in the following section of this paper.

¹² Dagne (n 9) 445.

¹³ Ibid 446, 451.

deserve special protection. As a result, GIs are an appropriate tool for protecting goods such as basmati rice (from the Punjab State in India and the Punjab State in Pakistan)¹⁴ or jasmine rice¹⁵, the argan tree from Morocco, or white giant maize from Peru, among others. In these cases, the goods or products involved could not only obtain the protection provided for by Article 22 of TRIPS, but the stronger one for wines and spirits under Article 23 of this instrument.

Protecting plants, animals and other resources originating from particular areas prevents foreign companies from patenting them to monopolize their commercialization, a practice known as biopiracy.¹⁶ Collective trademarks or GIs could grant this protection.

As opposed to collective trademarks, GIs link products to their quality and reputation and contribute to maintain traditional procedures and production methods that make goods distinguishable from their equivalent, such as environmental, moral, and ethically based standards established within a community. Geographical indications grant protection to certain goods produced by a community and could help to promote compliance with those 'sustainable' standards, while preserving biodiversity.¹⁷

In the absence of adequate protection for these valuable natural resources, biopiracy is more likely, as in the case of India with Basmati rice, which was patented by an US company¹⁸, or Rooibos tea from South Africa, registered as a trademark in the same market.¹⁹ However, in both cases the original producers have recovered their rights. 'Rooibos' benefits from strong protection since 2013.²⁰ Furthermore, lack of protection can result in

overexploitation of a biodiversity resource and its consequent extinction, whereas its protection under a GI that is adequately managed by a local community or indigenous people, can contribute to its conservation.

In addition to the arguments discussed above, all these goods (plant varieties obtained through traditional methods, traditional knowledge and biodiversity resources) are a source of livelihood for populations in developing countries in remote and rural areas. Therefore, those goods need to be adequately protected, in order to allow the developing world to take advantage of international intellectual property regimes. Intellectual property rights are currently reaching only a handful of companies and private organizations from developed countries, those who monopolize the trade in patented goods and trademarks.

The effectiveness of GIs in boosting development in a particular region is notable. They are directly related to enhancing commercial opportunities for local producers. For instance, they contribute to activities related to the production of protected goods such as tourism, investment in infrastructure and the creation of new jobs.²¹ Additionally, as stated by Banerjee and Majumdar, they help to protect 'the region's agricultural, artisanal, and culinary heritage, as well as protecting consumers from deceptive geographic misdescriptions of goods'.²²

Finally, as opposed to other forms of intellectual property, in the Colombian Intellectual property System, GI protection can be claimed by local authorities such as the mayor of a municipality or the governor of a department. In these cases, it is necessary to demonstrate the legitimate interest of the requesting authority according to Section 7.1.2.1.2 of Resolution 57530 (2012).²³

Accordingly, obtaining GI protection for renowned goods produced locally could serve as a public policy mechanism to promote development in rural or remote areas. This policy should be designed and

¹⁴ Ibid 454.

¹⁵ Ritika Banerjee and Mohar Majumdar, 'In the Mood to Compromise? Extended Protection of Geographical Indications under TRIPS Article 23' (2011) 6 *Journal of Intellectual Property Law and Practice* 660.

¹⁶ As defined by the Action Group on Erosion, Technology and Concentration (ETC Group) and cited by Correa and others, biopiracy is the 'appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions seeking exclusive monopoly control (usually patents or plant breeders' rights) over these resources and knowledge'. Correa and others (n 4) 74.

¹⁷ Dagne (n 9) 451.

¹⁸ Banerjee and Majumdar (n 16) 661.

¹⁹ María Paola Rizo, 'La Protección de Las Indicaciones Geográficas' (2011) 10 *Perspectivas Rurales*. Nueva época 51.

²⁰ Andre van der Merwe, 'South and Southern Africa—Recent Developments in the Legal Protection of Traditional Knowledge and Traditional Cultural Expressions' (2014) 9 *Journal of Intellectual Property Law and Practice* 416-17.

²¹ Superintendencia de Industria y Turismo, 'Manual de Denominaciones de Origen' (2013)

<http://www.sic.gov.co/drupal/recursos_user/documentos/denominacion_de_origen/cartilla_manual_denominaciones_de_origen.pdf> accessed 27 October 2014 8.

²² Banerjee and Majumdar (n 16) 658.

²³ Superintendencia de Industria y Comercio, 'Resolución 57530 de 2012 'Por la cual se adiciona el Capítulo VII, titulado Denominaciones de Origen, al Título X sobre Propiedad Industrial de la Circular Única de la Superintendencia de Industria y Comercio'. <http://www.sic.gov.co/drupal/sites/default/files/normatividad/get_file%3Fuuid%3D254248f9-0c32-41e4-84f5-56194d3907cf%26group%3D10157_0.pdf> accessed 15 October 2014.

managed by the government authorities, reducing the costs associated with obtaining protection, which most indigenous and local communities in developing countries cannot afford.

III. GEOGRAPHICAL INDICATIONS GRANTED BY COLOMBIA'S IP AUTHORITIES

International laws govern Colombia in certain matters. As a member of the Andean Community, Colombia, together with Ecuador, Peru and Bolivia, has a common intellectual property regime. The Andean intellectual property regime is contained in Decision 486 of 2000 issued by the Andean Commission. This Decision follows the guidelines established under the TRIPS Agreement. In addition, Colombia has national laws related to intellectual property, such as the Commercial Code and a variety of laws, decrees, resolutions and circulars from the Ministry of Trade, Industry and Tourism and its Superintendence of Industry and Trade (SIC, by its name in Spanish). The SIC is the authority responsible for the management and enforcement of industrial property law, competition and consumer rights law.

Andean Decision 486 of 2000 regulates two different kinds of GIs under Title XII thereof²⁴: appellations of origin (AO) (called denominations of origin (DO) in Colombia's intellectual property system)²⁵, similar to appellations of origin under the Lisbon Treaty and protected designations of origin (PDOs) in the European System.²⁶ These appellations of origin or denominations of origin link the quality and reputation of any product or good (not only agricultural products) to a particular location or community. The other type, indication of source (IS)²⁷, is comparable to indications of origin (IO) of the European Union, which simply designate the place where a product comes from, without making any association with its characteristics.

In order to obtain a denomination of origin under Colombian legislation, a good shall be linked to a quality or characteristics associated with a specific geographical environment, pursuant to Article 201 of the Andean Decision 486, which provides:

Article 201. An appellation of origin shall be understood to be a geographical indication consisting of the name of a particular country, region, or locality, or of a name which, without being that of a particular country, region, or locality, refers to a specific geographical area, which name is used to identify a product originating therein, the qualities, reputation, or characteristics of which are exclusively or essentially attributable to the geographical environment in which it is produced, including both natural and human factors.

A geographical environment is understood not only to be a particular place or geographical location, but also to contain human factors, which in turn incorporate the qualities or characteristics into the product that is claimed to deserve protection as a denomination of origin.

From 2005 to 2014, the Superintendence of Industry and Trade granted protection to 20 different products covering agro-food and handicrafts, in compliance with the stated requirements. The table below sets out a list of existing denominations of origin in Colombia, including the applicants and the resolution that granted the protection:

²⁴ Commission of the Andean Community, 'Decision 486 Common Intellectual Property Regime (non official translation)' [2000] <<http://www.comunidadandina.org/INGLES/normativa/D486e.htm>> accessed 6 September 2014.

²⁵ Ibid Arts 201-20.

²⁶ Patricia Covarrubia, 'The EU and Colombia/Peru Free Trade Agreement on GIs: Adjusting Colombian and Peruvian National Laws?' (2011) 6 *Journal of Intellectual Property Law and Practice* 334.

²⁷ Articles 221-23.

Table 5.1. Denominations of Origin (DOs) granted in Colombia by the Superintendence of Industry and Trade			
AGRO-INDUSTRIAL PRODUCTS			
	Denomination of Origin	Applicant	Declaration
1	<i>Café de Colombia</i> (Colombian Coffee)	<i>Federación Nacional de Cafeteros de Colombia</i> (Colombian National Federation of Coffee Growers)	Resolution 4819 4 March 2005
2	<i>Café de Cauca</i> (Coffee of Cauca)	Colombian National Federation of Coffee Growers	Resolution 43536 21 December 2007
3	<i>Café de Nariño</i> (Coffee of Nariño)	Colombian National Federation of Coffee Growers	Resolution 4819 4 March 2005
4	<i>Café de Huila</i> (Coffee of Huila)	Colombian National Federation of Coffee Growers - National Coffee Fund	Resolution 23115 20 April 2012
5	<i>Cholupa del Huila</i> (<i>Passiflora maliformis</i> L of Huila)	<i>Gobernación del Huila – Secretaría de Salud Departamental</i> (Governor of Huila - Department of Health)	Resolution 43536 21 December 2007
6	<i>Queso del Caquetá</i> (Caquetá Cheese)	<i>Comité Departamental de Ganaderos del Caquetá</i> (Departmental Committee of Livestock of Caquetá)	Resolution 68463 30 November 2011
7	<i>Queso Paipa</i> (Paipa Cheese)	<i>DTS Alcaldía Municipal de Paipa</i> (Municipality of Paipa)	Resolution 70802 6 December 2011
8	<i>Bizcocho de Achira del Huila</i> (Achira of Huila)	<i>Gobernación del Huila</i> (Governor of Huila)	Resolution 23115 20 April 2012
9	<i>Clavel de Colombia</i> (Carnations of Colombia)	<i>Asociación Colombiana de Exportadores de Flores (ASOCOLFLORES)</i> (Colombian Association of exporters of flowers)	Resolution 53956 10 May 2010
10	<i>Crisantemo de Colombia</i> (Chrysanthemum of Colombia)	Colombian Association of exporters of flowers	Resolution 12071 29 February 2012
11	<i>Rosa de Colombia</i> (Rose of Colombia)	Colombian Association of exporters of flowers	Resolution 12076 21 April 2010
HANDICRAFTS			
12	<i>Cerámica del Carmen de Viboral</i> (Ceramic of Carmen de Viboral)	<i>Alcaldía del Municipio del Carmen de Viboral</i> (Municipality of the Carmen de Viboral)	Resolution 71791 12 December 2011
13	<i>Cerámica Artesanal de Ráquira</i> (Handmade Ceramic of Ráquira)	<i>Acción de Artesanos Muisca de Ráquira-Asomuisca</i> (Action of Muisca Artisans of Ráquira)	Resolution 66272 29 November 2010
14	<i>Tejeduría Zenú</i> (Zenú's Weaving)	<i>Resguardo Indígena Zenú de San Andrés de Sotavento</i> (Zenu indigenous reservation of San Andrés de Sotavento)	Resolution 71097 29 February 2012

Table 5.1. Denominations of Origin (DOs) granted in Colombia by the Superintendencia de Industria y Comercio			
15	<i>Sombreros de Sandoná</i> (Hats of Sandoná)	<i>Gobernación de Nariño</i> (Governor of Nariño)	Resolution 69304 30 November 2011
16	<i>Sombrero Aguadeño</i> (Aguadeño Hat)	<i>Alcaldía Municipal de Aguadas</i> (Municipality of Aguadas)	Resolution 69302 30 November 2011
17	<i>Tejeduría San Jacinto</i> (<i>San Jacinto's Weaving</i>)	<i>Alcaldía de San Jacinto-Bolívar</i> (Municipality of San Jacinto-Bolivar)	Resolution 70849 6 December 2011
18	<i>Cestería en Rollo de Guacamayas</i> (Roll baskets of Guacamayas)	Creatividad Artística Cooperativa de Guacamayas (CREARCOOP LTDA) (Cooperative Artistic Creativity of Guacamayas)	Resolution 30000 19 June 2009
19	<i>Tejeduría Wayuu</i> (<i>Wayuu's Weaving</i>)	Gobernación de la Guajira (Governor of Guajira)	Resolution 71098 7 December 2011
20	<i>Mopa Mopa Barniz de Pasto</i> (Mopa Mopa Varnish of Pasto)	Alcaldía de Pasto (Municipality of Pasto)	Resolution 70002 30 November 2011

Note: Translation, Superintendencia de Industria y Comercio, 'Productos con Denominación de Origen' <<http://www.sic.gov.co/drupal/productos-con-denominacion-de-origen>> accessed 10 September 2014.

Two features are to be noted from the list above. First, in many cases, the request for protection came from a public office or local authority.²⁸ This demonstrates the existing link between GIs and the public interest, as the protected products constitute the main economic activity conducive to the development of the region. Second, it shows the existing relationship between GIs and the collective efforts among the members of a local community. As indicated before, the collective nature of GIs makes inapplicable other forms of intellectual property, which confer exclusive rights to individuals or companies. Therefore, GIs are ideal to protect collective works and traditional knowledge associated with communities.

In fact, 11 out of the 20 denominations of origin granted are related to traditional knowledge; seven of them belong to traditional knowledge of indigenous peoples²⁹, while four are linked to communities from particular locations that have transmitted their artisanal heritage from generation to generation.³⁰ One of the denominations of origin is a biodiversity product (*Cholupa* of Huila [*Passiflora maliformis* L]) from Colombia, which grows

²⁸ Consistent with Section 7.1.2.1.2 of Resolution 57530 of 2012 (n 24).

²⁹ Handmade Ceramic of Ráquira, *Zenú's Weaving*, Hats of Sandoná, *San Jacinto's Weaving*, Roll baskets of Guacamayas, *Wayuu's Weaving*, and Mopa Mopa Varnish of Pasto.

³⁰ Caquetá Cheese, Paipa Cheese, *Achira* of Huila and Aguadeño Hat.

exclusively in the north region of the Department of Huila. Finally, the remaining agricultural products such as varieties of coffee and flowers are goods which represent a considerable investment by their producers to improve their production methods and marketing. These goods are exported to Colombia's main trading partners.

IV. ARGUMENTS IN FAVOUR OF EXTENDING THE PROTECTION GIVEN TO WINES AND SPIRITS UNDER ARTICLE 23 OF THE TRIPS AGREEMENT TO OTHER GOODS

Articles 22 and 23 of the TRIPS Agreement govern the protection of GIs. Article 22 covers all products. This provision provides for a standard level of protection with the aim of preventing misleading consumers or unfair competition. Article 23, on the other hand, applies only to wines and spirits, providing a higher protection for these goods. The use of terms or names of wines and spirits have to be protected even when misleading consumers is improbable.

As noted by Banerjee and Majumdar, the protection given to GIs other than wines and spirits under Article 22 of TRIPS is inadequate. The additional protection of Article 23 through a multilateral registry should be granted to all kind of goods, since GIs not only apply to wines and spirits, but also to dairy products, plants, poultry, handicrafts, and many other commodities.³¹ Therefore, the two-tier

³¹ Banerjee and Majumdar (n 16) 659.

system accorded under the TRIPS Agreement is discriminatory.

Likewise, Evans and Blakeney³² called attention to the contradiction between the limited protection of Article 23 of the TRIPS Agreement and the objectives of the Doha Declaration, as expressed in paragraph 2 thereof³³:

International trade can play a major role in the promotion of economic development and the alleviation of poverty. We recognize the need for all our peoples to benefit from the increased opportunities and welfare gains that the multilateral trading system generates.

It is difficult to deny the manner in which the TRIPS Agreement has favoured the economic interests of intellectual property rights' holders in WTO Members within the developed world through patents, industrial designs, trademarks, copyrights and combinations of these systems. However, the benefits of this Agreement have not affected developing countries to the same extent.

India, Egypt and Kenya, countries well positioned in the world trade of commodities, support the wider scope of an additional protection under Article 23 of the TRIPS Agreement. These countries promote the potential positive effects in favour of developing countries.³⁴ The enhanced protection could benefit Colombia and other developing countries. Colombia has started to promote the protection, through GIs, of a wide range of domestically well-known products, ranging from foodstuffs and agricultural goods to handicrafts.

The advantages of GI protection are numerous. For instance, protecting a product's geographic origin, can serve as a mechanism for preventing biopiracy and the misappropriation of natural resources in developing countries.³⁵ On the other hand, protecting products in recognition of the human factors associated with them is an adequate measure to protect and raise the commercial value

of traditional knowledge of local communities and indigenous peoples.

In the short-term, GIs will help to preserve existing biodiversity and cultural heritage in the developing world, and help its sustainable development. In the long-term, this will necessarily contribute to a rise in the income of local communities and indigenous peoples, helping to alleviate poverty and food security problems, and meet their educational and health needs.

To that end, GIs used to protect biodiversity, and plant varieties and other goods produced through traditional knowledge should be combined with other forms of intellectual property protection, some of which have yet to be provided. Since GIs may only prevent others from using similar names for their products, combined strategies are needed to minimize the weaknesses of these intellectual property rights.

Protection by itself is not a sufficient strategy that automatically results in development. Development requires a well designed marketing and commercialization policy. The success in the market of a product granted a GI also depends on the consumer's willingness to pay a higher price for a protected product than for an unprotected one. This is one of the challenges for GIs. However, products granted a GI could be more attractive given their reputation for quality. This will ensure they are more successful in relation to other competitors when they are commercialized in foreign markets.

The case of Café de Colombia is notable. Café de Colombia gained an important market share in Europe after its recognition as a GI within the EU market. This achievement was the result of a lengthy process initiated by the Colombian Coffee Growers Federation to offset the low prices of coffee, which had fallen sharply since the 1950s.³⁶ Moreover, in a globalized world, where consumers can access commodities from everywhere, they are prone to buy more quality products, distinguishable from the average commodities, as occurs with coffee.³⁷

Additionally, rights holders and governments from developing countries must be aware of potential misappropriations of their GIs in other countries through other intellectual property mechanisms such as trademark registries and patent claims. While enhanced protection of all GIs is achieved under TRIPS, developing country Members must direct their efforts to include registry obligations as a commitment in the free trade agreements they are subscribing with developed countries. As suggested

³² Evans and Blakeney, 'The Protection of Geographical Indications After Doha: Quo Vadis?' (2006) 9 *Journal of International Economic Law* 607.

³³ WTO Doha Ministerial Declaration, adopted on 14 November 2001.

³⁴ Evans and Blakeney (n 34) 607.

³⁵ In order to avoid patent claims issued outside the territory from which these products originate (as happened with some Indian plants such as Basmati rice, Jasmine rice, Neem, and Turmeric), as well as trademark registration of these geographical names as in Rooibos from South Africa. Some of these cases, mentioned by Evans and Blakeney (n 34) 607, were largely reported by Banerjee and Majumdar (16) 660, and Rizo (n 20) 51.

³⁶ WIPO (n 3) 16.

³⁷ Evans and Blakeney (n 34) 608.

by Correa, this could be the best way to move forward in the same direction at the main multilateral forums such as WIPO and the WTO.³⁸

It is important to mention that GIs are not merely a property-oriented intellectual property means that confers a local community with an economic asset. On the contrary, a GI is nothing but the recognition of the reputation, quality or value added of a product due to its geographic or human factors. Thus, international GI registries and the extension of the additional protection granted to wines and spirits to all goods will not necessarily contribute to the proliferation of undeserved recognition of GIs, because this intellectual property mechanism still has its specific requirements. In other words, as explained by Rizo, not every product is 'GI-able'.³⁹

Colombia and other such countries should become a signatory to the WIPO-administered Lisbon Treaty, and ratify it. This will allow reciprocal recognition of Colombia's GIs within the Contracting Parties' territories, which bodes well for the protection of its 20 denominations of origin and those forthcoming in the global market. The efforts in the main intellectual property and development forums should be ongoing until progress is made towards the protection of traditional knowledge, biodiversity, international registration of GIs and additional protection for all GIs.

V. CONCLUDING REMARKS

Geographical indications do not constitute the ideal mechanism for intellectual property protection of all creations and products. Plant breeders' rights provide effective protection for new varieties of plants, however, they do not protect plant varieties produced using traditional knowledge-based techniques and methods. Therefore local communities and indigenous peoples from developing countries lack an adequate tool to protect their creations. Geographical indications constitute such a tool, temporarily. As for biodiversity, GIs are a valuable alternative, where there is a lack of a proper instrument for this asset. Well managed GIs that are registered, advertised and commercialized could prevent the granting of patents and trademarks in foreign countries over natural resources, whose origin is from a different country. This could assist in preventing biopiracy and misappropriation of resources from developing countries, while enabling local communities and

indigenous peoples to continue protecting these resources as they have done for centuries.

In the same vein, GIs are undoubtedly suitable for artisanal works, handicrafts and foodstuffs, among others. However, they are not suitable for protecting intangible traditional knowledge such as dances, poetry and other forms of folklore.

Geographical indications are a valuable alternative or complementary means to protect some of the main intellectual property creations and assets from developing countries. In Colombia, where national and local public authorities are entitled to file a request for a GI, this mechanism could be used as a public policy instrument in order to achieve collective goals.

However, GIs are not a remedy to protect all traditional knowledge, plant varieties and biodiversity resources that come from developing countries. In a global market, GIs have to compete against similar unprotected goods with lower prices.

Protecting GIs from developing countries must be part of a wider intellectual property policy, accompanied by marketing and commercialization strategies in local and foreign markets. Under these conditions, GIs will contribute to an increase in income of poor populations from rural and remote areas, which accompanied by adequate policies, will be translated in their development.

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³⁸ This idea is attributed to Carlos Correa, 'Trade Related Aspects of Intellectual Property Rights' (6th edn 2007) 274, cited by Banerjee and Majumdar (n 16) 662.

³⁹ That is to say, protectable under a GI. Free translation for Rizo (n 20) 60.

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**6 PROTECTION OF TRADITIONAL KNOWLEDGE
RELATED TO BIOLOGICAL AND GENETIC
RESOURCES: EXAMINING THE ACCESS AND BENEFIT
SHARING REGIME IN ETHIOPIA**

Dr Biruk Haile*

ABSTRACT

In the 21st century political economy, attention is shifting from material assets to intangible, creative national wealth. However, developing countries do not have a great deal of individual creative wealth protectable by conventional areas of intellectual property and they are looking to community creations, accumulated over generations, resulting from societal interaction with the environment. Even though the Convention on Biological Diversity (CBD) has changed the perception that genetic resources and related knowledge are sovereign resources of the respective territories, there is doubt as to whether national access and benefit sharing (ABS) regimes can be effective without an adequate international legal framework. In fact, there is growing curiosity whether national ABS systems will open new horizon for misappropriation of traditional knowledge if not supported by a proper international legal framework. This article examines the adequacy of national and international legal frameworks for the protection of traditional knowledge associated with genetic resources. To this end, the Ethiopian experience is taken in to account.

Keywords: *traditional knowledge, access, benefit sharing, prior informed consent, biological and genetic resources, Teff Agreement, local communities, Convention on Biological Diversity (CBD)*

I. UNDERSTANDING TRADITIONAL KNOWLEDGE

The term "traditional knowledge" is applicable both to biodiversity-related traditional knowledge (also called traditional ecological knowledge) and to traditional expressions. There is no officially agreed upon legal definition of traditional knowledge at the international level despite initiatives for protection

in certain multilateral forums such as WIPO and the CBD.²

Most legal scholars find it difficult to define traditional knowledge for a number of reasons:

- (a) Some traditional knowledge is sacred while some is commercially available;
- (b) some subjects protected are difficult to identify specifically;
- (c) some subjects protected are not documented in many cases and this breeds legal uncertainty;
- (d) it is difficult to identify specifically who holds the right;
- (e) it is difficult to apportion ownership among communities inhabiting diverse territories, all claiming authorship and custody of given traditional knowledge; and
- (f) it is difficult to ascertain the duration of protection.

Defining traditional knowledge is also difficult, partly because traditional knowledge encompasses knowledge relating to the history, ethics, aesthetics, and traditions of societies. Nonetheless, the notions of traditional knowledge, indigenous knowledge, and indigenous people have recently acquired prominence in international intellectual property discourse.³ Noteworthy, the notion of indigenous peoples is not coextensive with traditional people.⁴ Indigenous knowledge is defined as follows:

Knowledge that is held and used by a people who identify themselves as indigenous of a place based combination of cultural distinctiveness and prior territorial occupancy relative to a more recently arrived population with its own distinct and dominant culture.⁵

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¹ Graham Dutfield, 'Developing and Implementing National Systems for Protecting Traditional Knowledge: A Review of Experiences in Selected Developing Countries: Developing and Implementing National Systems for Protecting Traditional Knowledge: A Review of Experiences in Selected Developing Countries' (Genève UNCTAD 2000), p3.

² Graham Dutfield, 'Developing and Implementing National Systems for Protecting Traditional Knowledge: A Review of Experiences in Selected Developing Countries: Developing and Implementing National Systems for Protecting Traditional Knowledge: A Review of Experiences in Selected Developing Countries', (Genève UNCTAD 2000), p3.

³ John Mugabe, 'Intellectual Property Protection and Traditional Knowledge: An Exploration in International Policy Discourse', (African Centre for Technology Studies, Nairobi), <wipo-unhcr-ip-pnl-98-4>, accessed 5 September 2015.

⁴ While indigenous people are traditional, traditional people may not be indigenous as they may not be prior territorial occupants to current habitat even though they have their own distinct culture.

⁵ UNEP/CBD/COP/3/Inf. 33, Annex 2, accessed 5 September 2015.

Traditional knowledge, on the other hand, is defined as:

knowledge which is held by members of a distinct culture and/or sometimes acquired by means of inquiry peculiar to that culture, and concerning the culture itself or the local environment in which it exists.⁶

The WIPO Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore defines traditional knowledge as follows:

[T]he term "traditional knowledge" refers to the content or substance of knowledge that is the result of intellectual activity and insight in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge that is embodied in the traditional lifestyle of a community or people, or is contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources.

Ethiopian law follows a similar approach by defining community knowledge as the 'knowledge, practices, innovations or technologies created or developed over generations by local communities on the conservation and use of genetic resources'.⁷

Most efforts to define traditional knowledge have commonalities:

- (a) 'Traditional' reflects creation and use of knowledge as part of cultural community traditions and in no way signifies age;
- (b) it is a collectively held right; and
- (c) it is not limited to any specific field of technology.⁸

This comports with the approach employed under the Convention on Biological Diversity that avoids definitions and makes lengthy reference to 'knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles' and also refers to 'indigenous traditional technologies'.

⁶ Ibid.

⁷ Article 2 (14) of Proclamation No 482/2006.

⁸ Daniel Gervais, 'TRIPS, Doha and Traditional Knowledge', *The Journal of World Intellectual Property* 403.

Yet, most agree on the need to protect traditional knowledge because it improves the livelihood of indigenous and local communities, benefits national economies, conserves the environment, and reduces biopiracy.⁹

II. INTELLECTUAL PROPERTY PROTECTION OF TRADITIONAL KNOWLEDGE

Means advocated to protect traditional knowledge often take a defensive or offensive/positive protection. The former refers to measures preventing the acquisition of intellectual property rights, whereas the latter refers to granting positive rights that enable the right holder to resist third parties.¹⁰ The main weakness of defensive models is that it exposes traditional knowledge to exploitation and does not enable right holders to object to exploitation of the knowledge.

Protection of traditional knowledge became of international concern for two main reasons, namely, the exploitation of traditional knowledge without benefit sharing and the increased political prominence of aboriginal communities in various countries.¹¹ These reasons were coupled with increased awareness of the significance of traditional knowledge in the lives of a majority of the world's population and the contribution of protection to conservation of biodiversity.¹² Additionally, 'Western science' discovered that traditional knowledge may provide effective solutions to technological problems.¹³

Until relatively recently, traditional knowledge was regarded as information in the public domain or common heritage of human beings, freely accessible and exploited by companies across territories. This was particularly the case with food, medicinal, agricultural, and body products, in part because traditional knowledge significantly contributed to plant breeding, genetic enhancement, drug development, and biodiversity conservation. Current intellectual property holders of traditional knowledge in many instances appropriated rights

⁹ Graham Dutfield (n1), pp 5- 11.

¹⁰ Alois Leidwein, 'Protection of Traditional Knowledge Associated with Biological and Genetic Resources: General Legal Issues and Measures Already Taken by the European Union and its Member States in the Field of Agriculture and Food Production', (2006), 9 (3), *The Journal of World Intellectual Property*, 251, 251.

¹¹ Daniel Gervais, (n7), p 403.

¹² Sophia Twarog and Promila Kapour (eds), 'Preserving, Protecting and Promoting Traditional Knowledge: National and International Dimensions', (UNCTAD 2004), p 61.

¹³ Carlos M Correa, 'Traditional Knowledge and Intellectual Property: Issues and Options Surrounding the protection of Traditional Knowledge', (the Quaker United Nations Office, 2001), p 3.

without the consent of and compensation to creators of such knowledge. And initiatives for intellectual property protection of traditional knowledge face resistance from these rights holders who fear such protection would undermine their rights.

The protection of traditional knowledge has also become of interest to some developed countries in Europe that have realized the potential of applying traditional knowledge to agricultural pursuits.¹⁴ However, one can easily discern that protection of traditional knowledge is not a pressing issue for most developed countries.

Proponents of the protection of traditional knowledge argue that such protection promotes technological innovation and provides an incentive to indigenous communities to conserve the environment and manage biodiversity.¹⁵ The argument against protection of traditional knowledge holds that such protection will destroy the social basis for generating and managing knowledge - it denies future generations' and industries' access to such knowledge.¹⁶

Numerous international legal bodies and treaties address the protection of traditional knowledge: the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources for Food and Agriculture (promoting conservation and sustainable use of biodiversity); ILO Convention 169 Concerning Indigenous and Tribal Peoples in Independent Countries, the UN Draft Declaration on Indigenous Peoples Rights, UDHR (protecting the rights of indigenous people); the World Intellectual Property (WIPO) (protection of intellectual property); UNESCO (promoting culture); and UNCTAD and WTO (promoting trade).¹⁷

The existing system of international intellectual property law does not adequately protect traditional knowledge. The main difficulties in accommodating the protection of traditional knowledge within the prevailing system of intellectual property relate to the notion of ownership/authorship, which for traditional knowledge does not vest in a particular person, and the notion of temporal limitation. The Paris Convention provides for protection in the context of trademarks, utility models, industrial designs, service marks, and indications of source or appellations of origin. Particularly relevant to protecting origins of communal creations is the collective trademark, certificate, or geographical origin protection afforded under Article 7*bis* of the

Paris Convention and TRIPS Article 22. Protecting the origin indirectly protects the underlying knowledge of a certain good. Traditional knowledge can be protected in the context of undisclosed information under TRIPS Article 39. But most traditional knowledge will not meet the requirements of patentability.¹⁸ Also, the requirement of disclosure in patent laws will make traditional knowledge even more vulnerable. What is obvious is that the prevailing intellectual property system is suited to protect knowledge held in developed countries, not traditional knowledge.

III. TRIPS AND THE CONVENTION ON BIOLOGICAL DIVERSITY

The Convention on Biological Diversity and the International Treaty on Plant Genetic Resources (ITPGR) are the two main international instruments protecting rights relating to biological resources and genetic resources. The Convention on Biological Diversity deals with protection of both biological resources and the traditional knowledge associated with it. Articles 3, 4 and 15 of the Convention on Biological Diversity clearly reveal that states have the sovereign right to regulate access to genetic and biological resources and also the right to exploit such resources themselves. In addition, Article 15 introduces the notion of prior informed consent (PIC) and benefit sharing in relation to genetic resources.¹⁹ The ABS principle has the effect of restricting access to genetic resources; Article 15.5 provides a counter-balance by disallowing contracting parties from imposing restrictions that run counter to the objectives of the convention.

Article 8(j) of the Convention on Biological Diversity states:

Each contracting party shall, subject to its national legislation, respect, preserve, and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant to the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization

¹⁸ Unless one argues that traditional knowledge is new to the world beyond that community, the requirement of novelty will not be met; similarly there will be issues of non-obviousness and utility.

¹⁹ However, ABS principles as enshrined in the CBD are not susceptible for direct implementation and instruments like the Bonn and Nagoya protocols are developed to give effect to the principles.

¹⁴ Alois Leidwein, (n 9), 251, 257-58.

¹⁵ Jhon Mugabe, (n 2).

¹⁶ Ibid.

¹⁷ Sophia Twarog and Promila Kapour (n 11), p 61.

of such knowledge, innovations and practices.

Many writers argue that the Convention on Biological Diversity does not impose a definitive obligation on members to protect the knowledge, innovation or practices of indigenous and local communities, because of its reference to national legislation. Additionally, Article 8(j) requires parties to 'respect, preserve, and maintain' traditional knowledge and as such does not enable traditional and local communities to invoke proprietary rights in traditional knowledge. The Convention on Biological Diversity - the pioneer instrument for genetic resources and traditional knowledge in certain respects—is not fully clear as to why a proprietary approach is not applied to traditional knowledge as it is with conventional intellectual property rights. The fact that local communities conceive genetic resources and traditional knowledge, according to principles of openness and broader exploitation, does not conflict with a proprietary approach. The ABS system would have been more effective with the property conception/intellectual property rights regime of traditional knowledge and genetic resources. The Convention on Biological Diversity is premised on the prevention of misappropriation and not on proprietary notions, despite recognizing the sovereignty of states over such resources.

Under TRIPS Article 27, states have an obligation to provide patent protection to inventions and protect plant varieties with either a patent or effective *sui generis* system of protection or any combination thereof. However, that Article does not guarantee recognition or remuneration to communities whose traditional knowledge is used in new inventions or in the new plant varieties. Noteworthy, TRIPS does not incorporate the Convention on Biological Diversity, at least with respect to traditional knowledge. This omission generated arguments that TRIPS undermines and in fact conflicts with the Convention on Biological Diversity, as it does not give effect to the ABS principles of the latter. In other words, under TRIPS, an inventor who benefited from traditional knowledge in creating the new invention or variety can secure patent protection without complying with his/her prior informed consent and ABS obligations under the Convention on Biological Diversity. This puts TRIPS on a collision course with the Convention on Biological Diversity. Even though TRIPS Article 27.3(b) does not prohibit countries from providing protection following the ABS principles of the Convention on Biological Diversity, such protection may not be effective without an international framework; TRIPS patent protection undermines ABS principles in the Convention on Biological Diversity.

In fact there is a strong argument that intellectual property protection of traditional knowledge is not trade related, such that issues can be negotiated either within WIPO or the Convention on Biological Diversity framework, and not in the WTO context. This is mainly because TRIPS Article 2.1 defines intellectual property in terms of 'all categories of intellectual property that are the subject of Sections 1 through 7 of Part II'. When we examine this definition of intellectual property in depth, it appears that intellectual property, for the purposes of TRIPS, refers to the exclusive rights recognized (either conventional or *sui generis*) with respect to creative works in Part II, not creation itself. The provisions in Part II do not recognize exclusive rights regarding traditional knowledge, either as conventional intellectual property or *sui generis* protection. Article 1.1, paragraph 2 of TRIPS allows countries to exceed the minimum standard of protection provided in the Agreement; this can only be seen as referring to stronger exclusive rights recognized in relation to conventional or *sui generis* rights referenced in Part II.

The Doha Declaration addresses the issue of traditional knowledge in the context of TRIPS. It instructs the Council for TRIPS, in pursuing its work programme, to examine, *inter alia*, the relationship between TRIPS and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. This brought Article 27.3(b), which deals with biological inventions, to the forefront. And this generated various proposals regarding the relationship between TRIPS and the Convention on Biological Diversity.

The first proposal, presented by many developing countries, required amending TRIPS in such a way that patent applicants are required to disclose the country of origin of the genetic resource and the traditional knowledge on which the invention is based and disclose any evidence of prior informed consent and fair and equitable benefit sharing.²⁰ The second proposal required amendment of WIPO's Patent Cooperation Treaty (WPCT) for domestic patent laws to require disclosure as a condition for grant of patent or its invalidation.²¹ The third proposal, championed by the European Union, supported the requirement of disclosure but suggested that consequences for non-compliance should be dealt with outside the patent regime. The last proposal, by the United States, argued that the Convention on Biological Diversity's objectives on

²⁰ WTO, TRIPS: Review, Article 27.3(b) and Related Issues, http://www.wto.org/english/tratop_e/trips_e/art27_3b_ba ckGRsound_e.htm, last accessed on 3 October 2014.

²¹ *Ibid.*

access to genetic resources and benefit sharing can best be served by national legislation and contractual arrangements involving obligations to disclose commercial applications of genetic resources and traditional knowledge based on such laws. But the main weakness of the United States' proposal seems to lie in the fact that contractual mechanisms of access framed on national legislation cannot have effect with respect to cross-border misappropriation, and many cases of misappropriation are carried out by foreign companies that obtain intellectual property rights abroad based on traditional knowledge.²²

No proposal aims at providing exclusive rights for traditional knowledge. In fact, one can argue whether the members even needed a declaration or agreement to require disclosure of satisfaction of the ABS principles within the context of TRIPS Article 29. These proposals do not address situations where traditional knowledge and biological resources are misappropriated and used elsewhere without patent application. Furthermore, no provision of any proposal directly recognizes or gives effect to ABS rules in the Convention on Biological Diversity. This may be due to members believing that protection of traditional knowledge is not related to trade. Developing countries should have seized the opportunity to utilize TRIPS for positive protection of traditional knowledge, thereby putting such matters in a trade context. After all, one of the main justifications for protection is to protect commercial interests of local communities, which cannot be realized through a defensive approach alone.

IV. OWNERSHIP AND EXPLOITATION OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN ETHIOPIA

Ethiopia is a centre of biodiversity.²³ The country has adopted the Convention on Biological Diversity and the ITPGR. The country enacted a legal framework providing an ABS regime in 2006 under Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation No. 482/2006 (access proclamation). To implement the proclamation, the Government has also issued Regulation No. 169/2009. Prior to enactment, there had not been a legal framework requiring informed consent and ensuring equitable sharing of benefits by legitimate holders of traditional knowledge. The access proclamation applies both to genetic resources (both *in situ* and *ex situ*) and community knowledge. However, under Article 4(2), the access proclamation does not apply to the customary use and exchange of genetic resources and community knowledge by and among Ethiopian local

communities, and the sale of produce of biological resources for direct consumption does not involve the use of the genetic resource thereof.

Article 5(1) of the access proclamation vests ownership of genetic resources in the state and the Ethiopian people. This approach is in consonance with the Convention on Biological Diversity, which reiterates the sovereign right of member states over natural resources in their territories. Accordingly, Article 11(1) of the access proclamation provides:

without prejudice to the provisions of Sub-Article 2(a) of Article 4 of this Proclamation, no person shall access genetic resources or community knowledge unless in possession of written access permit granted by the Institute (i.e., the Federal Institute of Biodiversity) based on prior informed consent.

Ethiopia is a federal state and interested parties that intend to access genetic resources even in regional states have to seek an access permit from the federal government.²⁴ However, paragraph 7 of the preamble of the access proclamation deviates from this by recognizing the necessity to involve communities in the decision-making process regarding the use of genetic resources and community knowledge and benefit sharing thereof. Dr Fikremarkos alludes to this line of argument when he says 'it seems strange that the ABS law, while based on the premise that communities have been responsible for the conservation and preservation of genetic resources and consistently referring to the genetic resources as "their" resources, failed to grant them the right to say no to access "their" resources'.²⁵ The approach followed by the access proclamation also contradicts, at least partly, the constitution's empowerment of regional states to administer natural resources (including genetic resources) in accordance with federal laws.

Article 5(2) provides that ownership of community knowledge shall be vested in the local community concerned. Article 2(9) defines 'local community' as a human population living in a distinct geographical area in Ethiopia that acts as a custodian of a given

²⁴ Article 40(1) of the FDRE constitution vests ownership of land and 'other natural resources' in the state and the people of Ethiopia. The power to legislate is also vested in the federal government under Article 55 (5) of the FDRE constitution, which empowers the federal government to enact laws for the utilization and conservation of natural resources; regional governments are vested with the power to administer the resources in accordance with federal laws.

²⁵ Fikremarkos Merso, 'Challenges and Prospects of Implementing the Access and Benefit-Sharing Regime of the Convention on Biological Diversity in Africa: the Case of Ethiopia', (2010), Springer, 250, 258.

²² Carlos M Correa, (n 12), p 17.

²³ <http://www.biodiv.org>.

genetic resource or is the creator of a given community knowledge. Therefore, it does not affect ownership of traditional knowledge in Ethiopia that the same knowledge is held elsewhere by other communities outside the country. Also, it is possible for the same knowledge to be shared among different communities within Ethiopia, in which case, Articles 21 and 26 to 33 of the regulations provide for a community consent procedure.

Regarding the exploitation of traditional knowledge, Article 7(2) of the access proclamation provides the conditions and the procedure by which local communities shall give prior informed consent for access to their community knowledge. Article 22 of the regulations stipulates the manner of soliciting consent of local communities through representation.

V. RIGHTS OF LOCAL COMMUNITIES

Article 6 of the access proclamation recognizes the following rights of local communities over genetic resources and community knowledge:

- The right to regulate access to their community knowledge;
- the inalienable right to use their genetic resources and community knowledge; and
- the right to profit from the benefits arising out of the utilization of their genetic resources and community knowledge.

The right of local communities to regulate access to their community knowledge includes the right to give prior informed consent, the right to refuse consent, the right to withdraw or place restrictions on prior informed consent given for access to community knowledge, and the right to demand restrictions or withdrawal of prior informed consent given by the federal Biodiversity Institute (BDI) for access to their genetic resources.²⁶ In relation to access to genetic resources, local communities can only 'demand' restriction or withdrawal of prior informed consent given by the BDI and there is no provision which states that such demand will bind the BDI. There is no procedure to seek consent of local communities before the grant of the permit, except that they will have opportunity to cast their objection when the access application is published under Article 6 of the regulations.

Article 7(1) of the access proclamation makes clear that local communities cannot refuse consent or restrict or revoke consent arbitrarily, but can only on

grounds of integrity of culture or natural heritage and detriment to socioeconomic life. Further, grounds for denial of a permit by the BDI are provided under Article 13 and mainly relate to biodiversity conservation and sustainable use of biological resources, as spelled out in the objective of the access proclamation under Article 3.

Under Article 11 of the access proclamation, anyone who wants to access genetic resources or traditional knowledge must acquire a written access permit from the BDI based on prior informed consent. Article 19 of the access proclamation sets economic and non-economic terms that may be included in the ABS agreement. The Article 15 procedure for accelerated access provides Ethiopian higher learning and research institutions and intergovernmental organizations access permits outside of the procedures described above.

We can infer that local communities have a right of action against anyone who exploits traditional knowledge acquired in any manner without their consent. Article 2(1) of the access proclamation defines access as the collection, acquisition, transfer, or use of genetic resources and/or community knowledge. In this regard we can characterize the system of protection in the access proclamation as positive protection that prevents commercial exploitation by others. It can also be seen as providing negative protection that prevents others from acquiring intellectual property rights on creations based on traditional knowledge as such presupposes access. However, other laws, including the patent proclamation, do not give effect to this right as the requirement of disclosure of origin of underlying traditional knowledge – prior informed consent and proof of benefit sharing - are not a precondition for a grant of patent.

When we see the exploitation of access to money, Article 9(1) of the access proclamation entitles local communities to money collected from access to community knowledge. Under Sub-Article (2), local communities also are entitled to 50 per cent of the money derived from utilization of their genetic resources; the other 50 per cent goes to the federal government. Article 28 of the regulations provides that access money, which devolves to local communities, should be used to finance development projects designed to benefit the concerned communities. The money that goes to the federal government will be used, under Article 27 of the regulations, for biodiversity conservation based on selected project proposals.

²⁶ Article 7(1) of the access proclamation.

VI. SOME EXPERIENCE WITH ACCESS AND BENEFIT SHARING AGREEMENTS IN ETHIOPIA

Based on the legislation discussed above, Ethiopia passed two ABS agreements: an agreement on teff (*Eragrotis tef*) and an agreement on vernonia (*vernonia galamensis*). The latter agreement was made between the Ethiopian Federal Institute of Biodiversity and Vernique Biotech Ltd in July 2006. Vernique terminated this agreement in 2009, mainly on alleged grounds of lack of profit. Teff is gluten-free grain heralded for its value over other grains such as wheat, barley, and maize, and it is used mainly in making the Ethiopian staple called *injera*, not to mention its use in gruel, cakes, and homemade beverages.²⁷ The teff agreement was signed in April 2005 with a Dutch Company, Health and Performance Food International (HPFI), for a duration of ten years, and this agreement was retained within the framework of the access proclamation enacted later in 2006. The agreement, under Article 3, gives the company the exclusive right to access and use the genetic resource of teff for the purpose of developing non-traditional teff-based food and beverage products that are listed in Annex 3 of the agreement. The agreement imposes some obligations on the company, including the obligation not to use teff for other purposes, not to access traditional knowledge on conservation, cultivation and use of teff, and not to claim any right on such knowledge without explicit agreement of the other party. Additionally, the company could not claim intellectual property on the genetic resource of teff (except joint ownership of plant variety protection over new teff varieties), must acknowledge Ethiopia as the genetic origin of teff, and must not transfer any component of teff to third parties.

In addition, the agreement imposed benefit-sharing obligations, including payment of a lump sum, an annual royalty of 30 per cent of net profit of seed sales, an annual licence fee, a dividend of 5 per cent of annual profit, and an obligation to involve Ethiopian scientists in any research.

However, over time it became clear that the company failed to comply with almost all of the benefit sharing obligations. In addition the company succeeded in seeking product and process patents for processing teff in the Netherlands, Europe, and beyond; it also secured protection for new varieties of teff.

The current patent law of Ethiopia allows foreigners to claim patent-based reciprocity or international

agreement.²⁸ But it is unlikely that the teff-processing patent will pass the test of novelty as the patent claims are preempted by traditional Ethiopian knowledge. However, disclosure of origin of genetic material and proof of benefit sharing is not required under current patent law and a patent may be claimed in relation to an invention based on pirated genetic material.²⁹

PHFI transferred its teff patent rights to another company founded by PHFI and then insisted that the new entity was not bound by ABS obligations. This placed the ABS agreement at a cross roads and whatever obligations the company assumed under the Ethiopian law vanished, placing the issues at the mercy of the Netherlands' domestic law. In fact, whatever remedy may be available under the Netherlands' domestic law is simply beyond the reach of least developed countries such as Ethiopia, who cannot cover cost of litigation abroad.

Compounding the frustration and upset of such situations is that upfront payments are often not agreed up on and no security to ensure performance by recipients of traditional knowledge and genetic resources of their obligations are granted. The proclamation, under Article 12(4), provides that an access applicant who is a foreigner shall present a letter from the competent authority of his national state or his domicile assuring that it shall uphold and enforce the access obligations of the applicant. In the teff case, only the Ambassador of the Netherlands signed as a witness and this in no way imposes a contractual obligation. One may strongly argue in a situation where a multilateral framework is helpful, states should devise bilateral arrangements before ABS agreements are concluded. The anticipated Nagoya Protocol itself will not make much difference when/if it is implemented, as it does not have an effective mechanism for settlement of ABS disputes.

At its outset, the teff agreement was hailed as a success of the ABS system under the framework of the Convention on Biological Diversity. Yet, it ended up in bitter lessons, and Ethiopia views the subject with extreme caution; no other material transfer agreements have been signed to date.

²⁸ Article 5, Patent Proclamation No 123/1995.

²⁹ The obligation of the permit holder to recognize the origin of genetic resources or traditional knowledge under Article 17(14) in the application for commercial property protection of the product developed therefrom is not incorporated in the patent proclamation as a condition for the issue of a patent.

²⁷ Regine Anderen and Tone Winge, 'The Access and Benefit-Sharing Agreement on Teff Genetic Resources: Facts and Lessons', (Fridtjof Nansen Institute, 2012), p 7.

VII. CONCLUSION

Both developing and developed countries have opted not to employ a positive intellectual property right approach to protect traditional knowledge. This has emboldened the suspicion that protection of traditional knowledge is not trade related, and no proposal for minimum standards was tabled by developing countries during the Doha Round of trade negotiations. The legitimate quest for positive intellectual property protection has been sacrificed for the sake of retaining the status quo designed to benefit only the conventional intellectual property sector. The lack of minimum standards of intellectual property rights, coupled with the lack of effective dispute settlement mechanisms in the Convention on Biological Diversity, means that ABS agreements, in principle, do not have effect beyond the territorial frontiers of the countries concerned. As a result, there are indications that foreign companies have started using ABS agreements to facilitate biopiracy and misappropriation of traditional knowledge. The teff agreement clearly reveals that foreign companies can access genetic resources and traditional knowledge using ABS agreements and renege on such agreements with impunity. To leave regulation of ABS agreements to contracts and domestic laws is an utter bias against traditional knowledge. To leave out traditional knowledge from TRIPS is a glaring discrimination. In this vein, the Ethiopian access proclamation failed to give effect to property rights of local communities over their traditional knowledge recognized under the federal constitution.

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7 THE ISSUE OF WORKING OF PATENTS AND ITS IMPLICATIONS FOR DOMESTIC TRADE, ECONOMIC DEVELOPMENT AND TECHNOLOGY TRANSFER

Dr Prabuddha Ganguli*

ABSTRACT

This article analyses issues related to working of patents and the unique statutory requirement of periodic reporting on the working of patents in India via Form 27 by the patentee and any licensees. The consequence of failure to report, late reporting, and wrong reporting of working of patents in India is discussed. It is concluded that the current Form 27 is outdated and out of context in the framework of present day international business practices and an immediate revision of Form 27 is recommended in India.

Key words: Working, Patents, Form 27, reporting, compulsory licence, Indian, 'non-practising entities'

I. INTRODUCTION

The world of patents has undergone metamorphic changes since its inception. The TRIPS Agreement through its tortuous negotiating history has attempted to harmonize intellectual property laws within its Member states. However, contentious

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issues involving diverse interest groups have kept debates alive regarding balancing the interests of inventors, intellectual property right owners and business groups on the one hand, and making the benefits of the patent system timely and affordably accessible to the public on the other. This tug-of-war between seemingly non-converging parties becomes complicated due to its multidimensional features, as is best enunciated and recognized in the preamble of the TRIPS Agreement, thereby capturing the sentiments and spirit of the agreement and laying the foundation for a holistic interpretation and understanding of its nuances.

The proceedings at the WTO in these bygone years have demonstrated that the last word acceptable to all Members of the WTO on the harmonious interpretation of the rights and obligations of a patentee has not yet been inscribed.

The preamble of the TRIPS Agreement is fairly comprehensive in its effort to reduce distortions and impediments to international trade by recognizing diverse aspects and interests related to the creation of adequate standards for intellectual property rights, which are private rights, including: effective enforcement, intranational policies, inter-governmental agreements, conventions (such as those administered by WIPO), special needs of least developed countries, and multilateral procedures for disputes between governments. The preamble additionally recognizes the further need for a multilateral framework of principles and rules for dealing with international trade in counterfeit goods.

The various articles of the TRIPS Agreement therefore are to be read and interpreted in conjunction with the provisions of other agreements and/or conventions. Specifically, in the case of patents, the TRIPS Agreement has to be considered together with the provisions in the Paris Convention and the other conventions administered by WIPO.

II. CONTOURING THE ISSUES

A patent grants a negative right by way of a monopoly to the patentee for a limited period of time in the country of the grant to stop others from making, using, selling or vending the patented invention without the patentees consent.

One of the central points in the current debate continues to be whether the TRIPS Agreement precludes the possibility of legislated local working in certain Member states. The key questions raised are therefore 'whether the patentee is obligated to work the patent that has been granted to him', and if so, 'is the patentee obligated to local working of the patent granted to him in the country of grant' and further, if local working is an obligatory requirement, then, what is the interpretation of the expression 'local working' and further, 'the consequences of not having locally worked the granted patent'.

Historically 'local working' has been viewed as a device for the transfer of technology and industrialization, a means for foreign investments, for generating partnerships between the 'technology haves and have-nots', and the like. From a utilitarian perspective, arguments have mostly been in favour of the local working of patents, though there have been counter arguments from a bargain theory standpoint.¹ Local working requirements have generally been considered as a tool to balance the exclusive rights of a patentee with his obligations towards contributing to public interests. Critical examination of local working brings forth several 'for and against arguments' to be considered. A recent study provides a checklist of elements to be considered in evaluating the benefits of local working requirements and suggests that below a certain threshold, which is malleable to the principle of graduation, exceptions to obligations under the TRIPS Agreement should be made.²

There is yet another dimension to the issue related to 'local working'. A legitimate question that may be posed is whether periodic reporting on 'local working' is a statutory requirement in the country in which the patent has been granted and what are the implications of non-reporting, insufficient reporting, wrong reporting and delayed reporting of the 'local working' to the appropriate authority in the country in which the patent has been granted. Further, what are the detailed statutory requirements of reporting of local working of patents?

The answers to these questions have major implications on trade-related and societal issues, especially when addressing the complex and strategic management of such patents/patent portfolios.

A patent grants the patentee the monopoly over his patented invention. However every system certainly discourages any monopolistic practices that would discourage or reduce competition in society. It ought to be appreciated that overuse of the monopoly could cross into the forbidden zone of monopolistic practices, a problem which anti-trust or competitive

laws could address. 'Failure to work a patent' may be deemed to be abusive and, thus, may become a subject to the remedy of compulsory licensing.

III. IDENTIFYING THE RELEVANT PROVISIONS FOR CONSIDERATION

Working the patent is not mandatory as per US patent law. However this requirement features prominently in several other countries where 'failure to work the patent' in the country of grant, in a specified time-period, makes the granted patent vulnerable to the grant of a compulsory licence or even leads to the cancellation of the patent in that country.

A historical perspective of a few pre-TRIPS provisions is of significance:

- As early as in the 15th century, the Venetian Patent Act of 1474 mandated the active working of patents, and any failure to do so, could result in the cancellation of the patent.
- As early as 1623, the English Statute of Monopolies mandated provisions for the working of a granted patent.
- Article I, Section 8, Clause 8 of the US Constitution also provides the philosophical backdrop for the patent system as it considers it: 'To promote the Progress of Science and useful Arts'.
- The American Patent Act of 1790 provided Americans with monopoly rights to import foreign technology, without any obligation to protect foreign inventors' rights.
- The Bayh-Dole Act in the United States provides for march-in provisions for the government, if a federally funded invention is not worked in a specified time.
- Article 5(A)(2) of the Paris Convention states that each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licences to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

The TRIPS Agreement in Article 27(1) states that patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

¹ Adam Bierylo, 'Importing Doesn't Work: Justifying Local Working Requirements through a Historical, Theoretical, and Contractual Perspective' (2013) Volume 3, Issue 1 <<http://ir.lib.uwo.ca/cgi/viewcontent.cgi?article=1065&context=uwoils>>

² Cottier Thomas, Lalani Shaheez and Temmerman Michelangelo, 'Use It or Lose It: Assessing the Compatibility of the Paris Convention and TRIPS Agreement with Respect to Local Working Requirements' Working Paper n 2012/11| June 2013, NCCR Trade Regulation, <http://www.wti.org/fileadmin/user_upload/nccr-trade.ch/wp3/Use_it_or_Lose_it_June_2013.pdf>

The key issue is whether the provision of Article 27(1) of the TRIPS Agreement is to be interpreted in isolation to the other provisions, such as Articles 2(2), 7, 8, 30, 31, 66³ of the TRIPS Agreement and other related international conventions and agreements, and what would be its ramifications?

A combined reading of the above interrelated provisions leads to the conclusion that Article 27.1 is to be read alongside all the other provisions and therefore 'local working' is an essential precondition for the patentee to meet his obligations to the

³ TRIPS Article 2.2:

'Nothing in Parts I to IV shall derogate from existing obligations that members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits'.

Article 7 of TRIPS

Objectives

'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'.

Article 8 of TRIPS

Principles

'1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement'.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology'.

Article 30

Exceptions to Rights Conferred

'Members may 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'.

Article 31

Other Use without Authorization of the Right Holder

'Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: Subclauses (a) to (l)'.

Article 66

Least-Developed Country Members

'2. Developed country Members shall 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'.

society and to the country in which the patent is granted. Cottier *et al*³ argues that an analysis of the apparent legal conflict between Article 5 of the Paris Convention and TRIPS Article 27 and whether countries should impose the local production of inventions, for which they grant a patent, should take into consideration broad concepts such as 'made in the world', a calculation of the costs and benefits of a local production for local communities, regions and technology sectors, and the economic reality.

The question of whether mere importation should be considered to be 'local working' would have to be responded to in a contextual manner, based on the nature of the patented product, the manufacturing capabilities in the country in which the patent has been granted, the cost of production, and several other business-related issues, and whether the mere act of importation would meet the reasonable requirements of the public in the country in which the patent has been granted without compromising national interests.

A recent article provides a detailed analysis of the diverse issues related to this debate.⁴ The matter related to *United States v Brazil* in the Dispute Settlement Body (DSB) led the WTO to consider the legality of local working requirements. In support of its arguments, Brazil claimed that Article 5.A(2) of the Paris Convention explicitly grants a right to make use of local working requirements. Further, it claimed the validity of Article 5.A(2) was reaffirmed by its incorporation into TRIPS Article 2.2, which requires that the Paris Convention's obligation should not be derogated. Interestingly, in July 2001, the case was mutually settled before a final decision could be reached. The settlement required that Brazil provide US officials with advance notice, prior to invoking Article 68 of the Brazilian Industrial Property Law. The legal position of this provision has remained unsettled.⁵

IV. OTHER EXTERNALITIES OF NON-WORKING REQUIREMENTS

Mandatory 'local working' may be considered as a corrective measure against the growing menace of 'Non-Practising Entities' (NPEs) and 'Patent Trolls'.

⁴ Bierylo Adam, 'Importing Doesn't Work: Justifying Local Working Requirements through a Historical, Theoretical, and Contractual Perspective', (2013) 3:1 online: UWO J Leg Stud 2 <<http://ir.lib.uwo.ca/uwoils/vol3/iss1/2>>

⁵ Champ Paul and Attaram Amir, Patent Rights and Local Working under the WTO TRIPS Agreement: An Analysis of US-Brazil Patent Dispute, *The Yale Journal of International Law* 365-393, Vol 27 (2002); SSRNID 348660 : <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=348660>

The United States is already facing the heat of the proliferation of NPEs and 'Patent Trolls' as abusive patent litigation drags on its economy in terms of the wasted capital that could have been used to create new jobs, fund research and development (R&D), and create new innovations and technologies that would promote the progress of science and useful arts. This recognition has led to the passing on 5 December 2013 by a sound margin of 325 to 91 of the 'Innovation Act' (H.R. 3309), which is principally aimed at curtailing certain patent infringement litigation practices of Non-Practising Entities.

An exhaustive and illustrative study of US jurisprudence on patents and their non-use by Tyler⁶ makes cautionary remarks on the existing US patent system and strongly argues that utilizing compulsory licensing to combat patent non-use and technology suppression can help to better achieve the primary goal of the intellectual property clause of the US Constitution. Compulsory licensing that compensates inventors through reasonable and marketplace-based royalty rates will ensure that inventors continue to develop and disclose their research and discoveries to the public. Furthermore, by weakening intellectual property rights on a limited scale, Congress can ensure that patents are made available to the highest value users who can best use these patents to achieve efficient societal innovation and progress. Tyler therefore questions why patentees are not required to at least make good faith efforts to practice their patents.

A report entitled 'Patent Assertion and US Innovation' prepared by the President's Council of Economic Advisers, the National Economic Council, and the Office of Science and Technology Policy⁷ summarizes the present concerns in the US system as follows:

Patent Assertion Entities (PAEs) often abuse the US intellectual property system's strong protections by using tactics that create outsize costs to defendants and innovators at little risk to themselves. The PAE business model is based on the presumption that, in many cases, targeted firms will settle out of

court rather than take the risky, time-consuming course of allowing a court to decide if infringement has occurred.

The practices of this group of firms, which has come to file 60 per cent of all patent lawsuits in the US, act to significantly retard innovation in the United States and result in economic 'dead weight loss' in the form of reduced innovation, income, and jobs for the American economy.

Improving policy in this area is challenging because maintaining the incentives for innovation provided by patents requires allowing litigation when patents are infringed, and because practicing firms sometimes act badly as well.

A key factor in the rise of patent assertion by non-practicing entities in each of these cases was a change in law or technology that led to uncertainty about whether a patent had been infringed (for example, the granting of large numbers of patents that were broadly written or that met only a low standard of non-obviousness). History suggests that it should be possible to address these challenges. There have been two periods when conditions arose for the PAE or "shark" business model to be profitable (Lamoreaux *et al* 2013). In both instances, once the underlying conditions were changed, this business model was no longer profitable and litigation of this type fell dramatically.

Thus, the best approach to resolving today's patent troll problem is not to ban firms specialized in patent assertion, but rather to reduce the extent to which legal rules allow patent owners to capture a disproportionate share of returns to investment (Lemley 2008). We see three main areas for improvement: clearer patents with a high standard of novelty and non-obviousness; reduced disparity of litigation costs between patent owners and technology users; and greater adaptability of the innovation system to challenges posed by new technologies and new business models.

Another recent report⁸ that summarizes studies from diverse sources, using different methodologies and

⁶ Tyler Neil, 'Patent Non-use and Technology Suppression: The Use of Compulsory Licensing to Promote Progress, 162 U. PA. L. REV. 451 (2014),

<http://scholarship.law.upenn.edu/penn_law_review/vol162/iss2/5>

⁷ 'Patent Assertion and US Innovation' prepared by the President's Council of Economic Advisers, the National Economic Council, and the Office of Science and Technology Policy and issued in June 2013 by the Executive Office of the President.

<https://www.whitehouse.gov/sites/default/files/docs/patent_report.pdf>

⁸ Bessen James, 'The Evidence Is In: Patent Trolls Do Hurt Innovation' Harvard Business Review, November 2014, <<https://hbr.org/2014/07/the-evidence-is-in-patent-trolls-do-hurt-innovation>>

performed by different researchers, concludes that a consistent picture is emerging about the effects of patent litigation initiated by patent trolls:

- It costs innovators money;
- many innovators and venture capitalists report that it significantly impacts their businesses;
- innovators respond by investing less in R&D; and
- venture capitalists respond by investing less in start-ups.

Rajkumar⁹ presents a multijurisdictional analysis of issues related to trolls and legitimate actors in diverse patent systems. He concludes that an open post-grant review system with punitive measures for non-working within a reasonable period after grant and reformulation of criteria for indemnifying patent holders could discourage the practice of 'patent trolls'.

Hildreth¹⁰ reviews the pros and cons of working of patents and Non-Practising Entities from the US and European perspectives. He concludes that introducing a statutory working of patents would be a positive step that would benefit the society at large and discourage hoarding of inventions by the Non-Practising Entities.

V. SPECIAL PROVISIONS IN THE INDIAN PATENT LAW ON WORKING OF PATENTS AND ON MANDATORY REPORTING OF WORKING OF PATENTS'

Several countries have a statutory requirement concerning 'working of patents'. In such countries, the failure to work a patent within three to four years without reasonable justification after the grant has been considered to be an 'abusive' act by the patent holder, making the patent vulnerable to the issuance of a compulsory licence³.

In Turkey, to satisfy the working requirement the patentee must file a 'one-time' certificate of use or file importation documents making an offer for licensing with the Turkish Patent Institute.¹¹ The

⁹ Rajkumar.V 'The Effect of Patent Trolls on Innovation : A Multi-Jurisdictional Analysis' <<http://www.nalsar.ac.in/IJPL/Files/Archives/Volume%201/5.pdf>>

¹⁰ Hildreth Heather, 'Should an Inventor be Required to "Work" the Patent?' December 2012.

<<http://www.slideshare.net/hph5sr/should-inventors-be-required-to-work-the-patent>>

¹¹ <<http://www.deris.com.tr/faqs-for-patent-in-turkey.aspx>>

minimal specific action a patentee would need to take in order to fulfil the working requirements is filling a request with the Turkish Patent Institute for the publication of an offer for licensing in the Official Turkish Patent Bulletin. In the absence of the prosecution of any course of action regarding the working requirements, it is to be noted that the patent cannot ex-officio be revoked by the Turkish Patent Institute on grounds of non-use or failing to meet the working requirement of a patented product and/or process. The Turkish patent is not abandoned or invalidated due to the fact that no working requirement is met in the prescribed deadline of three years as from the publication date of the grant decision. The possible consequence of not fulfilling the working requirement either by filling a 'Certificate of Use' and/or importation documents would be a compulsory licence granted by the courts upon request of third parties. Until now, there is only one case for which the court has granted a compulsory licence.

Interestingly, India is the only country that has a statutory requirement of 'working of a patent by the patent holder' and also statutory annual reporting of working of patents.

This unique feature in the Indian Patents Act is an outcome of the detailed analysis of Justice Ayyangar¹², whose report formed the basis of the Indian Patents Act 1970.

The most scholarly document that became the basis of the Indian Patents Act 1970 and subsequent amendments was the 'Report on the Revision of the Patent's Law' by Shri Justice N. Rajagopala Ayyangar, of September 1959, who had foreseen the value of 'working of patents' and recommended its mandated reporting in paragraphs 33-36 and 165-167. A few sentences from these paragraphs are of immense significance, even in the complex business ecology of today:

If for the maintenance of a patent in force the law requires that the invention should be adequately worked in the country, the patentees would be as anxious as licensees to ensure adequate working in their own interests. (paragraph 166)

Clause 105 of the Bill enables the controller to obtain information from patentees regarding the working of patents. Besides the Government, the Controller is in a position to know

¹²<<http://www.scribd.com/doc/201678355/Ayyangar-Committee-Report>> and <http://spicyip.com/wp-content/uploads/2013/10/ayyengar_committee_report.pdf>

whether the commercial working of a patent relevant to such industry has been started, and if so, what the current level of working is. In these circumstances, if the commerce minister is entrusted with the task of obtaining information regarding such working of patents, the Central Government would be well positioned to be a central gathering point for information regarding the working of patents. I would accordingly recommend the setting up of a unit in the Government for this purpose. This unit might also have the function assigned to it of selecting 'approved persons' for the grant of licences to work patented inventions relating to food and drugs etc. (paragraph 167)

Section 146 of the Indian Patent Act 1970 (as amended in 2005) mandates the submission of a statement of 'working of patent' either when directed by the controller or annually, even without the controller's direction:

(1) The Controller may, at any time during the continuance of the patent, by notice in writing, require a patentee or a licensee, exclusive or otherwise, to furnish to him within two months from the date of such notice or within such further time as the Controller may allow, such information or such periodical statements as to the extent to which the patented invention has been commercially worked in India as may be specified in the notice.

(2) Without prejudice to the provisions of subsection (1), every patentee and every licensee (whether exclusive or otherwise) shall furnish, in such manner and form and at such intervals (not being less than six months) as may be prescribed, statements as to the extent to which the patented invention has been worked on a commercial scale in India.

(3) The Controller may publish the information received by him under subsection (1) or subsection (2) in such a manner as prescribed.

Under Rule 131, the annual statement is to be submitted in Form 27 at the latest within three months from the end of the calendar year:

(1) The statements shall be furnished by every patentee and every licensee under subsection (2) of Section 146 in Form 27 which shall be duly verified by the patentee or the licensee or his authorized agent.

(2) The statements referred to in sub-rule (1) shall be furnished in respect of every calendar year within three months of the end of each year.

Details to be furnished in Form 27 are:

(i) The patented invention: { } Worked { }
Not worked

(a) If not worked: reasons for not working and steps being taken for working of the invention.

(b) If worked: quantum and value (in rupees), of the patented product:

i) manufactured in India;

ii) imported from other countries (give country wise details);

(ii) licences and sub-licences granted during the year;

(iii) State whether public requirement has been met partly/adequately/to the fullest extent at reasonable price.

If a patentee or licensee refuses or fails to furnish information required under Section 146, the patentee or licensee will be punished with a fine, which may extend up to ten lakh rupees under Section 122(1)(b). Further, in the event of wrongful information or statement, the patentee/licensee, can face up to six months imprisonment or a fine or both.

The expression 'working of patents' has not been defined in the Indian Patents Act 1970 (as amended in 2005). However the submission of the mandated Form 27 requires the patentee/licensee to fill out the details regarding working of patents, which have serious implications for decisions related to the meeting of a patentee's obligations in India.

The title of Section 83 of the Indian Patents Act is 'General principles applicable to working of patented inventions', which states:

Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely:

(a) patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;

(b) they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;

(c) the protection and enforcement of patent rights 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;

(d) patents granted do not impede protection of public health and nutrition and should act as an instrument to promote public interest, specially in sectors of vital importance for socioeconomic and technological development of India;

(e) patents granted in no way prohibit Central Government in taking measures to protect public health;

(f) the patent right is not abused by the patentee or the person deriving title or interest on patent, by, for example, resorting to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and

(g) patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public."

It ought to be appreciated that lawmakers in India have clearly defined terms and expressions in the Act. However, Section 83 provides only 'Guiding principles', meaning all the factors will have to be taken into consideration when deciding 'whether a patent has been worked'. Therefore no single factor such as 'local manufacture' ought to be considered alone to arrive at the decision on whether a patent has been worked or not. Failure to file Form 27 or an incomplete Form 27 can lead to a possible presumption of non-working for the purposes of a compulsory licence

The recent decision on the granting of a compulsory licence to Natco in the *Bayer v Natco* case with respect to Indian Patent No. 215758 ought to be viewed from such a perspective. The question addressed in that case was 'whether Bayer had met the reasonable requirements of the public at affordable prices'. The arguments put forth by Bayer, as are apparent from the judgement of the

Controller General of Patents¹³, Trademarks, Designs and Geographical Indications and the subsequent judgements of the IPAB¹⁴ and the High Court¹⁵ were not convincing and hence the compulsory licence in favour of NATCO was upheld. The details of 'working of the patent' via Form 27 by Bayer were one of the factors considered in deciding whether Bayer had met the requirements of 'working of the said patent'.

The details of Form 27 provided in the Controller's judgement [paragraph 10(a)] are reproduced below:

Table 7.1

	Total Patients	Demand for 80 per cent of patients	Bottles per month required	Bottles imported in 2008	Bottles imported in 2009	Bottles imported in 2010
Liver Cancer	20,000	16,000	16,000	Nil	200 bottles	Unknown
Kidney Cancer	8,900	7,120	7,120			

The Controller, based on the details available in Form 27 as declared by Bayer and other arguments presented before him by both the parties in the matter, observed in paragraph 10(b) of the judgement:

Bayer imports the drug into India but has not taken adequate steps to manufacture the product in India to make full use of the invention. The drug is exorbitantly priced and out of reach of most people in India. The product is available in pharmacies attached to certain hospitals and in metro cities such as Mumbai, Chennai, Kolkata, and Delhi. The product is often out of stock or not available in common pharmacies even in metro cities. The product in question is not a luxury item but a life-saving drug and it is highly important that substantial part of the demand be met strictly. In the present case, even 1 per cent of the public does not derive benefit of the patented drug.

The information submitted in Form 27 has yet another function in infringement-related proceedings. Under Section 108 of the Act, a patent owner may file suit for infringement, including seeking an injunction and at the option of the plaintiff, either damages or an account of profits. The information submitted in Form 27 may be used

¹³ <http://www.ipindia.nic.in/iponew/compulsory_license_12032012.pdf> (see page 13 of the controller's judgement).

¹⁴ <http://www.ipab.tn.nic.in/045-2013.htm>

¹⁵

<<http://bombayhighcourt.nic.in/generatenewauth.php?auth=cGF0aD0uL2RhdGEvanVkZ2VtZW50cy8yMDE0LyZmbmFtZT1PU1dQMTEyODEzLnBkZiZzbWZsYWw9Tg==>>

by the court to arrive at the amount of the appropriate relief.

VI. RECOMMENDATIONS

The argument in this article so far analyses that 'working of a patent' by the patentee/licensee and its structured annual reporting ought to be statutorily mandated. Such a mandatory 'working of patents' reporting system would have a positive influence on society and the business ecosystem at large, as it would encourage 'technology haves' to service the markets in which they hold patents, and simultaneously allow the 'technology have nots' to identify the technologies they wish to acquire. Such a self-alert system would also promote technology transfer and possibly create a self-regulated system, where the need for compulsory licensing would be minimized. Further, it would minimize the growth of undesirable patent trolls and expensive time-consuming litigations. If structured appropriately, such a framework would also deliver the unfinished agenda of the TRIPS Agreement especially those agenda items related to innovation, technology and socioeconomic development.

Such mandated 'working of patents' reporting would also seamlessly interface with clauses in national competition laws to monitor possible abusive conduct of patentees or the creation of unfair dominant positions in the marketplace that are detrimental to public interest and competition.

The issue that remains to be addressed is whether the content and nature of disclosure, uniquely mandated in the Indian Patent Act, is useful to serve the purpose for which it was enacted.

The business ecosystem has remarkably changed since 1970 when the Indian Patents Act was first enacted. The concept of one product linked to one patent is fairly outdated. The innovation system creates patent portfolios that include several inventions to create a domain of protection in an aggressive competitive environment. In its present form, Form 27 in the Indian Patents Act and Rules fails to live up to the present day business realities and hence needs to be redesigned such that its content and structure are relevant in today's global business and realities.

Global businesses in today's context are largely governed by a framework that attempts to minimize the barriers to crossborder trade, keeping in mind the national interest by the respective member states. The TRIPS Agreement has also been driving the political and socioeconomic agenda and occupies a significant status in most bilateral and multilateral negotiations. In such a demanding platform, it is recommended that the following factors be taken

into consideration in redesigning mandatory disclosures regarding 'working of patents' disclosure by the patentee/licensees:

- The quantity and quality of patents in the relevant market sector;
- the extent to which those patents have been put to practice and/or incorporated in local products;
- the portion of the market segment being serviced by those patents and whether those patents have been licensed and properly registered;
- whether the patented invention is produced through local manufacturing or created through imports; and
- whether the patented invention is not being used for local manufacture and the reasons for importation, if not.

Many such questions need to be addressed when redesigning Form 27 which will, on the one hand, meet the requirements of the patent system, and on the other hand, meet the modern demands of management practices of domestic trade, economic development and technology transfer.

A constructive debate on 'working of patents' and associated issues is now imperative in view of the ever increasing challenge to deliver 'the most from the least' and the metamorphic changes in international knowledge-led business transactions and trade. Is there any option other than a globally functioning cooperative fast delivering innovation chain, coupled with real-time optimized shared use of global physical, fiscal and human resources?

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8. PROTECTION OF TRADITIONAL KNOWLEDGE AND TRADITIONAL CULTURAL EXPRESSIONS IN KENYA

Dr Marisella Ouma*

ABSTRACT

Kenya, like many other countries, is in the process of developing a legal and administrative structure for the protection of traditional knowledge at the national level. This has been necessitated by the increased interest in the use of traditional knowledge. The purpose of the legal framework being developed is to protect and preserve Kenya's traditional knowledge, as well as to allow for access and sustainable use. The article examines the existing legal and policy framework and the proposed law, which draws from the ARIPO Swakopmund Protocol on the Protection of Traditional Knowledge.

Keywords: *traditional knowledge, policy, prior informed consent, access, sui generis protection.*

I. INTRODUCTION

Every other day, the **kiondo**, **kikoi**, and **Maasai shuka handicrafts**, among others, are mentioned as having been misappropriated by third parties. While this may not necessarily be the case, the main issue that arises is the protection of traditional knowledge in Kenya. Traditional knowledge has gained currency in the rapidly globalized world and the demand for traditional knowledge has increased over the last 20 years. The various holders of traditional knowledge in the country and the government have been working towards a protection system to ensure that Kenya's traditional knowledge is preserved and protected against misappropriation by third parties. This may be through different legal regimes or a *sui generis* system of protection.

Kenya currently does not have a specific law that protects traditional knowledge although, as will be discussed later in this article, the current legal

regime may to a certain extent be used to protect traditional knowledge.

There is no universal definition of traditional knowledge, but according to the World Intellectual Property Organization (WIPO), traditional knowledge may be defined as knowledge, know-how, skills, and practices that are developed, sustained, and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity.¹ These include traditional medicines and healing processes, rituals, preservation of food and diet, agriculture and animal husbandry, preservation of the ecological systems, as well as traditional cultural expressions such as music, art, handicrafts, folktales, and dances among others. For the purposes of this article, traditional knowledge shall be construed in the broader sense to include traditional cultural expressions.

II. RATIONALE FOR PROTECTION

Kenya, like most countries in Africa, has a rich cultural heritage and many local communities are holders of traditional knowledge. There has been an increased interest in traditional knowledge recently, especially as it relates to genetic resources and traditional cultural expressions. Traditional knowledge has been used for commercial purposes by third parties and in some instances has been misappropriated. Any time the issue of traditional knowledge is raised in various forums within the country, the issue of the purported misappropriation of the **Kiondo**² or the **Kikoy**³ always comes up. While the two are not necessarily cases of misappropriation, they raise pertinent issues. Is traditional knowledge protected in Kenya? How do the communities that are custodians/holders of the traditional knowledge control the use of their traditional knowledge? Is there any specific legal regime that addressed these concerns?

There are several reasons why we should protect traditional knowledge in Kenya. First, as noted above, there is increased interest in the use of traditional knowledge in trade, pharmaceuticals, the creative industry, agriculture, animal husbandry, and management of the environment. This usage needs to be well defined and applied within the confines of a structured legal and administrative framework. Second, traditional knowledge is usually passed

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¹ WIPO Traditional Knowledge <<http://www.wipo.int/tk/en/tk/>> accessed 10 October 2014.

² Sylvance Sange Kiondo Idea Theft: An Intellectual Property Myth! (KIPI 2009) <http://www.kipi.go.ke/images/docs/kiondo_idea_theft_a_n_%20ip_%20myth.pdf> accessed 31 October 2014.

³ Sylvance Sange . Loss of the Kikoy to the UK; An intellectual Property Drama (KIPI 2010) <http://www.kipi.go.ke/images/docs/loss_of_kikoi_to_the_uk_%20an_ip_drama.pdf> accessed 31 October 2014.

down from generation to generation and until recently was not captured in writing. This creates a risk of the knowledge being lost when the knowledge holder dies, without documentation of the same. There is need to preserve the knowledge. This also brings about the issue of providing access to this information for the public good.

Third, protection is needed from undue or uncontrolled exploitation by third parties. There are instances where the traditional knowledge is used for purposes that are contrary to the spiritual values of a community, especially as it relates to sacred traditional cultural expressions. It is important to preserve the moral integrity of the community as part of the cultural heritage. In summary, the main purpose for the protection of traditional knowledge is to guard against misappropriation and misuse, especially by third parties, preservation of genetic resources and cultural goods, and protection against unfair competition. This will in turn ensure access as well as benefit sharing.

The protection of traditional knowledge may either be defensive or positive. The former provides strategies that ensure that third parties are prevented from gaining intellectual property rights for the use of traditional knowledge.⁴ Examples of defensive protection are the Traditional Knowledge Digital Library in India and documentation of traditional knowledge to prevent acquisition of patent rights or trademarks over the same.⁵ Positive protection on the other hand, prevents unauthorized use and promotes active exploitation by the originating community. Positive protection of traditional knowledge includes the use of existing intellectual property systems, adaptations, and *sui generis* elements of existing intellectual property regimes, and wholly *sui generis* protection.⁶ In Kenya, the proposed legal regime and administrative framework seeks to provide positive and defensive protection as will be discussed in the article.

III. POLICY FRAMEWORK FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE IN KENYA

The Government of Kenya recognized the need to have a clear policy framework for the protection of

traditional knowledge. The Task Force on Traditional Knowledge was established to come up with the policy framework. Members of the Task Force included representatives from the Office of the Attorney General, the National Museums of Kenya, the then National Council for Science and Technology, the Department of Culture, the Kenya Industrial Property Institute, and the Copyright Section within the department of the Registrar General. The Task Force successfully completed its work in 2009 and handed over its report to the Attorney General, who in turn mandated the Kenya Copyright Board to implement the policy.

The policy takes into account the various challenges, such as the lack of recognition and mainstreaming of traditional knowledge systems into national policies and decision-making processes, the lack of documentation, inadequate capacity, and the linkage between intellectual property, creativity, and innovation.

The main objective of the policy is:

to enhance and coordinate the application of traditional knowledge, innovations and practices in sustainable use of genetic resources and sustainable development in Kenya⁷.

This will:

- (a) Provide a legal and institutional framework to support the integration of various aspects of traditional knowledge, genetic resources, and traditional cultural expressions in national development planning and decision-making processes.
- (b) Promote the preservation, protection, and development of traditional knowledge, genetic resources, and traditional cultural expressions for multiple applications and use.
- (c) Promote and foster the documentation, use, and dissemination of traditional knowledge, genetic resources, and traditional cultural expressions with mechanisms to acknowledge, protect, and benefit the sources and/or custodians.
- (d) Promote the protection of traditional knowledge associated with conservation and sustainable use of biological diversity and equitable sharing of accrued benefits.

⁴ World Intellectual Property Organization (WIPO), 'Consolidated Analysis of the Legal Protection of Traditional Cultural Expressions/Expressions of Folklore' Geneva (2003).

⁵ WIPO has prepared a toolkit to provide practical assistance for the documentation by traditional knowledge holders.

<<http://www.wipo.int/tk/en/resources/tkdocumentation.htm>> accessed 10 October 2014.

⁶ WIPO, Consolidated Survey of Intellectual Property Protection of Traditional Knowledge, WIPO/GRTKF/IC/5/7, Geneva (2003).

⁷ Office of the Attorney General *National Policy for the Protection of Traditional Knowledge and Genetic Resources* (2009).

(e) Enhance collaboration and partnership in the generation, access to and utilization of traditional knowledge, genetic resources, and traditional cultural expressions.

The guiding principles underlying this policy include respect, full disclosure, prior informed consent, confidentiality, good faith, compensation, equitable benefit sharing, access, sustainable development, and international cooperation.

Another policy that, to a certain extent, addresses issues of traditional knowledge is the 2009 National Policy on Culture and Heritage, which requires the government to promote culture as a driving force for social and economic development and to ensure that appropriate measures are put in place for the protection, conservation and preservation of national heritage, both tangible and intangible. This would have a bearing especially on traditional cultural expressions and other knowledge systems that form part of the national heritage.

In 2012, the Natural Products Industry Policy was prepared by the Ministry of State for National Heritage and Culture to encourage the manufacturing of local products from natural resources including medicinal, cosmetic, household, and agricultural products. The main objective of the policy is to facilitate the requisite legal and administrative framework to enable the use of existing genetic resources and other natural products to spur economic growth and development. The policy to a certain extent espouses the positive protection of traditional knowledge.

The draft National Intellectual Property Policy of 2013 fails to provide clear policy direction for the protection of traditional knowledge in Kenya. The draft policy only proposes the administrative framework. This is a major oversight, as it mainly covers conventional intellectual property, namely copyright, industrial designs, and plant breeders' rights. However, as the policy is yet to be adopted, there is room for improvement to include clear policy directives for traditional knowledge protection.

These policies especially the National Policy on Traditional Knowledge and Genetic Resources form the basis of the proposed legal framework for the protection of traditional knowledge at the national level, as shall be discussed in the following paragraphs.

IV. LEGAL FRAMEWORK AND ADMINISTRATIVE FRAMEWORK

The legal protection of traditional knowledge can either be through the existing intellectual property framework or a *sui generis* system of protection. At the international level, norm setting for the protection of traditional knowledge is ongoing at WIPO through the Intergovernmental Committee (IGC) on Intellectual Property, Genetic Resources, Traditional Knowledge and Expressions of Folklore. The IGC was set up in 2000 to provide member states with a forum to discuss the various issues arising from the exploitation of genetic resources, including access and benefit sharing, and the protection of traditional knowledge.⁸ The IGC is currently working on three different texts on the proposed protection for genetic resources, traditional knowledge and traditional cultural expressions. Kenya has been an active participant at the IGC and some of the discussions have influenced the draft law on the protection of traditional knowledge.

There have been several attempts at the regional level in Africa to address the issue of access and benefit sharing, especially as it relates to biological resources. In 2000, the African Union (then Organization of African Unity) adopted the African Model Legislation for the protection of the rights of local communities, farmers and breeders, and for the regulation of access to biological resources. The model law made provisions that could be adopted by African countries in relation to community rights, regulations of access, and benefit sharing of genetic resources and plant breeders' rights.

The model law, among other things, recognizes the rights of local communities over genetic resources, traditional knowledge, farmers' rights, local innovations and practices. It also recognizes the customary law, the collective rights of the local communities, and the need for prior informed consent.⁹ The model law provides a strong basis for the formulation of national laws on the protection of traditional knowledge.

The Diplomatic Conference of Africa Regional Intellectual Property Organization (ARIPO) adopted the ARIPO Swakopmund Protocol in Swakopmund,

⁸ WIPO Briefing Paper n 2 'The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources Traditional Knowledge and Folklore'.

http://www.wipo.int/export/sites/www/tk/en/resources/pdf/tk_brief2.pdf accessed 3 November 2014.

⁹ Regional laws on traditional knowledge and access to genetic resources <http://biocultural.iied.org/regional-laws-traditional-knowledge-and-access-genetic-resources/> accessed 6 November 2014.

Namibia, on 9 August 2010.¹⁰ This was a result of negotiations within the ARIPO Member States. The Protocol covers the protection of traditional knowledge and traditional cultural expressions. It provides for exclusive rights for traditional knowledge holders to control the use and access of their traditional knowledge. The Protocol defines traditional knowledge in a narrower sense.

Under Article 2.1, traditional knowledge refers to:

... any knowledge originating from a local or traditional community that is the result of intellectual activity and insight in a traditional context, including know-how, skills, innovations, practices and learning, where the knowledge is embodied in the traditional lifestyle of a community, or contained in the codified knowledge systems passed on from one generation to another. The term shall not be limited to a specific technical field, and may include agricultural, environmental or medical knowledge, and knowledge associated with genetic resources.

Article 2.1 also defines expressions of folklore to include:

... any forms, whether tangible or intangible, in which traditional culture and knowledge are expressed, appear or are manifested, and comprise the following forms of expressions or combinations thereof:

(i) Verbal expressions, such as but not limited to stories, epics, legends, poetry, riddles and other narratives; words, signs, names, and symbols;

(ii) musical expressions, such as but not limited to songs and instrumental music;

(iii) expressions by movement, such as but not limited to dances, plays, rituals and other performances; whether or not reduced to a material form; and

(iv) tangible expressions, such as productions of art, in particular, drawings, designs, paintings (including body-painting), carvings, sculptures, pottery, terracotta, mosaic, woodwork, metal ware, jewelry, basketry, needlework, textiles, glassware, carpets, costumes; handicrafts; musical instruments; and architectural forms

The Protocol provides for access and benefit sharing, prior informed consent, and exclusive rights for the

custodians/holders of traditional knowledge and traditional cultural expressions. The Protocol provides for positive protection. It clearly defines the beneficiaries of protection, exceptions and limitations, and compulsory licensing. It is important to note that this Protocol takes the format of conventional intellectual property laws but can still be used to guide national processes in drafting relevant laws. In Kenya, the draft law on the protection of traditional knowledge borrows heavily from the Swakopmund Protocol.

At the national level, the Constitution of Kenya 2010 provides a strong basis for the creation of enabling laws and policies for the protection of traditional knowledge. Article 260 of the Constitution specifically defines property to include intellectual property. In addition, the Constitution, under Article 11(1), recognizes culture as the foundation of the nation and as the cumulative civilization of the Kenyan people and the State. Under Article 11(2), the Government of Kenya has a duty to promote all forms of national cultural expression, to recognize the role of indigenous technologies in development, and to promote the protection of intellectual property rights. In addition, the State is required to support, promote and protect the intellectual property rights of the people of Kenya under Article 40(5).

On the issues of sustainable management and use of natural resources and protection of biodiversity and genetic resources, Article 69(1) of the Constitution is very clear. These provisions provide the potential framework for drafting laws that will ensure not only the protection, but also the preservation of traditional knowledge in Kenya.

Already existing intellectual property laws may, to a certain extent, provide for the protection of traditional knowledge in Kenya. These include the Copyright Act, the Industrial Property Act, the Trademarks Act, and the Seeds and Plant Varieties Act. We shall examine each in the following paragraphs in relation to how they protect or may be used to protect traditional knowledge.

A. THE INDUSTRIAL PROPERTY ACT

The Industrial Property Act of 2001 provides for the protection of patents, industrial designs, and utility models. For a work or a process to qualify for patent protection, it must be new, non-obvious, and industrially applicable. Likewise, for the protection under industrial designs and utility models, the issue of novelty is key. Unfortunately, most of the traditional knowledge will fail the novelty test, as it already constitutes prior art.

¹⁰http://www.wipo.int/wipolex/en/treaties/text.jsp?file_id=201022.

B. THE COPYRIGHT ACT

The Copyright Act¹¹ grants protection to works that are eligible for copyright protection, including literary, artistic and musical works. The Act provides exclusive rights to the authors/owners of copyright, subject to certain exceptions and limitations.¹² For works to be eligible for copyright protection, they shall be original and reduced to some tangible form. This protection is granted for a limited period of time. This would create a problem for traditional cultural expressions, as they are works that have been generated by a community and passed on from generation to generation. They would not be eligible for copyright protection on account of originality and in some instances the fixation requirement.¹³ However, there are certain ways in which the copyright law may be used to protect traditional cultural expressions.

Section 28 of the Act provides for the protection of sound recordings. Where the traditional knowledge has been recorded in a sound recording, the sound recording shall enjoy protection under related rights, but protection does not extend to the underlying works.

The fixation of the work in a performance may also enjoy copyright protection under Section 29 of the Copyright Act, but this protection only extends to the fixed performance. The underlying work remains unprotected.

Section 49(d) of the Copyright Act requires that any person, who wishes to use expressions of folklore for commercial purposes, to obtain permission from the Attorney General. Several artists have used this provision to create performances and recordings that incorporate expressions of folklore such as lullabies, folk songs, and poetry. This helps in the documentation and preservation of traditional knowledge, a key policy objective. Several artists have taken advantage of these provisions to record folksongs and lullabies. An example is the group, Kayamba Africa, who has released several albums that contain folk songs from around the country. The sound recording is protected, but the underlying work is not.

The proposed amendments to the Copyright Act, which have recently been submitted to the Office of the Attorney General and Department of Justice for publication, seek to incorporate more provisions for the protection of traditional cultural expressions.

¹¹ Chapter 130 of the Laws of Kenya.

¹² Section 26 of the Copyright Act.

¹³ Sections 22(3) and 23 of the Copyright Act.

C. TRADEMARKS ACT

A trademark is a sign capable of distinguishing the goods or services of one enterprise from those of other enterprises; trademarks are protected by intellectual property rights.¹⁴ The trademark can be a sign, a word, a combination of words and symbols, a smell, or colour. This is the closest that the conventional intellectual property system can be used to protect traditional knowledge. This is because the holder of the traditional knowledge can use a trademark to distinguish the goods or product. The protection of the trademark will last for as long as it is renewed.

In the recent case involving the **Kikoy**, a UK-based company would have succeeded in the registration of the trademark 'Kikoy' were it not for the intervention of the Kenya Intellectual Property Institute, with the help of the development charity, Traidcraft Exchange, and law firm, Watson Burton. The company subsequently dropped the trademark application.¹⁵ The protection using trademarks may be applied to traditional knowledge, including traditional cultural expressions, pharmaceutical products, and cosmetics. However it is important to note that the trademark protection does not extend to the actual goods themselves, and protection will not stop a third party from using the traditional knowledge as a different product.

Communities that are custodians of traditional knowledge may use collective marks to protect their traditional knowledge. Collective marks refer to the signs, words, or a combination of both, to distinguish the goods of one group of people from those of another. These would be particularly useful for communities that are separated by geographical borders. Traditionally, some communities used symbols to brand their products; the same principle applies here.

D. ENVIRONMENTAL MANAGEMENT AND COORDINATION ACT

This Act deals with access and benefit sharing under the Environmental Management and Coordination Regulations (2006) and was formulated by the Ministry of Environment and Natural Resources in accordance with Section 147 of the Environmental Management and Coordination Act (1999). The Act

¹⁴ WIPO Trademarks
<<http://www.wipo.int/trademarks/en/>>accessed 3 November 2014.

¹⁵ M Torsen M and J Anderson, *Intellectual Property and the Safeguarding of Traditional Cultures: Legal Issues and Practical Options for Museums, Libraries and Archives* (WIPO 2010)
<http://www.wipo.int/edocs/pubdocs/en/tk/1023/wipo_pub_1023.pdf> accessed 3 October 2014.

has articulated issues regarding access and benefit sharing.

E. NATIONAL MUSEUMS AND HERITAGE ACT

The Act provides for the identification, protection, conservation, and transmission of the cultural and natural heritage of Kenya. This Act may be extended to protect traditional knowledge as it relates to the cultural and natural heritage of Kenya. It would be limited to specific cultural goods identified by the National Museums of Kenya, which would have to work closely with the local and indigenous communities. This would also require the establishment of a database.

F. GEOGRAPHICAL INDICATIONS BILL

Geographical indications have traditionally been used to protect products such as wine and cheese. According to WIPO, a geographical indication is a sign used on goods that have a specific geographical origin and possess qualities, reputation, or characteristics that are essentially attributable to that place of origin.¹⁶ A geographical indication includes the name of the place of origin of the goods. This may be extended to the protection of traditional knowledge and traditional cultural expressions that may be attributed to a particular geographical location, e.g. Kisii soapstone carvings. This also has limitations, as it will only apply to goods from a specific geographical area.

V. PROPOSED LEGAL FRAMEWORK

A. SUI GENERIS PROTECTION OF TRADITIONAL KNOWLEDGE?

From the above discussion, it is clear that the existing intellectual property regime does not offer an effective solution for the protection of traditional knowledge in Kenya. The alternative is to have a *sui generis* system of protection, as set out in the African Union model law or the Swakopmund Protocol. Several countries, such as Peru, have a *sui generis* law on the protection of traditional knowledge.

The Kenya Copyright Board, in collaboration with the Kenya Industrial Property Institute, the National Museums of Kenya, the Department of Culture, the National Council of Science and Technology, and other government institutions, established a working group to draft the national law for the protection of traditional knowledge in Kenya. The task force, after

extensive consultations with the stakeholders, came up with a draft bill that was submitted to the Office of the Attorney General and Department of Justice for publication. The Bill borrows heavily from the Swakopmund Protocol.

The Bill, like the Swakopmund Protocol, defines traditional knowledge and traditional cultural expressions under Article 2. The Act also identifies the beneficiary persons, grants exclusive rights to the local community/custodians of the traditional knowledge, and provides for access and benefit sharing, administration, and enforcement of the rights.

Since it takes a rights-based approach, it also provides for exceptions and limitations as well as compulsory licensing. This, however, can be quite restrictive as it treats traditional knowledge like other intellectual property rights. The main aim of the *sui generis* type of protection is to offer protection that is unique to traditional knowledge systems, as well as to ensure that traditional knowledge is preserved, is protected against misuse and misappropriation, and allows for access and benefit sharing.

It is thus important to look at the traditional methods of protecting and preserving traditional knowledge. There were systems of customs and taboos that were used by various communities to ensure that the knowledge was preserved. For instance, in the case of the sacred forests among the Meru and Miji Kenda communities in Kenya, access to these forests was forbidden and the only persons allowed to access the same were the traditional healers and spiritual leaders. This served to preserve the genetic resources by restricting access. There were various customs, as well as customary laws, used to ensure the preservation and protection of the traditional knowledge against misappropriation and misuse.

B. DEFENSIVE PROTECTION

Defensive Protection involves the creation of databases to ensure that information is not used, e.g. to obtain patent protection without the authority of the rights holder. Examples include the Traditional Knowledge Digital Library and the documentation of traditional knowledge in other forms

(i) THE TRADITIONAL KNOWLEDGE COMMONS

The Traditional Knowledge Commons is based on the idea that there is continual movement and growth in knowledge for the benefit of those who generate it

¹⁶ WIPO Geographical Indications
<http://www.wipo.int/geo_indications/en/>
accessed 3 November 2014.

as well as society at large.¹⁷ A commons allows for the protection and preservation of traditional knowledge and, at the same time, allows for access by third parties within a certain framework, taking into account the existing cultural norms and practices. This is important, especially in areas where an individual holds the traditional knowledge and there is a risk of the knowledge disappearing once the person dies.

This Traditional Knowledge Commons is also a good basis for defensive protection of traditional knowledge in Kenya, and is already considered in the National Policy on Traditional Knowledge and Genetic Resources.

(ii) THE TRADITIONAL KNOWLEDGE DIGITAL LIBRARY

Another way of guarding against misappropriation by third parties is to ensure that the traditional knowledge and traditional cultural expressions are well documented. A good example is the Traditional Knowledge Digital Library in India.¹⁸ India has successfully set up and uses the library to ensure that patents are not granted for works that have been produced from the use of traditional knowledge. The digital documentation of such information provides an avenue for dissemination, as well as cross-checking any applications that may be based on traditional knowledge, thus eliminating the grant of patents which will not fulfil the requirement of novelty.

The Kenya Copyright Board, in collaboration with the Kenya Industrial Institute and the National Museums of Kenya, are in the process of establishing a Traditional Knowledge Digital Library in Kenya. This will not only provide defensive protection especially in the area of patents, but will also help to preserve the knowledge and provide for access and equitable benefit sharing, where the knowledge is used after obtaining prior informed consent.

(iii) OTHER FORMS OF DOCUMENTATION

The documentation of traditional knowledge is also important, as illustrated in the recent project on the documentation and recording of Maasai Culture undertaken by WIPO and the Maasai Community in Laikipia, Kenya. The local community was provided with the training and equipment to record the

¹⁷ E Abrell, 'Implementing a Traditional Knowledge Commons: Opportunities and Challenges' Natural Justice (2009) <http://naturaljustice.org/wp-content/uploads/pdf/Implementing_a_TKC-2009.pdf> p 16 (accessed 29 October 2014).

¹⁸ Traditional Knowledge Digital Library <<http://www.tkdil.res.in/tkdil/langdefault/common/Home.asp?GL=Eng>> accessed 16 October 2014.

Maasai culture and archive it.¹⁹ This ensures that knowledge, initially handed down by oral tradition, is documented and preserved, eliminating the risk of the knowledge holder taking it to the grave.

The Traditional Knowledge Digital Library and the documentation of culture all require a sound legal regime that (i) controls access to works and ensures that prior informed consent is obtained where necessary; and (ii) provides for equitable benefit sharing. Otherwise, the proposed *sui generis* system may be mainstreamed into existing intellectual property laws especially as it relates to patents.

VI. SUMMARY AND CONCLUSION

The main objective of providing protection for traditional knowledge is to guard against misappropriation and misuse by third parties and to preserve the knowledge. In addition, the protection seeks to ensure that where access has been granted, there is prior informed consent and where the knowledge has been used, there is equitable benefit sharing. The local communities and individuals who are custodians of this knowledge should benefit from the commercial exploitation of the same.

In the absence of a specific legal regime in Kenya, the rights holders can only rely on existing laws, which do not offer effective protection. Although the Kenya's Constitution specifically provides that the government shall ensure that traditional knowledge is protected, there is still a need to have specific laws providing this protection. The draft Traditional Knowledge Bill offers a good basis, but it requires further work to ensure that it provides effective legal protection.

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¹⁹ WIPO Digitizing Traditional Culture in Kenya <http://www.wipo.int/portal/en/wipo_univ_maasai.html> accessed 3 November 2014.

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<http://www.wipo.int/export/sites/www/tk/en/resources/pdf/tk_brief2.pdf> accessed 3 November 2014

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9 INTELLECTUAL PROPERTY RIGHTS AND PUBLIC HEALTH: THE CONSTITUTION AND PRACTICE IN MALAWI

Dr Zolomphi Nkowani*

ABSTRACT

The paradox of health care and intellectual property (IP) rights protection provokes strong debates on the utility of protecting one over the other. There is a silent consensus that health and economic development are inseparable factors for improving living standards. Healthy people are better and efficient economic actors. The cost of ill health or occupational injuries has a direct effect on productivity and efficiency¹. However innovation and creativity are at the cutting edge of development and are a catalyst for pioneering breakthrough in medical and health-care sectors that are vital for health-care provision. The dilemma for policymakers is how to balance the two with manageable trade-offs.

This article focusses on Malawi and how it deals with the issues of intellectual property rights and public health. The institutionalization of health as a constitutional right in the 1994 Constitution (Sections 13, 16, 19, and 30) is an acknowledgement that a healthy population is a prerequisite for sustainable human development and increased productivity. Challenges that Malawi faces are similar to those of most least developed countries (LDCs). Currently, Malawi does not have an IP policy. The country's IP policy has been in draft form for some time. Much of the county's IP laws are outdated and ill-suited to 21st century needs and

challenges. In health-care delivery Malawi, like most LDCs, can take advantages of flexibilities under paragraph 7 of the WTO Doha Declaration 2001 until 2016.² Regionally, there are flexibilities³ that Malawi can harness through its regional memberships to ease the challenge of access to medicines and health-care services such as the SADC pooled procurement of essential medicines and health commodities⁴.

Within SADC, under Article 5 of the Treaty, Malawi is obliged to promote the living and working standards of its people. The SADC Protocol on Health reinforces the principle that productivity and efficiency are affected by the health status of economic actors. Healthy populations are better economic actors and without this a functional integration of the region is a dim possibility. Lack of a pharmaceutical manufacturing base in the region is a challenge for countries such as Malawi to take advantage of flexibilities in international IP regimes.⁵

In this article, the author reflects on the symbiotic relationship between intellectual property rights and the right to health as a subset of public health. The context for the discussion is local, but the outlook is regional and international. It is concluded that there are flexibilities under TRIPS, the General Agreement on Tariffs and Trade 1994 (GATT 1994), WIPO frameworks, and regional frameworks such as ARIPO, from which Malawi can benefit. However, this is dependent on internal structural constraints such as lack of an effective IP policy, lack of a pharmaceutical manufacturing base, and low level awareness of IP issues nationally.

Keywords: *Public health, intellectual property rights, TRIPS, SADC, Malawi, and Nkowani*

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¹ Z Nkowani, 'Injury unto Death, Occupational Health and Safety Regulation in Malawi' *Comparative and International Law Journal for Southern Africa* (2008) Vol 41 Issue 1. <<http://www.unisa.ac.za/Default.asp?Cmd=ViewContent&ContentID=21046>> Also see Z Nkowani, 'Occupational Health and Safety in the SADC Region: Exploring an Economic Approach' (2007) *Labour and Development Law Monograph*, University of Cape Town. [ISBN: 978-0-7992-2332-3].

²BK Baker (2003) 'Analyses and Response to WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' United Nations Millennium Development Goals Project, Task Force 5: Infectious Diseases and Access to Essential Medicines, Sub-Group Access to Essential Medicines. New York: United Nations.

³Such as under Article 5 of the SADC Treaty and Articles 16 and 24 of the Protocol on Trade. Article 9 of the Protocol on Trade allows for GATT 94 Article XX (b) Exceptions to the Most –Favoured-Nations treatment (MFN) and National Treatment (NT) obligations in the face of health concerns.

⁴<http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0CCIQFjABahUKEwi4s6a43_3HAhVKOhQKHWMUCmA&url=http%3A%2F%2Fwww.sadc.int%2Ffiles%2F7614%2F1898%2F8449%2FSADC_Strategy_for_Pooled_Procurement_of_Essential_Medicines_and_Health_Commodities.pdf&usq=AFQjCNHieNlxFraxz8qPiXT87EGNs4fTOA&sig=2KgOyPf-1pxmD9GO0VAgbQ>

⁵ See Fink Carsten, (2005) 'Intellectual Property and Public Health: The WTO's August 2003 Decision in Perspective' in Richard Newfarmer (ed.), *Trade, Doha, and Development: Window into the Issues* (The World Bank).

I. BACKGROUND

Recent decades have been marked by policy shifts, reversals, and reconciliation of potentially conflicting social and economic priorities. On the one hand, competition has led to a surge in the urge to stimulate trade and investment to maintain global competitiveness. On the other, the need to cushion against adverse impact of trade has led communities to demand 'something to be done' to guarantee fundamental rights as a prerequisite for sustainable peace and development. This has been more visible in the realm of intellectual property rights⁶ and public health. Whilst states desire to create conducive environments for trade and investment, they need to ensure that they do not race to the bottom⁷ of social standards such as health. Although on the surface the language of multilateral trading texts such as the World Trade Organization (WTO) agreements is economic, the underlying rationale is social. Humans are at the centre. The human rights movement began in part as a protest against a form of trade i.e. 'slave trade' that subordinated humans and their welfare to corporate greed. The goal of trade is to improve people's living and working standards.⁸ Through the GATT 1994⁹, States

undertake to conduct their economic relations with a view to raising standards of living.¹⁰ Intellectual property rights are some of the tools for stimulating growth through creativity and innovation. Intellectual property rights and public health are mutually inclusive and supportive.

Public health refers to measures, whether publicly or privately designed, to prevent disease, promote health, and prolong life among the population as a whole.¹¹ The issue of access to medicines and health care is a vital component of a public health discourse.¹² Its activities aim to provide conditions in which people can be healthy and focus on entire populations. Public health is concerned with the total system and not only the eradication of a particular disease. Often in discussion about health there is a blurring in the usage between 'health' and 'public health'. These refer to two different trajectories with policy implications. Public health refers to a system, while health is a state of human affairs.¹³ The World Health Organization (WHO) defines health as a state of complete physical, mental, and social wellbeing, and not merely the absence of disease or infirmity.¹⁴ Public health is concerned with the assessment and monitoring of the health of communities and populations at risk to identify health problems and priorities. It seeks to

⁶ Intellectual property rights refer to the products of the mind or intellect, which are in the form of ideas and tangible and intangible objects. There are two broad fields of intellectual property: industrial property and copyright and related rights. Industrial property covers patents, trademarks, industrial designs, geographical indications, and trade secrets

⁷ 'Race to the bottom' is a socio-economic phenomenon in which governments deregulate the business environment or taxes in order to attract or retain economic activity in their jurisdictions, resulting in lower wages, worse working conditions and fewer environmental protections. See Z Nkowani, 'When Elephants Dance, FDI and the SADC Charter of Fundamental Social Rights; A Beacon of Hope or Confusion Compounded? Commonwealth Law Bulletin, Volume 33, Issue 1 March 2007, pages 41–54.

⁸ This Commitment is expanded in the Marrakesh Agreement Establishing the World Trade Organization (WTO) to include trade in services and trade and environment. The social base for International Trade is expanded. In the preamble, Member States recognize that their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment, and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development <http://www.wto.org/english/docs_e/legal_e/04-wto_e.htm> See <<http://www.sadc.int/>> (accessed November 2014).

⁹ Under Article II of the Marrakesh Agreement Establishing the World Trade Organization and the General Agreement

on Tariffs and Trade 1994 (GATT 1994).

¹⁰ <www.wto.org>

¹¹ Article 1 of the WHO Constitution.

¹² JO Lanjouw and I Cockburn 'Do Patents Matter? Empirical Evidence after GATT' (2000) NBER Working Paper n 7495. See also K Balasubramaniam 'Access to Medicines: Patents, Prices and Public Policy – Consumer Perspectives', paper presented at the Oxfam International Seminar on Intellectual Property and Development: What Future for the WTO TRIPS Agreement?, Brussels, 20 March 2001.

¹³ See the preamble of the WHO Constitution for the definition of health. This definition has been adopted in other multilateral treaties and conventions such as the International Labour Organization's (ILO) Occupational Health and Safety Convention C155. For a general discussion of this aspect, see the latter which states that the term 'health', in relation to work, indicates not merely the absence of disease or infirmity, but also includes the physical and mental elements affecting health which are directly related to safety and hygiene at work, R Loewenson, C Nhachi, W Murambiwa and P Gona (1991), 'Epidemiology of the Health Impact of Pesticide Use in Developing Countries': Epidemiological research in Zimbabwe, Mimeo, Harare and Nkowani 'Occupational Health and Safety in the SADC Region: Exploring an Economic Approach' (2007) *Labour and Development Law Monograph*, University of Cape Town. [ISBN: 978-0-7992-2332-3].

¹⁴ Preamble to the WHO Constitution, as adopted by the International Health Conference, New York, 19-22 June 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the WHO, n 2, p 100; entered into force on 7 April 1948. See WHO (1948) *The Constitution of the WHO* International Health Conference, New York, 2 June 1945. New York WHO.

ensure that all populations have access to appropriate and cost-effective care, including health promotion and disease-prevention services.

Production costs and the cost of medicines are impacted by IP regimes such as patents. Access in the context of the General Comment 14 and the WHO Constitution can be economic (affordability), or legal, informational, or structural.¹⁵ There is a call for a balancing act between the promotion, acquisition, commercialization, and enforcement of intellectual property rights and provisions of public goods, such as health care.

II. CONSTITUTIONAL FRAMEWORK

A discussion about law is preceded by an acknowledgment of law as an abstract and a socio-political construct. The source and validity of law has preoccupied jurists for millennia.¹⁶ As a discussion of the jurisprudence is beyond the scope of this article, it will suffice to contextualize the constitutional threshold for law and policy on intellectual property rights and health in Malawi. Our point of departure is Hans Kelsen's pure theory of law.¹⁷ This is a theory of positive law, whereby a basic norm (grundnorm)¹⁸ underlies a hierarchy of laws.¹⁹ All other norms are related to each other by being either inferior norms, when one is compared to the other, or superior norms.²⁰ Grundnorm is a concept in the *Pure Theory of Law* that denotes the basic norm, order, or rule that forms an underlying basis for a legal system²¹. The theory is based on a need to find a point of origin for all law, on which basic law and the constitution can gain their legitimacy.²²

¹⁵ Ibid.

¹⁶ Joseph Raz, 'Legal Validity' *The Authority of Law: Essays on Law and Morality* Oxford University Press, 2 August 1979 Oxford Scholarship Online 22 March 2012 (accessed 15 September 2015)

<<http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780198253457.001.0001/acprof-9780198253457-chapter-8>>

¹⁷ Joseph Raz, 'Kelsen's Theory of The Basic Norm' *The Authority of Law: Essays on Law and Morality* Oxford University Press, 2 August 1979 Oxford Scholarship Online. 22 March 2012 (accessed 15 September 2015). <<http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780198253457.001.0001/acprof-9780198253457-chapter-7>>.

¹⁸ A basic norm is something postulated for the purpose of bringing order to our conception of the legal system being examined.

¹⁹ George C Christie, 'The Notion of Validity in Modern Jurisprudence' *Minnesota Law Review* [Vol 48, 1049]

²⁰ See Hans Kelsen *General Theory of Law and State* 11-78 (Wedberg Tranl. 1949).

²¹ See generally HLA Hart *The Concept of Law*, Joseph Raz, and Penelope A Bulloch (eds) Clarendon Press.

²² Ronald M. Dworkin *Law's Empire* (Legal Theory), Clarendon Press; 2nd edition (24 April 1997), *Madzimbamuto v Lardner Burke* (PC) (1969) 1 A.C. 651. See

The Constitution as a basic norm²³ provides a minimum threshold for the validity of public decisions, actions or inactions. The peculiar feature of the Malawi Constitution is that it has both vertical and horizontal application.²⁴ Section 10(1) of the Constitution of Malawi provides that in the interpretation of all laws and in the resolution of political disputes, the provisions of the Constitution shall be regarded as the supreme arbiter and ultimate source of authority. Section 11 provides for a value-based approach to statutory interpretation that promotes fundamental values underlying an open and democratic society. Such interpretation ought to take account the provisions of Chapter III and Chapter IV of the Constitution²⁵. Chapter III deals with the fundamental principles of the constitution, while Chapter IV domesticates the United Nations Universal Declaration of Human as a bill of rights in the constitution.²⁶ Section 11(2)(c) introduces an important aspect in terms of the content and application of domestic laws and policies. Current norms of public international law and comparable foreign case law ought to be taken into account in the interpretation and application of the constitution or any law. Under Section 5, any act of Government or law that is inconsistent with the provisions of the Constitution is, to the extent of such inconsistency, invalid. What this means is that in a contest between the right to health and trade and IP protection, health takes precedence. Malawi is obliged to protect and safeguard the right to health under various international frameworks such as the WHO²⁷, WTO²⁸ and WIPO frameworks.²⁹

Among the fundamental values the Constitution promotes is the right to health in Section 13, as read with Section 16, Section 19, and Section 30. Section 13(n) advocates an economic management

also Lord Alfred Denning, *The Discipline of Law* Lexis Nexis Butterworth.

²³ In Pure Theory of Law, this 'basic norm', however, is often ascribed as hypothetical. The reception of the term has fallen into three broad areas of discernment including: (i) Kelsen's original introduction of the term; (ii) the Neo-Kantian reception of the term by Kelsen's critics and followers; and (iii) the hypothetical and symbolic use of the term through the history of its application.

²⁴ Danwood Chirwa, *Human Rights under the Malawi Constitution* Juta Publishing Press (2011).

²⁵ <<https://www.icrc.org/.../Constitu>>

²⁶ <[https://www.icrc.org/applic/ihl/ihl-at.nsf/0/4953f2286ef1f7c2c1257129003696f4/\\$FILE/Constitution%20Malawi%20-%20EN.pdf](https://www.icrc.org/applic/ihl/ihl-at.nsf/0/4953f2286ef1f7c2c1257129003696f4/$FILE/Constitution%20Malawi%20-%20EN.pdf)> (accessed October 2014)>

²⁷ See Articles 1 and 2 of the WHO's Constitution.

²⁸ Article XX(B) of GATT 1994, Article 31bis of the TRIPS Agreement and the WTO Doha Declaration on TRIPS and Public Health.

²⁹ See M Koivusalo 'Impact of WTO Agreements on Health and Development Policies Globalization and Social Policy Programme' (2003) in B Deacon, E Ollila, M Koivusalo, P Stubbs (eds) *Global Social Governance: Themes and Prospects*. Helsinki: Ministry for Foreign Affairs: 77–129.

regime that strikes a balance between creation and distribution of wealth through the nurturing of a market economy. It also provides for long-term investment in health, education, and economic and social development programmes with the aim of raising living and working standards, a central feature of the multilateral trading system. This section is a call to balance social and economic policy. There is a realization that sustainable development requires stimulation of the economy and social policies that cushion against market externalities such as social costs. Underinvestment in health can wipe out the gains of economic growth through reduced productivity and efficiency besides the cost of providing public services. The Ebola epidemic in West Africa has had a measurable negative effect on the economies of the countries affected³⁰. This is a sad footnote to the need for a balance between social and economic.

The other right relevant to IP and health is provided under Section 29. This is the right to economic activity. The constitution does not define 'property' but entrenches the right to acquire property, either alone or in association with others.³¹ Property in law includes tangibles and intangibles such as intellectual property rights. Section 28(2) protects against arbitrary deprivation of property. Section 29 provides that every person has the right to freely engage in economic activity, to work, and to pursue a livelihood anywhere in Malawi. The combined effect of Sections 28 and 29 is that they provide a seedbed for the acquisition and commercialization of intellectual property rights. In tandem with Section 10 and Section 11, the emerging jurisprudence is that provisions of the Constitution are to be read not to destroy but to reinforce each other.³² Thus government has to balance the quest for stimulation of investment and economic growth through the promotion and protection of intellectual property rights, on the one hand, and the promotion of the realization of the right to health, on the other. Where the trade IP and human rights such as health compete for priority, the right to health as a human right in principle ought to take precedence.

³⁰ For estimating the worldwide economic cost of ebola, see <<http://blogs.worldbank.org/developmenttalk/estimating-economic-cost-ebola>> See also Z Nkowani 'Injury unto Death, Occupational Health and Safety Regulation in Malawi' Comparative and International Law Journal for Southern Africa (2008) Vol 41 Issue 1 <<http://www.unisa.ac.za/Default.asp?Cmd=ViewContent&ContentID=21046>>

³¹Section 28 (1) of the Constitution.

³²*Fred Nseula v The Attorney General and Malawi Congress Party*, MSCA Civil Appeal no 32 of 1997 (unreported) (See also *Attorney General v The Malawi Congress Party*, LJ Chimango and Dr HM Ntaba, MSCA Civil Appeal no 22 of 1996 (The Press Trust case), *Bakili Muluzi and UDF v Malawi Electoral Commission* Constitutional Case n 1 of 2009, per Justice Chipeta).

Opinion is varied on the status of health under the Constitution of Malawi. The predominant view is that health is not a right under the constitution, but merely a directing or guiding principle.³³ The author questions this rendition of the law in view of principles of interoperation in Section 11 of the Constitution.³⁴ The standard approach to Constitutional interpretation is to render a liberal or generous construction of Constitutional provisions.³⁵ In terms of scope, Section 13(c) ought to be considered in the context of other rights such as the right to life under Section 16, the right to human dignity under Section 19, the right to a clean environment under Section 13, and the right to development under Section 30. Section 11, as read with Section 211, of the Constitution provides that the interpretation should take into account norms of public international law and foreign case law. Section 11 is similar to Section 39 of the South African Constitution, and the courts have (as has been done by Malawi courts) advocated a liberal or generous interpretation. One of the norms of Public International Law in relation to the right to health is contained in General Comment No. 14. General Comment No. 14 is binding on all member States. The definition of the right to health is expansive and includes the right to health as captured under Section 13(c), Section 16, Section 19, and Section 30 of the Constitution of Malawi.

As a national policy, Section 13(c) enjoins the state to promote the welfare and development of the

³³Leslie London and Aulline H Mabika 'Implications of the GATS and TRIPS Agreements for the Right to Health in Malawi' Southern and Eastern African, Information and Negotiation Institute (SEATINI) School of Public Health and Family Medicine, University of Cape Town (UCT) (2007). See also C Namelo and SWD Chavula, 'Aspects of Non-conformity in Malawi's Intellectual Property Legislation vis-a-vis International Agreements Conventions and Treaties on Intellectual Property' (2003). Robert Lewis-Lettington and Chikosa Banda '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 See Hoyt Webb 'The Constitutional Court of South Africa; Rights Interpretation and Comparative Constitutional Law' (1998) *Journal of Constitutional Law*, Vol 1:2, p 207. See also *State v Mak-wanyane*, 1995 (3)SALR 391, 451-52 (CC) (striking down the death penalty in the face of large public support).

³⁵*Bakili Muluzi and UDF v. Malawi Electoral Commission* Constitutional Case no 1 of 2009 and *Fred Nseulav The Attorney General and Malawi Congress Party*, MSCA Civil Appeal no 32 of 1997 (unreported). For cogent analyses of theories of constitutional interpretation, see generally Lourens M du Plessis, 'Constitutional Interpretation: Theories and Practice' (1995) (unpublished manuscript, on file with the University of Pennsylvania *Journal of Constitutional Law*); Lourens M du Plessis and JR de Ville, 'Bill of Rights Interpretation in the South African Context (3): Comparative Perspectives and Future Prospects' *Stellenbosch Law Revue* 356, 356-392 (1993).

people of Malawi by progressively adopting and implementing policies and legislation that promote good health and self-sufficiency and adequate health care, commensurate with the health needs of Malawian Society and international standards of health.³⁶ Further, the state needs to put in place policies that enhance the quality of life in rural communities. Public health under the Constitution is a measure of government performance. Section 13(e) recognizes rural standards of living as a key indicator of the success or failure of government policies. Section 13(d)(iii) enjoins the government to manage the environment responsibility in order to provide a healthy living and working environment. This Section links trade to the environment and health and enjoins the state to ensure generational and intergenerational rights for sustainable development.

The right to health is also covered under Section 16. This Section provides for a right to life, the most basic of all the rights. In other words, courts have interpreted this right as being broader than mere prohibition of physical acts that denude it.³⁷ The Indian Supreme Court in *PachimBangaKhetMajoor-Samity v State of West Bengal, 1996* held that denial of the right to emergency medical care is a violation of the right to life guaranteed by the Indian Constitution. Related to this is the right to human dignity under Section 19. Human dignity encompasses all aspects of the human physiology.³⁸ The right to health is also linked to the right to life. The ICCPR committee in General Comment No. 6 (1966) gives a wider definition of the right to life and defines the state's role in protecting human life to include obligations to reduce infant mortality, increase life expectancy, and eliminate malnutrition and endemics. The right to health is indivisibly linked to the inherent dignity of the human person³⁹ and is indispensable for the fulfilment of other human rights.⁴⁰

³⁶ The State and the Chief Secretary to the President and Cabinet *Ex parte*, Dr Bakili Muluzi, Miscellaneous Civil Cause n 3 of 2011 (unreported).

³⁷ In *Olga Tellis v Bombay Municipal Corporation, 1985 Supp (2) SCR 51*, a Constitutional Bench of the Court held that the right to life includes the right to livelihood, because no person can live without the means of living i.e. means of livelihood. If the right to livelihood is not treated as part of the constitutional right to life, the easiest way of depriving a person of his right to life would be to deprive him of his means of livelihood to the point of abrogation. Such deprivation would not only denude the life of its effective content and meaningfulness, but it would make it impossible. By the same token, failure to provide health care would abrogate the right to life.

³⁸ UN Human Rights Commission, 1982.

³⁹ Covered under Article 19 of the Republic of Malawi's Constitution.

⁴⁰ Joint fact Sheet WHO/OHCHR/323: Right to Health <http://www.who.int/mediacentre/factsheets/fs323_en.pdf

The right to health has been defined in General Comment No. 14⁴¹ as containing both freedoms and entitlements. The freedoms include the right to control one's health and body, including sexual and reproductive freedom, and the right to be free from interference, such as the right to be free from torture, non-consensual medical treatment, and experimentation. By contrast, entitlements include the right to a system of health protection that provides equality of opportunity for people to enjoy the highest attainable level of health.⁴²

Under Article 5(1)(a) of the SADC Treaty, the main objective of the Organization is to promote sustainable and equitable economic growth and socioeconomic development that will ensure poverty alleviation with the ultimate objective of its eradication, and enhance the standard and quality of life of the people of Southern Africa. One of the founding principles for the organization is human rights, democracy and rule of law. Health is a human right and is covered under Articles 4 and 5 by the expression 'enhance the standard and quality of life'. Article 2 of the SADC Protocol on Health implements the WHO Constitution and Malawi has commitments under all these regional and international treaties and conventions.

Underinvestment in health care undermines the quality of human life and dehumanizes patients and families affected. The right to life is non-delegable under Section 44(1)(a).

There is also a framework that encompasses the right to health. This is the right to development that presupposes that healthy citizens make better economic actors. Section 30(2) calls upon the State to take measures for its realization. This includes equal opportunity to access basic resources, education and health services, food, shelter, employment, and infrastructure. Intellectual property rights such as patents have a double sword effect. They are an engine for innovation growth and development. However they have a direct impact on prices for pharmaceutical products that affect equality of opportunity to access basic life-saving medicines.⁴³ For a country like Malawi, its ability to

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⁴¹General Comment No. 14: The Right to the Highest Attainable Standard of Health - UN Committee on Economic, Social and Cultural Rights; see also:

<<http://www.nesri.org/resources/general-comment-no-14-the-right-to-the-highest-attainable-standard-of-health#sthash.7silKENP.dpuf>>

(Accessed November 2014).

⁴²Vide

<http://www.nesri.org/sites/default/files/Right_to_health_Comment_14.pdf (Accessed November 2014)>

⁴³Carsten Fink, Intellectual Property and Public Health: An Overview of the Debate with a Focus on US Policy - Working Paper 146, (2008) <<http://www.cgdev.org/publication/>

provide essential health care is constrained by systemic issues such as lack of a pharmaceutical manufacturing base and donor dependency. Its international commitments under the TRIPS Agreement and WIPO have an impact on its ability to provide requisite health care through the price effect of patent protection.⁴⁴ The international harmonization of the protection of intellectual property rights through the TRIPS Agreement robbed developing countries of their traditional ability to refuse granting patents, in order to address pressing health needs.⁴⁵ However, built-in exceptions to patent protection in defined circumstances such as in Articles 30 and 31 of the TRIPS Agreement provide flexibility for developing countries such as Malawi to address its health-care needs.

The right to health involves two values that can at times be irreconcilable: trade and human rights. Much as the two are mutually supportive, the trend has been in favour of stronger intellectual property right protection and for the foreseeable future this might be the trend. For instance, the United States favours strong protection of intellectual property rights in its bilateral agreements⁴⁶. These provisions

[intellectual-property-and-public-health-overview-debate-focus-us-policy-working-paper](#)> (accessed November 2014). See also Laxminarayan, Over, and Smith (2005) who point to another tension in promoting widespread access to medicines: cheaper prices may encourage drug misuse, leading to a more rapid development of drug resistance and thus a shortened duration of a drug's usefulness. Also F Abbott and J Reichman, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' *Journal of International Economic Law*, 2007, 10(4): 921–987.
<http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1025593> and F Abbott and R Van-Puybroeck, 'Compulsory Licensing for Public Health: A Guide of Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision' World Bank, Washington, D.C., 2005
<http://www-wds.worldbank.org/external/default/main?pagePK=64193027&piPK=64187937&theSitePK=523679&menuPK=64187510&searchMenuPK=64187283&siteName=WDS&entityID=00012009_20050830130225>

⁴⁴ Cynthia M Ho, 'A New World for Addressing Patent Rights and Public Health', 82 *Chicago-Kent Law Review*, 1469, [2007], *Ibid.* p 1470; see also Frederick M Abbott and Jerome H Reichmann, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' 10, *Journal of International Economic Law*, 921, December 2007, p 7.

⁴⁵ *Ibid.*, and Mor Bakhoun, 'TRIPS, Patent Rights and Right to Health: "Price" or "Prize" for Better Access to Medicine?' Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper Series no 10-07
<<http://ssrn.com/abstract=1619215>> (accessed November 2014).

⁴⁶ See Article 4 of the US-Jordan Free Trade Agreement, <[https://ustr.gov/trade-agreements/free-trade-](https://ustr.gov/trade-agreements/free-trade)

are often TRIPs-Plus.⁴⁷ The right to health has been enshrined in international and regional human rights treaties, as well as national constitutions all over the world⁴⁸: UN human rights treaties such as the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR); the 1979 Convention on the Elimination of All Forms of Discrimination against Women (CEDAW); and the 1989 Convention on the Rights of the Child (CRC). Regional treaties enshrining the right to health include the SADC Charter of Fundamental Social Rights; the 1961 European Social Charter; the 1981 African Charter on Human and Peoples' Rights; and the 1988 Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (the Protocol of San Salvador).

Multilateral instruments such as the General Agreement on Trade in Goods⁴⁹, recognize that this right provides an exception to the most-favoured-nation and national treatment obligation if measures are taken to protect human, animal or plant life or health.⁵⁰ Under the WTO regime, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) is devoted to the regulation of trade and health. For SADC, the SPS Agreement has been domesticated by being annexed to the Protocol on Trade.⁵¹ The Protocol on Trade in Article 16 provides that Member States shall base their sanitary and phytosanitary measures on international standards, guidelines, and recommendations, so as to harmonize sanitary and phytosanitary measures for agricultural and livestock production. Further, under Article 16(2), Member States should, upon request, enter into consultation with the aim of achieving agreements on recognition of the equivalence of specific sanitary and phytosanitary measures, in accordance with the WTO SPS Agreement. Article 24 of the Protocol on Trade calls upon Member States to adopt policies

[agreements/jordan-fta/final-text](#)>

⁴⁷ *Ibid.*

⁴⁸ Graeme B Dinwoodie, William O Hennessey, Shira Perlmutter. Graeme W Austin, *International Intellectual Property Law and Policy*. It is pointed out that the future international framework of intellectual property rights should be shaped in the light of the UN Millennium Development Goals. The Millennium Development Goals should have a strong influence in the future intellectual property framework.

⁴⁹ Cynthia M Ho, *op. cit.* (note 3).

⁴⁹ GATT 1994 Article XX(b).

⁵⁰ Under the WTO and SADC SPS Annex to the Protocol on Trade, 'animal' includes fish and wild fauna; 'plant' includes forests and wild flora; 'pests' include weeds; and 'contaminants' include pesticide and veterinary drug residues and extraneous matter.

⁵¹ <http://www.sadc.int/files/7413/5817/6371/SADC_Sanitary_and_Phyto_Sanitary_ANNEX.pdf> SADC/CMT/20/2008/10 >

and implement measures within the Community for the protection of intellectual property rights, in accordance with the TRIPS Agreement. The regional domestication of the TRIPS and WTO covered agreements recognize the right to health and exceptions under Article XX(b) and Article 31*bis* of the TRIPS Agreement. It is clear that, in trade terms, the symbiotic relation between intellectual property rights and health is a frontline consideration.

The International Covenant on Economic, Social and Cultural Rights (1966) in Article 12 states that steps for the realization of the right to health include those that reduce infant mortality and ensure the healthy development of the child; improve environmental and industrial hygiene; prevent, treat, and control epidemic, endemic, occupational, and other diseases; and create conditions to ensure access to health care for all. The WHO Constitution⁵² states in the preamble that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition. It further states that the extension to all peoples of the benefits of medical, psychological, and related knowledge is essential to the fullest attainment of health.⁵³ States under Article 1 of the WHO Constitution seek the attainment by all peoples of the highest possible level of health.

The right to health contains four elements:

- (a) Availability - this refers to a sufficient quantity of functioning public health and health care facilities, goods and services, as well as programmes;
- (b) Accessibility - this means that health facilities, goods, and services should be accessible to everyone;
- (c) accessibility has four overlapping dimensions - non-discrimination, physical accessibility, economical accessibility (affordability) and information accessibility;

(a) ⁵²The Constitution was adopted by the International Health Conference held in New York from 19 June to 22 July 1946, which was signed on 22 July 1946 by the representatives of 61 States (Off. Rec. WHO, 2,100), and entered into force on 7 April 1948. Amendments adopted by the Twenty-Sixth, Twenty-Ninth, Thirty-Ninth and Fifty-First World Health Assemblies (Resolutions WHA26.37, WHA29.38, WHA39.6 and WHA51.23) came into force on 3 February 1977, 20 January 1984, 11 July 1994 and 15 September 2005 respectively and are incorporated in the present text.

⁵³<http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf?ua=1>

(d) acceptability - this means that all health facilities, goods, and services must be respectful of medical ethics and culturally appropriate, as well as sensitive to gender and life-cycle requirements; and

(e) quality - this refers to health facilities, goods, and services that must be scientifically and medically appropriate and of good quality.

The right to health imposes upon States Parties three types of obligations:

- (a) Respect - this means simply not to interfere with the enjoyment of the right to health ('do no harm');
- (b) Protect—this means ensuring that third parties (non-state actors) do not infringe upon the enjoyment of the right to health (e.g. by regulating non-state actors); and
- (c) Fulfil - this means taking positive steps to realize the right to health (e.g. by adopting appropriate legislation, policies or budgetary measures).⁵⁴

Section 13(c) of the Constitution introduces the principle of proportionality to the discourse of right to health. Courts normally take a textual and contextual approach on the interpretation and application of this right. Sections 10 and 11 of the Constitution guide the application and interpretation of the Constitution. In practice, courts will only resort to international case law if there is a lacuna in local principles.⁵⁵

⁵⁴ <http://www.who.int/mediacentre/factsheets/fs323/en/>

⁵⁵ In the words of J Chipeta in *The Public Affairs Committee v Attorney General*, Civil Cause no 1861 of 2003:

I have just advocated for a chance to be given to the Constitution to speak with an uninterrupted voice and to first try and understand what it means before rushing to borrow the influence of decisions in other jurisdictions for the construction of our Constitution. I should think it is only when a direct understanding of the Constitution proves difficult to capture that resort can be meaningful had to such other guiding materials or precedents.

The views of Mr Justice Chipeta are also reflective of the views in Supreme Court Reference no 2 of 1995 and Reference by Western Highlands Provincial Executives (1996) 3 LRC 28. J Mahomme in *Svs Makwanyane* (1995) 3 SA 391 (CC) emphasized the need to place context and text at the centre of interpretation. He had this to say:

What ... is required to do in order to resolve an issue is to examine the relevant provisions of the Constitution, their text and their context; the interplay between the different legal provisions; legal precedent relevant to the resolution of the problem both in South Africa and abroad; the domestic common law and public international law impacting on its possible solution;

In health-care rights, the courts' approach has been to apply the principle of proportionality by considering the wider context in which individual health-care rights interface with community health-care rights. In *Thiagraj Soobramoney v Minister of Health (Kwazulu-Natal)*⁵⁶, the court stated:

Health-care rights by their very nature have to be considered, not only in a traditional legal context structured around the ideas of human autonomy, but in a new analytical framework based on the notion of human interdependence. A healthy life depends upon social interdependence: the quality of air, water, and sanitation which the state maintains for the public good; the quality of one's caring relationships, which are highly correlated to health; as well as the quality of health care and support furnished officially by medical institutions and provided informally by family, friends, and the community.⁵⁷

In the words of Minow:

Interdependence is not a social ideal, but an inescapable fact; the scarcity of resources forces it on us. Who gets to use dialysis equipment? Who goes to the front of the line for the kidney transplant?⁵⁸

Traditional rights analyses accordingly have to be adapted so as to take account of the special problems created by the need to provide a broad framework of constitutional principles governing the right of access to scarce resources and to adjudicate between competing rights bearers. When rights by their very nature are shared and are interdependent, striking appropriate balances between the equally valid entitlements or expectations of a multitude of claimants should not be seen as imposing limits on those rights (which would then have to be justified in

factual and historical consideration bearing on the problem; the significance and meaning of the language used in the relevant provisions of the content and sweep of the ethos expressed in the structure of the Constitution; the balance to be struck between different and sometimes potentially conflicting considerations reflected in its text; and by a judicious interpretation and assessment of all factors to determine what the Constitution permits and what it prohibits.

⁵⁶ (CCT32/97) [1997] ZACC 17, at p 28.

⁵⁷ Minow, participating in an interdisciplinary discussion held at Harvard Law School in 1993, 'Session I: Applying Rights Rhetoric to Economic and Social Claims' *Economic and Social Rights and the Right to Health* (Harvard Law School Human Rights Programme Cambridge MA 1995) 1 at 3.

⁵⁸ *Ibid.*

terms of Section 36), but as defining the circumstances in which the rights may most fairly and effectively be enjoyed.

Section 13(c) of the Constitution obliges the state to actively promote the welfare and development of the people of Malawi by progressively adopting and implementing policies and legislation that aim to provide adequate health care, commensurate with the health needs of Malawian society and international standards of health care. It introduces the principle of proportionality in the provision of health care to Malawian society. This principle is internationally recognized as demonstrated by the South Africa case of *Thiagraj Soobramoney v Minister of Health (Kwazulu-Natal)*⁵⁹ and English cases such as *Re J (a minor)*⁶⁰ [1992] 4 All ER 614 (CA) at 625g; *Airedale NHS Trust v Bland*⁶¹, and *R v Cambridge Health Authority, ex parte B.*⁶² This is also reflected in UNESCO's position on the issue.⁶³ The Social and Economic Council in General Comment No. 14 alludes to the proportionality principle when it states that the notion of 'the highest attainable standard of health' in Article 12.1 takes into account both the individual's biological and socioeconomic preconditions and a state's available resources.⁶⁴

There are a number of aspects that cannot be addressed solely by the relationship between States and individuals; in particular, good health cannot be ensured by a state, nor can states provide protection against every possible cause of human ill health. Genetic factors, individual susceptibility to ill health, and the adoption of unhealthy or risky lifestyles may play an important role with respect to an individual's health. Consequently, the right to health must be understood as a right to the enjoyment of a variety of facilities, goods, services, and conditions necessary for the realization of the highest attainable standard of health. These cases show that the principle of proportional allocation of limited state resources and the realization of the right to life

⁵⁹ (CCT32/97) [1997] ZACC 17.

⁶⁰ [1992] 4 All ER 614 (CA) at 625g.

⁶¹ [1993] 1 All ER 821 (CA) at 857b.

⁶² [1995] 2 All ER 129 (CA) at 137d-f.

⁶³ Brody, *Biomedical Technology and Human Rights* (UNESCO, Paris 1993) at 233. South Africa is a middle income country where 'despite their high profile, modern lifesaving medical treatments are only available on a limited scale', Benatar 'History of Medical Ethics: Africa' *Encyclopaedia of Bioethics Vol 3*, Revised (Macmillan, New York 1995) 1465 at 1467.

⁶⁴ General Comment No. 14: The Right to the Highest Attainable Standard of Health - UN Committee on Economic, Social and Cultural Rights.

See more at: <<http://www.nesri.org/resources/general-comment-no-14-the-right-to-the-highest-attainable-standard-of-health#sthash.7siKENP.dpuf>>(accessed November 2014).

and health for everyone by the state requires rationing and setting of criteria.

In *Thiagraj Soobramoney v Minister of Health (Kwazulu-Natal)*,⁶⁵ the court stated:

The hard and unpalatable fact is that, if the appellant were a wealthy man, he would be able to procure such treatment from private sources; he is not and has to look to the state to provide him with the treatment. But the state's resources are limited and the appellant does not meet the criteria for admission to the renal dialysis programme. Unfortunately, this is true not only of the appellant, but of many others who need access to renal dialysis units or to other health services. There are also those who need access to housing, food and water, employment opportunities, and social security. These too are aspects of the right to:

" human life: the right to live as a human being, to be part of a broader community, to share in the experience of humanity".⁶⁶

The state has to manage its limited resources in order to address all these claims. There will be times when this requires it to adopt a holistic approach to the larger needs of society, rather than to focus on the specific needs of particular individuals within society.

J O'Regan in *State v Makwanyane and Another*⁶⁷ and J Combrinck in *R v Cambridge Health Authority, ex parte B*⁶⁸ equally offer guidance in approaching health-care rights as opposed to other rights. Emphasis is placed on context, and our Constitution in Section 13(c) is in tandem with this approach. The learned Judge in that case had this to say:

I have no doubt that in a perfect world any treatment which a patient, or a patient's family, sought would be provided if doctors were willing to give it, no matter how much it cost, particularly when a life was potentially at stake. It would however, in my view, be shutting one's eyes to the real world if the court

were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet. They cannot pay their nurses as much as they would like; they cannot provide all the treatments they would like; they cannot purchase all the extremely expensive medical equipment they would like; they cannot carry out all the research they would like; they cannot build all the hospitals and specialist units they would like. Difficult and agonizing judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the court can make.

The jurisprudence emerging from authorities and Section 13(c) of the Constitution is a holistic approach to health-care rights anchored on the principle of proportionality. The right to health under Section 13(c), like all rights, is not an absolute right. It is limited through the principle of proportionality by the availability of resources and its allocation must be proportionate to the greater needs of society. Thus, access to essential medicines, though constitutionally guaranteed, is constrained by resources. For Malawi, intellectual property rights are an opportunity to stimulate growth in the economy and biotech innovations that will expand the resource base for the actualization of the right to health. There is need to ensure that preconditions for such capacity building in the pharmaceutical manufacturing base, modernization of laws on intellectual property rights, and pooled procurement mechanisms are in place. Thus, there is a business case for the promotion, protection, and enforcement of intellectual property rights, as well as a social imperative for utilizing flexibilities in intellectual property right regimes for raising the living and working standards of people in Malawi and the SADC region.

In Section 44(1), the Constitution provides a list of rights from which there can be no derogation, restriction, or limitation. The right to health is not one of them. This gives efficacy to the proportionality principle in Section 13(c), because if it were non-derogable it would be in conflict with the proportionality principle, as well as norms of public international law referred to in Section 11. However, two of the related rights to health are non-derogable; there is the right to life (Section 16) and the right not to be subjected to torture and cruel, inhuman, or degrading treatment (Section 19). Without prejudice to Section 44(1), Section 44(2) allows restrictions or limitations prescribed by law, which are reasonable, recognized by international human rights standards and necessary in an open

⁶⁵See, *supra* P Chaskalson, at p 16.

⁶⁶Per O'Regan J in *S v T Makwanyane and M Mchunu* (CCT3/94) [1995] ZACC 3; 1995 (6) BCLR 665; 1995 (3) SA 391; [1996] 2 CHRLD 164; 1995 (2) SACR 1 (6 June 1995) at para 326.

<http://www.saflii.org/za/cases/ZACC/1995/3.html> (accessed November 2014).

⁶⁷1995 (3) SA 391 (CC); 1995 (4) BCLR 665 (CC) in relation to the right to life.

⁶⁸See *supra*.

and democratic society. In *Thiagraj Soobramoney v Minister of Health (Kwazulu-Natal)*⁶⁹, P Chaskalson had the following observations to make:

The Constitution is forward looking and guarantees to every citizen fundamental rights in such a manner that the ordinary person-in-the-street, who is aware of these guarantees, immediately claims them without further ado – and assumes that every right so guaranteed is available to him or her on demand. Some rights in the Constitution are the ideal and something to be strived for. They amount to a promise, in some cases, and an indication of what a democratic society aiming to salvage lost dignity, freedom and equality should embark upon. They are values which the Constitution seeks to provide, nurture and protect....

The learned Judge then turned to the issue of limitation of such rights at paragraph 43 on page 22 and had this to say:

However, the guarantees of the Constitution are not absolute, but may be limited in one way or another. In some instances, the Constitution states in so many words that the state must take reasonable legislative and other measures, within its available resources 'to achieve the progressive realization of each of these rights'. In its language, the Constitution accepts that it cannot solve all of our society's woes overnight, but must go on trying to resolve these problems. One of the limiting factors to the attainment of the Constitution's guarantees is that of limited or scarce resources.

Thus, the right to health in constitutional terms is limited by the principle of proportionality. However, in the case for Malawi, the fact that related rights, such as the right to life and the right against subjection to degrading and inhuman treatment (lack of access to medicines degrades and dehumanizes patients by diluting the quality of life), are non-derogable points to the heightened duty of the State to safeguard this right. The status of intellectual property rights and their protection and enforcement have a bearing on this. The need to review laws on intellectual property rights and the symbiotic relationship between these and health need no emphasis. Within intellectual property right legal frameworks there exist flexibilities that can be utilized to address the challenges of access to essential medicines and health-care. One example is to use valuable TRIPS flexibilities under Article 31*bis* of the TRIPS agreement, as well as under Article XX

⁶⁹ *Supra* page 22.

exceptions of GATT 1994. Within SADC, Malawi can participate in the pooled procurement and ease its current problem on the health-care bill.

III. LEGAL FRAMEWORK

The legal framework for intellectual property rights and public health consists of a number of laws, much of which were received during colonial interaction from Britain and have become obsolete. It also includes Malawi's international obligations under various multilateral agreements. As a WTO Member, Malawi assumes obligations both under GATT 1994 and TRIPS in Annex 1C. Thus Malawi has intellectual property right obligations not only under the TRIPS Agreement, but also under the covered agreements, as defined under Article 1.1 of the Understanding on Rules and Procedures Governing the Settlement of Disputes.⁷⁰ The scope of obligations under Article 1.3 includes obligations under the Paris Convention (1967), the Berne Convention (1971), the Rome Convention, and the Treaty on Intellectual Property in Respect of Integrated Circuits.⁷¹ Article 2.2 of the

⁷⁰ In *Brazil — Desiccated Coconut*, the Appellate Body defined the term 'covered agreements' as follows:

The 'covered agreements' include the *WTO Agreement*, the Agreements in Annexes 1 and 2, as well as any Plurilateral Trade Agreement in Annex 4 where its Committee of signatories has taken a decision to apply the *DSU*. In a dispute brought to the DSB, a panel may deal with all the relevant provisions of the covered agreements cited by the parties to the dispute in one proceeding.

In *Guatemala — Cement I*, the Appellate Body examined the Panel's interpretation of the relationship between Article 17 of the Anti-Dumping Agreement and the rules and procedures of the DSU. In this context, the Appellate Body made the following general statement about Article 1.1 of the DSU:

Article 1.1 of the DSU establishes an integrated dispute settlement system which applies to all of the agreements listed in Appendix 1 to the DSU (the 'covered agreements'). The DSU is a coherent system of rules and procedures for dispute settlement which applies to 'disputes brought pursuant to the consultation and dispute settlement provisions of the covered agreements. The *Anti-Dumping Agreement* is a covered agreement listed in Appendix 1 of the DSU; the rules and procedures of the DSU, therefore, apply to disputes brought pursuant to the consultation and dispute settlement provisions contained in Article 17 of that Agreement."

⁷¹ In the TRIPS Agreement, the 'Paris Convention' refers to the Paris Convention for the Protection of Industrial Property; 'Paris Convention (1967)' refers to the Stockholm Act of this Convention of 14 July 1967. 'Berne Convention'

TRIPS Agreement provides that nothing in the Agreement shall derogate from existing obligations that Members have to each other under the Paris Convention, the Berne Convention, the Rome Convention, and the Treaty on Intellectual Property in Respect of Integrated Circuits. Although Malawi is a signatory to those WIPO conventions, their incorporation under the TRIPS Agreement brings a new dimension in terms of enforcement and dispute settlement. Article 64.1 of the TRIPS Agreement provides that provisions of Articles XXII and XXIII of the GATT 1994, as elaborated and applied by the Dispute Settlement Understanding, apply to consultations and the settlement of disputes under it, except as otherwise specifically provided therein.⁷²

Under Sections 10 and 11 of the Constitution, the content, application, and interpretation of our domestic laws and policies include a number of international treaties and conventions. Courts are enjoined to take into account principles and norms of public international law. For intellectual property rights they include the Trademarks Act (Cap. 49:01), the Patents Act (Cap. 49:02), the Copyright Act (Cap. 49:03), the Trade Descriptions Act (Cap. 49:04), and the Registered Designs Act (Cap. 49:05) of the Laws of Malawi. In addition, there are the Competition and Fair Trading Act and the Environment Management Act (Caps. 48:09 and 60:02) respectively, of the Laws of Malawi. The industrial property statutes (trademarks, patents, and industrial designs), which are administered by the Department of the Registrar, were enacted during the Federation of Rhodesia and Nyasaland. The Patents and Trade Marks Act came into force on 1 April and the Registered Designs Act on 1 December 1958. These laws have never been amended except for the Patents and Registered Designs Acts in 1985. The Competition and Fair Trading Act was enacted in 1998 to regulate and monitor monopolies and concentrations of economic

refers to the Berne Convention for the Protection of Literary and Artistic Works; 'Berne Convention (1971)' refers to the Paris Act of this Convention of 24 July 1971. 'Rome Convention' refers to the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, adopted at Rome on 26 October 1961. 'Treaty on Intellectual Property in Respect of Integrated Circuits' (IPIC Treaty) refers to the Treaty on Intellectual Property in Respect of Integrated Circuits, adopted at Washington on 26 May 1989. 'WTO Agreement' refers to the Agreement Establishing the WTO. See:

<http://www.wto.org/english/docs_e/legal_e/27-trips_03_e.htm>

⁷² *United States – Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/AB/R, 2 Jan. 2002 ('*US – Havana Club*'), WT/DS176. Also see *United States – Section 110(5) of the US Copyright Act*, WT/DS160, 15 June 2000. ('*US – Copyright Exemption*').

power, as well as to prohibit anti-competitive trade practices. The Trade Descriptions Act was promulgated in 1987 to criminalize certain uses of trade descriptions and trademark forgery. In addition, the Environment Management Act (1996) is being repealed by another statute of a similar title, to take into account the protection of genetic resources. The main legal framework for public health is the Public Health Act, Cap.34:01. This is complemented by other pieces of legislation such as the Mental Treatment Act, the Pharmacy, Medicines and Poisons Act, the Dangerous Drugs Act, the Pesticide Act, and the Occupational Safety, Health and Welfare Act.

Malawi is a member of the WTO, the World Intellectual Property Organization (WIPO), and the United Nations Educational, Scientific and Cultural Organization (UNESCO). Among the WTO Agreements that bind Malawi, the most important in the field of intellectual property is the TRIPS Agreement. Malawi has not acceded to some treaties such as the Washington Treaty on Intellectual Property in Respect of Integrated Circuits and the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations. In the area of copyright and related rights, Malawi is also a party to the Berne Convention for the Protection of Literary and Artistic Works and the Universal Copyright Convention, which is administered by WIPO and UNESCO respectively. An important additional dimension to Malawi's IP regime is the country's adherence to the Convention on Biological Diversity (CBD) adopted in 1992.

Malawi is a founding member of ARIPO. Within the framework of ARIPO, Malawi is a party to ARIPO's Protocol of Patents and Industrial Designs, 1984, and the Banjul Protocol on Marks of 1993. Malawi is also a founding member of both the Common Market for Eastern and Southern Africa (COMESA) and the Southern Africa Development Community (SADC). The constitutive texts establishing these economic groups' intellectual property rights have provisions that are binding on Malawi.⁷³ For instance, the SADC Protocol on Culture, Information and Sports also

⁷³For example, the COMESA Treaty obliges member states to:

jointly develop and implement suitable patent laws and industrial licensing systems for the protection of industrial property rights and encourage the effective use of technological information contained in patents.

The SADC Treaty is a little robust in this respect. Article 24 of the Protocol on Trade in the SADC, entitled 'Intellectual Property Rights, states that 'Member States shall adopt policies and implement measures within the Community for the protection of Intellectual Property Rights, in accordance with WTO Agreement on Trade-Related Aspects of Intellectual Property Rights.'

calls on Member States to provide effective copyright and related rights protection and to fight against piracy. At the continental level, the African Union Heads of State and Government have decided to establish the Pan African Intellectual Property Organization.

There are a number of intellectual property service providers in the country, which range from the two main national intellectual property offices, the Registrar General and the Copyright Society of Malawi (COSOMA), to the judiciary, police, Malawi Revenue Authority, Malawi Law Society and the Institute of Patent and Trademark Agents of Malawi. Apart from a loose cooperation framework between the two main national intellectual property offices, there is virtually no coordination among the intellectual property service providers.

IV. CHALLENGES

For Malawi, an apparent lack of a sustainable innovation culture is a huge challenge toward utilization of available flexibilities in laws on intellectual property rights. This is manifested in the state of legal frameworks for intellectual property rights in the country. The state of the laws is indicative of the country's inability to see things differently.⁷⁴ Drivers for innovation include production, organization, and consumption. To innovate there must be a need to see the need for new production methods and new ways of organizing the production and products to satisfy new forms of consumption. Malawi is stuck in an agro-based economy and has yet to shift to the new order. The state of the policy on intellectual property rights and laws is an indicator of policy delusion. For as long as the preconditions for utilizing available flexibilities are not in place, the country will struggle to manoeuvre its way through its international obligations and meet pressing health-care needs.

Malawi has assumed international obligations for intellectual property rights. It also enjoys some flexibility such as compulsory licensing and parallel importation as an LDC. The challenge is that these flexibilities require that Malawi have in place TRIPS-compliant legislation. In the area of access to medicines, the principal act is the Malawi Patent Act (1992). Section 29 of the Act grants protection on the first-to-file principle for 16 years with a possibility for extension and renewal fees payable from the fourth year. This is not consistent with TRIPS, which provides a 20-year patent protection period.⁷⁵ Further biological materials and

biotechnology processes are not patentable in Malawian law, in conflict with TRIPS provisions.⁷⁶ Malawi's patent legislation does not take advantage of key flexibilities available under TRIPS, the subsequent Doha Declaration (2001) or the Paragraph 6 Implementation Agreement, although it does have some potential flexibility built in. Malawi's entire patent regime can be described as TRIPS-Plus because it prematurely provides patent protections for medicines. This is unhelpful. Malawi needs to review its patent laws to take advantage of the flexibilities.

Malawi's major public health challenge is malaria and infant mortality. Malaria kills more Malawians than HIV-AIDS. However, the publicity around HIV-AIDS overshadows other public health issues. For a national budget that is 40 per cent donor funded, this creates donor bias in funding. Faced with financial and institutional challenges, such as lack of local capacity for pharmaceutical manufacturing, Malawi needs to turn to regional and international mechanisms. One example is to use TRIPS flexibilities such as compulsory licensing.⁷⁷ There are both economic and legal prerequisites for compulsory licensing. A compulsory licence is a business transaction between the importer and the new producer. The compulsory licence will only attract a regular for-profit company if it can expect reasonable returns on the investment. The importer, on the other hand, will only conclude a deal if the new producer can offer a price below the patent holder's price. Legally, the rules on compulsory licensing can only be used if they are legally implemented and not contradicted by other international commitments. It may become impossible to use the new rules if the countries in question have implemented provisions that go beyond TRIPS (so-called 'TRIPS-Plus').

Other challenges include inadequate institutional and infrastructure capacity, lack of awareness at all levels of the benefits of the intellectual property system, outdated intellectual property statutes, and inadequate intellectual property human resource cadre at almost all national, sectoral and organization levels. These problems are not unique to Malawi, but are symptomatic of the challenges LDCs face. Malawi, like most developing countries,

2000 ('Canada – Patent Term').

⁷⁶ Leslie London and Aulline H Mabika 'Implications of the GATS and TRIPS Agreements for the Right to Health in Malawi and Southern and Eastern African' Information and Negotiation Institute (SEATINI) School of Public Health and Family Medicine, University of Cape Town (UCT) (2007).

⁷⁷ J Love, 'Compulsory Licensing: Models for State Practice in Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord' (prepared for the United Nations Development Programme), (2001), <<http://www.cptech.org>> (accessed November 2014).

⁷⁴ See generally:

<<http://www.newandimproved.com/newsletter/2120.php>> (accessed November 2014).

⁷⁵ Canada – Term of Patent Protection, WT/DS170, 18 Sept.

has many problems relating to public health and access to essential medicines.

The problem of capacity can be addressed by a policy of local manufacturers patterning manufacturers in the West and elsewhere, such as in India, China, and Brazil.⁷⁸ However without an effective legal framework, the country is ill-positioned for this. For now it will have to rely on buying branded drugs from manufacturers in the West.

The country policy response has been to draft policy that aims at ensuring that intellectual property contributes to public health and access to medicines. The policy allows for the exploitation of flexibilities in domestic intellectual property legislation and international treaties, such as those under Article 31*bis* of the TRIPS Agreement. The policy advocates the development of guidelines for the exploitation of these flexibilities in the domestic legislation and various treaties. It advocates the dissemination of information that outlines flexibilities in the protection of intellectual property rights under the TRIPS Agreement. Crucially, it seeks to explore the grant of compulsory licences to manufacture essential medicines. The basic premise of this policy is that intellectual property has a symbiotic relationship with socioeconomic development in that it improves the quality of life through technological advancements and enjoyment of literary and artistic works. Malawi cannot, therefore, effectively implement its development agenda without a comprehensive and clear policy on how an intellectual property system can play this vital role.

The Malawi Government, in its desire to be a technologically driven middle-income economy, intends to reduce poverty through sustainable economic growth and infrastructure development. Just as information and communication technology and science and technology are critical for socioeconomic development, it is imperative that intellectual property be prioritized as it forms part of the basis of development in the key sectors of Malawi's economy such as trade, industry, agriculture, health, culture, and natural resources management.

V. REGIONAL DIMENSION

Malawi is a member of the Southern African Development Community. SADC is a treaty-based

Regional Economic Community-based inter-governmental organization. The SADC Treaty (The Treaty)⁷⁹ and its protocol⁸⁰ provides an all-encompassing framework⁸¹, for countries in the region to coordinate, harmonize, and rationalize⁸² their socioeconomic policies⁸³ and facilitate the movement of factors of production in the region. It commits Member States to fundamental principles of sovereign equality of members⁸⁴, solidarity, peace and security⁸⁵, human rights⁸⁶, democracy and rule of law⁸⁷, equity, and balance and mutual benefit⁸⁸, as well as peaceful settlement of disputes.⁸⁹ SADC's objectives⁹⁰ include the achievement of development and economic growth, alleviation of poverty, enhancement of the quality of life of the peoples of Southern Africa⁹¹ and supporting the socially disadvantaged⁹² through regional integration.⁹³ SADC seeks to build a region with a high degree of harmonization and rationalization⁹⁴,

⁷⁹ SADC is an inter-governmental organization comprising Angola, Botswana, Lesotho, Malawi, Mauritius, Mozambique, Namibia, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe. It was established by Treaty in 1992 and seeks to foster closer economic and political relations among its membership as a step towards the creation of an economic community.
<<http://www.sadc.int/index/browse/page/120>> (accessed November 2014).

⁸⁰ The definition of 'protocol' in Article 1 of the Treaty refers to a protocol as an instrument of implementation of the treaty, having the same legal force as the treaty. See <http://www.sadc.int/files/6213/2808/8365/CONSOLIDATED_PROTOCOL_ON_TRADE_vers_30-01-2012.pdf> (accessed 12 September 2012).

⁸¹ Article 1 of the Treaty.

⁸² Article 21(2).

⁸³ Chengetai C Madziwa 'Social Charter: Towards People-Centered Development' SADC Today Southern African Development Community Vol 6 no 4 October 2003 p 10.

⁸⁴ Article 4(a).

⁸⁵ Article 4(b).

⁸⁶ Article 5(1) of the Treaty. One instrument made hereunder for implementation is the SADC Charter of Fundamental Social Rights (the Charter), which spells out SADC's social policy. The charter embodies recognition by stakeholders in the region of the universality and individuality of basic human rights proclaimed in instruments such as the United Nations Universal Declaration of Human Rights, the African Charter on Human and People's Rights, and the Constitution of the ILO. See Article 3 of the Charter.

⁸⁷ Article 4(c).

⁸⁸ Article 4(d).

⁸⁹ Article 4(e).

⁹⁰ Generally contained in Article 5 of the Treaty.

⁹¹ Article 5(a) of the Treaty as read with Article 11 of the Charter.

⁹² Article 5(a) of the Treaty as read with Article 10(2) of the Charter. This Article provided for social security for persons that have been unable to re-enter the labour market and have no means of subsistence.

⁹³ Similar objectives are aspired to by COMESA, to which a majority of SADC States are members. See Article 3 of the Treaty of COMESA, below.

⁹⁴ Article 5(2)(a).

⁷⁸ See S Chaudhuri, 'Indian Generic Companies, Affordability of Drugs and Local Production in Africa with special reference to Tanzania' IKD Working Paper no 37 Milton Keynes, Open University Research Centre on Innovation Knowledge and Development 2008.
<<http://www.open.ac.uk/ikd/documents/working-papers/ikd-working-paper-37.pdf>>

enabling pooling of resources (such as medicines) to achieve collective self-reliance⁹⁵ and improve the living standards⁹⁶ of the people of the region.⁹⁷

SADC's objective is to promote sustainable and equitable economic growth and socioeconomic development in the region⁹⁸ through efficient productive systems⁹⁹, deeper cooperation and integration¹⁰⁰, good governance, and durable peace and security.¹⁰¹ The understanding is that through this formula the region would emerge as a competitive and effective player in the global economy.¹⁰² The attainment of these objectives is premised on principles of sovereign equality of Member States, solidarity, peace and security, human rights, democracy, rule of law, and peaceful settlement of disputes among others.¹⁰³ In furtherance of these goals, SADC focusses on key enablers for deeper regional integration¹⁰⁴ such as good governance.¹⁰⁵ There is a shared understanding that the convergence of the region's economies and deeper integration will not be attained in the absence of sound macroeconomic management and harmonization and rationalization of socioeconomic policies.¹⁰⁶

Article 5(1)(a), Article 5(i), and Article 5(2)(g) of the Treaty provide a foundational base for health care

and public health. The treaty places cooperation at the heart of its methodology.¹⁰⁷ Member States are to coordinate, rationalize and harmonize their macroeconomic policies, strategies, programmes, and projects.¹⁰⁸ The Treaty sets out priority areas for cooperation that include health, infrastructure, services¹⁰⁹, trade, industry, finance, and investment.¹¹⁰ The Treaty is implemented by protocols.¹¹¹ For intellectual property rights, the first package comes under the Consolidated Protocol on Trade (1996)¹¹² (the Protocol), the Protocol of Trade in Services, and the Protocol on Health. Article 23(2) of the Protocol encourages Member States to facilitate cross border investment. Members commit to adopting policies in line with their multilateral obligations such as the TRIPS Agreement.¹¹³

SADC's quest for harmonization of economic laws, such as intellectual property right laws, to facilitate free movement of goods, services, capital, and people in the region stems from the organization's economic foundation. It seeks to promote sustainable and equitable economic growth and socioeconomic development in the region¹¹⁴ through efficient productive systems¹¹⁵, deeper cooperation and integration¹¹⁶, good governance and durable peace and security.¹¹⁷ The goal is for the region to emerge as a meaningful player in the global economy.¹¹⁸ The attainment of these objectives is premised on principles of sovereign equality, solidarity, peace and security, human rights, democracy, rule of law, and peaceful settlement of disputes among others¹¹⁹ in line with Article 2(3) of the Charter of the United Nations. In furtherance of these goals, SADC focusses on key enablers for deeper regional integration¹²⁰, such as good

⁹⁵ Article 5(d).

⁹⁶ The Social Charter contains the region's blueprint on social policy designed to improve living and working standards of people in the region.

⁹⁷ Marius Olivier 'Social Security for Migrants: Does the EU Framework Provide Lessons for Developments in SADC?' sub-theme: 'Immigration and promoting social security abroad' Paper presented at symposium in the Hague, Netherlands (2001).

⁹⁸ Article 5 1)(a) of the Declaration and Treaty as amended (the Treaty).

⁹⁹ See Article 2 of the SADC Protocol on Trade.

¹⁰⁰ Article 2 of the Trade protocol seeks to further liberalize intra-regional trade in goods and services on the basis of fair, mutually equitable and beneficial trade arrangements.

¹⁰¹ Article 5(1)(a) of the Treaty.

¹⁰² Z Nkowani 'When Elephants Dance, FDI and the SADC Charter of Fundamental Social Rights; A beacon of Hope or Confusion Compounded?' Commonwealth Law Bulletin, Volume 33, Issue 1 (2007) 41.

¹⁰³ Article 4 of the Treaty. The ongoing boarder dispute between Malawi and Tanzania is a litmus test of the region's capacity and resolve for peaceful resolution of disputes between states in the region.

¹⁰⁴ The importance of financial service to poverty eradication is reiterated in the recent SADC Declaration on Poverty Eradication and Sustainable Development. In particular paragraphs 2(iii) and 2(vii)

<http://www.sadc.int/conference/content/english/SADC%20Declaration%20on%20Poverty%20Eradication%20and%20Sustainable%20Development.pdf> (accessed 18 February 2009).

¹⁰⁵ Article 5(2)(g) of the Treaty.

¹⁰⁶ Article 5 of the Treaty.

¹⁰⁷ Article 21 of the Treaty.

¹⁰⁸ Article 5(2)(a) and (d).

¹⁰⁹ Article 21(3)(b) of the Treaty.

¹¹⁰ Article 21(3)(c) of the Treaty.

¹¹¹ Article 22 of the Treaty.

¹¹²

http://www.sadc.int/files/6213/2808/8365/CONSOLIDATE_D_PROTOCOL_ON_TRADE_vers_30-01-2012.pdf

¹¹³ Article 23(2).

¹¹⁴ Article 5(1)(a) of the Declaration and Treaty, as amended (the Treaty).

¹¹⁵ See Article 2 of the SADC Protocol on Trade.

¹¹⁶ Article 2 of the Trade protocol seeks to further liberalize intra-regional trade in goods and services on the basis of fair, mutually equitable and beneficial trade arrangements.

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¹¹⁸ Z Nkowani 'When elephants Dance, FDI and the SADC Charter of Fundamental Social Rights; A beacon of Hope or Confusion Compounded?' Commonwealth Law Bulletin, Volume 33, Issue 1 (2007) 41.

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¹²⁰ The importance of financial service to poverty eradication is reiterated in the recent SADC Declaration on

governance and international rule of law.¹²¹ The understanding is that the convergence of the region's economies and deeper integration will not be attained in the absence of harmonization and rationalization of socioeconomic policies such as intellectual property rights and health.¹²²

With cooperation at the heart of its methodology¹²³, the Treaty seeks to achieve this through deeper integration such as infrastructure, services¹²⁴, trade, industry, health, finance, and investment.¹²⁵ Relevant protocols have been adopted in areas such as health, trade in goods¹²⁶, trade in services¹²⁷, and finance and investment.¹²⁸ In terms of dispute settlement they mimic the GATT/WTO regime on dispute settlement. This flows from the fact that regional trade agreements such as SADC are authorized under the GATT/WTO regime, in particular under Article I of GATT 1947, Article XXIV of GATT 1947, and Article V of the General Agreement on Trade in Services (GATS) as building blocks for deeper and faster trade liberalization.¹²⁹ Regional trade agreements are subject to the criteria of transparency, commitment to deep intra-region trade liberalization, and neutrality *vis-à-vis* non-parties' trade.

Under Article 29(b) of the Protocol on Health, Member States are required to cooperate and assist one another in the production, procurement, and distribution of affordable essential drugs. This is the mechanism under which Malawi participates in the pooled procurement of essential drugs. However, the jury is still out on how well this mechanism has been utilized. The reality on the ground, at least for Malawi, suggests that not much joy is coming from this facility. There are operational challenges, but as a policy tool for improving access to health care it is a great incentive. The role of intellectual property rights in health is not limited to patents, but extends to traditional knowledge. The Protocol on Health in Articles 1, 20 and 29 is clear on the link and role of intellectual property rights in public health. Article 29(f) of the SADC Protocol on Health

Poverty Eradication and Sustainable Development. In particular paragraphs 2(iii) and 2(vii) <<http://www.sadc.int/conference/content/english/SADC%20Declaration%20on%20Poverty%20Eradication%20and%20Sustainable%20Development.pdf>> (accessed 18 February 2009).

¹²¹ Article 5(2)(g) of the Treaty.

¹²² Article 5 of the treaty.

¹²³ Article 21 of the Treaty.

¹²⁴ Article 21(3)(b) of the Treaty.

¹²⁵ Article 21(3)(c) of the Treaty.

¹²⁶ <<http://www.sadc.int/>>

¹²⁷ *Ibid.*

¹²⁸ *Ibid.*

¹²⁹ Z Nkwani 'The EU-ACP Development Cooperation - Governance Challenges for Non-State Actors: the Case of Malawi' *Commonwealth Law Bulletin*, 36: 4, 679—689; visit <<http://dx.doi.org/10.1080/03050718.2010.524289>>

recognizes the role of traditional knowledge in health care and provides for the establishment of a regional databank of traditional medicine, medicinal plants, and procedures in order to ensure their protection in accordance with regimes and related intellectual property rights governing genetic resources, plant varieties and biotechnology.¹³⁰ The challenge for Malawi is true for most LDCs in a weak intellectual property regime and outdated legislation that result in poor enforcement of intellectual property rights. With poor enforcement there is less incentive from innovation and commercialization of intellectual property rights with a negative impact on health. The draft intellectual property policy for Malawi seeks to respond to this problem by repositioning intellectual property rights and having a frontline for economic development. Malawi, through the draft intellectual property policy puts technology and innovation at the cutting-edge of its growth and strategic agenda. In recognition of this year, the Malawi University of Science and Technology has opened its doors to sow seeds for an economy in which intellectual property rights are a catalyst.

VI. FLEXIBILITIES

The objective of intellectual property rights is to grant its beneficiaries a monopoly by means of an exclusive right.¹³¹ However, the system undertakes a balancing act between private and public interests.¹³² The law provides this in the form of limitations and exceptions to general obligations.¹³³ For instance, Article 9.2 of the Berne Convention provides a three-step test exception in relation to copyrights.¹³⁴ Also, Article 13 of the TRIPS Agreement contains limitations and exceptions to exclusive rights in copyrights in general. Unlike the Article 9.2 exception of the Berne Convention that relates to reproduction, the Article 13 exception of TRIPS is expansive in application and covers the right of reproduction, the right of communication and the right of rental among others.¹³⁵ Article 17 of TRIPS provides exceptions and limitations to trademarks, while Article 26.2 provides for exceptions and

¹³⁰ For the text of the protocol vide <<http://www.sadc.int/>>

¹³¹ Bruno de Vuyst et al, (Exceptions to the Intellectual Property Rights : Lessons from WTO-TRIPs Panels 2003) available at

<<http://www.austlii.edu.au/au/journals/MurUEJL/2003/31.html>> (accessed November 2014)

¹³² *Ibid.*

¹³³ In *A&M Records v Napster, Inc.*, 239 F.3d 1004 (9th Cir. 2001), the 9th Circuit Court of Appeals decided that free downloading of music qualified as an infringement of copyrights.

¹³⁴ See Sam Ricketson, *The Berne Convention for the Protection of Literary and Artistic Works: 1886-1986*, London, Kluwer, 1987, p 477 ff.

¹³⁵ Mihály Ficsor, *The Law of Copyright and the Internet*, Oxford, University Press, 2002, 301-302.

limitations to industrial designs.¹³⁶ Exceptions and limitations for patents are provided under Article 30. Overall the scheme is one of striking a balance between private and public interest. As the scope of our discussion is in relation to access to essential health care, I will limit my discussion to patents.

One of the flexibilities Malawi can use to enhance access to medicines is Article 31*bis* of the TRIPS Agreement. The article stipulates that countries that intend to manufacture pharmaceutical products targeting countries with insufficient or no manufacturing capacity need not comply with TRIPS Article 31(f), which only legalizes compulsory licensing, where the target market is predominantly local and allows exporting only on a limited scale. The Article 31(f) obligation does not apply where a Member State grants a compulsory licence in favour of domestic generic manufacturers who intend to export large quantities of pharmaceutical products to countries with little or no manufacturing capacity.¹³⁷ Article 31*bis* creates a formal waiver of the domestic use requirement in Article 31(f).

However, Article 31*bis*(2) obliges exporting Member States to ensure that patent holders are given adequate remuneration in the event that a compulsory licence is issued against them. But this compensation is supposed to be calculated in reference to the market value of the product in the importing country. The article further provides that, where the patent holder has been remunerated under this provision, he will not be entitled to further remuneration in the importing country, even if the importing country issues a compulsory licence on the product.¹³⁸

Article 31*bis* endeavours to solve the problem of 'insufficient manufacturing capacity' by attempting to harness economies of scale using regional trade blocs. The article does this by waiving certain TRIPS obligations in favour of developing or LDCs for WTO Members that are parties to regional trade agreements such as SADC. Article 31*bis* allows these Members to authorize the manufacture of pharmaceutical products both for their own domestic use and for export to other regional group member states that have health problems targeted by the pharmaceutical product in question. The waiver attempts to achieve the following: harnessing economies of scale, enhancing purchasing power in the regional bloc, and facilitating local production of the pharmaceutical products. Malawi can take

advantage of the TRIPS Article 31*bis* waiver through the mechanism of the SADC Protocol on Health under Article 29(b). However, there is need for Malawi to review its intellectual property laws incorporating the flexibilities provided for under Article 31*bis* to import products from countries that produce generic pharmaceutical products. Given that the system requires compulsory licences to be issued by both the exporting and importing states, there is need for Malawi to domesticate the system within our laws and regulations in order to comply with the requirements of Article 31*bis*.

The other measure would be for Malawi, as a part of SADC, to explore the possibility of using the Article 31*bis* system, in order to harness economies of scale, enhance purchasing power, and facilitate local production of pharmaceutical products within their territories. Given that the Article is flexible enough to allow both developing countries and LDCs to manufacture or import pharmaceuticals, the SADC should explore the possibilities of harnessing the R&D and procurement capabilities of some of its Member States such as South Africa, in order to achieve this objective. In terms of building a manufacturing base for pharmaceuticals, Malawi needs to explore the possibility of collaborating with other countries that have a manufacturing base either in the region, such as South Africa, or internationally, such as China, India, the European Union, or the United States. Achieving the objectives of Article 31*bis* is premised on the fact that respective Member States will respect patents and modernize their patent systems. It is imperative that SADC promotes the development of systems for granting regional patents and harmonizing patent systems within the regional bloc.

A number of rationales for a regional policy on health as contained in the Protocol on Health¹³⁹ could be advanced. The starting point is the impact of globalization and liberalization of the international economy, which has brought about increased trade and investment mobility.¹⁴⁰ Globalization is having both positive and negative effects to public health. On a positive note, increased trade has been beneficial to Sub-Saharan economies.¹⁴¹ On the negative side, the increased trade and foreign

¹³⁶ Generally see Robert Howse, 'The Canadian Generic Medicines Panel - A Dangerous Precedent in Dangerous Times' *Journal of World Intellectual Property*, July 2000, n 4, Vol 3, 493.

¹³⁷ Article 31*bis*(1).

¹³⁸ Article 31*bis*(2).

¹³⁹ ILO convention 155 on Occupational Health and Safety states that the term 'health' in relation to work, indicates not merely the absence of disease or infirmity; but also includes the physical and mental elements affecting health, which are directly related to safety and hygiene at work.

¹⁴⁰ R Loewenson, C Nhachi, W Murambiwa and P Gona *Epidemiology of the Health Impact of Pesticide Use in Developing Countries: Epidemiological research in Zimbabwe*, Mimeo, Harare (1991).

¹⁴¹ See Article 1(C) of the Constitutive Act of the African Union. See also the NEPAD Objectives at <<http://www.nepad.org/>>

investment brings about new health hazards and risks that SADC economies are ill equipped to handle.¹⁴² The technological gap between pharmaceutical manufacturing countries and SADC states means there are intellectual property right issues that the region has to deal with, in order to provide access to essential medicines.¹⁴³ Faced with serious institutional limitations in the area of social protection and the impact of health on integration, it is in SADC's interest to improve its record on health if its economic gains are not be nullified or impaired by adverse social effect of ill-health.¹⁴⁴

Other reasons can be given why public health is crucial to SADC. These include the integrationist rationale. This is premised on the fact that harmonization of laws and social values are the cornerstone of any integration agenda. For the integration process to move forward, Member States need to find common ground in their national policies and plans.¹⁴⁵ Emerging health problems with a regional dimension¹⁴⁶ stimulate intergovernmental cooperation, as envisaged in Articles 21 and 22 of the SADC Treaty¹⁴⁷, and as read with Articles 20 and 29 of the Protocol on Health. Secondly, common health standards assist economic integration.¹⁴⁸

VII. CONCLUSION

There is a symbiotic relationship between intellectual property rights and public health. Intellectual property rights are a catalyst for economic development and can contribute to a reduction of poverty and improvement in access to essential medicines. However, intellectual property rights can impinge on access to medicines and health-care through their impact on prices for pharmaceutical products. Within the legal framework for intellectual property rights there are

flexibilities that can be utilized to improve access to medicines and enhance the right to health for the population. The preconditions for this include modernization of intellectual property right laws that incorporate TRIPS flexibilities.¹⁴⁹ There is need for Malawi, within the SADC context, to build capacity for pharmaceutical manufacturing. This has to be guided by a policy framework for intellectual property rights to attract technologically based foreign direct investment (FDI). The WTO Doha Declaration on Public Health points to the opportunity for LDCs, where need arises, to use the flexibilities to provide public health services; however, the prerequisite for this is a legal framework that enables a country to take advantage of such flexibilities and, in the absence of such a legal framework, as is the case in Malawi, this is unattainable.¹⁵⁰ Intellectual property rights and public health are mutually supportive and complementary.¹⁵¹ Malawi needs to reposition itself to take advantage of existing flexibilities and fulfil its constitutional mandate of improving the living standards of the people through, among others, safeguarding the right to health, whilst protecting the right to economic activity through effective protection and enforcement of intellectual property rights. The current state of affairs does not encourage investments in intellectual property rights and utilization of flexibilities for the provision of access to essential medicines and health services.

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¹⁴² Alberto López-Valcárcel (Dec. 2001) 'New Challenges and opportunities for Occupational Safety and Health (Occupational Health and Safety) in a Globalized World' *The African Newsletter of Occupational Health and Safety*.

¹⁴³ See Memorandum on The Economic Viewpoint in Occupational Safety and Health Supervision, Ministry of Social Affairs and Health Department for Occupational Safety and Health ampere, Finland 1999 International Publications.

¹⁴⁴ Ali Taqi, 'Globalization of Economic Relations: Implications for Occupational Safety and Health An International View' XIVth World Congress on Occupational Safety and Health Madrid, 23 April 1996.

¹⁴⁵ Article 21 of the Treaty.

¹⁴⁶ See our discussion on the effects of globalization on occupational health and safety.

¹⁴⁷ In Article 12 of the treaty, as amended, social and human development is one of the core areas for integration. Poor living and working conditions would not advance the case for social and human development.

¹⁴⁸ Section 29(a) of the Protocol. See also Frank B Wright *Law of Health and Safety at Work*; Sweet and Maxwell, (London, 1997) pp 32-33.

¹⁴⁹ Leslie London and Aulline H Mabika 'Implications of the GATS and TRIPS Agreements for the Right to Health in Malawi and Southern and Eastern African, Information and Negotiation Institute (SEATINI) School of Public Health and Family Medicine, University of Cape Town (UCT) (2007).

¹⁵⁰ C Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, WHO, Geneva (2002).

¹⁵¹ See generally, the World Health Organization 'Public Health, Innovation and Intellectual Property Rights' Report of the Commission on Intellectual Property Rights, Innovation and Public Health. (Geneva: WHO 2006).

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10. THE IMPLICATIONS FOR MOROCCO OF THE 2013 MARRAKESH TREATY TO FACILITATE ACCESS TO PUBLISHED WORKS FOR PERSONS WHO ARE BLIND, VISUALLY IMPAIRED OR OTHERWISE PRINT DISABLED

Khalid Chaouch*

It is humbling to know that when the weakest amongst us is in need, you answered the call with a steely determination and a steadfast courage to make a difference.

Stevie Wonder

ABSTRACT

This article intends, first, to shed light on the situation of visually impaired persons in Morocco, which has only recently reinforced its legal framework with adequate legislation, bringing relief to persons with different disabilities. Yet the access of visually impaired persons and persons with print disabilities to education and to different artistic activities has been hindered by the lack of more 'advanced' laws. The Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled (2013) meets these long awaited needs. This article highlights the implications of this Treaty for Morocco, with a particular focus on the provisions providing access to published works – both Braille e-books and other digital or hard copy works – and the new horizons it will open up for visually impaired persons in the areas of education, scientific research, culture, arts, media and communication. This article also discusses the new opportunities offered by the cross-border exchange of published works and the new prerogatives of 'authorized entities'. These considerations show how Morocco – in the light of many considerations – can be a model for developing countries in general and North African ones, in particular, in matters of implementing the provisions of this Treaty.

Keywords: *Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled (VIP) Treaty, Morocco, cross-border, authorized entities, accessible works, format copies*

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I. INTRODUCTION

In spite of being a developing country, Morocco has substantial intellectual property legislation. Its intellectual property system arose from a combination of two main traditions (the French 'droit d'auteur' tradition and the Anglo-Saxon copyright tradition). Morocco has been party to most international conventions and treaties in copyright and related rights. Not only has Morocco signed most of the relevant conventions, but it has also hosted a number of global treaties that bear the name of Marrakesh: the 1994 Marrakesh Agreement Establishing the World Trade Organization and the Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled of 2013 (Marrakesh VIP Treaty (2013)). Yet access of visually impaired persons and persons with print disabilities to educational, cultural and artistic activities, until recently, is still hindered in Morocco by some obstacles due to a lack of more 'advanced' and more targeted laws.

Before discussing the Marrakesh VIP Treaty (2013) within the Moroccan context, this article will provide an historical overview of the legal treatment of visually impaired persons.

II. THE SITUATION OF VISUALLY IMPAIRED PERSONS IN MOROCCO AND INTERNATIONAL LEGISLATION

A. Overview of the situation of the visually impaired in Morocco

According to Governmental statistics, in 2004 there were approximately 1,530,000 disabled persons, representing 5.12 per cent of the Moroccan population. In 2010 this number had increased to 1,664,000. Among these persons, visually impaired persons represent approximately 10.32 per cent (15,900 persons in total).¹ In Morocco, visual disability affects over 1,000 individuals between 0.5 and two years of age.²

Historically, these individuals have been neglected in Morocco and face many difficulties in accessing education and the job market. Two factors have primarily contributed to these barriers: societal prejudice, and, most importantly, the scarcity of clearly defined laws providing rights.

Notably, the Moroccan Law on Copyright and Related Rights, both in its 2000 form (Law No. 2.00) and in its 2006 modifying version (Law No. 34.05), makes no mention of the disabled. Yet many

¹ Ministère de la Solidarité, de la Femme, de la Famille et du Développement Social. *Guide des normes d'accessibilité pour les personnes en situation de handicap* (Rabat 2011) 9 <<http://www.social.gov.ma/>> accessed 19 April 2014

² *ibid* 10.

emerging factors have contributed to change this situation. At the external level, the signing of the Free Trade Treaty between Morocco and the United States in 2004 and the signing of the UN Convention on the Rights of Persons with Disabilities, as well as the Optional Protocol in 2006, have given a boost to disabled and visually impaired persons' rights. Morocco signed the TRIPS Agreement in 1995 and the WIPO Copyright Treaty in 2011, thus paving the way for more advanced improvements in this field.

Morocco now attaches special importance to legislation that promotes the situation of visually impaired persons, evidenced more particularly by:

(a) King Mohamed VI of Morocco's speeches and policies, which have been more favourable to all persons with disabilities. For example, those individuals occupy a privileged place in the National Initiative for Human Development (INDH), a programme launched by King Mohamed VI and designed to help the different governmental administrations and non-governmental agencies in matters of improving inclusiveness.

(b) The Moroccan Government's recent policies to improve the lives of persons living with these disabilities. In addition to a yearly celebration, the focus of the National Day of Disabled Persons on 30 March, a new initiative by the Ministry of Social Development, Family and Solidarity (which has become the Ministry of Solidarity, Women, Family and Social Development) is for disabled persons. Nouzha Skalli, the former Minister of Social Development, Family and Solidarity, stated that the Government of Morocco had prepared, in cooperation with various government departments and civil society, a bill relating to persons with disabilities. She stressed that:

This Convention reflected the country's commitment to guaranteeing the rights of the disabled through a global strategy.³

In the same vein, the present Minister, Bassima Haqqaoui, supervised the launching of a four-year programme (2012-2015) to facilitate the access of disabled persons to public administration services and to cultural life.⁴ Additionally, this Department released a set of documents and notes on the

accessibility of Disabled Persons, the 'Guide des normes d'accessibilité pour les personnes en situation de handicap' (Guide of Accessibility Standards for Disabled Persons).⁵ Mrs Haqqaoui is also conscious that it is no longer time to think only about 'concrete accessibilities' and that the complex digital situation presupposes providing more forms of accessibility hand in hand with technological developments in ICT.⁶

(c) International legislation which encourages more national legislation: Morocco has always been among the first countries to sign and ratify international legislation on the rights of the disabled and visually impaired, on the one hand, and on copyright and related rights, on the other.

(d) The Moroccan civil society: a number of national organizations and human rights associations are dealing with questions concerning disabled persons in Morocco. Their attitudes and views are decisive, as evidenced by the newly adopted Constitution in Morocco (2011) that confers a significant role to Civil Society organizations. Among these national organizations, three have played a key role: the Conseil Consultatif des Droits de l'Homme (CCDH) (Advisory Council of Human Rights), the Alaouite Organization for the Protection of the Blind in Morocco (OAPAM) and the Coalition for the Promotion of the Rights of Persons in a Situation of Handicap.

These factors and measures have resulted in legislation being introduced that seeks to meet the needs outlined of disabled persons.

B. The need for national and international legislation

Morocco has only recently, especially under King Mohamed VI, enhanced its legal framework for disabled persons. Karim Cherkaoui, from the 'Coalition' points out that national legislation on the disabled in Morocco could be considered 'general principles that lack some precision at the level of implementation and a clear definition of roles and responsibility for implementation'.⁷

Furthermore, in their report on Copyright in Morocco, Moroccan academicians, Saïd Aghrib *et al* spell out that:

Morocco suffers from a scarcity of copyright research, except for a very limited number of theses and dissertations compiled within the realm

³ 'Protecting Rights of Persons with Disabilities: Towards a Full and Integrated Approach' <<http://www.ccdh.org.ma/an/bulletin-d-information/protecting-rights-persons-disabilities-towards-full-and-integrated-approach>> accessed 03 April 2014

⁴ Sana Karim, 'Ay siyassah li-Imaghrîb li-nnuhudhi bi awdaa al-muaaq?' (Which Policy in Morocco to Promote the Situation of the Disabled?) *Attajdid* (Rabat, 01 April 2014) 6

⁵ Ministère de la Solidarité [1]

⁶ Karim [4] 6.

⁷ *ibid*

of academic research⁸ and that such researchers were more 'seeking answers regarding the lack of compliance with copyright and often blaming the laxity of state control.⁹

Indeed, although Morocco has signed and ratified all the main international copyright treaties, including acceding to the WIPO Copyright Treaty in 2011, what it needed more urgently is to bring its national legislation in line with this treaty, in order to be consistent with more recent international conventions and obligations concerning digital copyright and Article 10(1) of the Marrakesh Treaty, which calls on contracting parties 'to adopt the measures necessary to ensure the application of this Treaty'. This would ensure that Morocco is able to implement the Marrakesh Treaty, especially with regard to the limitations and exceptions of digital copyright and the definition of the panoply of national devices of 'rights management information', as provided by Article 2 of the WIPO Copyright Treaty. In short, the visually impaired in Morocco need both national and international conventions and obligations, especially at the copyright level.

C. Contribution of the Marrakesh Treaty

In this context, Morocco hosted the Marrakesh VIP Treaty. This Treaty was a significant first step, but now more crucial progress is needed, namely, the enforcement of the Treaty. In the Moroccan context, this Treaty bears high expectations for the integration and accessibility of visually impaired persons. First, it will contribute to the rehabilitation of the rights of visually impaired persons and persons with print disabilities, especially in Morocco, as a developing country. Second, it will open up new horizons in the fields of education, scientific research, culture, arts, and media and communication.

The codification and proliferation of artistic works of the blind and visually impaired persons has already been debated in Morocco. For example, since 2010, the Louis Braille Association for the Blind (Association Louis Braille pour les Personnes Aveugles) has hosted an annual Festival of Blind and Visually Impaired Musicians, with the participation of blind artists from Morocco, Egypt, Canada, Algeria, and Tunisia, Japan, the United Kingdom, and Poland.

⁸ Said Aghrib, Noufissa El-Moujaddidi and Abdelmalek El-Ouazzani, ACA2K Country Report, *Morocco* (African Copyright and Access to Knowledge Project, July 2009) 25 <<http://www.aca2k.org/attachments/ACA2K%20Morocco%20CR.pdf>> accessed 2 May 2014

⁹ *ibid*

In 2011, this association also organized a conference on the 'Writing of Music in Braille'.¹⁰

III. THE DEBATE OVER THE IMPLEMENTATION OF THE TREATY IN MOROCCO

A. Implementing the Treaty in Morocco

Though the main Moroccan Law on Copyright, No. 34-05 (2006), makes no mention of disabled users, who sometimes need to circumvent technological protection measures (TPMs) in order to convert works from one format to another¹¹, it has limited anti-circumvention of such measures mentioned in Article 65, 'for the benefit of some non-profit entities'.¹² This is a deliberate effort on the part of Moroccan legislators to create necessary limitations and exceptions for visually impaired persons.

Among the questions that are currently under debate, the shortage of copyright laws in Morocco and the vague nature of some of those currently enacted, in particular, make it difficult for Morocco to comply with the provisions of the Marrakesh Treaty. In this regard, a set of measures should be given chief importance:

- At the legislative level, Morocco needs to issue new laws that will facilitate the availability of works in accessible formats for visually impaired persons and persons with print disabilities. This is one of the direct recommendations of Article 4(1) of the Marrakesh Treaty.
- At the administrative level, Morocco is already endowed with a National Office of Copyright (Bureau National du Droit d'Auteur – BMDA), but this will need to be reformed, reinforced and updated, in order to be able to cope with the new copyright issues. In addition, more regional offices and agencies will be needed to help implement the provisions of the Marrakesh Treaty.

At the technological level, the different institutions – both governmental and non-governmental – that are in charge of the educational and artistic activities of visually impaired persons will have to enhance their Information Communication Technology (ICT)

¹⁰ 'Festival des musiciens malvoyants à Tétouan' *Libération* (Rabat, 30 Novembre 2011); 'Festival international des musiciens non-voyants et malvoyants' *La Nouvelle Tribune* (Casablanca, 12 Novembre 2013) <<http://www.lnt.ma/culture-maroc/festival-des-musiciens-mal-voyants-a-tetouan-90068.html>> accessed 6 May 2014

¹¹ Aghrib [7] 19.

¹² *ibid*

infrastructures, in order to facilitate the 'cross-border exchange of accessible format copies' and to help both national and international 'authorized entities' carry out the functions assigned to them by the Marrakesh Treaty.

B. The cross-border exchange of accessible format copies

Article 9 of the Marrakesh VIP Treaty provides that:

Contracting Parties shall endeavor to foster the cross-border exchange of accessible format copies by encouraging the voluntary sharing of information to assist authorized entities in identifying one another.

It also stipulates that 'The International Bureau of WIPO shall establish an information access point for this purpose'. The scope of 'authorized entities' in this Treaty includes the right to exchange accessible material with other 'authorized entities' within the same country (Article 4(2)(a)) or with 'authorized entities' in other Contracting States (Article 5(2)(a)).

These new limitations and exceptions are further strengthened by the right of importation given to individuals, which means that applicable persons, their representatives, or the nationally recognized 'authorized entities' will be able to import any accessible work directly from authorized entities that are located in Europe, the Middle East and the United States. This makes cross-border exchanges of rights and materials easier, allowing a more accessible use of global material by visually impaired persons in Morocco and a free dissemination of their own works.

Notably, Morocco and its North African neighbors have Arabic as the first official and national language and French as the main foreign language. Many relevant works are expressed in these languages, and translation to and from these languages, as well as English, is easily obtained. Thus no linguistic barrier exists to the cross-border exchange or circulation.

The challenge Morocco faces at this level is the ability to provide national legislation that would complement international conventions and obligations. There is a need for national provisions that secure the 'cross-border exchange of accessible format copies' for the sole benefit of visually impaired persons and persons with print disabilities without the authorization of authors, provided that they are not for commercial purposes and, at the same time, the rights of authors/publishers by guaranteeing that the distribution of 'accessible format copies' to anyone other than the beneficiary

persons will be prevented. Since the making, circulating, and exchanging of 'accessible format copies' will be more associated with the digital world and the information society, Morocco must first strengthen its technological infrastructure and, second, improve its copyright legislation.

C. The extended role of 'Authorized Entities'

'Authorized Entities' are given an important and vital role in the Marrakesh VIP Treaty. In Article 2(c) of the Treaty an 'authorized entity' is defined as:

an entity that is authorized or recognized by the government to provide education, instructional training, adaptive reading or information access to beneficiary persons on a non-profit basis.

According to this definition, many educational and academic institutions and libraries can fulfil these functions in Morocco. But the definition is further broadened in Article 2(c) by allowing non-governmental, non-profit organizations to offer 'the same services to beneficiary persons as one of its primary activities or institutional obligations'.

At the international level, 'authorized entities' will be primarily libraries and organizations working for the promotion of the blind and visually impaired, especially at the educational, cultural and artistic levels. If such institutions are recognized in developed countries, it is hoped they will play an essential role in providing 'accessible format copies' to libraries, educational institutions and similar organizations recognized as 'authorized entities' in developing and least developed countries. Therefore, the main challenge now is the acceleration of recognizing these institutions and enforcement of the Treaty. Further delay may, unfortunately, be considered or understood as a 'pocket veto' of the Treaty itself.

At the national level, Moroccan institutions such as the Alaouite Organization for the Protection of the Blind in Morocco (OAPAM) and the Coalition for the Promotion of the Rights of Persons in a Situation of Handicap have already been serving blind and visually impaired persons at the social, educational and cultural levels. Accordingly, they may very well act as 'authorized entities' that will be entitled to:

make an accessible format copy of a work, obtain from another authorized entity an accessible format copy, and supply those copies to beneficiary persons (...) (Article 4(2)(a)).

The possibility of obtaining 'accessible format copies' – both Braille e-books and other digital or hard copy works – from foreign authorized entities is an opportunity for authorized entities in Morocco, because it will offer the possibility to provide ready-made copies without cost or legislative barriers that have so far hindered the making and the circulation of such copies.

As for the obligations imposed on these 'authorized entities' by Article 2(c) of the Marrakesh Treaty, some of them, especially ones having to do with 'beneficiary persons' (Article 2(c)(i)), have already been partially fulfilled as a part of the access conditions of the Moroccan institutions that deal with visually impaired persons. But there is still much work to be done, at the level of national legislation:

to discourage the reproduction, distribution and making available of unauthorized copies; (Article 2(c)(iii))

and, at the technical level, to enable and empower the Moroccan authorized-entities-to-be:

to maintain due care in, and records of, its handling of copies of works ... (Article 2(c)(iv)).

The focus here should be on the role of the already existing organizations of civil society (non-governmental organizations or NGOs) which are concerned with the rights and the daily life of the blind and the visually impaired in Morocco, in implementing the provisions assigned to 'authorized entities' in the Marrakesh Treaty. Such organizations have been working hard to sustain this group, and they will be empowered by this Treaty to serve visually impaired persons. Some of them even attended the Diplomatic Conference of the Treaty, after being officially admitted as observers by WIPO.¹³

IV. THE MARRAKESH VIP TREATY AND MOROCCO AS A MODEL FOR NORTH AFRICAN COUNTRIES

A. Valorizing the skills of visually impaired persons and persons with print disabilities

For the moment, the different centres of the Alaouite Organization for the Protection of the Blind in Morocco (OAPAM) provide a high quality education that, in line with international standards, results in a high percentage of success in the Baccalaureate among visually impaired persons in

Morocco. Many visually impaired persons are excellent teachers of religious sciences in institutions of classical education (*attaalim al-atiq*) and other disciplines; some are gifted artists, and others are singers or talented musicians. The effective implementation of the different provisions of the Marrakesh Treaty and the open access to published works in adequate format copies, especially with the digital revolution, will undeniably open up new horizons for the cultural emancipation and artistic expression of the visually impaired in this country. They will also enhance the efforts of Morocco in the fight against illiteracy, in general, and Braille illiteracy, in particular.

Thanks to the Treaty, instead of being passive consumers, visually impaired persons will be empowered to produce their own creative works, based on accessible material and on their own gifts, since there will be fewer or no legislative or technical barriers. Besides, these persons will, it is to be hoped, be promoted at the economic level, since the new provisions will allow them to use their skills and have access to the labour market.

In this case, the potential skills of visually impaired persons and persons with print disabilities in the economic, educational and artistic fields will benefit not only Morocco, but also the whole world thanks to the fluid exchange and circulation of works, provided for by the clauses of this Treaty.

B. Offering the example to developing countries

Two main factors have been crucial in helping Morocco to be more committed, at the legislative level, to the situation of the blind and the visually impaired:

First, Morocco has always reacted positively to international treaties and agreements in this domain and has also been more active in its trade and economic interactions with developed countries. Such interactions have been continually pushing and even urging Moroccan lawmakers to continuously reconsider and review their national legislation. For example, the Free Trade Agreement between Morocco and the United States in 2004 was decisive and resulted in Morocco passing some copyright laws, in order to harmonize its legal system with the more advanced American one. Some even think that the latest Moroccan 34-05 Law on Copyright, which was issued in 2006, was brought about by this bilateral agreement.

Second, hosting international agreements and conventions has also played an important role in making Morocco more involved in the actual making of such treaties and paying them more attention and importance.

¹³ WIPO's VP/DC/5, 14 June 2013. The Moroccan organizations admitted are l'Association marocaine pour la réadaptation des déficients visuels (AMARDEV); la Ligue Braille Maroc (LBM); and l'Organisation alaouite pour la promotion des aveugles au Maroc (OAPAM).

Though Morocco benefits from a kind of political, economic, and social stability when compared to some neighbouring countries, this awareness of the new opportunities offered by the Marrakesh Treaty for the visually impaired and print disabled is not wholly particular to Morocco. Neighbouring countries, especially those of the Arab Maghreb (or the Arab World in general), can follow suit and implement the same measures to benefit from this Treaty in the same way.

In addition, WIPO stands ready to organize joint training sessions in Morocco or in some of the neighbouring countries to help both Moroccan officials, non-governmental agencies and the 'Authorized Entities' concerned with the rights of the visually impaired to maximize the benefits of the Treaty and to help Moroccan and regional lawmakers to make related laws tailored to the situation of their countries.

V. CONCLUSION

The signing of the Marrakesh VIP Treaty in June 2013 was nothing short of a miracle. But if progress stops here, it will be just another thwarted agreement. American singer, Stevie Wonder, at the closing ceremony of the Conference, was acutely conscious of this situation when he declared:

While the signing of this treaty is a historic and important step, I am respectfully and urgently asking all governments and states to prioritize ratification of this treaty so that it will become the law of the land in your respective countries and states.¹⁴

This Treaty has brought unprecedented opportunities for these persons, especially by facilitating easier and more fluid exchange and circulation of published works. Morocco must create all the necessary legislative, administrative and logistic conditions for the effective and fruitful implementation of the provisions of this Treaty. At the international level, WIPO must call on developed countries to sign and ratify the Marrakesh Treaty and to work for its entry into force.

¹⁴ 'Stevie Wonder Hails Landmark WIPO Treaty Boosting Access to Books for Blind and Visually Impaired Persons' (Marrakesh/Geneva 28 June 2013) PR/2013/742 <http://www.wipo.int/pressroom/en/articles/2013/article_0018.html> accessed 05 January 2014

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<http://www.wipo.int/pressroom/en/articles/2013/article_0018.html> accessed 5 January 2014

11 POOLED PROCUREMENT AS A PANACEA FOR ACCESS TO MEDICINES IN THE SOUTHERN AFRICAN DEVELOPMENT COMMUNITY REGION

Dr Amos Saurombe*

ABSTRACT

In 2011, the United Nations Conference on Trade and Development (UNCTAD) reported that nearly two billion of the world's population, many of whom live in least developed countries (LDCs), lacked access to essential medicines. Two years later in 2013, access to medicines has improved marginally and the total number of people who lack access to essential medicines is estimated to be between 1.3 and 2.1 billion people. Access to essential medicines is crucial for developing countries, particularly those in Sub-Saharan Africa, as they are vulnerable to deaths caused by preventable diseases. Currently, African countries are now most vulnerable to the spread of the Ebola epidemic. In August 2014, the World Health Organization (WHO) Director-General, Margaret Chan, declared the West Africa Ebola crisis a 'public health emergency of international concern', triggering powers under the 2005 International Health Regulations (IHR). Southern African Development Community (SADC) countries remain in desperate need for access to essential medicines that are patented in developed countries. The need to access essential medicines and drugs, especially generic drugs, is made dire by the high disease burden, attributable mainly to HIV/AIDS, tuberculosis, and malaria. With such a dilemma still unresolved, questions arise about improving the efficacy of TRIPS flexibilities for developing countries in general and the SADC region in particular. This article proposes pooled procurement as the panacea for the problems facing SADC concerning access to medicines.

Keywords: *access, medicine, Southern African Development Community, SADC, patents, public health, TRIPS flexibilities, developing countries*

I. INTRODUCTION

Over a decade ago, in March 2004, the World Health Organization (WHO)¹ estimated that one third of the

world's population lacked access to essential drugs.² Further, the WHO estimated that over 50 per cent of the population in Africa and Asia had no access to basic and essential drugs.³ On a closely related note, five years later, a comparison between access to essential drugs in the public and private sectors painted a worse picture.⁴ In 2011, the United Nations Conference on Trade and Development (UNCTAD) reported that nearly two billion of the world's population, many of whom live in LDCs, lacked access to essential medicines.⁵ By 2013, the situation with respect to access to medicines had improved marginally and the total number of people without access to medicines was estimated to be between 1.3 and 2.1 billion people.⁶ Access to essential medicines is important for developing countries, particularly those in sub-Saharan Africa as they are vulnerable to deaths caused by preventable diseases.⁷ African countries are now most vulnerable

providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends (see WHO website at <http://www.who.int/about/en/>, last visited 04/10/2014).

² See WHO, 'Equitable Access to Essential Medicines: a Framework for Collective Action' in *WHO Policy Perspectives on Medicines* (2004) 1 available at http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.4.pdf (accessed 10 January 2014). The actual number was estimated to be between 1.2 and 1.3 billion. At the time of writing, these were the most recent statistics on the subject.

³ Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness (see note 1 above).

⁴ According to the United Nations report dated 4 September 2008, titled 'Delivering on the Global Partnerships for Achieving the Millennium Development Goals', available at <http://who.int/medicines/mdg/en/> (accessed 9 April 2014), in the public sector, generic medicines are only available in 34.9% of facilities, and on average cost 250% more than the international reference price. In the private sector, those same medicines are available in 63.2% of facilities, but cost on average about 650% more than the international reference price.

⁵ UNCTAD *Investment in Pharmaceutical Production in Least Developed Countries: A Guide for Policy Makers and Investment Promotion Agencies* (2011).

⁶ WHO 'Essential Medicines and Health Products Information Portal: A World Health Organization Resource' at <http://apps.who.int/medicinedocs/en/d/Js6160e/9.html> (accessed 13 October 2014).

⁷ Examples that easily come to mind are malaria, cholera, Ebola and avian flu among other diseases that are easily curable in an environment where drugs are accessible and available. One other nagging health problem is the issue of HIV/AIDS and access to antiretroviral and other immunity -boosting treatment. With specific reference to access to medicines in the context of HI/AIDS, see generally D Mushayavanhu, 'The Realisation of Access to HIV and AIDS - Related Medicines in Southern African Countries: Possibilities and Actual Realisation of International Law Obligations' in F Viljoen and S Precious (eds) *Human Rights Under Threat: Four Perspectives on HIV, AIDS and the Law*

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¹ The WHO, a specialized agency of the United Nations, was established on 7 April 1948; a day now celebrated across the globe as World Health Day. The WHO constitution came into force on this date, thus giving the Global Health Organization its legal existence. Broadly speaking, the mandate of the WHO straddles *inter alia*,

to the spread of the Ebola epidemic. In August 2014, the World Health Organization (WHO) Director-General Margaret Chan declared the West Africa Ebola crisis a 'public health emergency of international concern', triggering powers under the 2005 International Health Regulations (IHR).⁸

Access to medicines, a concept with no clear definition, is generally considered as a collection of different dimensions⁹ such as accessibility¹⁰, affordability¹¹, acceptability¹², and availability.¹³ In developed nations, over 70 per cent of drugs are publicly funded or reimbursed, whereas in Africa, 50 to 90 per cent of pharmaceutical expenditure is funded out of pocket.¹⁴ This is not good news regarding access, because unregulated drug prices create 'affordability barriers'.¹⁵

Not being able to access essential drugs and vaccines limits the enjoyment of the right to health and by extension the right to life on the part of the citizens of the developing countries.¹⁶ For example, to

in *Southern Africa* (2007) 127 -169. In this paper, essential drugs and essential medicines are used interchangeably and should be regarded as carrying the same meaning.

⁸ See WHO Statement on the Meeting of the International Health Regulations Emergency Committee Regarding the 2014 Ebola Outbreak in West Africa. <<http://www.who.int/mediacentre/news/statements/2014/ebola-20140808/en/>>. 8 August 2014. (accessed 30 October 2014).

⁹EK Tetteh 'Providing Affordable Essential medicines to African Households: The Missing Policies and Institutions for Price Containment' (2008) 66 *Social Science and Medicine* at 570.

¹⁰ Referring to health services coverage.

¹¹ This relates to prices and volumes of consumption.

¹² This refers to quality, safety and efficacy.

¹³ This refers to drug production, procurement and distribution.

¹⁴ Tetteh note 9 above at 570.

¹⁵ *Ibid.*

¹⁶ The right to health and the right to life are closely intertwined and are not mutually exclusive. The right to life is encapsulated in article 3 of the Universal Declaration of Human rights and most, if not all constitutions of civilised nations of the world contain the right to life. For example, section 11 of the South African constitution of 1996 provides that everyone has the right to life. The applicability of that provision was tested by country's constitutional court in the landmark South African case of *S v Makwanyane and Another* 1995 (3) SA 360 (SCA) on 6 June 1995. In the case, the majority decision of the court was that the death penalty is inhuman and degrading hence unconstitutional. The Universal Declaration of Human Rights indirectly provides for the right to health in article 25 in which it is stated among other things, that everyone has the right to a standard of living that is adequate for their wellbeing and that of the family inclusive of medical care. The right to health is also recognised in article 12(1) of the International Covenant on Economic, Social and Cultural Rights while article 16 of the African Charter on Human and Peoples' Rights recognizes the right of every individual to enjoy 'the best attainable state of physical and mental

safeguard Zimbabweans' right to health, the Patents Act¹⁷ was amended¹⁸, in order to 'enable the state or a person authorized by the Minister in terms of Section 34 of the Act' to make or use any patented drug used in the treatment of persons suffering from HIV/AIDS-related conditions or import any generic drug to treat HIV/AIDS.¹⁹ While the right to health has traditionally been regarded as a civil and political right²⁰, it has, nevertheless, been increasingly applied broadly and has been extended in some instances to cases involving access to medicines.²¹ The right to health is one among a range of socioeconomic rights for which States accept an obligation at international law.²²

The right to life is part of the International Covenant on Civil and Political Rights²³, while the right to health is part of the International Covenant on Economic, Social, and Cultural Rights.²⁴ It may be argued that the separation of the two is artificial and misleading, because the right to life not only

health'. Other international instruments relevant to the right to health are the International Covenant on Civil and Political Rights (article 6), the Convention on the Rights of the Child (article 24), Convention on the Elimination of all forms of Discrimination against Women (article 12) and the Convention on the Elimination of all Forms of Racial Discrimination (art 5). On a related note, see O Olowu 'Environmental Governance and Accountability of Non-state Actors in Africa: A Rights-Based Approach' (2007) 32 *South African Yearbook of International Law* 261 at 279. For a general overview of the right to health and in its democratic context, see A Hassim A, M Heywood, and J Berger (eds) *Health and Democracy: A guide to Human Rights, Health Law and Policy in Post-Apartheid South Africa* (2006). For a comprehensive compilation of essential documents, international agreements and treaties pertaining to the right to health, see G Bekker (ed) *A Compilation of Essential Documents on the Right to Health* (2000).

¹⁷ Chapter 26:03 of 1972.

¹⁸ This was done by the then Justice Minister (Zimbabwe), the Honourable Patrick Chinamasa, in terms of sections 34 and 35 of the Patent Act and thus General Notice 240 of 2002 was introduced as an emergency measure for six months.

¹⁹ See paragraphs 2(a) and (b) of the Declaration of Period of Emergency (HIV/AIDS) Notice, 2002.

²⁰ See for instance Article 6(1) of the International Covenant on Civil and Political Rights which provides that the right to life shall be protected by law and provides further, that no one shall be arbitrarily deprived of his life.

²¹ *Mushayavanhu* above at 135. For example, in the case of *Odir Miranda v El Salvador* cited by the author in footnote 26 on page 136, the Inter-American Commission held that El Salvador's refusal to purchase triple therapy HIV medication amounted to a violation of the rights to life and health as provided for in the American Convention.

²² See T Evans, 'A Human Right to Health?' (2002) 23 *Third World Quarterly* 197.

²³ Per Article 6 of the International Covenant on Civil and Political Rights.

²⁴ Per Article 12 of the International Covenant on Economic, Social and Cultural Rights.

depends on the realisation of the right to health, but also on other composite rights such as the right to food and nutrition.

Although the Southern African Development Community (SADC)²⁵ Protocol on Health (the Protocol)²⁶ does not expressly refer to the right to health, the Protocol does highlight the importance of access to essential medicines for the SADC region.²⁷ So important is the issue of access to medicines that the African Union²⁸, the European Parliament²⁹, and the World Trade Organization (WTO)³⁰ have been

²⁵ Current Member States of the SADC are Angola, Malawi, Namibia, Mauritius, Botswana, Lesotho, South Africa, Seychelles, Democratic Republic of Congo, Tanzania, Swaziland, Zambia and Zimbabwe. Each member state has a responsibility to coordinate a sector or sectors on behalf of others. Angola coordinates energy, Botswana livestock production and animal disease control, Lesotho environment and land management, Malawi forestry and wildlife, Mauritius tourism, Mozambique transport and communications, Namibia marine fisheries and resources, South Africa finance and investment, Swaziland human resources development, Tanzania industry and trade, Zambia mining and Zimbabwe food, agriculture and natural resources. For detailed discussion of the SADC institutional history and its gradual evolution into a free trade area, see PC Osode, 'The Southern African Development Community in Legal Historical Perspective' (2003) 28 *Journal for Juridical Science* 1; SADC Secretariat, *The Official SADC Trade Industry and Investment Review* (1997) 5-9; C Chipeta C and I Mandaza 'The Future of the SADC' (1998) 11 *Southern African Political and Economic Monthly* 35; R Kamidza 'Is SADC Ready For Free Trade?' (2000) 14 *Southern African Political and Economic Monthly* 23; S Moyo, P O' Keefe and M Sill, 'The Southern African Environment' (1993) 28 -36; C Jenkins, J Leape and L Thomas (eds) *Gaining from Trade in Southern Africa: Complementary Policies to Underpin the SADC Free Trade Area* (2000) 1-20; and RH Thomas 'The World Trade Organization and Southern African Trade Relations' (1999) 3 *Law, Democracy and Development* 105 at 105-106.

²⁶ The Protocol on Health was approved by the SADC Heads of State in August 1999 and entered into force in August 2004. The full text of the Protocol is available at <<http://www.sadc.int/index/browse/page/152>> (accessed 12 October 2014)

²⁷ See generally Article 29 of the Protocol dealing with pharmaceuticals.

²⁸ See Article 3(n) of the Constitutive Act of the African Union, which was adopted in Lome, Togo on 11 July 2000 and entered into force on 26 May 2001. The full text of the Constitutive Act is available in C Heyns and M Killander (eds) *Compendium of Key Human Rights Documents of the African Union* (2007) 4 – 12. One of the African Union's paramount objectives is to work with progressive partners in eradicating preventable diseases and promoting good health in the continent.

²⁹ By passing a resolution on the WTO TRIPS Agreement and Access to Medicines on 12 July 2007. The Resolution is Available at:

<http://www.un.org/esa/policy/mdggap/mdggap_matrix_d_rugs.htm>(accessed 2 October 2014).

³⁰ Important decisions and declarations in this regard are the Declaration on TRIPS and Public Health (2001); the Decision of the General Council to implement paragraph 6

seized with the matter for more than a decade now. To ameliorate the problem of access to medicines in the SADC region, the SADC Pharmaceutical Business Plan³¹ was adopted. It outlines the specific flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and spells out a concrete plan to take full advantage of the flexibilities from 2007 to 2013 and beyond³².

Most countries in Southern Africa remain in desperate need for access to essential medicines that are patented in developed countries. Specifically, in the SADC region, the need to access essential medicines and drugs, especially generic drugs, is made dire by the high disease burden, attributable mainly to HIV/AIDS, tuberculosis, and malaria. With such a dilemma still unresolved, questions about improving the efficacy of TRIPS flexibilities for developing countries, in general, and the SADC region, in particular, arise.

A number of solutions have been suggested to mitigate the problem of access to medicines in the SADC region.³³ One of the most touted solutions has been the suggestion that SADC Members should take full advantage of TRIPS flexibilities provided by the WTO framework since the introduction of the Doha Declaration in 2001. While we acknowledge the availability of various TRIPS flexibilities such as compulsory licences, parallel imports, research exceptions, bolar-type exceptions, and others, we equally bemoan the difficulty of using the flexibilities and suggest that other solutions ought to be pursued.

In the spirit of pursuing alternative solutions, this article argues that pooled procurement may be the panacea for SADC access to medicines problems. In a bid to make a case for the adoption of pooled procurement as a solution in the SADC, this article explores the following pertinent themes: firstly, it lays the background for the introduction of pooled procurement as an access to medicines solution in the region by rendering an expository account of the pertinent regional instruments that may be used as legal solutions to the access to medicines problem in the SADC. The article then introduces pooled

of the Doha Declaration (2003); and most recently, the Amendment of the TRIPS Agreement, commonly known as Article 31 *bis* of TRIPS (2005).

³¹ Available at:

<http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/SADC%20PHARMACEUTICAL%20BUSINESS%20PLAN%20-APPROVED%20PLAN.pdf> (last visited 13/10/14).

³² See operational paragraph 4.1.8 of the SADC Pharmaceutical Business Plan.

³³ See for instance, E Munyukwi and R Machedemeze 'Implementing the TRIPS Flexibilities by the East and Southern African Countries: Status of Patent Law Reforms by 2010' (2010) 80 *Equinet Discussion Paper* at 9.

procurement and contextualizes it within access to medicines in the SADC region. It then becomes necessary to evaluate efficacy in the SADC by drawing from WTO guidelines and actual practice in the region. Finally, the article draws conclusions and recommendations, making a strong case for pooled procurement.

II. THE RIGHT TO HEALTH AND ACCESS TO MEDICINES IN THE SADC REGION: AN OVERVIEW OF PERTINENT LEGAL INSTRUMENTS

Apart from the SADC Strategy on Pooled Procurement³⁴, there are a number of instruments that are important in any discussion on the right to health and access to medicines in the SADC region.

Generally, in terms of the United Nations General Assembly Resolution 179 of 2003³⁵, access to medication in the context of pandemics such as HIV/AIDS³⁶, tuberculosis and malaria, is a fundamental element of the right to health. Consequently, the obligation to respect access to medicines as part of a human right to health, culminating in the respect of the 'human right to medicines', are identifiable in international customary law.³⁷ The provisions relating to access to medicines as a human right are, however, imprecise and international instruments, such as the Alma Ata Declaration on Primary Health Care³⁸ and the UN General Assembly Resolution (2003)³⁹, explicitly commit state parties to the promotion of access to medicines as part of human rights law.⁴⁰ Jonathan Mann⁴¹, cited in Heywood⁴², is said to have once argued that the 'contribution of medicine to health, while undeniably important (and vital in certain

situations), is actually quite limited'. However, side by side with the foregoing observation, when one looks at the emergence of 'treatable pandemics (HIV/AIDS), the resilience of others (tuberculosis), breakthroughs in some crucial areas of medicine and paralysis in others', access to drugs as part of the right to health remains extremely crucial.

In the SADC context, the most important instruments dealing with the right to health and access to medicines are the SADC Protocol on Health⁴³, the SADC Pharmaceutical Business Plan⁴⁴ and the Draft SADC Strategy for Pooled Procurement of Essential Medicines and Commodities.⁴⁵ The three documents 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.⁴⁶ The health programme has developed, taking into account the global and regional health declaration and targets.⁴⁷

None of the three SADC instruments mentions the right to health directly. However, they mention the right to health as a fundamental principle underpinning regional integration in terms of the SADC treaty.⁴⁸ This is no surprise given SADC's main objective has always been on regional integration.

A. THE PROTOCOL

The Protocol does not define health nor expressly references access to medicines.⁴⁹ Instead, the Protocol talks about 'coordinating and supporting individual and collective efforts of the Member States to attain an acceptable standard of health for

³⁴ See a detailed discussion of the strategy in paragraph III below.

³⁵ See UN General Assembly Resolution 179 (2003), UN Doc A/RES/58/179, paragraph 1.

³⁶ In the acute context of HIV/AIDS, access to medicines is a crucial factor to ensure health and life for millions who are now infected (Van Gulik above 9).

³⁷ Niada above at 708.

³⁸ Declaration of Alma Ata 1978 available at: <http://www.euro.who.int/_data/assets/pdf_file/0009/113877/E93944.pdf> (last visited on 12 October 2014), provides in Article I that *Health is a fundamental human right* [emphasis added] and that the attainment of the highest possible level of health is a most important worldwide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector.

³⁹ See note 35 above.

⁴⁰ *Ibid.*

⁴¹ J Mann, S Gruskin, M Grodin and G Annas (Eds), 'Medicine and Public Health, Ethics and Human Rights' in J Mann *Health and Human Rights: A Reader* (1999) 439-452.

⁴² M Heywood 'Drug Access, Patents and Global Health: "Chaffed and Waxed Sufficient"' (2002) 23 *Third World Quarterly* 217 – 231 at 220.

⁴³ SADC Protocol on Health (1999) signed in Maputo, Mozambique on 18 August 1999 and came into force on 14 August 2004.

⁴⁴ SADC Pharmaceutical Business Plan 2007 – 2013, published by the SADC Secretariat on 27 June 2007.

⁴⁵ Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013 – 2017, published by the SADC Secretariat in September 2012.

⁴⁶ See executive summary of the SADC Pharmaceutical Business Plan paragraph 2 at 3.

⁴⁷ *Ibid.*

⁴⁸ See the 'Values and Principles' of the SADC Strategy on Pooled Procurement of Essential Medicines and Health Commodities (hereafter SADC Strategy document) 5, wherein the values of human rights, transparency, equity, gender, sustainable ownership, efficiency, and the principle of subsidiarity are expressly mentioned as guides. The Protocol does not expressly recognize individuals' right to access medicines, but instead bluntly observes that in its preamble that a healthy population is a prerequisite for sustainable human development and increased productivity in Member States and calls for closer cooperation in the area of health.

⁴⁹ The closest defined term is 'health promotion', defined as 'the process of enabling people to increase control over and to improve their health' (Article 1 of the SADC Protocol on Health).

all their people⁵⁰ and to promote health care for all 'through better access to health services'⁵¹ (not medicines). The most logical implication would be to view access to medicines within the context of 'better access to health services'. The preamble to the Protocol begins by acknowledging that SADC Member States are aware that a healthy population is a prerequisite for sustainable human development and increased productivity.⁵² Furthermore, the preamble points out clearly that rendering coordinated and comprehensive health services in a concerted manner is a prerequisite for the improved health status of the people in the region in the 21st century and beyond.⁵³

SADC Member States are urged to cooperate in addressing health problems and challenges facing them through effective regional collaboration and mutual support for the purpose of identifying and supporting those initiatives that have the potential to improve the health of the population within the region;⁵⁴ promoting education, training, and effective utilization of health personnel and facilities;⁵⁵ fostering cooperation and coordination in the area of health with international organizations and cooperating partners;⁵⁶ developing common strategies to address the health needs of women⁵⁷, children, and other vulnerable groups;⁵⁸ and progressively achieving equivalence, harmonization, and standardization in the provision of health services in the region.⁵⁹

Noteworthy, the Protocol does not refer to intellectual property rights in general terms, neither does it refer to the flexibilities provided by the TRIPS Agreement. However, intellectual property rights are only mentioned in the context of establishing a regional databank of traditional medicines and attendant procedures, ensuring the protection of **medicinal plants in accordance with the regimes and related intellectual property rights (emphasis added)** governing genetic resources, plant varieties and biotechnology.⁶⁰ The fact that intellectual

property rights relating to medicines are not specifically mentioned in the Protocol remains a serious omission, because health is synonymous with medicines or medication, produced by pharmaceutical companies holding patents (intellectual property rights) over the medicines.

The most relevant and pertinent provision of the Protocol deals with pharmaceuticals.⁶¹ The Protocol calls upon Member States to explore and share with other States in searching for additional financing to acquire medicines, technology, and other resources needed by the citizens in the respective States.⁶²

The pharmaceutical provision of the Protocol provides that State parties shall cooperate and assist one another in the various ways ranging from the production, procurement and distribution of affordable essential drugs;⁶³ development of an essential drugs' programme and the promotion of the rational use of drugs;⁶⁴ establishing quality assurance mechanisms in the supply and conveyance of vaccines, blood and blood products;⁶⁵ conducting research and documenting aspects of traditional medicine and its utilization;⁶⁶ and establishing a regional databank of traditional medicines.⁶⁷

The SADC Protocol on Trade spells out in general terms the envisaged health outcomes for the region. The Protocol on Trade recognizes that close cooperation in the area of health is essential for the effective control of communicable and non-communicable diseases and for addressing common health concerns.⁶⁸ The specifics are later laid down in more detail in later instruments, namely the Pharmaceutical Business Plan and the Draft Strategy for Pooled Procurement of Essential Medicines (discussed immediately below).

B. THE SADC PHARMACEUTICAL BUSINESS PLAN 2007-2013

The business plan was launched against the background of the need to develop and implement a pharmaceutical programme in line with the SADC Protocol on Health and SADC health policy.⁶⁹ The purpose of the programme is to enhance the

⁵⁰ Article 2(b) of the Protocol.

⁵¹ Article 2(d) of the Protocol.

⁵² The Protocol, preamble paragraph 3.

⁵³ Ibid paragraph 6.

⁵⁴ Article 3(a). The Draft SADC Strategy may be regarded as an example of such cooperation.

⁵⁵ Article 3(c).

⁵⁶ Article 3(e).

⁵⁷ This resonates with the provisions of the SADC Protocol on Gender and Development, wherein in Article 26 thereof, state parties are urged to have implemented, by 2015, legislative frameworks, policies, programmes and services to enhance gender sensitive appropriate and affordable health care.

⁵⁸ Article 3(g).

⁵⁹ Article 3(h). Once again, the Draft SADC Strategy on Pooled Procurement may be regarded as a good example of an attempt at standardization/harmonization.

⁶⁰ Article 29(f) of the SADC Protocol on Health.

⁶¹ See generally, Article 29 of the SADC Protocol on Health. See further, A Moyo 'The Protection and Promotion of Socio-Economic Rights in the SADC Region' (2010) 11 ESR Review 12 – 15 14.

⁶² Moyo above at 14.

⁶³ Article 29(b).

⁶⁴ Article 29(c).

⁶⁵ Article 29(d).

⁶⁶ Article 29(e).

⁶⁷ Article 29(f).

⁶⁸ See 'Introduction and Background information' to the SADC Pharmaceutical Business Plan 3.

⁶⁹ SADC Pharmaceutical Business Plan, executive summary 3.

capacities of the Member States to effectively prevent and treat diseases that are of major concern to public health in the region.⁷⁰

The overall goal of the Business Plan is to ensure the availability of essential medicines, including traditional medicines, in the region in a sustainable way.⁷¹ The Pharmaceutical Business Plan identifies priority areas, objectives, and major activities that will be implemented, both at the regional and national levels, to improve access to quality and affordable essential medicines including African Traditional medicines.⁷² These priorities resonate with the pertinent provisions of the ICESCR and the 2008 Resolution of the African Union Commission on Access to Health and Needed Medicines in Africa.

In order to achieve its objective of improving access to quality and affordable essential medicines, the SADC Pharmaceutical Business Plan will adopt the following strategies⁷³:

- Harmonizing standard treatment guidelines and essential medicine lists;
- rationalizing and maximizing the research and production capacity of the local and regional pharmaceutical industry of generic essential medicines and African traditional medicines;
- strengthening the regulatory capacity, supply, and distribution of basic pharmaceutical products through ensuring a fully functional regulatory authority with an adequate enforcement infrastructure;
- promoting joint procurement of therapeutically beneficial medicines of acceptable safety, proven efficacy, and quality at affordable prices;
- establishing a regional databank of traditional medicine, medicinal plants, and procedures in order to ensure their protection, in accordance with the regimes and related intellectual property rights governing genetic resources, plant varieties, and biotechnology;

⁷⁰ Ibid.

⁷¹ SADC Pharmaceutical Business Plan 4. The main object is to improve sustainable availability and access to affordable, quality, safe, efficacious essential medicines.

⁷² SADC Pharmaceutical Business Plan, executive summary 4.

⁷³ See SADC Pharmaceutical Business Plan Executive summary 4 for a list of objectives that are regarded as crucial, reproduced verbatim here in the form of bullet points.

- developing and retaining competent human resources for the pharmaceutical programme;
- developing mechanisms to respond to emergency pharmaceutical needs of the region; and
- facilitating the trade in pharmaceuticals within the region.

In summary, the Pharmaceutical Business Plan emphasizes:

(1) harmonization of treatment guidelines and essential medicines lists;

(2) maximization of research and the production capacity of the pharmaceutical industry in the region, so that essential generic medicines and their traditional counterparts may be produced;

(3) harmonization within the regulatory infrastructure applicable to pharmaceuticals, so that there will be a positive improvement in the supply and distribution chain of pharmaceuticals;

(4) promotion of joint procurement of essential medicines in the region, where necessary; and

(5) development of a pharmaceutical databank on traditional medicines, and the respect of intellectual property rules will be one of the key objectives of the business plan.

The SADC Pharmaceutical Business Plan also aims to develop and retain human resources while at the same time establishing mechanisms to respond to regional pharmaceutical emergencies. Finally, the plan aims to facilitate intra-regional pharmaceutical trade.

It is important to point out that the SADC Pharmaceutical Business Plan forms part of the broad SADC health programme, which takes into account global health declarations and targets.⁷⁴ In the context of access to medicines that cure

⁷⁴ SADC Pharmaceutical Business Plan, paragraph 1.2. The global and regional health declarations and targets include *inter alia*, the Millennium Development Goals; the New Economic Partnership for Africa's Development; the Abuja Declaration on HIV/AIDS; Tuberculosis and Other Related Infectious Diseases (2001); the United Nations General Assembly Special Session on HIV and AIDS (UNGASS) 2001; the Maseru Declaration on HIV and AIDS (2003); the Brazzaville Commitment on Scaling-Up towards Universal Access to HIV and AIDS Prevention, Treatment, Care and Support in Africa by 2010 (2006); and the Lusaka Declaration on African Traditional Medicine (2001).

common epidemics in the SADC region, the business plan specifically seeks to enhance the capacities of the Member States to effectively prevent and treat diseases that are of major concern to public health in the region.⁷⁵ The plan focusses on HIV/AIDS, tuberculosis, and malaria, as well as other communicable and non-communicable diseases.⁷⁶

With specific reference to access to medicines in the context of this article, the business plan identifies 'outdated medicine laws and intellectual property laws which are not TRIPS compliant' as a major weakness of SADC countries' pharmaceutical regulatory framework.⁷⁷ To address this major weakness, the plan acknowledges that the TRIPS Agreement does contain flexibilities which allow countries to 'import or manufacture pharmaceuticals that are still under patent without the consent of the patent holder'. The plan urges Member States to take advantage of this opportunity which has been utilized before by three SADC Member States.⁷⁸ Another opportunity urged by the plan is for more than half of SADC Members that are LDCs to trade within that block without restrictions.⁷⁹ These two opportunities can improve accessibility, thereby lowering medicine prices in the region.⁸⁰

The suggested methodology for taking advantage of and coordinating the implementation of the TRIPS flexibilities to improve access to medicines within the SADC region will involve a three-pronged approach.⁸¹ First, a regional assessment of intellectual property and medicines legislation in SADC countries will be conducted to determine TRIPS compliance and adaptability.⁸² Second, specialized legal resources from within and outside the SADC region will be identified to give reliable and specialized legal advice.⁸³ A roster of legal and other experts, who are able to offer technical assistance on TRIPS, will be maintained.⁸⁴ Finally the SADC region will collaborate with regional development partners to protect and take advantage of TRIPS flexibilities and assist in bilateral trade negotiations to sign agreements not detrimental to public health.⁸⁵

The other weakness identified by the SADC Pharmaceutical Business Plan having a direct bearing

⁷⁵ See the SADC Pharmaceutical Business Plan paragraph 1.3.

⁷⁶ Ibid.

⁷⁷ SADC Pharmaceutical Business Plan paragraph 2.2(i).

⁷⁸ Namely Mozambique, Zambia and Zimbabwe in the context of compulsory licences.

⁷⁹ This is provided for in paragraph 6 of the WTO Decision of 30 August 2003.

⁸⁰ SADC Pharmaceutical Business Plan, paragraph 2.3(iv).

⁸¹ Ibid paragraph 4.18.

⁸² This suggestion is in line with the approach that was adopted by this study in chapter 4.

⁸³ SADC Pharmaceutical Business Plan paragraph 4.18(ii).

⁸⁴ Ibid.

⁸⁵ Ibid paragraph 4.18(iii).

on access is the fact that the region has an acute overdependence on imported medicines, both patented and generics.⁸⁶ The overdependence may be alleviated by enhancing the 'regional capacity for pharmaceutical manufacturing, as well as conducting research in medicines and other pharmaceutical products including African Traditional Medicines.'⁸⁷

The SADC Pharmaceutical Business Plan, though ambitious, realistically and correctly identifies SADC access issues to medicines and proffers honest and plausible strategies as solutions. The Pharmaceutical Business Plan provides the priorities and focus for the SADC pharmaceutical programme.⁸⁸

To further bring about the harmonization in the pharmaceutical procurement field, the Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities was adopted in September 2012. The next section of this article introduces pooled procurement generally and focusses on the pertinent provisions of the SADC Strategy in that context as a panacea of access to medicines.

III. POOLED PROCUREMENT AS AN ACCESS TO MEDICINES STRATEGY IN THE SADC REGION

A. WHAT IS POOLED PROCUREMENT?

Pooled procurement, also known as joint procurement or procurement cooperation occurs when part or all of the procurement processes of different procurement entities are jointly executed by one of those procurement entities or a third party procurement entity.⁸⁹

The SADC region decided to embark on the strategy of pooled procurement, because studies conducted in the region between 2009 and 2011 found considerable differences in pharmaceutical procurement practices of Member States, as well as in the application of regulations and other procedures such as quality assurance.⁹⁰

The region, therefore, agreed that through the establishment of the SADC Pharmaceutical Procurement Services, pooled procurement would be used as a vehicle **to improve sustainable availability and access to affordable, quality, safe,**

⁸⁶ Ibid paragraph 2.2(vii). About 85 per cent of generic ARV medicines used in the region are imported from India and 15 per cent are manufactured in the region.

⁸⁷ SADC Pharmaceutical Business Plan paragraph 1.3.2.

⁸⁸ See Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013–2017, discussed in detail in paragraph 3.5.2.3 below 1.

⁸⁹ SADC Draft Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013–2017 (2012) at viii.

⁹⁰ SADC Draft Strategy for Pooled Procurement above at v.

efficacious medicines (emphasis in original).⁹¹ The Strategy includes cooperation-focussed initiatives, so that countries can learn and benefit from each other.⁹² The Strategy allows for reducing the costs of medicines by creating economies of scale⁹³ through collaboration in procurement by SADC Members.⁹⁴ Should the Strategy be fully implemented, there will be harmonization in pharmaceutical registrations for the benefit of the Members who will adopt similar approaches in the future, theoretically cutting costs in registration and inspection of pharmaceutical facilities, thus creating savings across the region.⁹⁵

With savings made through information and work sharing by procurement agencies in Member States, more funds will become available for procurement, which will in turn increase the availability of and access to essential medicines and health commodities.⁹⁶

B. SALIENT ASPECTS OF THE SADC STRATEGY FOR POOLED PROCUREMENT OF ESSENTIAL MEDICINES AND HEALTH COMMODITIES

The Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities (Pooled Procurement Strategy) is a response to the objective of improving 'sustainable availability and access to affordable, quality, safe, efficacious essential medicines', as provided for in the SADC Pharmaceutical Business Plan.⁹⁷ Therefore, the Pooled Procurement Strategy is an important step in the pursuit of improving access to 'affordable, quality, safe, and efficacious essential medicines'. The pertinent question to ask at this stage will be how does the Pooled Procurement Strategy purport to improve access to medicines?

According to the Pooled Procurement Strategy, if SADC Member States can cooperate on issues such as pharmaceutical procurement and supply chain management, as well as procedural issues such as quality assurance and public procurement, then access to safe, high quality and efficacious medicines

might be improved.⁹⁸ The Pooled Procurement Strategy argues for adopting a regional approach to the procurement of pharmaceuticals, including the application of 'good practices' in the pharmaceutical procurement and supply management systems.⁹⁹ One advantage of pooled procurement, also called joint procurement or procurement cooperation¹⁰⁰, is the considerable savings made through information and work sharing by procurement agencies in the Member States.¹⁰¹ With such savings, more funds become available for procurement. This will, in turn, increase availability of and access to essential medicines and health commodities.

The Pooled Procurement Plan envisages the establishment of an entity called the SADC Pharmaceutical Procurement Services, which will manage the implementation of the strategy, relying on guidance from the relevant SADC structures for policy development, monitoring and evaluation functions, general oversight, and implementation processes.¹⁰²

In summary, the main objective of the pooled procurement strategy is to achieve regional integration¹⁰³ in the procurement of essential medicines, a practice which will, in addition to fostering deeper integration, facilitate the adoption of a uniform pharmaceutical procurement strategy, ensuring access to essential medicines in the region. This overall objective should be applauded as a regional initiative, which will work alongside implementation of the TRIPS flexibilities. The SADC Pooled Procurement Strategy identifies a number of access issues and concerns which are directly relevant to this study.¹⁰⁴ This article will now

⁹¹ SADC Pharmaceutical Business Plan 2007 at 4.

⁹² M Potsanyane, 'Southern African Regional Programme on Access to Medicines to Medicines (SARPAM): a Key Partner in SADC's Pharmaceutical Sector' (2013) 80 South African Pharmacy Journal at 59.

⁹³ See on a related note a discussion of the possible use of paragraph 6/Article 31*bis* above.

⁹⁴ Government of Botswana 'The Implementation of Trade-Related Aspects of Intellectual Property Rights (TRIPS) Flexibilities in the National Intellectual Property Legislation for Strengthening Access to Medicines in Botswana' (2013), A UNDP-SAPARM-Botswana Government Workshop held in Gaborone, Botswana from 25-27 March 2013 at 12.

⁹⁵ Potsanyane above at 59.

⁹⁶ Government of Botswana above at 13.

⁹⁷ See 'Executive Summary' of the Pooled Procurement Strategy paragraph 1 V.

⁹⁸ *Ibid* paragraph 2.

⁹⁹ *Ibid* paragraph 3.

¹⁰⁰ Pooled procurement (or joint procurement or procurement cooperation) is defined as 'the overarching term for procurement where part of all of the procurement process of different procurement entities (agencies or departments of bigger entities) are jointly executed by either one of those procurement entities or a third party procurement entity' (see 'Definition of terms') in the Pooled Procurement Strategy document viii.

¹⁰¹ See 'Executive Summary' of the Pooled Procurement Strategy paragraph 3 v.

¹⁰² Pooled Procurement Strategy 'Executive Summary' paragraph 4 v.

¹⁰³ The SADC common agenda includes the promotion of sustainable and equitable economic growth and socio-economic development that will ensure poverty alleviation with the ultimate objective of its eradication, enhance the standard and quality of life of the people of Southern Africa and support the socially disadvantaged through regional integration [emphasis in the Pooled Procurement Strategy original 1].

¹⁰⁴ See generally 'Situational Analysis' in the Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013–2017 3–9.

highlight briefly some of the issues and contextualize them.

Information on pharmaceutical procurement is not easily accessible in the SADC region due to different and disparate transparency levels in the private and public pharmaceutical sectors.¹⁰⁵ This implies that the availability of essential medicines will vary between countries of the region with serious access implications.¹⁰⁶ In light of these challenges, pooled procurement would be a possible solution in addressing access challenges and lack of uniformity in the relevant sectors.

The compilation of data for the Pooled Procurement Strategy on pharmaceutical budgets and expenditure was hard to obtain. Further complications came from the fact that most SADC Member States rely considerably on donor support for the purchase of essential medicines, especially in relation to HIV/AIDS, malaria, and tuberculosis.¹⁰⁷ It is submitted that, while reliance on donor support is inevitable, given that more than 50 per cent of SADC Member States are LDCs¹⁰⁸, this continued reliance on donors will frustrate access to medicines in the long term, because TRIPS flexibilities will not be exploited and the development of in-country pharmaceutical capacity will be compromised. Once again, with specific reference to the problem outlined briefly above, pooled procurement may be the solution in resolving the access problem in the specific context.

The SADC Pooled Procurement Strategy also bemoans the fact that four member states do not have a medicines regulatory authority responsible for regulating the quality of medicines in the market and five countries do not actively register medicines.¹⁰⁹ Therefore, in the region, the capacity and capability of the member states' regulatory authorities, responsible for the assessment and approval of medicines, are severely limited.¹¹⁰ The global implication of the foregoing observation is that medicines allowed in one member state will not automatically be allowed to be used in other SADC

Member States. One can envisage that once the region adopts pooled procurement, as suggested in the Draft Strategy, regulatory variations and inconsistencies will fade away and access to medicines will significantly increase.

The other pertinent observation made by the Draft Strategy is that countries provided no information on their use of TRIPS flexibilities in the national legislation to increase access to essential medicines.¹¹¹ This is noteworthy in light of the pertinent provisions of the SADC Protocol on Health and the Pharmaceutical Business Plan¹¹², as well as the objectives of this article.

On a positive note, the Draft SADC Pooled Procurement Strategy observes that despite the shortcomings identified above, national policy regulations are fairly similar in all SADC Member States. Additionally, all Member States have a national medicines policy and an essential medicines list in place, and all but South Africa have a public procurement act.¹¹³

From the situational analysis made in the Draft Pooled Procurement Strategy, it is clear that progress towards improving access to essential medicines has been registered across the region.¹¹⁴ However, the identified progress is hampered by limited resources, lack of standardization in the public sector procurement practices, and lack of regional pharmaceutical market intelligence.¹¹⁵ For pooled procurement to succeed in the SADC context, information and work sharing must be prioritized with the progressive move towards group contracting across Member States to reach the minimum standards of good practice.¹¹⁶ Achievement of such an option should be viewed as a long-term rather than short-term goal, and its full realization will depend on whether technical assistance is forthcoming from fellow WTO Members and other development partners.

The common thread through all the three SADC instruments is that access to essential medicines' cries for regional attention and the solution to the access problem lies in taking advantage of TRIPS flexibilities in the context of pharmaceutical regional integration. It is quite clear that all three instruments are aware of the existence of TRIPS flexibilities, but why SADC Members are reluctant to take advantage of the flexibilities in an access to essential medicines context remains a mystery.

¹⁰⁵ Pooled Procurement Strategy paragraphs 2.2.1 – 2.2.2 at 3.

¹⁰⁶ Despite the fact that it would be simplistic to expect a uniform availability of essential medicines across the SADC, in an ideal world, the expectation would be that the basic medicines are available across the region.

¹⁰⁷ SADC Pooled Procurement Strategy, paragraph 2.2.4 at 4.

¹⁰⁸ SADC Member States which are classified as LDCs are Zambia, Malawi, Angola, Mozambique, Seychelles, Swaziland, Lesotho, Democratic Republic of Congo and Tanzania.

¹⁰⁹ See paragraph 2.2.6 of the SADC Pooled Procurement Strategy 4. The five countries, all of whom are LDCs, are Angola, Lesotho, Seychelles, Democratic Republic of Congo and Swaziland.

¹¹⁰ *Ibid.*

¹¹¹ *Ibid* paragraph 2.2.8.

¹¹² See Article 29 of the SADC Protocol on Health and paragraph 2.3 VI of the SADC Pharmaceutical Business Plan.

¹¹³ Draft SADC Pooled Procurement Strategy paragraph 2.3.1 at 4.

¹¹⁴ *Ibid* paragraph 3 at 5.

¹¹⁵ *Ibid.*

¹¹⁶ *Ibid.*

(i) IPOOLED PROCUREMENT AS A POSSIBLE ACCESS TO MEDICINES SOLUTION IN SADC: A BRIEF EVALUATION

In August 2011, the Southern African Regional Programme on Access to Medicines and Diagnostics (SARPAM), which is funded by DFID and managed by Re-Action (South Africa), was appointed by the SADC Secretariat on a consultancy basis to help the region with, among other things, the development of a Pooled Procurement strategy.¹¹⁷

The goal of SARPAM is to increase access to affordable essential medicines in the SADC region through supporting the development of a more efficient and competitive regional pharmaceutical marketplace.¹¹⁸

While pooled procurement is, strictly speaking, not an intellectual property issue, its scope for improving access to affordable essential medicines is very high. Hence, it is highly recommended that the SADC region implement pooled procurement in line with the broad objective of ensuring access to medicines for all. Using pooled procurement would complement local pharmaceutical production and the use of regional compulsory licences in terms of Article 31*bis*. Pooled procurement is therefore recommended for the SADC region because it will protect the right to life, human dignity and health by ensuring that Members benefit from economies of scale and mitigate the impact of medicines' prices on access.

IV. CONCLUSION

Pool procurement creates economies of scale that result in low transaction costs and better leverage in price negotiations. It can ensure a continuous supply of medicines at low prices that this poor region could afford. There is political will in the region to make sure that this will be a success.

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¹¹⁷ PD Spivey Kashi and KB Carasso 'SARPAM Annual Review Narrative Report' (2012) at 2.

¹¹⁸ *Ibid.*

Spivey PD Kashi and Carasso KB, 'SARPAM Annual Review Narrative Report' (2012) Johannesburg: SARPAM

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12 IMPROVEMENTS IN THE PROTECTION OF TRADITIONAL KNOWLEDGE IN AMAZONIAN COUNTRIES

Dr Zulay Poggi Gonzalez*

ABSTRACT

This article discusses recent advances in the protection of traditional knowledge in Amazonian countries comprising Bolivia, Brazil, Colombia, Ecuador, Peru, Suriname, and Venezuela. It highlights the trends in these countries towards registration for the protection of traditional knowledge associated with genetic resources, and collective marks and denominations of origin for the protection of traditional cultural knowledge. The article concludes that these countries should strengthen joint efforts to promote effective protection mechanisms holistically.

Keywords: *Traditional knowledge, indigenous, legal protection, Amazonian countries*

I. INTRODUCTION

Access to genetic resources and protection of associated traditional knowledge are topics that have gained considerable importance internationally since the approval of the Convention on Biological Diversity in 1992. The Convention aims, *inter alia*, to ensure the fair and equitable sharing of the benefits arising from the utilization of genetic resources.¹

A discussion regarding the protection of traditional knowledge systems requires an assessment of whether conventional intellectual property (IP)

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¹ Rodrigo de la Cruz, *Pueblos Indígenas y sus posiciones en las negociaciones internacionales sobre conocimientos tradicionales: (Taller de expertos para la discusión de propuestas regionales sobre la prevención y combate a la biopiratería y uso indebido de conocimientos tradicionales para países Miembros de la OTCA. Brazil, Noviembre, 2013).*

systems, or the adoption of *sui generis* legislation, or a combination of both, can provide effective protection of traditional knowledge. In this context, representatives of indigenous international organizations believe that traditional knowledge must be viewed holistically. Traditional knowledge should not be considered as separate, as stated in the Convention on Biological Diversity, which refers only to traditional knowledge associated with genetic resources.

II. POLICIES AND THE INTERNATIONAL REGULATION OF TRADITIONAL KNOWLEDGE

A number of factors contribute to the progressive loss of traditional knowledge systems of indigenous peoples, namely:

- The progressive loss of the languages of indigenous peoples due to other more dominant languages;
- the low value attached to traditional knowledge;
- permanent contact with other cultures;
- various acculturation factors that promote other values;²
- low participation of indigenous representatives in the development of public policies; and
- lack of adequate legislation for the legal protection of traditional knowledge, or ineffective implementation thereof.³

There has been extensive work at the international, regional and local levels to address the issue of the preservation and protection of traditional knowledge, as reflected in international guidelines, agreements, public policies, and proposals for protecting traditional knowledge, either by traditional IP regimes or by a *sui generis* mechanism. These efforts have been led by international organizations such as the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), the Secretariat of the Convention on Biological Diversity (CBD), the Food and Agriculture Organization of the United Nations (FAO)⁴, and the United Nations Permanent Forum on Indigenous

² Programa de Naciones Unidas para el medio ambiente. *Plan de acción para preservación CT.* (2007) UNEP/CDB/WG8I/5/3/Add.

³ Zulay Poggi, 'Avances en la protección de los conocimientos tradicionales en la Amazonía. Expectativas del protocolo de Nagoya' *Revista propiedad Intelectual.* Año X, N° 14. Pg 190-215.

⁴ The International Treaty on Plant Genetic Resources for Food and Agriculture

Issues (UNPFII).⁵ Moreover, international and regional indigenous organizations, such as the Indigenous Forum on Biodiversity (FIIB) and the Coordinator of the Amazon Basin Indigenous Peoples Organization (COICA), have been increasingly involved in discussions and development agreements.

To that end, a proposal is currently before the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore for a *sui generis* international protection scheme. The Committee is also discussing the adoption of mandatory disclosure of origin for genetic resources in patent applications, particularly for countries that are parties to the Patent Cooperation Treaty (PCT), as well as proof of legal access to genetic resources, prior informed consent, and benefit sharing.

The WTO has been involved as well, largely because the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is part of the Marrakesh Agreement Establishing the WTO. In April 2011, Brazil and other countries⁶ proposed to amend the TRIPS Agreement by inserting a new Article (29bis)—Disclosure of Origin of Genetic Resources and/or Associated Traditional Knowledge—which would apply when the patent application involves the utilization of genetic resources and/or associated traditional knowledge. This article proposes that Members require applicants to disclose:

- The country providing such resources; and
- the source within the country providing the genetic resources and/or associated traditional knowledge.⁷

The proponents of the proposed article believe that Article 29 of the TRIPS Agreement is incomplete without the disclosure of the origin of genetic resources and/or associated traditional knowledge.

In 2010 the adoption of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits made several advances

⁵ The United Nations Declaration on the Rights of Indigenous Peoples was adopted by the United Nations General Assembly in 2007.

⁶ China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, the ACP Group, and the African Group.

⁷ WTO Draft Decision to Enhance Mutual Supportiveness between the TRIPS Agreement and the Convention On Biological Diversity. Communication from Brazil, China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, The ACP Group, and The African Group. Trade Negotiations Committee (2011) <http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm> accessed 10 January 2013.

in this area. The Protocol proposes, *inter alia*, the development of community protocols for indigenous communities relating to access to traditional knowledge associated with genetic resources, and the fair and equitable sharing of benefits arising out of the utilization of such knowledge (Article 12).

Some Community protocols have been developed to ensure benefit sharing, including the Protocol of the Council for Scientific and Industrial Research (CSIR) in South Africa and the San peoples for the commercialization of the Hoodia plant (with associated traditional knowledge);⁸ the protocol with respect to the access and use of biological resources by the Bushbuckridge Community;⁹ the protocol with respect to access to mining areas in Alto de San Juan, Colombia (2010);¹⁰ and the biocultural community protocol to support the Tanchara community in the Upper West Region of Ghana.¹¹

III. POLICIES AND REGULATING TRADITIONAL KNOWLEDGE IN AMAZONIAN COUNTRIES

Since the Amazon Cooperation Treaty Organization, whose origins date back to 1978, Amazonian countries¹² have implemented a series of strategic plans, programmes and projects, in order to carry out joint actions to preserve the most biodiverse zones in the world, which host about 400 different indigenous groups.

In an effort to regulate the protection of traditional knowledge, some Amazonian countries have implemented policies and rules regarding access to genetic resources and the protection of traditional knowledge through intellectual property regimes or *sui generis* mechanisms. Peru, Venezuela and Brazil have adopted specific laws to protect traditional knowledge. Peru and Venezuela have established

⁸ WIPO 'La Propiedad Intelectual como motor de crecimiento económico. Colaboración de las universidades y la industria'. N° 121 (S). (2003).

⁹ Sibuye Rodney, Uys Marie-Tinka, Cocchiaro Gino, Lorenzen Johan. "PCB Bushbuckridge: Curanderos tradicionales se organizan para el APB en Surafrica". (s/f). <<http://pubs.iied.org/pdfs/G03476.pdf>> accessed 9 November 2013.

¹⁰ PNUMA, IIAP, Natural justice. 'Protocolo Comunitario Biocultural Para el territorio del Consejo Comunitario Mayor del Alto de San Juan'. Asocasan <http://naturaljustice.org/wp-content/uploads/pdf/Alto_San_Juan_BCP.pdf>

¹¹ Kate Kerry and Sarah A Laird, Los Acuerdos de Bioprospección. La Distribución De Beneficios A Las Comunidades Locales (s/f) <http://siteresources.worldbank.org/INTRANETTRADE/Resources/Pubs/303936-1130792844111/PoorPeoplesKnowledge_Chap6_Sp.pdf> accessed 6 February 2014.

¹² Bolivia, Brazil, Colombia, Ecuador, Guiana, Peru, Suriname and Venezuela (all were signatories to the Amazon Cooperation Treaty (ACT) in 1978).

registration systems for the protection of traditional knowledge, and Brazil prevents the unauthorized usage and exploitation thereof. In other countries proposals are being discussed in their respective legislative bodies, for example, in Ecuador and Bolivia.

Different institutions of the various governments of Amazonian countries have been involved in the debate over these topics, for instance, the Public Defender's Offices of Colombia, Ecuador and Venezuela, which have a constitutional mandate to defend the collective rights of indigenous communities, as well as cultural institutions, health, education, and local organizations.

Some Amazonian countries recognize, constitutionally, the collective rights of indigenous people, namely, Bolivia, Colombia, Ecuador, and Venezuela. Others have spelled out the importance of protecting traditional knowledge in strategic biodiversity plans (in all countries excepting Suriname) and others such as Brazil, Peru, and Venezuela in *sui generis* rules.

Universities and Research Centres in Amazonian countries have contributed to the study of biodiversity associated with traditional knowledge and to the development of databases of plants, as well as to the studies of social cartography; for instance, the Nova Cartografia Social projects developed by the Amazonian Estadual University (UEA) and the Federal of Pará University (UFPA).¹³ Other efforts include the creation of institutions supporting indigenous communities such as indigenous universities in Tauca, Venezuela comprising more than 12 different ethnic groups (E'ñepa, Huottöja, Jivi, Kuiva, Malco, Pemón, Pumé, Shiriana, Warao, Ye'kwana and Yukpa). These institutions enable these communities to share their knowledge, experiences, traditions and myths. Another measure is the creation of indigenous museums such as the Museum Maguta in Brazil, whose purpose is to disseminate the traditional knowledge system of the indigenous Ticunas.

Amazonian countries have had some notable experiences with regard to community protocols proposed by the Nagoya Protocol. In Peru, the Potato Park Protocol developed by the local communities establishes minimum criteria for distributing benefits derived from the culture of five traditional communities. A major challenge for these types of protocols is achieving recognition and enforcement by governments.¹⁴

¹³ Proyecto Nueva cartografía Social <<http://novacartografiasocial.com/>> accessed 16 March 2013.

¹⁴ Alejandro Argumedo 'Descolonizando la investigación: el protocolo biocultural del Parque de la Papa para la distribución de beneficios' (2012)

International development funds tend to provide economic benefits based on the collective nature of traditional knowledge. For instance, Amazonian countries have developed the 'Forest Peoples Fund' in Suriname.¹⁵ In Peru, Law 27,811 establishes the creation of the Fund for the Development of Indigenous Peoples, which aims to contribute to the development of indigenous peoples through financing projects and other activities.

All this reflects the growing trend in Amazon countries towards addressing these topics in an inter-institutional and multidisciplinary manner, which is in itself progress.

IV. *SUI GENERIS* MECHANISM TO PROTECT TRADITIONAL KNOWLEDGE IN AMAZONIAN COUNTRIES

Bolivia adopted Andean Decision 391¹⁶, aimed at regulating access to genetic resources and associated traditional knowledge; and regulation Decree No. 24676 of 1997 enforces that decision. However, Andean countries have encountered difficulties implementing this decision, mainly because of deficiencies in the technical capacity of their institutions

In 2012, Bolivia presented a draft law before the Assembly for the promotion and protection of traditional and ancestral knowledge. This law proposes the implementation of a community register and a reserved recording of traditional knowledge.

Bolivia has experience establishing contract agreements for access to genetic resources. For example, in 2003 the Federation of Cooperatives (Migros) applied for access to native varieties of potato plants (*Solanum tuberosum*) for their exportation, propagation, and commercialization. In 2011, PROINPA and EMBRAPA¹⁷ requested access to wild peanuts and their use in breeding programmes for molecular studies.¹⁸

<<http://www.cbd.int/abs/infokit/revise/web/all-files-es.pdf>> accessed 10 May 2014.

¹⁵ Forest Peoples Programme 'Consentimiento Libre, Previo e Informado: Dos Casos en Surinam' (2007) <<http://www.forestpeoples.org/sites/fpp/files/publication/2010/08/fpicsurinamemar07sp.pdf>> accessed 19 February 2014.

¹⁶ Decision 391. Common Regime on Access to Genetic Resources.

¹⁷ Proinpra Foundation in Bolivia. (EMBRAPA) *Brazilian Agricultural Research Corporation*.

¹⁸ Rafael Murillo, 'La protección de conocimientos tradicionales en Bolivia' (Taller de expertos para la discusión de propuestas regionales sobre la prevención y combate a la biopiratería y uso indebido de conocimientos tradicionales para países Miembros de la OTCA. Brazilia, Noviembre 2013).

In 2001, Brazil approved Provisional Measure 2186-16 for regulating access to genetic heritage and the protection of associated traditional knowledge against illicit use and exploitation, which lays down sanctions and fines (Article 30). This measure established criteria for the authorization to: (1) access genetic heritage; and (2) access associated traditional knowledge. It also established criteria for benefit sharing, including prior consent (access for research, technological development, or bioprospecting).

According to experts in Brazil, Provisional Measure 2186-16 fails to regulate the issue of access authorization and benefit sharing at the border, an omission, which requires correction.¹⁹

Another example is Resolution 207/09 INPI, which requires patent applicants to present a declaration of the origin of the genetic resources, as well as prior and informed consent (Article 2) before the National Institute of Intellectual Property (INPI).²⁰

Colombia has passed a number of bills for the protection of traditional knowledge. Likewise, it has lobbied for the implementation of Article 8j of the Convention on Biological Diversity by creating several committees (interinstitutional²¹ and interethnic²²) that count on the participation of all the actors involved in the process.²³ This has led to capacity building for the indigenous communities and to the elaboration of a plan to implement Article 8j of 2007 through a broad consultation process.

Another regulation related to the protection of traditional knowledge in Colombia is General Culture Law No. 397 of 1997 that establishes a number of provisions relating to the country's cultural heritage. This law provides that the State shall guarantee the collective property rights of ethnic groups and support ethnic education processes, with a view to

protecting their languages, traditions, uses, customs, and wisdom.²⁴

Ecuador is developing a policy to combat biopiracy and provide protection of traditional knowledge through registration, and it has drafted a bill for the protection of traditional knowledge of indigenous and local communities (Montubio people, Afro-descendants and peasants), as well as of associated genetic resources and cultural expressions.

Moreover, the Instituto Ecuatoriano de la Propiedad Intelectual (INPI) is working to establish an office to combat biopiracy in 2015. Like Colombia and Venezuela, Ecuador has a Public Defender's Office that watches over the collective rights of the indigenous nations, peoples and organizations, among which are collective intellectual property rights.²⁵

Guiana has been working on a platform to regulate access to genetic resources by foreign researchers and companies through agreements signed with the Environmental Protection Agency (EPA), which regulates access to biodiversity. To this extent, a number of guidelines are available for research on biodiversity that establish mechanisms to obtain permits for research involving any form of biological resource in the country. Other guidelines facilitate access to genetic resources, based on prior informed consent and benefit sharing.²⁶

Peru adopted Law No. 27811²⁷ for the promotion of fair and equitable distribution of benefits derived from the use of collective knowledge. The law also ensures that the use of the knowledge is contingent on the prior informed consent of indigenous peoples and seeks to avoid situations where patents are granted for inventions made on the basis of traditional knowledge. This Law provides three types of traditional knowledge registers: a national public register, a national confidential register and local registers.

¹⁹ Juliana Santilli, 'Protección jurídica de los conocimientos tradicionales en Brasil' (Taller de expertos para la discusión de propuestas regionales sobre la prevención y combate a la biopiratería y uso indebido de conocimientos tradicionales para países Miembros de la OTCA. Brazilia, Noviembre, 2013).

²⁰ Only for resources accessed starting in June 2000.

²¹ Participant Institutions: Mincomercio, Mincultura, Minagricultura, Minrelext, Minambiente, Mineducación, Mininterior, ICANH, IIAP, SINCHI, IAVH, WWF, IC, Mincomunicaciones, Unal, Uexternado, Colciencias, DNP, Public Defense Office, among others.

²² Formed by representatives of indigenous and local communities of the permanent concertation panel of indigenous peoples, representatives of the ROM (gypsies), Raizales (grassroots), Peasants and Afro Colombians.

²³ Based on the Aide Memoire of the First Interethnic Committee held on 24–25 February 2005 in Bogota.

²⁴ Adriana Lagos 'Assessment of the Implementation of International Agreements Related to the Protection of Traditional Knowledge' (2005). Project to build capacity for the implementation of Article 8(j) of the CBD of the Ministry of Environment, Housing and Territorial Development. Bogota.

²⁵ <<http://www.defensordelpueblo.gov.ec/paginas/ini0.php>>.

²⁶ Environmental Protection Agency Georgetown, Guyana, 'National Policy on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization' (2007)

<<https://www.cbd.int/doc/measures/abs/msr-abs-gv3-en.pdf>> accessed 10 May 2014.

²⁷ Law No. 27811 of 24 July 2002 Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources.

The national registers will be administered by the National Institute for the Defence of Competition and Protection of Intellectual Property (INDECOPI), the national authority for consumer affairs, unfair trade law, and intellectual property rights. Registration systems for traditional knowledge (a) preserve and safeguard the collective knowledge of indigenous peoples and their rights therein; and (b) provide INDECOPI with information that enables it to defend the interests of indigenous peoples with respect to their collective knowledge.

Additionally, Article 42 of the Law protects the rights of indigenous peoples possessing collective knowledge against disclosure, acquisition, or the use of collective knowledge without their consent, provided that the collective knowledge is not in the public domain.

Law 28216 (2004) also protects access to Peruvian biodiversity and the collective knowledge of indigenous peoples. This Law aims to create a National Commission to protect access to Peruvian biodiversity and traditional knowledge.²⁸ The Commission will also create and maintain a register of biological resources and collective knowledge, providing protection against biopiracy, as well as patent-related protections, including monitoring patent applications for inventions using biological resources and traditional knowledge, and taking legal measures to veto the patent, among others (Article 5).

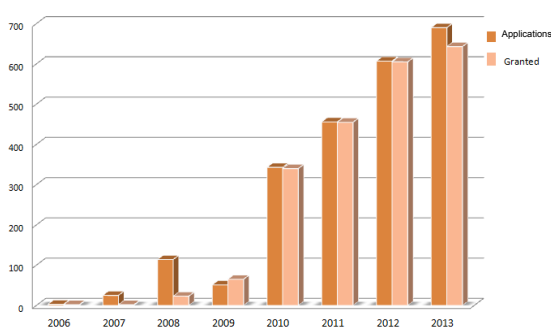
There has been a rapid increase in the registration of traditional knowledge by indigenous and local communities in Peru.²⁹

Venezuela also has several important regulations supporting the protection of traditional knowledge. The Law of the Indigenous Peoples and Communities of 2005 lays down a series of rights protected by the Venezuelan constitution, such as the collective rights of indigenous peoples, which the state shall guarantee and provide.³⁰ The law further establishes that third parties wishing to exploit genetic resources and associated traditional knowledge shall do so in accordance with traditions and customs (Article 102) and subject to prior informed consent (Article 11).

In 2008, Venezuela adopted the Management Biodiversity Law aimed at: (a) implementing mechanisms to ensure fair and equitable benefit sharing of biodiversity and traditional knowledge (Article 18.8); (b) forbidding patents for genetic resources; (c) establishing an authorization process for institutions to access genetic resources and traditional knowledge for scientific and academic purposes (Article 97); (d) facilitating 'contracts of access' with individuals and corporations (Article 98); and (e) creating a requirement of obtaining prior informed consent (Article 100).

In 2009, Venezuela approved the Indigenous Cultural Patrimony Law that created the Register of Indigenous Cultural Patrimonium. While this Law prohibits the protection of traditional knowledge by intellectual property rights, it has created problems because indigenous people, for instance, are unable even to apply for trademarks to protect traditional knowledge.

**Figure 12.1 Registration of traditional rights in Peru
2006-2013**



²⁸ INDECOPI (National Institute for the Defence of Competition and Protection of Intellectual Property), which presides it, CONAM (National Environment Council), INRENA (National Institute of Natural Resources), CONAPA (National Commission of Andean, Amazonian and Afro Peruvian Peoples), among others.

²⁹ According to the 2012 and 2013 INDECOPI Statistical Yearbook in 2012, the local communities, register 607 Traditional knowledge, and in 2013, 690 (547 confidential and 143 public).

³⁰ The protection of traditional knowledge receives special treatment in Chapter V of this law entitled 'Of the Knowledge and Collective Intellectual Property of Indigenous Peoples'.

Table 12.1 Advances in the protection of traditional knowledge in Amazonian Countries

Country	Policy	National Constitution	Traditional Knowledge	Access to Genetic Resources
Bolivia	Bolivia is developing policies to protect traditional knowledge obtained from public, confidential and communities' registers. Promotes the protection of traditional cultural knowledge through collective marks and denominations of origin.	Political Constitution (2009). The State shall protect knowledge and expertise through the registration of intellectual property to safeguard the intangible rights of indigenous peoples. (Article 100)	Draft law for the promotion and protection of traditional knowledge and ancestral knowledge (2012)	Andean Decision 391. The Common Regime on Access to Genetic Resources (Decision of the Andean Community – CAN Bolivia, Colombia, Ecuador and Peru). Regulation of Decision 391 Decree No. 24676 of 1997
Brazil	Policy to protect and regulate traditional knowledge through various relevant institutions.		Provisional Ruling 2186-16 (2001) Resolution 207/09 INPI (Establish criteria for patent applications derived from genetic heritage and traditional knowledge). Resolution 207/09 of 2009. Implements and regulates procedures for the application for patents derived from genetic heritage and associated traditional knowledge. Resolution No. 34 of 2009 C GEN related to permission to access genetic resources	Provisional Ruling 2186-16 (2001) establishes criteria for authorization to access genetic resources and associated traditional knowledge
Colombia	Policy consultation with local communities based on the implementation of Article 8(j) of the CBD.	The Political Constitution (1991) lays down the grounds for the development of regulations, including the protection of collective rights related to property and the environment, among others (Article 88).	Law 70/93 (proposed to protect plant varieties and traditional knowledge). Act 397 of 1997. Act of Culture which provides some standards on cultural heritage in Colombia.	Andean Decision 391 – Decree 1376 of 2013 regulating permission to collect wild specimens of biological diversity for scientific research. Decree 1375 regulating biological collections
Ecuador	Ecuador is developing policies to counter biopiracy and to protect traditional knowledge with the establishment of a register.	The Constitution (1998) incorporates collective rights, including the rights to protect systems, knowledge and traditional medicine practices (Article 84).	Draft law on the protection of traditional knowledge for indigenous people (Montubo people, Afro-descendants and peasants) and associated genetic resources and cultural expressions (2009). Intellectual Property Law No. 320 (Article 377 1998) proposes <i>sui generis</i> protection.	Andean Decision 391 The Common Regime on Access to Genetic Resources Regulated by Decree No. 908 2011

Country	Policy	National Constitution	Traditional Knowledge	Access to Genetic Resources
Guyana	Promotes access to genetic resources through guidelines.		Guyana does not have regulations to protect traditional knowledge.	National Policy on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (2006)
Peru	Peru has developed policies to promote the protection of traditional knowledge through a register and to combat biopiracy. Development of programmes for monitoring patents related to Amazonian biological resources.	The National Constitution (1993) recognizes the existence of peasant, native and indigenous communities and considers them autonomous legal entities in their organization, community work and the use and free disposal of their lands (Article 89)	Law No. 27811 Introduces a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources. Law 28216 - Creation of the National Commission against Biopiracy (7 April 2004)	Andean Decision 391. The Common Regime on Access to Genetic Resources Regulated by Ministerial Resolution No. 087-2008-MINAM
Venezuela	Venezuela has developed a regulatory framework that promises to protect the rights of indigenous peoples- but difficult to implement.	The Constitution (2000) recognizes the collective intellectual property of indigenous peoples over their knowledge, technologies and innovations, and determines that all activities related to genetic resources and traditional knowledge must pursue collective benefits.	Law on Indigenous Peoples and Communities (2005). Law on Indigenous Cultural Patrimonium (2009). Recognizes the Register of Indigenous Cultural Patrimonium. Law on Indigenous Artisans (2010). Criminal Law for the Protection of the Environment (2012) (Articles 46-50)	Law on the Management of Biodiversity, 2008

V. INTELLECTUAL PROPERTY FOR THE PROTECTION OF TRADITIONAL CULTURAL KNOWLEDGE IN AMAZONIAN COUNTRIES

There have been some advances in the protection of traditional knowledge through intellectual property rights. For instance, Amazonian countries have used collective marks and geographical indications to obtain rights for food, handicrafts and other goods.

The Guarani, who inhabit South-Eastern Bolivia, near the border with Paraguay and Argentina, have started producing coffee, chocolate, and flour prepared from the fruit tree 'cupes' (*Prosopis chilensis*); the sheath is high in calcium and phosphorus. The ancient techniques of roasting and drying also impart unique characteristics to these products. Capitanía Indígena Mayor de las Comunidades Indígenas filed a collective trademark application with the National Service of Intellectual Property in order to distinguish those products.

Table 12.2 Other examples of intellectual property for the protection of traditional cultural knowledge in Amazonian countries

Year	Countries	Collective Mark	Product	Applicant
2002	Bolivia	CIMCI Capitanía Indígena Mayor de las Comunidades Indígenas	Products prepared with <i>Prosopis chilensis</i>	Indigenous peoples' organization 'Capitanía del Alto y Bajo Izozog'
2009	Bolivia	Quinoa Real de Lipez	Quinoa Real de Lipez (<i>Chenopodium quinoa</i>)	Local community producer 'Quinoa de real Lipez'
2010	Ecuador	Asociación Hambí Kiea	Productos naturales procesados	Local community 'Asociación Jambi Kiwa (Chimborazo)'
2010	Brazil	'Arroz Tierra Libre'	Arroz	24 communities Río Grande do Sul, Cootap and Santa Rita and Tapes cooperatives
2011	Bolivia	Comart Tukuypay	Tissues, woods, textiles	Artisans' local organizations Sierra, Cruz, Potosí, La Paz, Oruro, Sucre
2011	Colombia	Zenu	Tejeduría Zenú	Indigenous communities 'Resguardo indígena Zenu de Sotavento'
2012	Colombia	Kankui.	Kankuanas backpacks	Asoarka. Kankumas artisans community
2013	Colombia	Palo Sangre	Furniture, mirrors, picture frames, and goods of wood	Amazon Artisans Community
2013	Colombia	Palma estera del Cesar	Carpets, rugs, mats and matting, linoleum and other materials for covering existing floors; wall hangings (non-textile)	Chimichagua artisans community (dpto del Cesar)
2013	Colombia	'Minajoya'	Precious metals and their alloys and goods in precious metals or coated therewith, not included in other classes; jewelry, precious stones; horological and chronometric instruments	Nariño artisans community
2013	Colombia	'Artesanías de Colosó'	Furniture, mirrors, picture frames, and goods of wood	Sucre artisans' community
2013	Colombia	'Palo Sangre'	Household or kitchen utensils and containers; combs and sponges; brushes brush-making materials; articles for cleaning purposes	Artisans' communities 'cerámica de Coco Viejo Atuma, de Puerto Inírida'

Year	Countries	Collective Mark	Product	Applicant
2013	Colombia	Asoimola	Textiles and textile goods, not included in other classes; bed covers; table covers.	Association of women artisans from Antioquia
2013	Colombia	Arhuaco	Mochilas Arhuacas	Indigenous community Arhuaco

Peru and Colombia have some experience of the protection of traditional knowledge through geographical names (Denominations of Origin). In July 2006, the INDECOPI governmental office of Peru granted the denomination of origin 'Chulucanas' to three organizations - Centro de Innovación de la Cerámica, Asociación de Ceramistas Vicus Chulucanas and Asociación de Ceramistas de Tierra Encantada - after determining that the ceramics were the 'result of the interaction of natural factors from the area (clay, sand, climate, mango leaf) and humans (TK Tallan and Vicus rescued—500 years AC), [thereby demonstrating the necessary] connection between geographical origin and product characteristics'.³¹

In March 2008, INDECOPI recognized the Regulatory Council of the Denomination of Origin 'Chulucanas' and granted the first six authorizations to use the denomination of origin. Today, 11 other ceramic crafters have obtained authorization to use that denomination, showing that previously their production complies with the requirements defined by relevant rules. Pursuant to the Lisbon Agreement, Peru has filed applications with the International Bureau of WIPO for recognition of the following appellations of origin: 'Pisco', 'Cusco Giant White Corn', 'Chulucanas Pallar Ica', and 'Café Villa Rica'.

There are other examples of supporting local communities' traditional knowledge. In 2009, the Superintendencia de industria y comercio of Colombia, granted the denomination of origin 'Guacamayas' for artisanal products from the Boyacá Department³² and in 2010, the denomination of origin 'Ráquira' for handmade pottery.³³

VI. CONCLUSION

The common weaknesses of protection of traditional knowledge in Amazonian countries are:

- Difficulties in implementing access regulations;
- deficient coordination between institutions involved in the protection of traditional knowledge and indigenous communities;
- lack of specific regulations to protect traditional knowledge in certain Amazon countries;
- lack of mechanisms for granting prior informed consent and benefit sharing; and
- lack of a joint Amazonian position.

Yet, there has been some success in ensuring the protection of traditional knowledge as well:

- (a) Amazonian countries have an integral vision and relevant institutions are involved;
- (b) a number of countries have prior experience in implementing regulations to protect traditional knowledge;
- (c) there is a trend towards incorporating indigenous communities in discussions about the protection of traditional knowledge;
- (d) the capacity exists to detect cases of misappropriation of genetic resources and traditional knowledge; and
- (e) the collective rights of indigenous communities have been incorporated into some constitutions.

Moving forward, it is important to consider the viewpoint of indigenous peoples, who have increasingly greater expectations of their right to prior informed consent and respect and preservation of their traditional knowledge. There is no doubt that collaboration between government institutions, non-governmental organizations (NGOs), universities, and indigenous communities is crucial, with a

³¹ Resolution 011517 OSD-2006. File 23038-2006.

³² Resolution 30000 19 June 2009.

³³ Resolución 66272 I 29 November 2010.

view to achieving the protection and preservation of traditional knowledge associated with Amazonian biodiversity. In order to ensure such protection and preservation, it is crucial to establish connections between institutions in the different Amazonian countries.

Institutional capacity is strengthening. But Amazonian countries must design policies to strengthen access mechanisms for genetic resources and traditional knowledge. Countries must also exchange experiences in these areas and promote the development of biocultural community protocols that define mechanisms for consultation, engagement and sharing of benefits. They must carry out joint actions to prevent biopiracy, and create a Benefit-Sharing Fund for indigenous communities of the Amazon Transboundary.

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