



WIPO-WTO COLLOQUIUM PAPERS

RESEARCH PAPERS FROM THE WIPO-WTO COLLOQUIUM
FOR TEACHERS OF INTELLECTUAL PROPERTY LAW 2015



WTO OMC





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RESEARCH PAPERS FROM THE 2015 WIPO-WTO COLLOQUIUM FOR TEACHERS OF INTELLECTUAL PROPERTY LAW

*Compiled by the WIPO Academy and the
WTO Intellectual Property, Government Procurement and Competition Division*

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FOREWORD



Mr Francis Gurry



Mr Roberto Azevêdo

This volume is the sixth 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 300 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 six 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 2015 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 *Colloquium 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 sixth 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 Intellectual Property, Government Procurement and Competition Division (IPD) 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 IPD 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 IPD. 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 SPECIALIZED COURTS FOR INTELLECTUAL PROPERTY IN BRAZIL

Márcia Maria Nunes de Barros*

ABSTRACT

This article discusses the process of specialization of intellectual property courts within the Brazilian federal judicial system. The article starts by providing a brief overview of the functioning of the Brazilian federal justice system and how it evolved over time, including its bodies, its competence for trial, and its existing trial courts. It then describes the increasing number of intellectual property cases in the courts, and finally highlights several specific cases and recent developments in the jurisprudence.

Keywords: *judicial power, competences of Brazilian courts in IP matters, IPRs under Brazilian law*

I. INTRODUCTION

This article aims to analyse the specialization of Brazil's justice systems, particularly at the federal justice level, with a focus on intellectual property, and highlights relevant cases that have occurred in recent years and recent developments in the jurisprudence.

II. HISTORY

A country of vast dimensions, Brazil is divided into 27 units - 26 States and a Federal District, where the capital, Brasília, is located. A brief overview of Brazil's judicial system is critical to comprehending the intellectual property landscape in this country.

On account of this geopolitical organization, traditionally there has always been a separation between the State Courts, also called regular courts, where judges preside over disputes between individuals, and the Federal Courts, whose jurisdiction is determined essentially by the person, i.e. any federal public entity concerned in the dispute.

The Federal Justice Court was established after Brazil became a Republic in 1889. The first legislative document was Decree No. 848 of 1890, which regulated the organization and function of the Court prior to the establishment of the first Republican Constitution in 1891. The creation of the Federal

Justice was deemed necessary to consolidate national sovereignty and the justice system deployed, under which federal and state entities coexisted independently and harmoniously. This system was inspired by the jurisdiction models of the United States, Switzerland and Argentina, all newly established republics back then.

During the period of military dictatorship, Brazil's Federal justice was temporarily dissolved under Institutional Act No. 2 of 27 October 1965. This act suspended the guarantees of life tenure and non-removability of judges and recreated the first Instance at the Federal Court. At that time, judges were appointed by the President, based on a list drawn up by the Supreme Court. Furthermore, with Institutional Act No. 5 of 13 December 1968, the constitutional guarantees for judges, such as life tenure, non-removability, stability, and performance of functions for a defined period, were suspended and all measures taken under this Institutional Act were excluded from being reviewed by the Judiciary.

On 17 October 1969, the Federal Court was reorganized under Constitutional Amendment No. 01 and adopted its current form, marking the return of judiciary guarantees.

The bodies of the Federal Justice are the Federal Judges and the Federal Regional Courts (Article 106 of the Federal Constitution).

The jurisdiction of the Federal Judges is defined in Article 109 of the Federal Constitution. Federal judges preside over Federal Courts in first instance and have jurisdiction to consider and judge the following matters:

- (i) Cases in which the Union, an autonomous government agency, or a federal public company, have an interest as plaintiffs, assistants or opponents, except cases of bankruptcy, workers' compensation, and the ones subject to the Electoral and Labour Courts;
- (ii) cases involving a foreign state, an international organization, a municipality or a person domiciled or residing in the country;
- (iii) cases based on a treaty or agreement between the Union and a foreign state or an international organization;
- (iv) political crimes and criminal offences committed against goods, services or interests of the Union or its autonomous agencies and public companies, excluding misdemeanours and excepting the competence of the Military Courts and Electoral Courts;

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- (v) crimes covered by an international treaty or convention when, once implemented in the country, the result has or should have taken place abroad, or conversely; v.A- cases regarding human rights referred to in § 5 of this article;
- (vi) crimes against a labour organization, and in cases determined by law, the ones against the financial system and the economic and financial order;
- (vii) habeas corpus, in criminal matters within their competence, or when the coercion is exercised by an authority whose acts are not directly subject to another jurisdiction;
- (viii) writs of mandamus and habeas data against an act of a federal authority, except for the cases of jurisdiction of federal courts of second instance;
- (ix) crimes committed aboard ships or aircrafts, excepting the competence of military courts;
- (x) crimes or illegal entry or stay of foreigners, execution of letters rogatory, after the 'exequatur', and the foreign judgment, after homologation, and for cases related to nationality, including the respective option, and to naturalization;
- (xi) disputes over indigenous rights.

All States and Federal District have judicial sections in their respective Capital, and courts of first instance are located where established by law (Article 110 of the Federal Constitution).

Nowadays, Federal Courts have been established in the Federal Capital and in the capitals of the Member States, as well as in several other cities of large metropolitan centres and in the countryside, according to economic and population criteria.

There are five Regional Federal Courts of Appeals, with powers defined under Article 108 of the Federal Constitution. They are responsible for:

- (i) processing and adjudicating, in the first instance:
 - (a) federal judges in their area of jurisdiction, including military justice and the Labour Courts, in common and liability crimes, and the prosecutors of the Union, except for the competence of the Electoral Courts;

- (b) criminal reviews and severance actions against their decisions or those of the federal judges of the region;
- (c) writs of mandamus and habeas data against an act of the Court itself or of a federal judge;
- (d) habeas corpus, when the constraining authority is a federal judge;
- (e) conflicts of jurisdiction between federal judges that are subject to the Court;
- (ii) judging, on appeal, cases decided by federal judges and by state judges in the exercise of federal competence within the area of their jurisdiction.

The dominant jurisprudential understanding with respect to industrial property shows that in actions involving concession or nullity of industrial property rights, even if there are two litigating companies, the Brazilian PTO (INPI – Instituto Nacional da Propriedade Industrial) should participate in the lawsuit as the defendant, because their role in the examination and granting is not limited to a formal or bureaucratic activity, but constitutes an effective verification of the legal requirements of registrability, seeking to preserve public interest.

According to a rule of jurisdiction pursuant to Article 94 of Brazil's Code of Civil Procedure (CPC) (contained in Article 46 of the new CPC), the motion should be brought, as a rule, in the defendant's domicile headquarters.

The PTO is an entity that has the authority to 'execute, at a national level, the rules governing industrial property, with a view to its social, economic, legal and technical function' (Article 2 of Law No. 5648/1970) and has always had its headquarters in the city of Rio de Janeiro, the state capital of Rio de Janeiro. For this reason, most of the actions involving industrial property, such as trademarks, patents, utility model patents and industrial designs, are processed in Rio de Janeiro.

These cases, however, were not prosecuted or tried sufficiently quickly to preserve the interests of industrial property right holders due to the excessive number of lawsuits in the Federal Court and the variety of subject matters involved.

Accordingly, the new intellectual property law (IPL) constituted an important step by providing in Article 240 for the possibility of establishing specialized courts in this field.

This was followed by intense management of intellectual property operators, especially through their professional associations - ABPI (Associação Brasileira da Propriedade Intelectual) and ABAPI (Associação Brasileira dos Agentes da Propriedade Intelectual), with the Federal Court of Appeal, for the development of this expertise.

In 2000, pursuant to a decision of the Plenary of the Federal Regional Court of the Second Circuit, the competence relating to intellectual property was added to the competence of the ten Courts which were specialized in social security matters, namely, the 31st, 32nd, 33rd, 34th, 35th, 36th, 37th, 38th, 39th and 40th Federal Courts.

In view of the urgent need for the establishment of Special Small Claims Federal Courts by the Regional Federal Courts, Law No. 10.259/2001 was enacted in 2001. Five of these Specialized Courts oversaw intellectual property and social security matters. The 31st, 32nd, 34th, 36th and 40th Federal Courts were transformed into specialized Special Small Claims Federal Courts, with lawsuits redistributed between the remaining specialized Federal Courts.

In 2003, the 33rd Federal Court was also transformed into a Special Federal Court, and its lawsuits were redistributed among the other Courts.

The 35th, 37th, 38th and 39th Federal Courts of Rio de Janeiro remained, specializing in intellectual property and were later renumbered respectively as the 25th, 13th, 31st and 9th Federal Courts - which remains to date.

In 2005 the Federal Regional Court of the 2nd Circuit (Federal Court of Appeals) decided the specialization of the 1st and 2nd Panels, which constitute the 1st Specialized Section of the Tribunal in criminal, in social security and in intellectual property matters, consolidating the process of specialization within the 2nd Circuit.

Intellectual property is not a specific part of the curriculum of most law schools in Brazil. On that note, the initiative of specialized thematic trial sessions significantly contributes to the work undertaken by lawyers, the oral arguments, the organization of judicial departments, as well as concentrating the discussion of legal arguments.

Indeed, specialization in intellectual property allows, both in the first and second instances, further study and training of judges and their assistants to be undertaken in this particular matter. This specialization also enhances the organization and standardization of procedures, leading to a significant improvement in the degrees of quality

and reliability of jurisdictional provisions, as well as expeditious and effective decisions.

Nowadays, the Federal Regional Court of the Second Circuit is the only Regional Federal Court with judges, in both first and second degrees, specialized in intellectual property.

In addition, in the Superior Court of Justice (STJ – Superior Tribunal de Justiça), which focusses on the uniform application of federal law in the country, regardless of the vital public interest intrinsic in intellectual property matter – recognized widely in Federal Regional Court of the Second Circuit decisions –intellectual property cases are decided in Private Law Chambers - due to an understanding that it is a matter limited to the scope of business law.

III. EVOLUTION

Given the need for computerization and modification of the data system in the Federal Court in the 2nd Region, reliable statistics are only available from 2006 onwards.

In the table below, the statistics for the month of May on an annual basis since then show a rise in the number of lawsuits that were in progress in the four specialized Courts, as shown in the table below:

| | Total | Social Security | Intellectual Property | Percentage |
|----------|--------|-----------------|-----------------------|------------|
| May 2006 | 22,465 | 21,736 | 729 | 3.24% |
| May 2007 | 20,833 | 20,043 | 790 | 3.79% |
| May 2008 | 18,141 | 17,389 | 752 | 4.14% |
| May 2009 | 17,751 | 16,871 | 880 | 4.95% |
| May 2010 | 15,141 | 14,219 | 922 | 6.08% |
| May 2011 | 12,132 | 11,172 | 960 | 7.91% |
| May 2012 | 9,253 | 8,369 | 884 | 9.55% |
| May 2013 | 9,214 | 8,187 | 1,027 | 11.14% |
| May 2014 | 7,588 | 6,551 | 1,037 | 13.66% |
| May 2015 | 6,519 | 5,608 | 911 | 13.7% |

The following table shows, on an annual basis, the number of new cases in the four specialized Courts, the number of new social security cases, the number of new intellectual property cases, and the percentage of new intellectual property cases in relation to the total number of new cases:

| | Total | Social Security | Intellectual Property | Percentage |
|----------------|-------|-----------------|-----------------------|------------|
| 2006 | 1,847 | 1,762 | 85 | 4.60% |
| 2007 | 1,585 | 1,500 | 85 | 5.36% |
| 2008 | 1,557 | 1,467 | 90 | 5.78% |
| 2009 | 1,529 | 1,440 | 89 | 5.82% |
| 2010 | 1,238 | 1,167 | 71 | 5.73% |
| 2011 | 1,126 | 1,076 | 50 | 4.44% |
| 2012 | 1,209 | 1,121 | 88 | 7.27% |
| 2013 | 1,288 | 1,184 | 104 | 8.07% |
| 2014 | 1,109 | 1,039 | 70 | 6.31% |
| 2015 (Jan-May) | 439 | 400 | 39 | 8.88% |

IV. LANDMARK TRADEMARK CASES

There are no reliable statistics on how many cases relate to each type of intellectual property rights, although the practice reveals that the largest number is related to trademarks, while fewer are related to industrial designs, utility model patents and patents.

The main advantages of specialization for trademarks are the consolidation of understandings, the acceptance of new theses, and the possibility of studies with analysis of comparative law.

There are numerous cases involving persons and also domestic and foreign companies of greater or lesser reputation. Some of the most notable are:

A. CESAR CIELO X CIELO

In Lawsuit No. 0031360-61.2012.4.02.510, the famous Brazilian swimmer and Olympic gold medallist, Cesar Augusto Cielo Filho, filed a lawsuit against Cielo S/A, a company that manages merchant payment options with credit and debit card machines. The company had contacted the athlete to use his likeness, but had not requested a special authorization to use his family name as a trademark.

It was decided that the company could not use Cielo's family name without authorization, because it was a well-known surname associated with the swimmer, and also because when the company contracted him they wanted to associate his image with the persona of the newly branded business.

B. APPLE FAMILY

Apple Inc. filed Lawsuit No. 0490011-84.2013.4.02.5101 against IGB Eletrônica S.A.,

another company dealing in electronic devices that had registered a trademark for GRADIENTE IPHONE in Brazil years before Apple.

The decision considered that, undoubtedly, when consumers and the market itself think of IPHONE, they are thinking of an APPLE device. Allowing the defendant company to use the expression 'IPHONE' freely, without any restrictions, would cause considerable damage to the Plaintiff, for the product's fame and clientele stemmed from Apple's level of competence and excellence. Trademark spreading, at this moment, would be considered equivalent to a punishment for the company that developed the product and worked hard for its success. The reservation determined by the decision refers solely to the prohibition by the appellant company, IGB Eletrônica S.A., to use the term 'IPHONE', in isolation, since it is closely linked, both in the domestic market and also internationally, to the products from the appellee, Apple Inc.

Similarly, Apple Company almost lost the name 'IPAD', as it was first registered for a defibrillator in Brazil called IPAD FAST, according to Lawsuit No. 0812089-04.2010.4.02.5101 - Apple Inc. and Apple Computer Brasil Ltda X Instituto Nacional Da Propriedade Industrial – INPI and the company Transform Tecnologia De Ponta Ltda, in which the plaintiff sought to nullify the registration of the trademark I-PAD FAST.

The decision considered that the trademark I-PAD FAST conflicted with the trademark IPOD owned by the Plaintiff. The possibility of confusion or association between the signs in question is evident, and the extensive knowledge of the consumer population of Apple Company's 'I' products is undeniable. For this reason, the granting of the trademark's registration in question to designate computers and recorded computer programs was considered mistaken owing to an existing prior registration of the trademark IPOD in the same product class belonging to the Apple Company.

The decision also stated that there was no obstacle to registration, in our country, of the term I-PAD FAST to designate medical products, given the fact that the term PAD is recognized, in English, to distinguish a defibrillator for public access, also known by the acronym AED.

C. PRINCIPALITY OF MONACO X MÁRCIO MÔNACO

In case No. 2002.51.01.523728-5, the Principality of Monaco's Government brought a lawsuit against the PTO and a company, Amonseg Insurance Broker S/C Ltda, for the annulment of the MONACO INSURANCE

trademark, created by a Brazilian citizen named Marcio Monaco, who used his last name with a small crown above the letter 'O' in its creation. The Principality claimed that the trademark induced false reference in relation to the royal family.

The decision considered that the trademark fell under Article 181 of Brazil's IPL, as the geographical name MONACO was not an indication or a designation of origin for bank-related services. It also may serve as a characteristic element of the service developed by the defendant and/or its company, as any average consumer would assume any correlation with the Principality of Monaco, so there was no possibility of false source induction.

In addition, the decision also argued that the mere fact that the defendant's trademark had a crown or mitre did not provide an immediate association with the royal family of Monaco for the average consumer, given that there were several other trademarks on the market that use such symbols, which translate the idea of excellence or quality of products or services.

D. ALL STAR X ALL STAR

In Case No. 2002.51.01.523832-0, the Converse Inc. company filed a lawsuit against a Brazilian company, All Star Sports Articles Ltda and against the PTO, seeking to invalidate the ALL STAR trademark, widely known in the international market, and obtained by the Brazilian company through the national patent office.

The decision recognized the trademark's notoriety, considered a special object of protection pursuant to Article 6*bis* of the Paris Convention for the Protection of Industrial Property, and also the bad faith of the defendant company, which sought a business partnership with the plaintiff, and afterwards proceeded with the trademark registration as if it were its own creation. The registrations obtained by the defendant company for the ALL STAR trademark were thus decreed null, and the company was also ordered to abstain from any use of the ALL STAR trademark or other confusingly similar sign throughout the national territory.

V. PATENTS

There are also many cases involving patents. After TRIPS, the landmark cases have been in the field of pharmaceuticals and related areas.

A. ARTICLE 40 OF BRAZIL'S PATENT LAW

Prior to TRIPS, pharmaceutical products were not protected under Brazilian laws. Surprisingly, the

transition periods provided in TRIPS were not used, and in 1996 a new IP law entered into force in accordance with the new agreement, which also included some TRIPS-plus provisions. One of them is the provision contained in Article 40.

Article 40 provides that the validity of a patent will be 20 years from the application date. The sole paragraph states that, if the examinations take too long, the patent will then be guaranteed a minimum period of validity of ten years from the date the patent is granted. This provision is being questioned directly in Brazil's Supreme Court due to its unconstitutionality. However, there has been no decision so far.

B. MAILBOX PATENTS

Article 229, the sole paragraph of the IPL, provides that patent applications for pharmaceutical products and chemical products for agriculture, which were deposited between 1 January 1995 and 14 May 1997, shall have the final date of validity as stated in the heading of Article 40 of the IPL, i.e. 20 years from the filing date. These are the mailbox patents, which are referred to in TRIPS Article 70.8.

In spite of the expressed legal provision, INPI, Brazil's patent office, fixed the period of validity of these patents incorrectly, based on the sole paragraph of Article 40 of the IPL, which provides for a period of ten years effective from the date of granting.

After granting several mailbox patents with an incorrect validity term, the office realized its mistake and filed 48 lawsuits, of which 42 were brought before Federal Courts in Rio de Janeiro, seeking to modify the period of validity of these patents.

Patent holders who questioned the merit of such lawsuits claimed the impossibility of the revision of the patents' validity term, arguing the principles of legitimate expectations, legal certainty and equality on the grounds that no single paragraph of the application of Article 40 of the IPL would consist of a discriminatory treatment of patents submitted to the mailbox.

The decisions rendered by the Judge of the 13th Federal Court were made to determine the correctness of the term of 20 years from the filing date, as determined by law, since these patents dealt with material that was not permitted under the applicable law at the time of the deposit, and were subject to a special transition rule which allowed patenting during the validity of the current patent law. They also recognize the prevalence of the principles of legality, free competition and public interest in correcting the monopoly duration time.

The Court of Appeals confirmed the decisions in first instance, as seen in Lawsuits No. 0132265-40.2013.4.02.5101 (*INPI v. Janssen Pharmaceutica N.V.*) and No. 0132265-40.2013.4.02.5101 (*INPI v. Keiko Otsu and Louis V. Kirchoff*).

C. TMC TEST OF OBVIOUSNESS – THE CREATIVE MOTIVATION TEST

In case No. 0802461-54.2011.4.02.5101, the Brazilian Association of Generic Drugs Industry, *Pró Genéricos*, filed a lawsuit against Astrazeneca AB and against the PTO, seeking to invalidate patent PI 0003364-2, which refers to the drug marketed under the CRESTOR denomination for the treatment of high levels of blood fat, particularly cholesterol and triglycerides, claiming that it did not meet the legal requirements of novelty and inventive steps, being in fact a mere combination of state-of-the-art elements.

As Brazilian law and the PTO had not yet developed an obviousness test for the determination of inventive step with objective criteria, such a test was developed in this decision and named Creative Motivation Test (*Teste de Motivação Criativa (TMC)*). This test was prepared after a study of comparative law had been undertaken, and adapted in the Brazilian system some of the criteria from American jurisprudence, such as in *Graham v. John Deere* and *KSR v. Teleflex*, and in the case law of the European Patent Office.

With the application of the TMC in this case, it was found that the technical solution claimed in the patent in question was already suggested by the prior art (combination of two documents: WO 7/23200 and PT547000E). It was decided that the claimed subject matter was obvious to be attempted with reasonable and well-founded expectation of success, which is why the patent was void for lack of inventive step.

The so-called TMC involves the following steps:

- (i) Determining the problem and the claimed technical solution;
- (ii) defining the prior art susceptible of knowledge for a skilled person in the art;
 - (a) determining relevant prior art: verifying the similarities and differences between the claimed technical solution and the prior art; identifying those that are relevant to the analysis;
 - (b) examining the creative motivation: examining whether a skilled person in the

art would have been motivated to carry out the combination or the necessary modifications to reach the claimed technical solution, given the prior art information;

- (iii) Subsequently, verifying evidence of inventiveness and thus rejecting obviousness, such as:
 - (a) the solution of a technical problem long-known but unsolved;
 - (b) overcoming a bias or technical barriers;
 - (c) obtaining commercial success if linked to the technical nature of the invention, and not for advertising;
 - (d) the fact that the technical solution provided by the invention is contrary to prior art teachings, and producing unexpected technical effect;
- (iv) In concluding for obviousness, provide reasons according to objective reasoning based on the following non-exhaustive illustrative list:
 - (a) the combination of prior art elements according to known methods, producing predictable results;
 - (b) the mere substitution of one known element for another without demonstrating unexpected advantageous technical effect, producing predictable results;
 - (c) using techniques generally known, neighbouring or suggested in the prior art in the area concerned, to enhance devices, methods, or similar products, producing predictable results;
 - (d) choosing an 'obvious to try solution', from a finite number of identified predictable solutions, with a reasonable expectation of success that proved justified;
 - (e) teaching, suggestion or motivation in the prior art, not necessarily explicit, that would have taken someone with average knowledge to modify the prior art reference or to combine the prior art reference teachings, to reach the claimed invention.

VI. CONCLUSION

The Federal Courts in Brazil that are specialized in intellectual property matters are working extensively to deliver quick, effective and high-quality decisions. A balance between the public interest and the needs of the owners is being pursued.

These Courts are essential entities to promote the enforcement of intellectual property rights in Brazil, without losing sight of important issues of concern, such as public health and access to medicines, issues that are especially crucial for developing countries.

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2 VALORIZATION OF INNOVATION AND RESEARCH RESULTS FOR SOCIAL AND ECONOMIC GROWTH IN BURKINA FASO

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ABSTRACT

The question of innovation and the utilization of scientific and technological research results has come to the forefront in recent years as a significant tool for socioeconomic development in African Countries. However, it could be argued that despite the multiplicity of works managed by different actors, research and innovation results in diverse areas remain unknown and unutilized, and are often unrecognized. This article examines the question of innovation and the valorization of research results in Burkina Faso. It also explores its inventory of research, together with the various constraints and opportunities associated with the utilization of research and innovation results. Finally, it proposes solutions to translate research and innovation into development tools for Burkina Faso.

Keywords: valorization, research issues, innovation, intellectual property, development, Africa

I. INTRODUCTION

Ranked among the poorest countries in the world, the vast majority of African countries have relatively low human development indices and face many challenges, both at present and in the future. Nonetheless, thanks to the increased awareness of the role of research, coupled with the efforts of researchers, inventors and innovators, many results have been generated in Africa in various spheres such as agriculture, environment, technology, health, and traditional medicine that are likely to contribute to the development of the entire continent.¹ Many of the results stemming from research and innovation have been published in scientific journals, papers and scientific meetings, as well as being the focus of topics in national, regional and international exhibitions.

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¹ Daniel P Kabore, *Dissemination mechanisms Analysis improved agricultural technologies and innovations in the ECOWAS*, (2011).

However, it is clear that despite the willingness of various African leaders to consider scientific research and innovation as a tool for socioeconomic development, the general public is largely confused about research and innovation results. These results thus remain largely unknown, unprotected, unvalued and unutilized by the general public². There is a significant gap in Africa between production results from research and innovation and their commercial value. Yet, there appears to be an increased focus on the utilization of research and innovation results in recent years in Africa with the involvement of several actors³. This paradoxical situation gives rise to many questions such as: What is the current state of research and utilization of the results in Burkina Faso? What are the constraints and opportunities relating to the intensive use of research results and innovation? What are the solutions for the utilization of research and innovation results as development tools in Burkina Faso?

II. GENERAL CONCEPTS

Scientific research, inventions and innovation activities undertaken throughout the African Continent have generated several results that could contribute to its social, economic and cultural development. These diverse outcomes or endeavors are applicable to many sectors, yet there is general agreement that they lack valorization. In order to provide some clarity, it seems judicious to define certain concepts such as valorization, assignment and merchandizing, while discussing the rationale for the valorization of research and invention results.⁴

A. VALORIZATION

The term 'valorization' has many definitions and is commonly used, along with such terms as 'merchandizing', 'utilization of research outcomes' and 'assignment'. However, these expressions imply unlike realities.⁵

Indeed, valorization may be defined as a process that is essentially undertaken in universities for the purpose of adding value to research issues, to knowledge, to an invention or to an existing technology, so as to convert them into usable or marketable goods, processes and services. In other words, valorization signifies making knowledge and

² Michel P Sedogo, *Research findings Development Programme and Innovations in Burkina Faso*, 2009.

³ OECD, *Knowledge-based Economy*, Paris, 1996.

⁴ University of Strasbourg, *Good Practice Guidance Valuation*, Strasbourg, 2009.

⁵ Souad Boussaid *Valuation of Research and Funding Mechanisms of Innovation in Tunisia*, 2013.

proficiency stemming from research and innovation usable and marketable.⁶

'Assignment' refers to the transmission and receiving of flow of knowledge and ability between partners, especially in the private sector and research centres, for the purpose of enhancing knowledge and value of one of the partners. Its concrete expression is by the way of a technology transfer agreement between an institute or university and an enterprise, by granting an exploitation licence or by the transfer of intellectual property rights.

Lastly, marketing refers to putting on the market products, processes, and services from the marketing exploitation of intellectual property rights, acquired from a university or institute.

B. WHY RESEARCH AND INNOVATION RESULTS SHOULD BE VALORIZED?

In the present-day context of the economy of knowledge, there are many reasons why States, institutes, research centres and universities are prioritizing the valorization of innovation and research results.⁷

The transfer of research and innovation outcomes toward the productive sector enhances the competitiveness of enterprises and leads to job creation, while also helping to produce research and innovation outcomes, for instance, the development of drugs.

Valorization avoids the use of results by another person without compensation; moreover, it also produces substantial incomes and helps to finance research in universities, institutes and research centres.

The delivery of knowledge and know-how by researchers and innovators in the economics field is a source of recognition, notoriety and enrichment of research through the supply of professional contributions.

Cooperation with the private sector encourages the professional integration of students in enterprises. Hence, research should help to respond to concerns from enterprises and people regarding issues relating to the utilization of results and investment feedback.

⁶ Caudle, *The Commercialization of University Research*, (Quebec 1992).

⁷ University of Strasbourg, *Good Practice Guidance Valuation Good Practice Guidance Valuation* (Strasbourg 2009).

III. STATUS OF RESEARCH

The status of research in Burkina Faso and across the African continent in general is characterized at the political and institutional level by the existing political views, private and public research, valorization structures and lack of valorization and protection available for research.⁸

As for financing of research and innovation, an inventory of fixtures shows a limited amount of state financing is channeled to this particular field; home research centres are subordinated towards foreign structures; and results are exported to foreign financing institutes.

The sector of innovation and research results is characterized by some existing value structures, lack of reward for researchers, a low level of scientific publishing protection, a weak use of innovation and research issues and non-satisfied societal needs of the products brought into focus.

Only less than 2 per cent of annual scientific publishing and 1 per cent of patents filed originate from Africa; despite numerous possibilities, only countries such as South Africa, Egypt, Tunisia, Nigeria, Algeria, and Morocco seem to be an exception, though there is no shortage of inventiveness and creativity within institutions, universities and research centres to meet the Continent's development priorities.⁹

A. CONSTRAINTS AND OPPORTUNITIES OF INNOVATION AND RESEARCH RESULTS

In African countries, there are numerous constraints and opportunities¹⁰ in relation to the valorization of research and innovation results:

(i) CONSTRAINTS

In this regard, African countries are confronted with a bewildering number of economic, political, institutional and sociocultural impediments:

(a) Economic constraints

There are considerable economic constraints, including¹¹:

⁸ OECD, *Science, Technology and Industry Outlook* (2012).

⁹ Pan African Conference on the role and place of the University in the 21st century, Rabat (Morocco) Africa, November 21-23 2011.

¹⁰ OECD, *Science, Technology and Industry Outlook*, 2012.

- Limited public funding granted to research and development, leading to dependence on investments abroad;
- smallness of industries unable to absorb research results;
- lack of training for industry and traders to provide an understanding of the research product and its application or use;
- lack of issues between research and the national research system of production;
- weak level of industrial property protection of the results;
- Lack of researchers' knowledge about issues related to the private sector, precluding suitable technical solutions from being proposed.

(b) Sociocultural and behavioral constraints

The sociocultural and behavioral constraints can be summed up as follows¹²:

- Brevity of training for researchers regarding the protection and valorization of results;
- broadcasting of research results is predominantly limited to exhibitions, publishing, and participation in congresses, conferences and forums;
- lack of a link between the private sector and socio-professional environments, institutions and research centres;
- mismatch between research and enterprise needs and/or realities;
- information withholding is still prevalent among inventors, innovators, and researchers;
- inadequate social recognition of the researcher in the society;
- researchers' lack of information concerning the necessity of filing a patent;

- lack of interest of certain researchers for market research products.

(c) Political and institutional constraints

The political and institutional constraints impeding the effective use of innovation and research results include¹³:

- Lack of buildings and plants dedicated to research;
- high school training is not geared towards current development needs;
- mismatch between major development goals and research projects;
- holding of intellectual property rights (for example, patents) is not taken into account in researcher career value;
- lack of legal texts governing the sharing, utilization and marketing of innovation and research result outcomes;
- influential role of academics in the field of research;
- research projects are conceived in order to respond to career enhancement without taking into account national priorities.

(ii) OPPORTUNITIES

Notwithstanding the foregoing constraints, it is hoped that Africa will eventually overcome these impediments. Several opportunities exist for more effective harnessing and leveraging of the results or findings stemming from inventions, innovation and research, which could translate into a source of a sustainable development and progress for African States.

Indeed, it is now acknowledged that research at the national, regional and international levels is crucial from the perspective of the socioeconomic and cultural development of states. The recognition of the role of research in development across the African continent is reflected in the desire of authorities to support research and the valorization of research results. Since 2006, the Member States of the African Union have decided to earmark at least 1 per cent of their GDP for research. In the

¹¹Michel P Sedogo, *Research Findings Development Programme and Innovations in Burkina Faso* (2009).

¹²OECD, *Science, Technology and Industry Outlook* (2012).

¹³Aw Samba, *Information and Optimization of the Results of Agricultural Research in West Africa*, Information Librarian - Sciences (2002).

same vein as the New Partnership for Africa Development (NEPAD), the African Union plans to establish a sub-regional research pole throughout the Continent.¹⁴

From the standpoint of natural and human resources, there are several African researchers and engineers working at present in foreign institutes and in large structured factories; students in well-known international universities can also provide a valuable contribution to supply valorization and optimization. Consideration should also be given to the importance of the richness of the subsoil in certain regions of the African continent that are still not sufficiently explored and hold enormous potential in pharmacopoeia and in other spheres.

Beyond the increase in the structures and actors involved in research and innovation, and the creation of several frameworks for the expression and broadcasting of research, invention and innovation results, it should be pointed out that Africans are looking more and more to entrepreneurship and becoming interested in innovation and intellectual property subject matters.

IV. PROSPECTS

Given the behavioral, sociocultural, institutional, political and economic constraints hampering research efforts and the development process of African countries, research and innovation results should be maximized at the political, institutional, social and economic levels.

A. POLITICAL AND INSTITUTIONAL LEVELS

(i) Reforming universities, institutions and research centres

In the current economic context and the race for knowledge, universities, institutes and research centres are changing their structures to take into account current concerns. These changes may not only involve redefining relations with their economic, social and cultural environment, but also with their traditional mission of valorization.

A new system for rewarding outcomes from the utilization of research results must be clearly established to serve as a stimulant for researchers. In order to promote the creation of enterprises through research results, researcher funding should be introduced, in order to assist contractors. Elsewhere,

a linkage must be made between industrial property title handling and researchers' career system of valorization and appreciation.

(ii) Universities, institutes and research centres must be provided with adequate structures

To improve the management of marketing and industrial activities in universities, institutes and research centres, valorization units should be established. The focus of their work should be on:

- Technical and marketing identification of issues relating to the valorization of various research outcomes so as to gauge potential for trade;
- protection of research and innovation results and findings;
- formulation of strategies for research issue valorization;
- transaction, writing and management of research contracts and allowances;
- development plan for setting up and financing these projects; and
- management of intellectual property title security.

Furthermore, in order to contribute to states' economic growth, universities, institutes and research centres must be allowed to undertake costly activities, create innovative enterprise incubators, exploit patents and licences and market their business products.

(iii) Establishing a framework of incentives for research and innovation

Establishing an innovation and research framework, which is subject to financial constraints, can help ease impediments to research, development and innovation, encouraging loans for the purpose of stimulating enterprises' research efforts.

B. ECONOMIC LEVEL

At the economic level, African countries must respect the agreement from 2006 to grant at least 1 per cent of their GDP to research.¹⁵ Therefore

¹⁴ Pan African Conference on the role and place of the University in the 21st century Rabat (Morocco), Africa, 21-23 November 2011.

¹⁵ Pan African Conference on the role and place of the University in the 21st century Rabat (Morocco), Africa, 21-23 November 2011.

diversification of research financing sources can be achieved through the development of partnerships with the private sector, and international cooperation and economical research results generation for the private sector. In addition, cooperation and collaboration of efforts between intra-nation and inter-African partnerships would enable the optimization of existing infrastructures and plants.

However, developing an appropriate loan system will be crucial to stimulating research efforts of enterprises through support processes.

C. BEHAVIORAL AND SOCIOCULTURAL LEVEL

At the behavioral and socio-cultural level, it is important to emphasize:

- Ongoing training of employees in the area of research and innovation;
- collaboration should be enforced between research units and enterprises to enhance comprehension of their research needs and issues;
- private sector actors' awareness of new technologies;
- promotion of mobility, exchange and inter-African and international cooperation;
- the valorization sector should be taken into account in the preparation of research plans;
- innovators and researchers should be encouraged to share their findings and protect and value innovation and research outcomes; and
- decision makers and partners should be made aware of the role and importance of research results and valorization in the development process.

V. CONCLUSION

The importance of research and development for enterprises and States' competitiveness is well known, especially in the current context of globalization, characterized by increased rivalry and competition and ever more demanding consumers.

In short, promoting research, development and innovation coupled with the valorization of innovation and research results is a real challenge for African countries. Meeting this challenge will lead to the creation of wealth and sustainable economic development in Africa.

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3 A CONTEXTUAL FRAMEWORK FOR DESIGNING AND IMPLEMENTING LAWS AND POLICIES TO PROMOTE ACCESS TO MEDICINES IN CAMBODIA

Dr Phin Sovath*

ABSTRACT

This paper briefly reviews the TRIPS public health-related flexibilities within the international legal framework, as well as Cambodia's national policies, laws and regulations, and then assesses to what extent such flexibilities have been incorporated and utilized under its intellectual property (IP) policies, laws and regulations. It concludes that Cambodia has failed to incorporate and utilize fully the TRIPS public health-related flexibilities for three reasons. First, the Patent Law followed the WIPO Draft Industrial Property Act, which was developed many years ago and lacked these flexibilities. Second, since its adoption in 2003, the Cambodian Patent Law has never been reviewed and modified so as to take advantage of these flexibilities, in particular those envisaged in the Doha Declaration and put in place after its adoption, such as the transitional period for pharmaceutical products until 2033 and the special compulsory licensing system under the August 30 Decision. Third and lastly, the draft Compulsory Licensing Law (CL), incorporating the flexibilities under the August 30 Decision, was finalized but has not been endorsed or adopted. These reasons also serve as lessons learned for other countries that need to address the same issue in relation to IP and public health.

Keywords: *Intellectual property, TRIPS Agreement, flexibilities, public health, compulsory licence, Doha Declaration, August 30 Decision, Paragraph 6*

I. INTRODUCTION

As a least developed country (LDC), Cambodia is not obliged to comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) until the lapse of the transitional period in July 2021.¹ In particular, Cambodia is not obliged to provide patent protection of pharmaceutical products under its patent law. Accordingly, at present Cambodia's patent law excludes pharmaceutical products from the subject matters of the patent protection. Although

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¹ In its draft working party report, Cambodia requested a 2009 transition period. Finally, WTO Members pressed Cambodia to accept a 2007 transition period. However, due to the status of Cambodia as an LDC, it is entitled to the general transitional period agreed upon by all WTO Members.

Cambodia does not provide patent protection for pharmaceutical products, it faces three main challenges in relation to intellectual property (IP) and public health.

The first challenge is access to affordable medicines. Cambodia has so far made significant progress in promoting access to affordable medicines for the anti-retroviral (ARV) treatment of persons living with HIV and for the treatment of both communicable and non-communicable diseases, such as hepatitis C, heart and vascular diseases, diabetes and cancer.² This achievement has been made possible owing to various global sources of funds and the increasing competition among generic versions of patent-protected medicines. However, Cambodia's access to affordable generic medicines is not guaranteed in the long term because the global fund resources on which Cambodia depends on to pay for the treatment are rapidly declining.³

The second challenge is diminished competition among generic versions of patent-protected pharmaceutical products in developing countries which have largely supplied those pharmaceutical products to Cambodian patients. Countries that supply Cambodia with generic medicines such as India could soon or later enter into bilateral or regional free trade agreements that might restrict them from exporting cheap and affordable generic medicines to Cambodia⁴ and consequently restrict Cambodia's access to cheaper generic versions of essential drugs that are under patent protection.

The third and last challenge is when Cambodia graduates from its LDC status due to its strong economic growth, an economic performance estimated by the Asia Development Bank and the World Bank to have shown solid growth in the previous three years. Such prolonged expansion has lifted Cambodia's gross national income per capita toward the \$1,045 threshold for entry into lower-middle-income status.⁵ As part of its economic development strategy, Cambodia plans to graduate from a lower-middle income country to a

² See World Bank, Overview: Cambodia <<http://www.worldbank.org/en/country/cambodia/overview#2>> accessed 17 January 2016. According to the World Bank, Cambodia has also been successful in combating HIV/AIDS, tuberculosis and malaria. HIV prevalence among adults aged 15 to 49 decreased from 0.9 per cent in 2006 to 0.7 per cent in 2012. In 2014, 89 per cent of active AIDS patients in Cambodia had access to antiretroviral treatment, a rate of coverage that is among the highest in the developing world.

³ It is expected that there will be a decline in the total global fund of 55.3% for the next three years 2015, 2016 and 2017. See the National Aids Authority, *Cambodia Country Progress Report* (National Aids Authority 2015) 33.

⁴ Those countries include India and other countries which are involved in bilateral and regional trade agreements such as TPP and the India-EU Trade Agreement.

⁵ See May Kunmakara and Ananth Baliga, *Nearing Lower-Middle Income* Phnom Penh Post (Phnom Penh 17 July 2015) <<http://www.phnompenhpost.com/business/nearing-lower-middle-income>>

higher-middle income country in 2030.⁶ At that juncture, Cambodia will no longer be classified as an LDC and will be obliged to comply fully with the TRIPS Agreement, in particular regarding the protection of pharmaceutical products.

In promoting access to affordable medicines, Cambodia recognizes this as a critical issue of public health and human rights, and ultimately of poverty reduction and human development. Cambodia has thus recently adopted the National Intellectual Property Strategy (NIPS), which addresses access to affordable medicines throughout the text. Cambodia is also in the process of drafting a law on compulsory licensing for public health, in order to address a public health crisis in the event of a national health emergency, extreme urgency or public non-commercial use.

The NIPS was questionable, however, in respect of its assumption, information and evidence and failed to give adequate consideration to the public health implications of patented pharmaceutical products. The drafting of the law on compulsory licensing for public health has also met, both at the national and international levels, with various political and legal challenges. Even its future adoption and implementation cannot be precisely predicted. Moreover, several other existing related laws and policies, including a law on patents and a law on the management of pharmaceutical products, have not been reviewed to assess whether they are supportive of public health and to what extent they have incorporated and utilized flexibilities available under the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health.⁷

These challenges and failures raise three key questions: (1) how to promote access to affordable medicines, as a critical issue of public health and human rights, and ultimately of poverty reduction and human development; (2) how Cambodia's existing laws and policies should be reviewed and revised within the national and international context; and (3) how to balance public health interests and the interests protected by IP laws and policies.

In order to address these three questions, this paper will briefly review the international legal framework of IP and public health in Part II, and the flexibilities provided to WTO Members in relation to public health. Part III of this Paper will review Cambodia's national laws and policies relating to IP and public health and assess whether they promote or obstruct access to affordable

medicines. Part IV will assess to what extent Cambodia has taken advantage of the IP and public health international legal framework and relevant flexibilities, and draw lessons learned and implications for other countries. Finally, after discussion, Part V will draw the relevant conclusions.

II. THE INTERNATIONAL LEGAL FRAMEWORK OF IP AND PUBLIC HEALTH

The TRIPS Agreement was adopted in 1994 and represents the most far-reaching international agreement that sets the global minimum substantive standard of protection for IPRs such as protectable subject matters, requirements and conditions for protection, protected rights, and minimum duration of protection, as well as enforcement obligations and dispute settlement mechanism.⁸ Regardless of its adoption, debates on the balance between the private interests of right holders and the public interests of users and governments for their development needs have started and continued both prior to and after the adoption of the TRIPS Agreement.

After continuous debates among WTO State Members, a number of flexible provisions were incorporated under the TRIPS Agreement to promote public health and access to medicines, and a declaration and decision on the intersection between IP and public health was adopted. The following sections will provide an overview of the public health-related flexibilities contained in the TRIPS Agreement, along with the declaration and decision within the international legal framework of the TRIPS Agreement.⁹

⁶ See National Strategic Development Plan 2014-2018 (RGC 2014) 118.

⁷ WTO, *Doha Declaration on the TRIPS Agreement and Public Health*, 14 November 2001 (the Doha Declaration) <https://www.wto.org/english/thewto_e/minist_e/min01_e/m_indecl_trips_e.htm> accessed 17 January 2016.

⁸ As a least developed country (LDC), Cambodia is granted an extension of the transition period up to 1 July 2021 to implement the TRIPS Agreement.

⁹ Owing to the limited space of this Paper, this subject is not discussed in detail. For a detailed explanation and discussion, see UNDP, *Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement* (UNDP 2010) (the UNDP Good Practice Guide).

A. PUBLIC HEALTH - RELATED TRIPS FLEXIBILITIES

Under the TRIPS Agreement, there are several provisions that relate to TRIPS flexibilities that can be utilized by WTO Members to promote public health. A good practice guide published by UNDP divides these public health-related TRIPS flexibilities into three types: preventive, remedial, and enforcement. The three types of public health-related TRIPS flexibilities are summarized in a table below.

Among these public-health-related TRIPS flexibilities, certain flexibilities were incorporated into the Patent Law of Cambodia. Part III of this Paper will examine and review the Patent Law and identify which flexibilities were incorporated, as well as explain why they were not used to the fullest extent.

B. DOHA DECLARATION AND DECISION ON IP AND PUBLIC HEALTH

The debate on public health and access to medicines was initiated in 2001 in Doha, Qatar to clarify the ambiguities between the need for governments to implement the TRIPS Agreement and to protect the right to health.¹⁰ Developed countries, developing countries and LDCs took part in this discussion concerning IP and access to medicines, which led to the adoption by WTO Members of the 'Doha Declaration on the TRIPS Agreement and Public Health' (the Doha Declaration) in 2001. The Doha Declaration affirms that the TRIPS Agreement 'does not and should not prevent Members from taking measure to protect public health' and that it:

| Public Health-Related TRIPS Flexibilities | Examples and Relevant References |
|---|---|
| <p>Preventative:</p> <p><i>Policy options to ensure that patents do not hinder access to affordable medicines.</i></p> <p><i>Advantages: easier, faster, less politically sensitive compared to some remedial measures.</i></p> | <p>Exclusion from Patentability: exclude new use of known substances, methods and processes (Articles 27.2 and 27.3)</p> <p>Patentability Criteria: develop and apply strict patentability criteria for examination of pharmaceutical patents. Mitigate frivolous patents and "evergreening" opportunities. (Articles 1 and 27.1).</p> <p>Patent Opposition: allow pre-grant and post-grant patent opposition in fast, accessible and cost-efficient manner.</p> <p>Waiver for LDCs: LDCs should utilize the waiver to provide patent protection for pharmaceuticals until 1 January 2016 (<i>now 1 January 2033</i>) (and possibly longer, if extended).</p> |
| <p>Remedial:</p> <p><i>Preventative flexibilities cannot always be used to meet existing and emerging needs to secure access to affordable medicines. Therefore, series of remedial flexibilities are included in the TRIPS Agreement.</i></p> | <p>Compulsory Licences and Government Use Orders</p> <p>(Article 31 (a)-(j))</p> <p>Compulsory Licences for Export under the WTO 30 August, 2003 Decision.</p> <p>Exceptions: Bolar (early working) exception, research and experimental use exception, individual use (Article 30)</p> <p>Use of National Competition Laws to prevent IPR abuse and provide remedies (Articles 8.2, 31(k) and 40)</p> <p>Parallel Importation (Article 6)</p> |
| <p>Enforcement:</p> <p><i>Related to obligations under Part III of the TRIPS Agreement, which sets minimum standards for IPR enforcement.</i></p> | <p>No border measures for suspected patent infringement (Article 51)</p> <p>No criminalization of patent infringement (Part III, Section 5)</p> |
| <p>UNDP, Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement, 15 (2010)</p> | |

¹⁰ See UNDP Good Practice Guide 6-8.

can and should be interpreted and implemented in a manner supportive of WTO Members' right to promote public health and, in particular, to promote access to medicines for all.¹¹

In paragraph 4, the Doha Declaration formally affirms that WTO State Members should have the right 'to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.'¹² The Doha Declaration then spells out in paragraph 5 that, within the context of the TRIPS Agreement, these flexibilities include:

- The right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted; and
- the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

The Doha Declaration, however, failed to address an issue under paragraph 6. Recognizing that:

WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.

The Ministers charged the Council for TRIPS to find 'an expeditious solution' to the issue. For about two years, the Council for TRIPS implemented its mandate and finally presented the expeditious solution to WTO Members. In August 2003, a decision on the implementation of Paragraph 6 of the Doha Declaration was adopted by WTO Members, establishing a system under which a country can issue a compulsory licence for the purpose of exporting generic medicines to countries with insufficient or no manufacturing capacity (the August 30 Decision).

The August 30 Decision introduced two important waivers to Article 31 of the TRIPS Agreement. The first waiver concerns the requirement of TRIPS Article 31(f) for predominant domestic use, which provides a mechanism that allows WTO Members to issue compulsory licences for the export of generic

¹¹ Ministerial Declaration on the TRIPS Agreement and Public Health, paragraph 4.

¹² *ibid.*

equivalents of patented medicines to countries with no or insufficient pharmaceutical manufacturing capacity. The second waiver concerns the obligation of importing countries under the requirement of TRIPS Article 31(h). A number of conditions must be satisfied in order to implement the August 30 Decision.¹³

The use and implementation of the August 30 Decision is optional, not mandatory and thus each WTO Member can decide whether or not to use and implement it. Among the WTO Members with express implementing laws or regulations, there are three categories of Members that have implemented the August 30 Decision:

- exclusively as exporters (41 Members);
- exclusively as importers (three Members); or
- both as exporters and importers (seven Members).¹⁴

On 1 November 2011, Cambodia expressly submitted an Instrument of Acceptance of the amendment of the TRIPS Agreement that it will use and implement the August 30 Decision, both as exporter and importer.¹⁵ However, Cambodia has not adopted any domestic law or regulation for such use and implementation. A law on compulsory licensing for public health is being drafted, but this process is lengthy and is proving challenging since the introduction of the first draft by experts and the Ministry of Health, who is in charge of this law. Section III below spells out the details of this draft law, while discussing some of the key challenges facing Cambodia.

III. NATIONAL LEGAL AND POLICY FRAMEWORK FOR IP AND PUBLIC HEALTH

Patents are the most relevant type of IP in the context of public health. In 2003 Cambodia adopted for the first time a Law on Patents, Utility Model Certificates, and Industrial Designs (the Patent Law). The Patent Law is supplemented by two important regulations on patents, utility models and industrial designs, namely the Prakas on Procedures for Granting Patents and Utility Model Certificates (2006) (the Patent Regulation), and the Prakas on Procedures for Registration of Industrial

¹³ For a detailed explanation on these requirements, see Frederick M Abbot and Rudolf V Van Puymbroeck, *Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*, World Bank Working Paper No. 61 (World Bank 2005).

¹⁴ See Roger Kampf, *Special Compulsory Licences for Export of Medicines: Key Features of WTO Members' Implementing Legislation*, Staff Working Paper ERSD-2015-07, 8 (Economic Research and Statistics Division, WTO 2015).

¹⁵ See WTO, WT/Let/833.

Designs (2006). These two regulations provide guidelines both for the Patent Office and inventors, on how to grant patents and utility model certificates and how to register industrial designs. The Patent Law and the two regulations are fundamental legal frameworks for the protection of patents, utility models and industrial designs in Cambodia.

The following sections will review the NIPS, the Patent Law and Patent Regulation in relation to public health.¹⁶

A. NIPS IN THE CONTEXT OF PUBLIC HEALTH

In line with objectives and challenges raised in the Second Health Sector Strategic Plan 2008-2015, the NIPS has identified five areas where the IP system should be managed to ensure that it contributes positively to public health in Cambodia:

- Fostering the growth of the pharmaceutical industry in Cambodia;
- controlling and reducing the price of pharmaceuticals by taking advantage of the flexibilities available under the TRIPS Agreement to access essential medicines;
- providing tools to assist with enforcement action against providers of counterfeit pharmaceuticals;
- facilitating collaboration with outside health organizations to share technologies, treatment methods and pharmaceuticals that otherwise may not be made available without adequate IP protection;
- providing mechanisms for the control and protection of traditional medicines and traditional medicine practices, and opportunities for protection of innovations in this area.¹⁷

In order to support these five areas, five initiatives were adopted in the NIPS in relation to IP and public health for implementation within short-, medium- and long-term timelines.¹⁸ Some of the initiatives have been launched and implemented by the relevant ministries in charge, while others have yet to start or be developed. Hence, an evaluation of what needs to be done and what has not been done by the relevant ministries should be undertaken to identify and share both the

success stories and the challenges facing the relevant ministries in their implementation.

B. PATENT LAWS AND REGULATIONS IN THE CONTEXT OF PUBLIC HEALTH

In addition to the NIPS, Cambodia has the Patent Law, which does not grant patent protection to pharmaceutical products until 1 January 2016. Pharmaceutical products were clearly excluded from the subject matters of patent protection¹⁹ and will be granted accordingly from 1 January 2016.²⁰

Although the Patent Law does not provide patent protection to pharmaceutical products, the Patent Office has, however, accepted patent applications for pharmaceutical products since 2007 under the Patent Regulation.²¹ Thus Cambodia has practiced a mailbox system, although it is not obliged under the TRIPS Agreement to have this system in place. The mailbox would be opened starting in January 2016, at which time Cambodia would need to grant patent protection in accordance with the Patent Law as from the grant of the patent and for the remainder of the patent term, counted from the filing date.²² Following the granting of patent protection, access to generic medicines would be potentially restricted because the medicines are patented.

Even though a patent is granted to pharmaceutical products, there are some situations in which a government agency or a designated third party can exploit the invention without the agreement of the patent holder²³, in particular when the public interest, including national security, nutrition, health or the development of other vital sectors of the national economy so requires; when the exploitation by an owner is anti-competitive;²⁴ when the patented invention is not worked or worked but not sufficiently;²⁵ or when there is an interdependent patent.²⁶ This is called a 'compulsory licensing' or 'a non-voluntary licensing' system. In such situations, however, a compulsory licence must be issued in compliance with the following requirements and conditions:

- Adequate remuneration (Article 47);
- an authorization may be obtained only if efforts have been made to obtain a contractual licence and have failed with exceptions (Article 52);

¹⁶ Owing to space limitation, this Paper will not discuss the laws and regulations on the management of pharmaceutical products, which also have a potential impact on the access to medicines in Cambodia.

¹⁷ *ibid.*, 43.

¹⁸ *ibid.*, 43-48.

¹⁹ The Patent Law, Article 4.

²⁰ The Patent Law, Article 136.

²¹ The Patent Regulation, Rule 45.

²² *ibid.*

²³ The Patent Law, Articles 11 and 12.

²⁴ The Patent Law, Article 47.

²⁵ The Patent Law, Article 56.

²⁶ The Patent Law, Article 59.

- non-exclusive (Article 51);
- limited transfer of the authorization (Article 50);
- predominantly used for the supply of the domestic market (Article 53);
- variation of decision (Article 48);
- termination of decision (Article 49);
- subject to appeal (Article 55).

Under the Patent Law, condition No. 2 above will not apply when the compulsory licence is issued for the purpose of national emergency, extreme urgency and public non-commercial use.²⁷ Conditions No. 4 and No. 5, however, are the same as Article 31 of the TRIPS Agreement and have not been modified since its adoption in 2003, even though these conditions are partially or fully waived by the August 30 Decision of the Council for TRIPS. These conditions will be spelt out in more detail in Part IV.

C. DRAFT LAW ON COMPULSORY LICENSING FOR PUBLIC HEALTH

Since 2004, with assistance and support from development partners such as UNDP, UNAIDS and WHO, the Ministry of Health of Cambodia has started the discussion about IP and public health and the process of drafting the law on compulsory licensing for public health (the CL Law) has already been initiated since that time. Until now, however, the draft CL Law has not yet been adopted. The current version of the draft CL Law has already been discussed and finalized by the technical working group of the Ministry of Health and other relevant ministries. The next step in the process will be the endorsement of the Council of Ministers, the submission to the National Assembly and the Senate, and then the promulgation of the CL Law by the King.

The draft CL Law is a standalone law, separate from the Patent Law. It intends to incorporate flexibilities under the Doha Declaration and the August 30 Decision, in order to promote access to affordable medicines through the use and implementation of the special compulsory licensing system, that is, the import and export of medicines through this system. As long as the CL Law has not been adopted, however, the use and implementation of the August 30 Decision have yet to be realized. Consequently, it will potentially impact the access to medicines for patients in Cambodia.

IV. LESSONS LEARNED AND IMPLICATIONS FOR OTHER COUNTRIES

After reviewing and discussing the international and national legal framework in Part II and Part III, some lessons can be learned from Cambodia's experience, together with implications for other countries when they seek to address the balance between IP and public health. The following sections will spell out those lessons and implications in more detail.

A. NO FULL USES OF PUBLIC HEALTH-RELATED TRIPS FLEXIBILITIES

The Cambodian Patent Law was adopted in 2003 and since then it has never been modified or amended. The drafting of the Patent Law followed a WIPO Model Law called 'Draft Industrial Property Act for [Country] and Commentary on Its Main Provisions'. Consequently, the Patent Law incorporated certain flexibilities and left other flexibilities unstipulated. The following table summarizes what flexibilities were incorporated and which flexibilities were not incorporated by using the three types of flexibilities developed by the UNDP Good Practice Guide.

²⁷ The Patent Law, Article 52, para 2.

| Type of Flexibilities | Incorporated | Not Incorporated |
|-----------------------|--|---|
| Preventative | Waiver for LDCs: Patent protection for pharmaceuticals until 1 January 2016 (Article 136 of the Patent Law). | Exclusion from Patentability: exclude new use of known substances, methods and processes (Articles 27.2 and 27.3) Patentability Criteria: develop and apply strict patentability criteria for examination of pharmaceutical patents. Mitigate frivolous patents and "evergreening" opportunities. (Articles 1 and 27.1). Patent Opposition: allow pre-grant and post-grant patent opposition in fast, accessible and cost-efficient manner. Waiver for LDCs: Cambodia has not yet amended its Patent Law to the exception for patent protection for pharmaceuticals until 1 January 2033 (and possibly longer, if extended). |
| Remedial | Government Use and Non-Voluntary Licence (Article 47-64 of the Patent Law) International Exhaustion (Article 44(i) of the Patent Law) Exceptions: Research and experimental use exception, individual use (Article (iii)(iv) of the Patent Law) | Compulsory Licences for Import and Export under the August 30 Decision. Exceptions: Bolar (early working) exception (Article 30) Use of National Competition Laws to prevent IPR abuse and provide remedies (Articles 8.2, 31(k) and 40) |
| Enforcement | No border measures for suspected patent infringement | No criminalization of patent infringement (Part III, Section 5) |

As set out in the above table, the Cambodian Patent Law has failed to incorporate fully the key TRIPS public health-related flexibilities. There are three main reasons for this failure: First, the Patent Law followed the WIPO Draft Industrial Property Act, which was developed several years ago and did not contain all of these flexibilities. Second, since its adoption in 2003, the Cambodian Patent Law has never been reviewed or modified to take advantage of these flexibilities, in particular those envisaged in the Doha Declaration and put in place after its adoption, such as the transitional period for pharmaceutical products until 2033 and the special compulsory licensing system under the August 30 Decision. Third and last, the draft CL Law, incorporating the flexibilities under the August 30 Decision, was finalized, but has not been endorsed or adopted.

In addition to the above findings, the Patent Regulation is also problematic since the Patent Office had adopted and implemented the mailbox system since 2007. In light of the recent development with regard to this issue, Cambodia as a LDC is not required to establish

such a mailbox system.²⁸ Therefore, the Cambodian Government needs to address two issues urgently. The first issue concerns the current version of the Patent Regulation, which should be amended to abolish the current mailbox system. The second issue concerns the applications which have been filed with the Patent Office since 2007 and particularly whether those applications should be opened from 1 January 2016 or they should not be opened until the lapse of the new transitional period (2033).

²⁸ See WTO Decision on Obligations under Article 70.8 and Article 70.9 of the TRIPS Agreement with respect to Pharmaceutical Products, dated 30 November 2015, WT/L/971.

B. CHALLENGES OF DRAFTING THE LAW ON COMPULSORY LICENSING FOR PUBLIC HEALTH

In the process of drafting the CL Law, Cambodia has faced many challenges and four of them can be summarized as follows²⁹:

- **Overlapping Jurisdiction:** there has been a lengthy debate over whether or not MIH should be in charge of implementing the Patent Law or MOH in charge of public health should be the institution in charge of issuing compulsory licences for public health.
- **Reasonable Royalty:** the stakeholders had little understanding about the standard reasonable royalty, which continues to be debated, or of other countries' experience.
- **Penalty:** a question has also been raised as to how to stipulate those provisions in the draft CL Law, without limiting the public health protection offered by the compulsory licence.
- **Implementing Regulations:** the draft CL Law sets forth only basic principles and procedures, but does not contain detailed provisions, which need to be provided for in subsequent implementing regulation.

The reasons for these challenges are threefold. First of all, there is a very limited human resource that can understand the intersection of IP and public health. Second, although there are some model provisions and guides available for drafting the compulsory licensing system³⁰, they are purported to be incorporated into the patent law, but not in a standalone law such as in Cambodia. Third, limited human resource and capacity have prevented Cambodia from using and taking advantage of those model provisions and guides, which are available mostly in English. The actual use and implementation of the August 30 Decision will take place within the context of each country's existing legislative and regulatory framework, practice and

²⁹ See Lim Ratanak, Cambodia's Draft Law on Compulsory Licensing and Public Health, Presented at the Workshop on Trade and Access to Medicines in Cambodia, 11-12 November 2013, Siem Reap, Cambodia.

³⁰ Those model provisions and guides include Frederick M Abbot and Rudolf V Van Puymbroeck, *Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*, World Bank Working Paper No. 61 (World Bank 2005), and Correa M Carlos, *Compulsory Licensing: How to Gain Access to Patented Technology*, in *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds A Krattiger, RT Mahoney, L Nelsen, et al), available online at <<http://www.ipHandbook.org>>

jurisprudence. Therefore, the Government of Cambodia should work closely with its own experts to draft and adopt the CL Law appropriate for Cambodia's unique situation.

V. CONCLUSION

Cambodia is a LDC Member of the WTO since October 2004. It has adopted all key laws and regulations related to IP rights, and at the same time it has made efforts to introduce new laws and policies to address public health issues. The opportunities and challenges facing Cambodia are interesting and are helpful lessons which should be shared with other policy makers and researchers from other countries or regions, in particular its experience and lessons on how the existing laws and policies should be reviewed and revised within the national and international context to balance public health interests and the interests protected by IP laws and policies.

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4 INTELLECTUAL PROPERTY PROTECTION OF CLINICAL TRIAL DATA

Dr Doaa Abdelrahman*

ABSTRACT

Researchers who conduct clinical research with human subjects face a profound problem related to the protection of their work throughout the study and before reaching the final result. Clinical trial processes are one of the most important and perilous scientific processes, particularly from the legal perspective. There are various legal instruments embodying the legal and ethical principles, rights and obligations of research subjects and investigators, and procedures relating to the clinical trial process.

Current protection under intellectual property rights (IPRs) does not provide appropriate legal coverage of the clinical trial process. In order to ensure a suitable degree of protection, a new form of IPR is required that would be compatible with the nature of the data and information collected. The form of IPR proposed in this Paper will be known as the Clinical Trials Right (CTR). The CTR would protect all data and information stemming from the drug development process. It would also cover the work carried out by investigators before and during the trial.

Creating a new form of clinical trial data and information protection would encourage investments in the field of pharmaceutical inventions and provide an effective process for the circulation of information. In addition to enhancing pharmaceutical research and industries, it would also ensure a balance of benefits between the sponsor and investigators on the one hand, and the competitors on the other.

Keywords: *Clinical trials, works of investigators, new form of intellectual property rights, data protection*

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I. INTRODUCTION

The clinical trial process is one of the most important and perilous medical and scientific processes, particularly from the legal perspective. There are several reasons for this. First, it is a vital step in the drug development process since no drug or medicine can enter the markets without undergoing a clinical trial. Second, if they have not been provided with a proper degree of legal protection, this process could infringe the safety, security and welfare of the individuals who are subject to it. Hence, the process should be governed by precise laws and legislations to ensure a suitable degree of protection for research subjects.

There are several international legal instruments dealing with the clinical trial process. These legal instruments deal with legal and ethical principles, the rights and obligations of both research subjects and investigators, and the procedures to be followed during the clinical trial process. The most important instruments are the Nuremberg Code and the Declaration of Helsinki.

Both of these international legal instruments, as well as others, are silent, whether explicitly or tacitly, as to the method of data and information collection during the clinical trial process. In fact, the clinical trials process is costly in most cases in the long run¹, and thus necessitates a proper degree of legal protection.²

The author's suggestion that the work undertaken by investigators during the clinical trial process should be protected is based on reviewing the different forms of legal protection available for intellectual property rights (IPRs), analysing the possibility and scope of application, and selecting the best form of protection and how it might be useful. This article will cover the following topics: a brief overview of clinical trials, the various types of protection for the IPR and finally, it will determine the best form of protection for clinical trial data and information.

II. WHAT ARE CLINICAL TRIALS?

It seems difficult to imagine our life without clinical trials because medicines and drug inventions have been developed as a result.³ A clinical trial is a process carried out in scientific fields to test and study the effects of a new medicine by experimenting it on human subjects. The aim of the clinical trial is to test the safety and

¹ Joseph A DiMasi, Ronald W Hansen and Henry G Grabowski, 'The Price of Innovation: New Estimates of Drug Development Costs', (2003) 22 Journal of Health Economics 151.

² Tomi Suryo Utomo, 'Pharmaceutical Patent Protection and the Introduction of Generic Drugs in Indonesia in the Post-TRIPS Era -- Is Patent Law the Only Factor Affecting the Introduction of Generic Drugs?', (2011) 42 International Review of Intellectual Property and Competition Law, 767.

³ Sara Fovargue, "'Oh Pick Me, Pick Me'"--Selecting Participants for Xenotransplant Clinical Trials' (2007) 15 Medical Law Review 176.

medical efficacy of the new drug, and establish its advantages and drawbacks, as well as its side effects and use.⁴ The European Union Council defines clinical trials as:

any investigation in human subjects intended to discover or verify the clinical, pharmacology and/or pharmacodynamics effects of one or more investigational medicinal products, and/or to identify any adverse reactions to one or more investigational medicinal products and/or to study the absorption, distribution, metabolism and excretion of one or more investigational medicinal products with the object of ascertaining the safety and/or efficacy thereof.⁵

Likewise, the Medicine for Human Use Regulations 2004 (UK) defines clinical trials as:

any investigation in human subjects, other than a non-interventional trial, intended: (1) to discover or verify the clinical, pharmacological or other pharmacodynamics effects of one or more medicinal products; (2) to identify any adverse reactions to one or more such products; or (3) to study absorption, distribution, metabolism and excretion of one or more such products, with the object of ascertaining the safety or efficacy of those products.⁶

At the international community level, there are numerous legal documents that deal expressly with the clinical trial process. The most important one and the oldest is the Nuremberg Code, which dates back to the Nuremberg trials, when Nazi physicians and researchers had been found to conduct medical experiments on prisoners and hostages without their consent and without any means of compensation or recovery. This Code sets out the principles that were embodied in the judgement of the Court that decided this case in August 1947, and these principles were subsequently approved by the United Nations in 1948.⁷

In addition, the Declaration of Helsinki enacted by the World Medical Association in June 1964 sets out the ethical principles relating to medical research that

should be adopted in every clinical research involving human subjects.⁸

Moreover, the European Union Council has adopted several directives for member States to manage all aspects of clinical trials, including EU Directive 2001\20\EC and EU Directive 2005/28/EC.

On the national level, not all countries have adopted laws or regulations on organizing and managing the clinical trial process. Indeed, there are no legal instruments or regulations in some countries governing clinical trial-related matters, except largely broad provisions in their constitutions or in their national civil codes and other related legislations. By contrast, other countries, such as the United States of America⁹ and the United Kingdom¹⁰, have a well-organized legal system dealing with the clinical trial process.

Indeed, it is crucial to ensure the legal and medical protection of human subjects in medical and scientific research, because in a few cases this process may lead to death or severe injuries and reactions being sustained. Recent examples of clinical trials ending in catastrophic results are TGN1412¹¹ and *Abdullahi v. Pfizer*.¹²

⁸ Declaration of Helsinki 1964, available at: <http://www.wma.net/en/30publications/10policies/b3/17c.pdf>

⁹ Mainly, the clinical trials process is governed in the United States by the Code of Federal Regulation, Title 21 (Food and Drug) and Title 45 (Public Welfare).

¹⁰ The clinical trials' process is governed by the Medicines for Human Use regulations 2004 and its amendments.

¹¹ In 2006, a scientific research centre called 'Parexel' was tasked to operate and manage the clinical trials of a new drug called 'TGN1412' for a German company for the industrialization of medical instruments called 'TeGenero'. The new drug was developed for the treatment of rheumatoid arthritis and leukaemia. In March 2006, phase I of the clinical trial took place involving six of the healthy volunteers in order to examine the safety of this drug. After the first dosage, all the subjects experienced severe reactions, including multiple organ dysfunction, and they were then hospitalized in critical care in Northwick Park Hospital in London. In June 2006, five of the volunteers recovered and left the hospital, while the sixth volunteer was in a coma for three weeks and after awakening, discovered that he might lose parts of his fingers and toes, which had turned black because of the reaction to the drug. For more details about this case, see Pamela R Ferguson, 'Clinical Trials and Healthy Volunteers' (2008) 16; Medical Law Review 23; Sara Fovargue, "'Oh Pick Me, Pick Me"--Selecting Participants for Xenotransplant Clinical Trials', (2007) 15 Medical Law Review, 176; MJH Kenter and AF Cohen, 'Establishing Risk of Human Experimentation with Drugs: Lessons from TGN1412' (2006) 368 The Lancet 1387:91.

¹² In this case, a new medicine called 'Trovan' invented in 2002 by Pfizer, one of the largest pharmaceutical companies in the United States, which applied to experiment this drug on children in Nigeria. The investigation team selected 200 children as subjects in this clinical trial, and divided them into

⁴Pamela R Ferguson, 'Clinical Trials and Healthy Volunteers' (2008) 16; Medical Law Review 24

⁵ European Union Directive 2001\20\EC, Part 2 – Definitions - (a).

⁶ Medicines for Human Use Regulation 2004, Article 2(1), clinical trials.

⁷ Code of Nuremberg 1947, available at: <http://history.nih.gov/research/downloads/nuremberg.pdf>

The clinical trials process involves the following steps:

- Preclinical Testing I: scientists in their laboratories predict that certain chemical components may be effective in the treatment of a certain disease. A series of scientific experiments is then conducted in a laboratory to understand how those components work and what the most suitable chemical form is. The resulting information may or may not be proved to be useful for the treatment of the illness in the subsequent steps.
- Preclinical Testing II: in this step, scientists and researchers test the new components, which may be deemed to be useful or not, on animals in the laboratories. The aim is to examine the safety and medical effects of these components on animals that may have certain medical features similar to those of human beings. If scientists find that the new chemical entity could be useful to treat a certain disease, they can move to the next step and apply for the 'New drug investigation' process through the competent administrative authority.¹³
- Clinical trial Phase I: this is considered the first step in the clinical trial process. In phase I of the clinical trial process, the investigators select a limited number of human research subjects. The purpose of this phase is to test the safety of the new components when used on individuals and whether or not they may cause severe problems. In this phase, the number of research subjects is limited to

two groups. The investigators used the new drug with the first group, while the second used a placebo. As a result, eleven children died, six from the first group and five from the second one. In addition, a large number of children from the two groups experienced severe reactions, including paralysis, amnesia, deafness and blindness. The guardians of those children brought a case before the US District Court, Southern District of New York, requesting legal protection, because Pfizer did not abide by the legal rules governing clinical trials regarding the necessity of informed consent of the research subjects.

For more details about *Abdullahi v. Pfizer*, see Dennis M Coyne, 'International Pharmaceutical Mistrials: Existing Law for The Protection of Foreign Human Subjects and a Proposal for Reform', (2011) 29 Boston University International Law Journal 427; Finnuala Kelleher, 'The Pharmaceutical Industry's Responsibility for Protecting Human Subjects of Clinical Trials in Developing Nations' [2004] Columbia Journal of Law and Social Problems 67.

¹³ 'Understanding the Clinical Research Process and Principles of Clinical Research' (HIV/AIDS Network Coordination), p.9, available at: <http://www.hptn.org/web%20documents/CIPDocs/CABTraini ngMaterials/Participant's%20Guide.pdf>

between five to ten, and they usually receive a small dosage of the new drug.

In most clinical trials, the subjects in this phase are healthy volunteers, who agree to participate in the study and provide informed consent to this end.¹⁴ Owing to the inherent danger of this step, the investigator and his or her team collect detailed data and an up-to-date description of the research subjects, in order to determine whether to continue with the study or not, based on the results obtained during this phase.¹⁵

- Clinical trial phase II: if the investigators of the clinical trial are satisfied with the results of the previous phase, they then move to Phase II of the study. In this step the purpose of the trial is to examine the medical effects of the drug, to determine the proper dosage for treatment and to ascertain its side-effects. In this phase, the number of research subjects is increased to between 50 and 100 subjects.¹⁶ Selected volunteers may be patients or a mix of healthy and patient volunteers. The testing method is the control group technique, in which the volunteers are divided into two groups: the first group are given the new drug, while the second group are given the placebo. The aim of this phase is to test the medical effects of the new drug when compared with the placebo or the old medicine. If this step is completed successfully, the investigators can proceed to the next one.¹⁷
- Clinical trial Phase III: in this phase, a large number of patient volunteers are used to establish the safety degree of the drug and its medical effect, as well as its side-effects.¹⁸ The number of research subjects that participate in this phase may be around 200 patients.¹⁹ During all these phases of the trial, the progress of all the subjects and the interaction of the new drug with their medical situation

¹⁴ Sara Fovargue, "'Oh Pick Me, Pick Me'--Selecting Participants for Xenotransplant Clinical Trials', (2007) 15 Medical Law Review, 177.

¹⁵ David B Resnik, 'Compensation for Research-Related Injuries: Ethical and Legal Issues' (2006) 27 Journal of Legal Medicine, 265.

¹⁶ Pamela R Ferguson, 'Clinical Trials and Healthy Volunteers' (2008) 16 Medical Law Review, 25.

¹⁷ Richard M Cooper, "'Response", a Response to an Article Published in the Harvard Law Review", (2008) 121 Harvard Law Review Forum, 36; Joseph A DiMasi, Ronald W Hansen and Henry G Grabowski, 'The Price of Innovation: New Estimates of Drug Development Costs', (2003) 22 Journal of Health Economics, 157.

¹⁸ Emma Cave, 'Seen but Not Heard? Children in Clinical Trial' (2010) 18 Medical Law Review, 3.

¹⁹ Pamela R Ferguson, 'Clinical Trials and Healthy Volunteers' (2008) 16 Medical Law Review, 25.

are recorded by the investigators and assistance team. All these data must then be submitted to the competent authorities, who review all the phases of the study and decide whether to approve, require revision or reject it.²⁰

During these phases, all the collected data and information is recorded and analysed by the investigators and the team of researchers, who have undertaken the clinical research, so as to decide whether to continue with the process or not. This critical data and information is of high commercial value and will be used in subsequent steps of the process and in the licencing of the new drug (New Drug Application process (NDA)). When deciding to grant a licence for the new drug, licencing authorities are required to review the clinical trial's protocol and the outcomes of the clinical trial phases.

There is a need to protect all such data for a reasonable period of time during and after the clinical trials, and during the application of a licence and after it has been granted. However, neither the Nuremberg Code nor the Declaration of Helsinki expressly provide for protection of such data. Similarly, the Food and Drug Administration or the Medicines for Human Use Regulation are silent on the protection of work undertaken by researchers during the clinical trial process.

The often conflicting interests of stakeholders and the possible forms of protection for data and information collected before, during and after the clinical trial process will be discussed below.

III. CONFLICT OF INTERESTS WITHIN THE CLINICAL TRIAL PROCESS

The clinical trial process embodies a wide range of rights, advantages and interests for stakeholders. All those involved stand to gain from this process with different degrees of interest, including the pharmaceutical companies that fund the trial, the researchers and investigators that conduct the research, the research subjects and the public itself. However, these benefits and interests potentially conflict with one other.

The desire to protect data collected during the clinical trial process is a clear example of how stakeholders' interests might often conflict. Indeed, all the individuals

involved in the clinical trial process have differing interests in the data and information collected.

First, the pharmaceutical companies that sponsor and fund the research from its early moments until the marketing stage want the protection of all the trial data and information to be used exclusively for an extensive period of time.²¹ This interest may be understood given the economic value of the clinical trial information, which gives the sponsor a chance to maximize profit from marketing the new drug.

The process of developing new drugs costs millions of dollars²² and lasts for a sustained period of time.²³ In order for this process to be profitable, all these expenditures need to be protected during the development process and for a reasonable period of time. Although this point of view somewhat contradictory to the strategies adopted in most countries, some scholars consider that in order to ensure profitability, all data and information from the development process should be obscured and kept undercover, so as to prevent others from knowing, utilizing or exploiting them.²⁴

Second, the researchers and investigators involved in the development of the new drug have a scientific interest in the clinical trial data and information. The work undertaken in laboratories and in research centres includes formulating a new chemical entity; investigating the new chemical entity in preclinical phases on animals; investigating the new chemical entity in the phases of the clinical trial on human subjects; and observing its medical effect and safety after marketing.²⁵ The interest of the researchers and investigators is reflected in their desire to declare any progress achieved in their research and studies, to make it public in academic conferences or by publication in scientific journals and reviews.²⁶ Researchers stand to

²⁰ Richard M Cooper, "'Response', a Response to an Article Published in the Harvard Law Review", (2008) 121 Harvard Law Review Forum, 36; Joseph A. DiMasi, Ronald W Hansen and Henry G Grabowski, 'The Price of Innovation: New Estimates of Drug Development Costs', (2003) 22 Journal of Health Economics, 157.

²¹ Pamela Andanda, 'Managing Intellectual Property Rights Over Clinical Trial Data to Promote Access and Benefit Sharing in Public Health', (2013) 44 International Review of Intellectual Property and Competition Law, 140.

²² A study in 2010 estimated the values of developing new drugs to exceed \$1.8 Billion. Steven M Paul and others, 'How to Improve R&D Productivity: The Pharmaceutical Industry's Grand Change', (2010) 9 Nature Reviews: Drug Discovery, supplementary information box2.

²³ The drug development process takes about ten to fifteen years to formulate a new chemical entity, to examine its safety and efficiency through clinical trials and to apply for the necessary licensing and marketing approvals.

²⁴ Pamela Andanda 'Managing Intellectual Property Rights Over Clinical Trial Data to Promote Access and Benefit Sharing in Public Health' (2013) 44 International Review of Intellectual Property and Competition Law, 140.

²⁵ Carl H Coleman, 'Duties to Subjects in Clinical Research' (2005) 58 Vanderbilt Law Review, 387.

²⁶ Pamela Andanda, 'Managing Intellectual Property Rights Over Clinical Trial Data to Promote Access and Benefit Sharing in

gain from the announcement of the clinical research results in terms of their academic and scientific careers.²⁷

Third, research subjects have a personal interest not to reveal research data and information as the publication and announcement of the research results constitute an infringement of their confidentiality and privacy, as well as exploitation of their personal data for the sake of economic profit and scientific reputation. Yet, some potential research subjects ask to be clearly aware of previous studies in deciding whether to participate in the research.²⁸ The double standards methodology makes it difficult for research subjects to decide whether to support or oppose the protection of clinical trial data.

Furthermore, it is in the interest of the public to have updated knowledge and access to all data and information related to health-care and medicines sectors. The principle of access and benefit sharing (ABS) with respect to public health means that all studies and research in the medical field should be available and accessible to the public.²⁹ The goal of applying this principle is to enhance the ability of workers in the medical sector to deal with diseases and to ensure a proper degree of welfare for the public. In this regard,

[...] the struggle to combat human disease and to promote health is inherently international in character and is recognized as an element of maintaining international peace and security.³⁰

As a result of the conflict of interests inherent in the clinical trial process and especially when dealing with clinical data and information, it could be argued that these opposing interests make it difficult to adopt one point of view over the other. At the same time, these opposing interests pose considerable challenges in creating a unified system to address the issue of clinical trial data on an equal footing of profit for all stakeholders.

Public Health' (2013) 44 International Review of Intellectual Property and Competition Law, 140.

²⁷ Rachel Kreppel, 'Clinical Trials: A New Form of Intellectual Property?' 4, available at:

<http://www.kentlaw.iit.edu/Documents/Academic%20Programs/Honors%20Scholars/2002/Rachel-Kreppel-paper.pdf>

²⁸ Pamela Andanda, 'Managing Intellectual Property Rights Over Clinical Trial Data to Promote Access and Benefit Sharing in Public Health' (2013) 44 International Review of Intellectual Property and Competition Law, 141.

²⁹ Pamela Andanda, 'Managing Intellectual Property Rights Over Clinical Trial Data to Promote Access and Benefit Sharing in Public Health', (2013) 44 International Review of Intellectual Property and Competition Law.

³⁰ Antony Taubman, 'The International Patent System and Biomedical Research: Reconciling Aspiration, Policy and Practice' (2008) 10 The American Association of Pharmaceutical Scientists Journal, 526.

IV. WHAT KIND OF DATA SHOULD BE PROTECTED?

Before and during the clinical trial process, a vast amount of data is collected during every phase and submitted for the licensing process. Broadly speaking, the clinical trial data, which are intended to be protected, include³¹:

- Chemical formulas;
- clinical trial protocols;
- files of information provided to potential volunteers to clarify their knowledge;
- data and statistics collected during the various phases of the clinical trial; and
- final research results.

It should be noted that these are the minimum amounts of data which require legal protection. The exact set of data differs from case to case according to the type of study and its scientific value.³²

A. POTENTIAL WAYS TO PROTECT CLINICAL TRIAL DATA

In order to ensure a suitable degree of protection for clinical trial data, it is important to determine, firstly, the nature of the data and information. Essentially, all the data and information collected should be considered a form of intellectual property resulting from the mental work and efforts undertaken by the researchers and investigators involved in the process. Accordingly, the best method to protect these data and information would be recourse to the legal protection provided for IPRs in international conventions and national legislations.

Generally speaking, the different types of IPRs are³³: copyright and related rights; trademarks; geographical indications; industrial designs; patents; layout-designs (topographies) of integrated circuits; and undisclosed information. The TRIPS Agreement and other international conventions dealing with IPRs fail to

³¹ Pamela Andanda, 'Managing Intellectual Property Rights Over Clinical Trial Data to Promote Access and Benefit Sharing in Public Health', (2013) 44 International Review of Intellectual Property and Competition Law, 145.

³² Rachel Kreppel, 'Clinical Trials: A New Form of Intellectual Property?' 4, available at:

<http://www.kentlaw.iit.edu/Documents/Academic%20Programs/Honors%20Scholars/2002/Rachel-Kreppel-paper.pdf>

³³ As stated in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), administrated by the World Trade Organization (WTO) 1994.

address the protection of clinical trial data.³⁴ Hence the focus will be on already established IPRs, especially those that lend themselves to ensuring suitable protection of clinical trial data and information. A detailed explanation will follow on the applicability of copyrights, patents and undisclosed information to clinical trial data.

Copyright: From the standpoint of the clinical trial process, copyright could be used to protect the broad range of work undertaken by both researchers and investigators, including written reports and statistics, published papers on the study's results, and any files and documents submitted to the administrative authorities as a condition for the application of a licence or for marketing approval.³⁵

As stated, protection under copyright could be applicable to the work undertaken by investigators in the clinical trial process. However, because copyrightable works need to be published or made available for the public to benefit from copyright protection, this type of protection is unsuitable in the clinical trial arena. In other words, this work cannot be covered by copyright since the goal is to protect the work undertaken by investigators during the clinical trial process and before arriving at the final results or publishing them in conferences or scientific reviews. It is well known that in order to protect the data and information gathered during the clinical trial process, the work must be announced to the public.³⁶

Patents: When patent rules are applied to clinical trial data, the patent protection may include the new chemical entity, the formulation of the new drug, and the final results of the study and the manufacturing method of this new drug. All these inventions are patentable as provided for in the TRIPS Agreement.

In the pharmaceutical industry, both the pharmaceutical product itself and the manufacturing process can be patented. The application for a patent should therefore clearly state the subject matter of the patent application, and whether it concerns a new drug or the manufacturing process or both, the patent protection being restricted to the subject matter of the patent application.³⁷

By contrast, the following are not patentable: the clinical trial's protocol; any data and statistics collected during the various phases of the clinical trial; and data and files submitted to the authorized licencing agencies.³⁸ This is normal, because the previous types of clinical trial data do not satisfy patent requirements, especially the condition of capability of industrial application.³⁹ From this perspective, sponsors and investigators do not have the right, either to have exclusive use of these data during the trial, or to prevent others from using, exploiting, selling or offering such data for sale.

In short, patent rights may be used to protect certain forms of clinical trial data, but are not applicable to other forms due to the absence of patent conditions and requirements.

Undisclosed Information: When the rules of Undisclosed Information (UI) are applied to clinical trial data, one can say that there is a wide range of data and information that may be protected by the UI, including the clinical trial's protocol; files and documents made available to potential research subjects; files and documents submitted to administrative authorities; data and statistics on the progress of research subjects; final results of the research; and any other information that may be useful during the research.

As this protection, according to UI rules, neither requires any administrative procedures nor must last for a certain period of time, this valuable information is protected as long as it is kept secret. Even when this information is submitted to administrative bodies for approval and the granting of a licence, it is still protected pursuant to paragraph 3 of TRIPS Article 39, which provides that:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.

³⁴ Jeremy de Beer, 'Applying Best Practice Principles to International Intellectual Property Law-making' (2013) 44 *International Review of Intellectual Property and Competition Law*, 885.

³⁵ Rachel Kreppel, 'Clinical Trials: A New Form of Intellectual Property?' 4, available at: <http://www.kentlaw.iit.edu/Documents/Academic%20Programs/Honors%20Scholars/2002/Rachel-Kreppel-paper.pdf>

³⁶ Article 9/2 of the TRIPS Agreement.

³⁷ *Daiichi Sankyo Co Ltd and Another v. DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon* [2013] Court of

Justice of the European Union [2013] All ER (D) 262 (Jul), All England Reporter, paragraph 84.3.

³⁸ Rachel Kreppel, 'Clinical Trials: A New Form of Intellectual Property?' 4, available at: <http://www.kentlaw.iit.edu/Documents/Academic%20Programs/Honors%20Scholars/2002/Rachel-Kreppel-paper.pdf>, 12.

³⁹ Rachel Kreppel, 'Clinical Trials: A New Form of Intellectual Property?' 4, available at: <http://www.kentlaw.iit.edu/Documents/Academic%20Programs/Honors%20Scholars/2002/Rachel-Kreppel-paper.pdf>, 12.

Pursuant to this article, Member States have a duty to maintain and guarantee the confidentiality of the information submitted to administrative agencies upon application for a licence.⁴⁰ This rule applies where the information submitted includes details about a new chemical entity, test data or any other secret information, if related to a pharmaceutical or agricultural licence.⁴¹ This article provides that, administrative bodies, which are authorized to receive such data, are obliged to protect the confidentiality of this data during the licensing process and after granting the licence for the stated period of time.⁴²

The interpretation of this article of the TRIPS Agreement raises many legal issues.⁴³ Developed Member States explain it in their national legislations as it grants the right of the exclusive use of the protected data and information for the stated period of time. On the other hand, developing Member States interpret it as it only protects the submitted data from being undisclosed, used or exploited by the competitors in a manner which is inconsistent with fair competition.⁴⁴

Another issue related to the application of this article concerns the impact on national legislations. This issue is related to the second application for the similar chemical entity. As a result of protecting the UI of the first registration of the new chemical entity, any other application for registering a similar entity must submit new data and information and cannot rely on the data of the previous application. This is the rule adopted by developed countries, which aim to control competition in the markets of the pharmaceutical industry. On the other hand, developed countries will permit the registration of the similar chemical entity, which relied on the data and information of the previously registered chemical entity. This is the rule even when the second

application is made during the period of the protection, as long as the first chemical entity was patented.⁴⁵

The variation in the application of Article 39.3 of the TRIPS Agreement among Member States raises many practical issues. For instance, Argentinian Courts adopt the second point of view to allow other companies to use the data and information of chemical entities already registered.⁴⁶

In short, the protection provided for UI under the TRIPS Agreement affords protection, first, for valuable secret information, as long as it is kept secret; and second, for information provided to administrative agencies under the licence procedures.

Consequently, it is apparent from this overview that among the potential forms of legal protection for clinical trial data and information, not all the types of protection are applicable to the various forms of clinical trial process data. Consequently, stakeholders need to resort to more than one track protection for their work, as follows:

- Chemical formula: patent;
- clinical protocol: undisclosed information;
- informed consent files: undisclosed information;
- clinical data and statistics: undisclosed information;
- final results: patent; and
- published papers and researches: copyright

Although UI seems to be the best technique, it only covers two types of data, namely, (1) secret data and statistics collected during the trial itself, and (2) data and statistics provided to administrative agencies for licence and approval.⁴⁷

⁴⁰ Jonathan de Ridder, 'Data Exclusivity: Further Protection for Pharmaceuticals', available at:

<http://www.findlaw.com.au/articles/1576/data-exclusivity-further-protection-for-pharmaceut.aspx>

⁴¹ Sam Ricketson, 'The Future of the Traditional Intellectual Property Conventions in the Brave New World of Trade-Related Intellectual Property Rights' (1995) 26 *International Review of Intellectual Property and Competition Law*, 890.

⁴² *Public Citizen Health Research Group v. Food and Drug Administration* [1997] United States District Court for the District of Columbia

⁴³ Karin Timmermans and Togi Hutadjulu, 'The TRIPS Agreement and Pharmaceuticals - Report of an ASEAN Workshop on the TRIPS Agreement and Its Impact on Pharmaceuticals' (World Health Organization 2000), 39.

⁴⁴ Tomi Suryo Utomo, 'Pharmaceutical Patent Protection and the Introduction of Generic Drugs in Indonesia in the Post-TRIPS Era -- Is Patent Law the Only Factor Affecting the Introduction of Generic Drugs?' (2011) 42 *International Review of Intellectual Property and Competition Law*, 768.

⁴⁵ Karin Timmermans and Togi Hutadjulu, 'The TRIPS Agreement and Pharmaceuticals - Report of an ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals' (World Health Organization 2000), 39.

⁴⁶ *Novartis Pharma AG v. Monte Verde SA and Varios Propiedad industrial e intelectual*, the Federal Civil and Commercial Court of Appeals in Argentina, Case No. 5.619/05. See text below to n 55.

⁴⁷ Undisclosed information is considered the best technique to protect researchers' work during the clinical trials' process as a result of the express protection provided by Article 39.3 of the TRIPS Agreement. See Jonathan de Ridder, 'Data Exclusivity: Further Protection for Pharmaceuticals', available at:

<http://www.findlaw.com.au/articles/1576/data-exclusivity-further-protection-for-pharmaceut.aspx>>(n 39).

Therefore, the UI remains for information already registered such as a chemical formula or published information such as final research results, which should be covered by other forms of IPRs. In addition, the UI is inapplicable in cases related to the approval of similar pharmaceutical products.

In *Novartis Pharma AG v. Monte Verde SA & Varios Propiedad industrial e intelectual*, under Argentine Confidentiality Act No. 24,766, the right of confidentiality is granted to the first pharmaceutical product applied for only and the information from any subsequent application containing similar ingredients is made available for public use. The Argentine Law provides that such data is not required to be protected where similar products have been approved in one of the other countries.⁴⁸ Hence, even in the case of applying Article 39.3 of the TRIPS Agreement regarding the protection of data submitted to licenced authorities, the UI remains a problematic issue.

The proposed solution in this case is the creation of a new form of protection under the umbrella of IPRs, in order to cover the mental work undertaken by researchers and investigators during the clinical trial process from A to Z. The proposed form of protection called Clinical Trials Rights (CTR) would provide the following set of rights for stakeholders in the clinical trial process:

B. PROPOSED FORM OF PROTECTION: THE CLINICAL TRIAL RIGHT

As stated, this Paper proposes the CTR as a form of IPR that would protect the work undertaken by investigators and researchers during clinical trials. The CTR would provide stakeholders with the following rights:

- The right to protect all data and information used, submitted or resulting from the clinical trials process against unfair competition: according to this right, the government would be responsible for providing a wide range of protection for work performed by investigators against any form of exploitation or misuse by other competitors in the field of drug development. Governments, in this regard, would be required to impose criminal sanctions i.e. fines and imprisonments, for violators of the protected CTR.
- The right to maintain the confidentiality of the registered data for a certain period of

⁴⁸ Jorge Otamendi, 'Confidential Data in the Approval of a "Similar" Pharmaceutical Product' No. 19, July 2011, available at: <[https://www.aippi.org/enews/2011/edition19/Pharmaceutica I Product.html](https://www.aippi.org/enews/2011/edition19/Pharmaceutica%20Product.html)>

time: the government administrative agencies responsible for receiving requests for licensing of the new drugs are obliged to maintain the confidentiality of the submitted data and information. This obligation lasts for a certain period of time to be expressly determined by national legislations. Accordingly, in case of negligent infringement to this right by the administrative agency, a remediable compensation would be paid to the owner of the CTR. Nevertheless, in case of intentional infringement by the responsible officials at the administrative agency or by other competitors, a criminal sanction would be imposed.⁴⁹ The aim of this right is to ensure a suitable degree of protection for data and information submitted to the licencing body, in order to guarantee effective protection against unfair competition in the drug development market.

- The right to exclusive use of the registered data for a certain period of time: as a result of granting the CTR to the sponsor of the new drug, both the latter and the investigators should have the right to exclusive use of the clinical trial data and information. This exclusive right includes using the data before, during and after the trial, as long as the period of the protection is still running. The duration of the protection should cover the various phases of the trial, as long as it did not exceed ten years. Such protection terminates after the declaration of the final results or after a lapse of ten (10) years, whichever is shorter. In case of intentional infringement of this right, a remediable compensation and a criminal sanction should be imposed.
- The right to prevent others from using or exploiting the registered data or for applying for a licence for a certain period of time: The foregoing right of exclusive use of the clinical trial data entails the right of the owner to prevent others from using or exploiting this data and to apply the required procedures in case of any infringement. This right also prevents others from applying to conduct clinical trials for the new drug as long as it is proved that the data utilized were obtained

⁴⁹ The intentional infringement of the CTR takes the form of disclosing, acquiring, using or exploiting such information by other competitors without the consent of the owner in a manner contrary to honest commercial practices. It may also take the form of facilitating the disclosure, use or exploitation of the information by the employee, who is responsible for its confidentiality.

by illegal means. The governmental body that grants the CTR should provide the CTR owner with all the necessary means to benefit from this right and to prevent others from minimizing or limiting such benefit.

The advantages of the CTR as a form of IPR are that it would provide a wide range of protection for clinical data before, during and after the trials. This protection would cover all forms of data and information used and resulting from the trials. This right would also be granted by a specialized governmental agency, which reviews the request for protection, grants the CTR and protects it against any unauthorized use by other competitors.

With regard to the governmental body which grants the CTR, a specialized agency should be established to deal with all matters related to this new right. This agency would have the authority to:

- Revise the request to obtain the CTR;
- register the protected data and information;
- grant the CTR to the sponsor of the drug development process;
- grant the licence for exclusive use of the registered data and information;
- create a registry of all protected drug development processes and protected data from each process;
- follow precautionary procedures to ensure the required protection of registered data and information; and
- apply the procedures for prosecution of violators of the CTR.

All details relating to the authorities and structure of the granting agency should be clearly mentioned in national legislations, according to the administrative system of each country.

Concerning the protection of data and information from failed clinical trials, the CTR aims to protect the work performed by investigators during clinical trials in order to allow them to benefit from their efforts after declaration of the final results. However, what is the aim of such protection if the clinical trial failed and the sponsor has declared its termination? In other words, what is the effect of declaration of the failure of the clinical trial on the conferred CTR?

Declaration of the failure of a clinical trial leads to the termination of the CTR granted and results in the possibility of registration of new trials to benefit from

the protection under the CTR. However, what is the legal situation of the ex-protected data and information? Are they still covered by the CTR or do they lose such protection and become available for public use?

Dealing with ex-protected data results in a conflict of interest between the owner of such data and other competitors who stand to gain from the protection under the CTR. On the one hand, the owner of the ex-protected data would clearly like to maintain protection as long as possible to preserve the efforts of the investigators during the period that preceded the clinical trial's declaration of failure. On the other hand, other competitors would like to have the ex-protected data made available for public use, in order to improve the work undertaken previously and benefit from any flaws.

Clearly, it would be unfair if the ex-protected data are disclosed and made available for public use, as the sponsor and the investigators would not benefit from all their efforts. It would also be unfair to provide protection for failed clinical trials and prevent other competitors from benefiting from such protection, signifying that the failed trial is still protected.

To resolve these conflicting interests, a special mode of protection should be adopted. In fact, the ex-protected data should be covered by the CTR, even after the declaration of the clinical trial's failure, however, this protection should last for three (3) years only from the date of the declaration. During this period, it should be prohibited to disclose, sell, use or exploit the ex-protected data without the consent of the owner. Other competitors would then have the right to register new clinical trials (of the same type) to be protected by the CTR as long as the submitted data and information stem from personal efforts of the investigators of the new trial.

After the expiry of the three-year period, the ex-protected data would be disclosed and made available for public use.

At the end of the clinical trials and after the final result is declared, the CTR would terminate and all the protected data and information should be disclosed to the public. Such a disclosure is part of the procedures for protecting new drugs through the patent system.

V. CONCLUSION

The clinical trial process differs from other types of mental works, since more than one form of IPR is required to ensure a suitable degree of protection. The CTR is a proposed as a form of protection covering any data and information provided or used during the drug development process or resulting from it. The CTR would cover any work performed by investigators

before and during the trial. After the termination of the clinical trial and declaration of the final results, the CTR would to an end and the new drug would be protected by patent rights, if applicable. The CTR would last for a specific period of time or for the completion of the trial, whichever is shorter.

Ultimately, this new form of protection for clinical trial data and information would encourage investments in the field of pharmaceutical inventions, while ensuring an effective process for the circulation of information. It would also ensure a balance of benefits between the sponsor and the investigators on the one hand, and other competitors on the other, as well as, enhancing pharmaceutical research and industries.

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5 ENFORCEMENT OF INTELLECTUAL PROPERTY LAW: SOME ASPECTS OF TRADE IN COUNTERFEIT GOODS IN THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA

Dr Katerina Tosevska-Trpcevska*

ABSTRACT

This paper examines the enforcement of the customs law of the Former Yugoslav Republic of Macedonia on the protection of intellectual property rights (IPRs). The Customs Administration has the main role in the enforcement of intellectual property rights and in hampering the trade of counterfeit goods in the country. In order to step up the fight against trade in counterfeit goods and the protection of intellectual property rights in 2015, a new Law on Customs Measures for the Protection of Intellectual Property Rights was enacted. In addition, the number of registered customs officers that use the World Customs Organization (WCO) Interface Public-Members Platform has steadily risen. As a result of the increased involvement of the customs community in the protection of intellectual property rights, more goods have been temporarily retained under suspicion of violating intellectual property rights. This paper also highlights the rise in the sale of counterfeit products on the Internet, and the need for enhanced international cooperation in this area.

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Keywords: enforcement of IP law, goods that violate IPRs, counterfeit goods, WCO Interface Public Members platform, customs seizures, online sale of counterfeit goods

I. INTRODUCTION

Counterfeit and pirated goods are being produced and consumed in virtually all economies in the world. In recent years there has been an alarming expansion of the types of products being infringed, from luxury items, such as watches and designer clothes, to personal health and safety items, such as pharmaceutical products, food and drinks, medical equipment, personal care items, toys, tobacco and automotive spare parts.

It might not be such an issue if this increase represented a small portion of world trade. Although it is difficult to quantify the volume of counterfeit products, and the data obtained from customs seizures of infringing products does not reflect the overall number of counterfeit products in the world, it is still possible to obtain a general overview based on available data. An OECD study on trade in counterfeit and pirated goods in 2007 concluded that this trade might have accounted for as much as US\$ 200 billion in 2005.¹ The updated estimates based on the growth and changing composition of trade between 2005 and 2007, suggest that counterfeit and pirated goods in international trade grew steadily over the period 2000 to 2007 and could have attained US\$ 250 billion in 2007. The share of counterfeit and pirated goods in world trade is estimated to have raised from 1.85 per cent in 2000 to 1.95 per cent in 2007.² For the sake of clarity, the data regarding counterfeit and pirated products do not include domestically produced and consumed products or non-tangible pirated digital products.

The latest report on illicit trade by the World Customs Organization also indicates that there is a significant increase in the number of cases of goods suspected of infringing intellectual property rights or failing to meet national standards.³ Among the countries that have reported the highest number of cases are the United States in first place with 33.63% of all cases, followed by Saudi Arabia, Italy, Germany and Japan. An analysis of the countries which reported the highest number of intercepted pieces, shows a drastic change, with Angola ranked first, followed by the Democratic Republic of Congo, Togo, Saudi Arabia and Madagascar.⁴

¹ OECD, *The Economic Impact of Counterfeiting and Piracy: Executive Summary* (OECD 2007).

² OECD, *Magnitude of Counterfeiting and Piracy of Tangible Products: An Update* (OECD 2009).

³ WCO, *Illicit Trade Report 2013* (World Customs Organization 2014).

⁴ WCO, *Illicit Trade Report 2013* (World Customs Organization 2014).

A snapshot of the structure of intercepted commodities reveals that more than half of the reported intercepted goods were illicit pharmaceutical products, followed by counterfeit electronic appliances and illicit foodstuff – all of which threaten consumer health and safety.⁵ This sharp increase in counterfeit products that endanger health and safety of consumers highlights the importance of the fight against counterfeit products and underlines the need for customs organizations to demonstrate their preparedness and dedication.

The aim of this paper is to provide an overview of the enforcement of intellectual property law in the Former Yugoslav Republic of Macedonia with a focus on trade in counterfeit goods. To this end, it is important to elaborate on the provisions of the Law on Customs Measures for Implementing Protection of Intellectual Property Rights. This law was enacted in 2015 for the purpose of replacing the Law on Customs Measures for the Protection of Intellectual Property Rights first enacted in 2005 and amended in 2007, 2011 and in 2013. There is also a Manual (Book of Rules) for implementation of the Law on Customs Measures for Protection of Intellectual Property Rights from 2013.

II. PROTECTION OF INTELLECTUAL PROPERTY RIGHTS IN THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA

After its independence in 1991, the Former Yugoslav Republic of Macedonia became a member of the World Intellectual Property Organization (WIPO) the same year. Some laws concerning the protection of intellectual property were enacted afterwards, but, after becoming a Member of the World Trade Organization (WTO) in 2003, the country was obliged to abide by the rules of the TRIPS Agreement. Since then, the country has enacted its main intellectual property laws on industrial property, on copyright and related rights, on breeder's rights and on protection of topographies of integrated circuits, along with several implementing rules and regulations. Besides those, a few IP-related laws have been enforced, including the Law on Customs Measures for Implementing Protection of Intellectual Property Rights (replacing the Law on Customs Measures for the Protection of Intellectual Property Rights), the Customs code with its amendments, the Code of Criminal Procedure, the Penal Code and the Law on Administrative Fees.

⁵ WCO, *Illicit Trade Report 2013* (World Customs Organization 2014).

III. LAW ON CUSTOMS MEASURES FOR IMPLEMENTING THE PROTECTION OF INTELLECTUAL PROPERTY RIGHTS

The enacting of the new Law on Customs Measures for Implementing Protection of Intellectual Property Rights is in line with the new European Union Regulation No. 608/2013. The previous Law on Customs Measures for Protection of Intellectual Property Rights was in line with the old EU Regulative No. 1383/2003. Moreover, the new law on implementing protection of intellectual property rights is harmonized with the new system for processing customs declarations and excises documents (CDEPS) of the Customs Administration.⁶

The Law on Customs Measures for Implementing Protection of Intellectual Property Rights regulates the customs procedures for taking action when there is reasonable suspicion that certain goods are violating intellectual property rights. According to this Law, goods that are under suspicion for violating intellectual property rights are defined as goods that:

- (a) Are the subject of actions that violate intellectual property rights;
- (b) represent devices, products or components which are primarily made for or adapted in order to allow avoidance of any technology, device or components which in their ordinary activities prevent or limit the activity not authorized by the holder of certain copyright or related right and which is connected to activity that violates those rights;
- (c) Represent any mould or matrix specially designed or adjusted for the production of goods that violate intellectual property rights, if the usage of those moulds or matrixes violates intellectual property rights.⁷

The Law also defines counterfeit and pirated goods. 'Counterfeit goods' are defined as:

- (a) goods that violate the right of the trademark when, without the consent of the holder of the right, the goods bearing an identical trademark sign with a certain registered trademark sign, or the goods

⁶ Customs Administration, *Report: Second Quartile 2015* (CARM 2015).

⁷ Law on customs measures for implementing protection of intellectual property rights 2015 art 4.

cannot be differentiated according to the essential features of that trademark;

- (b) goods violating the right of geographical indication when bearing or being described with a name or term protected in the sense of geographical indications; and
- (c) the shape of the goods or packaging, labels, brochures, instruction manuals, warranty documents or similar elements, even though separated from the goods, is subject to violation of the right of trademark or geographical indication, and when containing a sign (including: logo, words, letters, numbers, pictures, drawings, combination of colours, three dimensional forms and their combinations), name or term identical to the valid and registered trademark or protected geographical indication, or whose essential characteristics cannot be differentiated from that of the geographical indication.⁸

'Pirated goods' are goods that violate copyright or related rights or design right and are made or contain copies made without the consent of the owner of copyright or related right or design right of the person authorized by the owner of the right in the country of production.⁹

According to the new Law on Customs Measures for Implementing Protection of Intellectual Property Rights, the Customs authorities may postpone the clearance of the goods or may retain the goods after accepting the claim by the holders of intellectual property rights or when they have reasonable doubt that certain goods may violate IP rights acting 'ex officio'.

The Law first acknowledges a situation where holders of an intellectual property right file a claim with the customs authorities to undertake appropriate customs measures to deal with certain goods. The customs authorities may accept or deny the claim for undertaking customs measures with respect to the goods. If they accept the claim they may postpone the clearance of the goods or may retain the goods.¹⁰

The customs authorities may postpone the clearance or retain the goods before accepting the claim from

⁸ Law on customs measures for implementing protection of intellectual property rights 2015 Article 4.

⁹ Law on customs measures for implementing protection of intellectual property rights 2015 Article 4.

¹⁰ Law on customs measures for implementing protection of intellectual property rights 2015 Articles 11 and 12.

the holders of the rights if they identify goods under suspicion as violating intellectual property rights. When acting 'ex officio', Customs authorities should inform the holder of the intellectual property right of the possible infringement and await the official filing of complaint by the holder. If the holder of the intellectual property right does not file a complaint for IP infringement within four working days, the Customs authorities may release the retained goods.¹¹

The holder of the intellectual property right should inform the Customs authorities within ten working days if the goods retained violate intellectual property rights. If the holder of the intellectual property right confirms violation, the goods may be destroyed under customs supervision.¹²

The Law prescribes fees for persons and legal entities that violate certain provisions of the law, among which the highest are the fees of 2,500 to 5,000 euros for the legal entity and fees of 500 to 1000 euros for persons that seek to import or export goods that violate the right of the same trademark as the goods previously seized from them.¹³

IV. CUSTOMS ENFORCEMENT OF THE PROTECTION OF INTELLECTUAL PROPERTY RIGHTS

Customs administration has the main role in enforcing intellectual property rights and in hampering trade in counterfeit goods in the Former Yugoslav Republic of Macedonia. The Law on Customs Measures for Implementing Protection of Intellectual Property Rights prescribes a fast and efficient procedure for enforcement of the protection of intellectual property rights, and there are also several applicable tools.

In 2013, in order to improve the fight against trade in counterfeit goods and the protection of intellectual property rights, the Customs administration provided a manual for electronic evidence to be used in the process for protection of intellectual property rights. The aim of this evidence is to obtain a systematized and structured database to enable access to goods temporarily retained under suspicion of violating intellectual property rights and a detailed control of the registered trademarks.¹⁴

¹¹ Law on customs measures for implementing protection of intellectual property rights 2015 Articles 7 and 20.

¹² Law on customs measures for implementing protection of intellectual property rights 2015 Article 26.

¹³ Law on customs measures for implementing protection of intellectual property rights 2015 Articles 37-39.

¹⁴ Customs Administration, *Annual Report 2013* (CARM 2014).

The Customs administration has also provided a User's manual for working with the World Customs Organization platform for the protection of trademarks and intellectual property rights. This so-called Interface Public Members (IPM) platform is an effective online anti-counterfeiting tool that enables crucial information to be exchanged in real time in order to intercept counterfeited goods. Increasingly attracting more countries, Interface Public Members now hosts customs officers from more than 85 member countries.¹⁵

From the basic functionality of a database for genuine and fake products, featuring pictures and basic descriptions of products, the IPM has developed into a more complex system offering additional options, including the ability to send alerts to customs officers, an e-learning feature and a mobile application launched in 2014. Today the IPM tool has been redesigned and the two versions of the web and mobile platforms were made available in September 2015.¹⁶ The number of right holders to join IPM is also encouraging with over 700 brands covering a wide range of industry sectors from pharmaceutical, foodstuffs and pesticides to fast-moving goods and luxury items.

The number of registered customs officers that use the IPM platform in the Former Yugoslav Republic of Macedonia has steadily grown. The latest report shows that 530 customs officers have been registered of which 328 have been active users of the database.¹⁷

Besides the increased awareness among customs officers in the country of the importance of protecting intellectual property rights, the awareness of the business community has been growing, alongside the trust in the activities of the customs organization. The number of registered applications for customs protection of trademarks has been steadily growing. At the end of 2012, 222 applications were registered with the Customs administration for the protection of intellectual property rights. In 2013 334 applications were filed, in 2014 there were 345 and in the first six months of 2015 308 applications were filed for the protection of intellectual property rights.¹⁸

¹⁵ WCO launches the new IPM platform <www.wcoipm.org/news/wco-launches-the-new-ipm-platform/> assessed 27 October 2015.

¹⁶ WCO launches the new IPM platform <www.wcoipm.org/news/wco-launches-the-new-ipm-platform/> assessed 27 October 2015.

¹⁷ Customs Administration, *Report: second quartile 2015* (CARM 2015).

¹⁸ Customs Administration, *Annual Report 2013* (CARM 2014) and Customs Administration, *Report: second quartile 2015* (CARM 2015).

As a result of the increased involvement of the customs community in the protection of intellectual property rights, there is a rise in the number of pieces of goods that have been temporarily retained under suspicion of violating intellectual property rights. In 2013 the Customs administration retained 333,799 pieces of goods; in 2014 in 157 actions Customs authorities retained 945,302 pieces and 768 kg of goods; and in the first six months of 2015 587,455 pieces and 350 kg of goods were retained under suspicion of violating intellectual property rights.

Table 1. Goods retained temporarily in 2013, 2014 and from January to June 2015

| | Type of products | unit | 2013 | 2014 | Jan-June 2015 |
|---|---|--------------|---------|-----------------|----------------|
| 1 | Apparel, accessories and related materials | pieces | 17,960 | 200,864 | 9,769 |
| 2 | Footwear and accessories | pieces | 36,321 | 32,419 | 2,019 |
| 3 | Perfumes, deodorants, cosmetics | pieces kg | 19,041 | 546,317, 768 | 77,224 350 |
| 4 | Telephones, IT, audio, video, parts and equipment | pieces | 10,745 | 7,876 | 742 |
| 5 | Spare parts and equipment | pieces | 18,662 | 1,208 | 1,861 |
| 6 | Medicines | pieces | 80 | | |
| 7 | Other | pieces | 23,0990 | 156,618 | 495,840 |
| | Total | pieces kg | 333,799 | 945,302 768 | 587,455 350 |

Source: Customs Administration, *Report: second quartile 2015* (CARM 2015) and Customs Administration, *Annual Report 2013* (CARM 2014).

From the structure of the seized goods it is obvious that textile products and apparel usually dominated, except in 2014, when cosmetic products with 58 per cent of the goods were temporarily retained. These products were followed by shoes, phones, IT equipment and car accessories.

If we analyse the origin of the goods that have been temporary retained, it should be acknowledged that until 2014 the counterfeited goods usually originated from China. By contrast, in 2014, 63 per cent of the goods temporarily retained originated from Turkey. The trend continued in the first six months of 2015,

when 68 per cent of the goods also originating from Turkey.¹⁹

According to analyses undertaken by the Customs administration, the counterfeit goods retained in the country were directed to the domestic market or were transiting to Kosovo and the Republic of Serbia.²⁰

Every year the Customs administration organizes actions for destroying counterfeit goods or, in coordination with the representatives of trademark holders, donates seized goods to socially vulnerable families.

The Customs administration of the country is constantly involved in international activities, projects and operations under the auspices of the World Customs Organization and shares information about trade in counterfeit and pirated goods with other customs administrations and international organizations.

The efforts of the Customs administration aimed at protecting intellectual property rights were recognized in 2009 by the Yolanda Benitez Trophy awarded by the World Customs Organization as the best customs organization in the world in combating counterfeiting and piracy.

In 2014 the Customs administration developed an action plan for the protection of intellectual property rights for the period from 2014 to 2016. The new action plan involves several measures aimed at enhancing the protection of intellectual property rights, namely: enhancement of the regulatory framework in line with the new regulation of the European Union; enhancement of the risk management system; enhancement of the customs controls and surveillance of border crossing points and inside the country; enhancement of the customs intelligence system; enhancement of the training system employees; enhancement of the cooperation with domestic and international institutions and with the business community; further enhancement of transparency for the protection of intellectual property rights; and continued application of the WCO IPM platform.²¹

¹⁹ Customs Administration, *Report: second quartile 2015* (CARM 2015).

²⁰ Achievements of the Customs Administration of the Former Yugoslav Republic of Macedonia in combating counterfeiting and piracy (presentation from the Customs Administration 2014).

²¹ Customs Administration, *Action Plan for Protection of Intellectual Property Rights for the period 2014-2016* (CARM 2014).

V. ONLINE SALE OF COUNTERFEIT GOODS

Distribution channels for counterfeit and pirated products are expanding. Previously, counterfeit and pirated goods were largely distributed through informal markets, but nowadays these products are infiltrating legitimate supply chains. Additionally, the Internet has provided counterfeiters and pirates with a new and powerful means to sell their products through auction sites, stand-alone commercial websites and email solicitations. The online environment is attractive to counterfeiters and pirates for a number of reasons, including the relative ease of deceiving consumers and the market reach.²²

There are several factors that are driving the usage of Internet by counterfeiters and pirates. Anonymity or the ease with which counterfeiters and pirates can conceal their true identity and limit the risk of detection is one of the driving factors. Another factor is the flexibility or possibility to establish, take down or move online sites quickly and to jurisdictions where legislations and enforcement of intellectual property rights are weak. An important factor that enables the use of the Internet by counterfeiters and pirates is the size of the market or the huge number of e-commerce sites and volume of listings that makes it difficult for right holders and enforcement agencies to identify and respond to their actions. The Internet provides sellers with a means to reach a global audience at low cost and offers an opportunity to expand sales and market reach. Another important factor that drives the use of the Internet by forgers is the ability to use readily available software and images that can facilitate deception of consumers by creating a false sense of security.²³ The evasive role of the Internet has flooded new channels that drive the use by counterfeiters and pirates, amongst which are the increasingly used apps and social media platforms.

The Former Yugoslav Republic of Macedonia hosts the premises of the Internet Monitoring Team of REACT, a non-for-profit organization with over 20 years of experience in the fight against counterfeit trade with 200 members in more than 65 countries in the world. The REACT Internet Monitoring Programme is designed specifically to meet the needs of intellectual property right holders. The programme is founded on six pillars: monitoring and removal of advertisements from some 200 auction platforms worldwide; worldwide search and removal of web shops (B2B exchanges, e-commerce sites and search engines); monitoring and removal on social

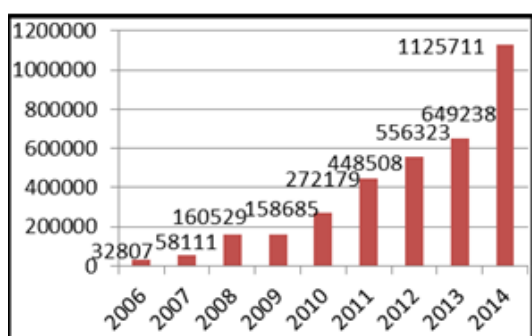
²² OECD, *The Economic Impact of Counterfeiting and Piracy: Executive Summary* (OECD 2007).

²³ OECD, *The Economic Impact of Counterfeiting and Piracy: Executive Summary* (OECD 2007).

media platforms like Facebook, Instagram, YouTube, Weibo and Twitter; monitoring and removal of infringing apps, including in iTunes store and Google play; monitoring and removal of unauthorized use of trademark keywords; and monitoring and removal of unauthorized use of trademarks in (sub)domain.²⁴

The REACT Internet Monitoring Programme offers advantages such that after identification of an Internet case follow up can take place through practical and law enforcement actions such as making test purchases; investigating registrants or any other connected addresses; initiating raids; blocking payments (PayPal, Master card, Visa); providing cluster analysis; localizing big traders and finding links to their Internet shops; initiating legal action through local lawyers and investigators; removal of search results from search engines; and domain dispute procedures.²⁵

Table 2. Number of auction pages removed in the period 2006-2014



Source: REACT (data are obtained directly through e-mail)

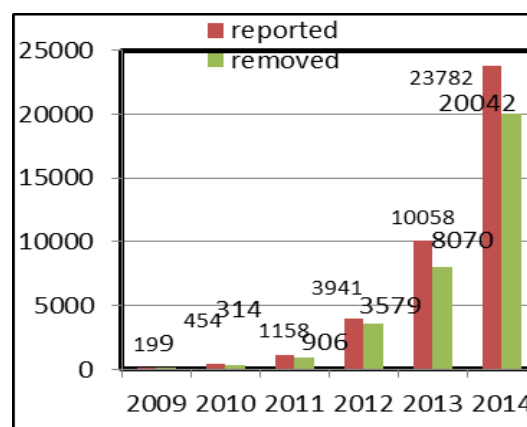
The dedication of the REACT Internet Monitoring Programme in the fight against global trade in counterfeit goods has resulted in success as reflected in Tables 2 and 3. Table 2 above gives the results from the number of auction pages that have been removed from the Internet during the period observed from 2006 to 2014. It shows that in the beginning, in 2006, 32,807 auction pages were removed from the Internet. There has been a steady rise in the number of pages removed as reflected in the sharp increase in 2011 when 448,508 pages were removed and especially in 2014 when 1,125,711 auction pages were removed from the Internet by the REACT Internet Monitoring Team. The data might appear to be encouraging, but also indicate there has been a sharp rise in the usage of the Internet to sell counterfeit products.

²⁴ React, *Service Guide 2015-2016* (SNB-REACT 2015/2016).

²⁵ React, *Service Guide 2015-2016* (SNB-REACT 2015/2016).

Table 3 below shows the number of commercial pages that have been reported as infringing intellectual property rights and the number of commercial pages that have been successfully been removed from the Internet because of IPR infringement in the period from 2009 to 2014. The data reflects the success of the team in the prevention of the online sale of counterfeit products, as exemplified by the fact that in 2014 more than 20,000 webpages were removed from the Internet because of infringement of intellectual property rights. But again it must be stressed that these results are relative since it is expected that there will be an even sharper increase in the usage of commercial pages for the sale of counterfeit products and other deception practices with regard to consumers.

Table 3. Number of commercial pages removed in the period 2009-2014



Source: REACT (data are obtained directly through e-mail)

From data obtained from REACT, two main conclusions can be formulated. First of all, it should be recognized that REACT is waging a serious, dedicated and successful fight against traders of counterfeit products as reflected by these results. By contrast, it should be recognized that the online sale of counterfeit products is flourishing throughout the world and different counterfeit products can reach consumers at every single point in the world. Although some may put into perspective the importance of the fight against the online sale of counterfeit products because such sales are usually via postal packages and for personal usage, the importance of this fight must be stressed because of the allegations of the representatives of pharmaceutical companies. At the last national seminar organized in the Former Yugoslav Republic of Macedonia on the fight against counterfeiting and piracy, under the auspices of the World Customs Organization and the Customs Administration of the

country, according to the representative of one pharmaceutical company, about 90 per cent of the medicines that were sold online were counterfeit.

Based on these declarations and the results of the report of the World Customs Organization that more than half of the seized goods were illicit pharmaceuticals, it should be noted that there has been a sharp rise in commodities endangering the health and safety of consumers. The report confirms the seriousness of the issue relating to the online sale of counterfeit products and acknowledges the pressing need to undertake proactive action.

In this respect, the organizations dealing with the online sale of counterfeit products offer standardized services such as removing commercial and auction pages; locating big sellers; comparing data and defining clusters; and creating local cases and investigations, but they also face serious problems. Some of the problems include fraudulent identifies, protected personal data or simply dealing with uncooperative Internet service providers. This has led these organizations to provide additional services such as local research, buying samples, blocking the payment systems, and performing additional investigations.²⁶

In short, it is crucial that those involved in the fight against the online sale of counterfeit products be provided with the appropriate means and tools to deal with abuses, supported by international cooperation.

VI. CONCLUSION

Based on the presentation of certain aspects of the enforcement of intellectual property rights and the customs measures applied in the fight against trade in counterfeit products, it can be concluded that the Customs administration is serious and dedicated to enforcing protection of intellectual property rights in the country. Protection of intellectual property rights has been one of the highest priorities of the Customs administration. The administration has constantly been working towards improving the legal procedures and regulations resulting in the enactment of a new Law on Customs Measures for Implementing Protection of Intellectual Property Rights in line with the new Regulation of the European Union.

The protection of intellectual property rights should be enforced through fast and efficient procedures prescribed by the Law on Customs Measures for Implementing Protection of Intellectual Property Rights and by the usage of several applicable tools.

Among the tools that are used, the Interface Public-Members platform designed by the World Customs Organization to ease the global fight against counterfeit products deserves special attention. The number of registered customs officers that use the Interface Public-Members platform in the country has been steadily growing. As a result of the increased involvement of the customs community in the protection of intellectual property rights, an ever increasing number of goods have been temporary retained under suspicion of violating intellectual property rights in the country.

Besides the increased awareness among customs officers of the importance of the protection of intellectual property rights, the awareness of the business community has been growing alongside the trust in the activities undertaken by customs organisations. The number of registered applications for customs protection of trademarks has been steadily growing.

It should also be stressed that the significant increase in the online sale of counterfeit products is becoming a central issue and international cooperation in this field should be encouraged. Moreover, more than 90 per cent of the drugs sold on the Internet are alleged to be counterfeit medicines. Online infringement of intellectual property is a global problem and adopting appropriate measures is crucial when dealing with this type of crime.

One of the most important aspects in the prevention of online counterfeiting is developing people's consciousness and raising political awareness and the will to deal with this issue. Several means are available to the organizations dealing with online sale of counterfeit products: cooperation with various auction pages and Internet service providers should be enhanced; civil investigations should be established; cooperation should be encouraged with other state organs responsible for the proper implementation of legal acts; cooperation with Google, Facebook and financial institutions like Visa, Master Card, PayPal should be encouraged; and additional and special measures should be undertaken.

²⁶ Mufisovski, E, *React – Association for the Fight against Counterfeit Products*, presentation in Skopje, 2015

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6 MANAGING COPYRIGHT IN MOOCs: THE VIABILITY OF THE TEACHING EXCEPTION

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ABSTRACT

Massive Open Online Courses (MOOCs) are becoming a new trend in the international development of education. MOOCs offer various resources online across the globe with the expectation that this will help towards reducing costs, widening access and increasing productivity. The scope of teaching is thus expanded since technological development enables easy access to information, to publishing, and to reusing and to sharing resources. Hence, it is important for policy makers, legal authorities and legal scholars to rethink the copyright exceptions that are currently available for teaching purposes, and whether they support teaching practices in the context of MOOCs. This paper first provides a brief overview of MOOCs. It then outlines some concerns and challenges concerning copyright and MOOCs. It analyses whether the teaching exceptions under Article 10(2) of the Berne Convention apply in the context of MOOCs. It also look examines the relation between the teaching exception and the three-step test. Finally, it discusses the relation between copyright protection and public interest and argues that flexibilities in interpreting the copyright exception are pertinent to serving the public interest.

Keywords: MOOC, copyright; online courses; three-step test, teaching exceptions.

I. INTRODUCTION

Massive Open Online Courseware essentially refers to the capacity to enrol a large number of course participants with adequate Internet connection in a different variety of courses, where open content for all to use and learn from is provided. While most MOOCs are free of charge at present, some do impose minimal fees either with or without any academic credit. The open content normally offers a

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coherent set of resources and follows a sequence of activities organized by an instructor in order to address specific learning objectives or goals bounded within a certain time period.¹ Further activities involve registration; a learning environment based on a set of curriculum and assessment; and communication, including interaction, collaboration, and sharing.² Access to materials, mainly scholarly publications on the Internet, will be in such a way that the materials are free for all to read, use, and reuse to a certain extent.

Since then emergence of MOOCs in 2012, this latest trend in online learning is well accepted by various universities around the world and outsourcing companies have been launched to provide the infrastructure for it. Malaysia, for instance was the first country in the world to implement a nationwide strategy that integrates MOOCs with its public on-campus university classes. Through the deployment of the Digital Malaysia 354 Roadmap in 2013, Malaysia focuses on MOOCs as one of the ways to transform the country into a digital economy by 2020. Through MOOCs, it is hoped that institutions will enhance the quality of graduates, enable more customized and remote learning opportunities, reduce costs for higher education, raise productivity and provide a holistic approach to the public.

Despite such aims, Malaysia, however, does not have a proper copyright licensing system like Australia, the United Kingdom or the United States. Some students still photocopy textbooks in order to save their limited educational loans to support their studies. Most lecturers are still vague about the issue of copyright in an educational setting. When using a traditional method of teaching, these problems may not be easily transparent but in MOOCs, where the courses will be offered globally, universities may leave themselves open to copyright infringement claims. Teaching is becoming more transparent and will be subject to criticism and copyright claims if proper copyright management is not put into place.

II. STUDIES ON MASSIVE OPEN ONLINE COURSES (MOOCs)

While MOOCs seem to offer free access to information and resources at present, MOOCs are ultimately meant to earn revenue within the formal higher education system as content licensed for use

¹ Fiona M Hollands and Devayani Tirthali, 'MOOCs: Expectations and Reality' (Center for Benefit-Costs Studies of Education, 2014) <https://oerknowledgecloud.org/sites/oerknowledgecloud.org/files/MOOCs_Expectations_and_Reality.pdf> accessed 27 October 2015.

² Xin Chen, Deborah R Barnett and Casheena Stephens, 'Fad or Future: The Advantages and Challenges of Massive Open Online Courses (MOOCs)', *Research-to-Practice Conference in Adult and Higher Education* (2013) <<https://www.lindenwood.edu/r2p/docs/ChenBarnettStephens.pdf>> accessed 27 October 2015.

by institutions awarding degrees. Open educational resources have become 'try before you buy' marketing tools that provide a way of leveraging scale in a new, potentially highly profitable educational industry.³ Some have even found that MOOCs are creating heavy debts for students.⁴ The educational industry is leaning more towards privatization leading to the question of whether such teaching is for profit or for non-profit purposes. While reusable educational resources are being created and disseminated, development in technology has managed to expand the scope of teaching by facilitating access to information, to publishing and to sharing.⁵

Various studies have shown that MOOCs present various complex copyright issues that can challenge the relationship between a higher education institution, its faculty, learners and MOOC providers.⁶ Dames questioned the situation when MOOC participants contributed copyrighted materials, either with or without any licence to do so.⁷ Thomson⁸ discussed the challenge of copyright compliance in MOOCs, stating that the global nature of MOOCs makes copyright difficult. Arnold viewed copyright as a challenge for MOOCs, especially with the commercialization of open resources that is underway.⁹ Some viewed it as being unlikely that the teaching exception or the fair use exception in the context of classroom teaching can be applied in the MOOC environment.¹⁰ The fair use defence may not apply on the basis that most MOOC providers are for-profit companies, MOOC are open to the mass¹¹

and not confined to certain group of students¹², and that some students access the content from jurisdictions where fair use or fair dealing principles are either weaker or entirely absent.¹³ It was viewed impossible for MOOCs to pass the three-step test elements.¹⁴

It is a concern that MOOCs lack the rich and vast resources necessary for true learning if resources and materials continue to be in the hands of publishers.¹⁵ In 2013, there was a call in Australia to reform the Copyright Act 1968 in order to allow more Australian university competence in world online education.¹⁶ Courtney¹⁷ focusses on different strategies to deal with copyright and access problems associated with MOOCs materials. However, it is arguable whether other institutions that might have lesser expertise and fewer resources can easily adopt the same strategies. Courtney's view is that the difficulties in creating MOOCs contents have led faculty authors to understand the pitfalls that a particular contract may involve, copyright issues, licence bounded restrictions and how this can impact education.¹⁸ In short, with MOOCs it is crucial for policy makers to begin rewriting rules about copyright and its impact on scholarship.

A normal course of teaching in MOOCs may include different acts of exploitation of copyright works. Different works such as journal, articles and books, sound recording of lectures, visual recordings, news or broadcasts may be made available online; sometimes translations of works may be necessary in certain circumstances. This article will examine to what extent the teaching exceptions provided by international conventions, particularly Article 10(2) of the Berne Convention, permit exploitations of copyright works in these different acts.

³ Richard Wellen, 'Open Access, Megajournals, and MOOCs: On the Political Economy of Academic Unbundling' (2013) 3 SAGE Open <<http://sgo.sagepub.com/lookup/doi/10.1177/2158244013507271>> accessed 4 June 2014.

⁴ Helen Hu, 'MOOC Migration' (2013) 30 Diverse: Issues in Higher Education 10 <<http://search.ebscohost.com/login.aspx?direct=true&db=aph&AN=86441058&site=ehost-live>> accessed 27 October 2015

⁵ *ibid.*

⁶ Educause, 'Copyright Challenges in a MOOC Environment' (2013) <<https://net.educause.edu/ir/library/pdf/PUB9014.pdf>> accessed 27 October 2015

⁷ K Matthew Dames, 'Copyright Norms Clash With MOOCs Learning by Example' (2013) 30 Intellectual Property 24.

⁸ Helen Thomson, 'Copyright, Compliance, and the Big Wide World of MOOCs' (2013) 34 Incite 30.

⁹ Stephen E Arnold, 'GADZOOKS, It's MOOCs.' (2013) 37 Online Searcher 10.

¹⁰ Meredith Schwartz, 'Massive Open Opportunity: Supporting MOOCs in Public and Academic Libraries' (*Library Journal*, 2013) <<http://li.libraryjournal.com/2013/05/library-services/massive-open-opportunity-supporting-moocs/#>> accessed 27 October 2015.

¹¹ Derek Whitehead and Luke Padgett, 'The Myth of MOOCs', *The Higher Education Technology Agenda* (THETA

2013) (2013) <https://www.caudit.edu.au/system/files/Media_library/Resources_and_Files/Presentations/THETA_2013_-_The_Myth_of_MOOCs_-_D_Whitehead_L_Padgett_-_Presentation.pdf> accessed 1 November 2015.

¹² *ibid.*

¹³ *ibid.*

¹⁴ Charis Palmer, 'Universities Seek Copyright Law Reform to Enable MOOCs' (*The Conversation*, 2013) 6 <<http://theconversation.com/universities-seek-copyright-law-reform-to-enable-moocs-11524>> accessed 1 November 2015, p6.

¹⁵ Kyle K Courtney, 'The MOOC Syllabus Blues Strategies for MOOCs and Syllabus Materials' (2013) 74 College and Research Libraries News 514 <<http://crln.acrl.org/content/74/10/514>\nhttp://crln.acrl.org/content/74/10/514.full.pdf> accessed 27 October 2015.

¹⁶ *ibid.*

¹⁷ *ibid.*

¹⁸ *ibid.*

III. RELATED INTERNATIONAL CONVENTIONS

As one of the 14 multilateral trade agreements in the World Trade Organization (WTO), the Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) is considered a comprehensive international Agreement on copyright and intellectual property that is binding on all WTO Members.¹⁹ Under TRIPS, Contracting States are required to comply with most of the provisions of the Berne Convention, irrespective of whether the country is a signatory to that Convention, by virtue of TRIPS Article 9, which provides that all Members shall comply with Articles 1 to 21 of the Berne Convention 1971. In other words, the Berne Convention is a source of rights and obligations for all WTO Members. Some commentators even conclude that the Berne Convention, to the extent incorporated, is a source of law.²⁰

The Berne Convention, before the revision of its substantive copyright provisions (Articles 1 to 20) at the Stockholm Conference 1967 has only provided for special copyright exceptions, as contained in Articles 10, 10bis, 11bis(3) and 13(1). Back then, different copyright exceptions in favour of various public and cultural interests were widespread and available in domestic laws. Recognition of the need for information and knowledge appears to constitute one of the most frequent exceptions recognized in various domestic laws; for instance those related to works used in public speeches, quotations, school books and chrestomathies, newspaper articles, reporting of current events, as well as reproduction by photocopying in libraries.²¹

IV. SPECIFIC COPYRIGHT EXCEPTION FOR TEACHING PURPOSES

Article 10(2) of the Berne Convention specifically permits utilizing copyright work for the purpose of teaching, by stating:

It shall be a matter for legislation in the countries of the Union, and for special agreements existing or to be concluded between them, to permit the utilization, to the extent justified by the purpose, of literary or artistic works by way of illustration in publications, broadcasts or

sound or visual recordings for teaching, provided such utilization is compatible with fair practice.

Article 10(2) of the Berne Convention is not mandatory in nature since it left the matter for national legislation or for bilateral agreements between Union members to decide on²² by using the words 'it shall be a matter for legislation'.²³ Nevertheless, should a country opt to use the specific teaching exception, it must do so within the ambit of Article 10(2) of the Berne Convention and this can be analysed as follows:

A. 'TO PERMIT THE UTILIZATION'

Article 10(2) uses a general term, namely it permits the 'utilization' instead of the term 'borrowing' used in the Brussels Act 1948. By using a general term, it covers a broad range of utilization.²⁴ It was viewed that Article 10(2) is an 'open, flexible and technology-neutral exception'.²⁵ The word is considered neutral enough to cover not only reproduction, but also other kinds of economic rights granted under the Berne Convention, namely the right of adaptation, translation, distribution or communication to the public, making available to the public and even extendable to the use of digital means in teaching.²⁶ Ultimately, it is left for each national legislation to determine what 'utilization' means²⁷ and this includes all the exploitation acts

¹⁹ Sam Ricketson and Jane C Ginsburg, 'International Copyright and Neighbouring Rights: The Berne Convention and Beyond' (Second, Oxford University Press 2006) 791.

²⁰ Samuel Ricketson, 'WIPO Study on Limitations and Exceptions of Copyright and Related Rights in the Digital Environment' (World Intellectual Property Organization 2003) 14.

²¹ Ruth L Okediji, 'The International Copyright System: Limitations, Exceptions and Public Interest Considerations to Developing Countries' (UNCTAD-ICTSD 2006) 13.

²² Raquel Xalabarder, 'On-Line Teaching and Copyright: Any Hopes for an EU Harmonized Playground?' in P Torremans (ed), *Copyright Law: A Handbook of Contemporary Research* (Edward Elgar Publishing 2007) 379.

²³ Raquel Xalabarder, 'Study on Copyright Limitations and Exceptions for Educational Activities in North America, Europe, Caucasus, Central Asia and Israel' (World Intellectual Property Organization 2009)1 15 <http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=130393>.

²⁴ Samuel Ricketson, 'WIPO Study on Limitations and Exceptions of Copyright and Related Rights in the Digital Environment' (World Intellectual Property Organization 2003) 14; Raquel Xalabarder, 'Study on Copyright Limitations and Exceptions for Educational Activities in North America, Europe, Caucasus, Central Asia and Israel' (World Intellectual Property Organization 2009) 15 <http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=130393>. accessed 27 October 2015

¹⁹ Adrian Sterling, *World Copyright Law* (Sweet and Maxwell 2003).

²⁰ Mitsuo Matsushita, Thomas J Schoenbaum and Petros C Mavroidis, *The World Trade Organization: Law, Practice and Policy* (Second Edition, Oxford University Press 2006) 58.

²¹ WIPO, 'Records of the Intellectual Property Conference of Stockholm' (1971) 112.

envisaged under the Berne Convention, TRIPS and later, by the WIPO Copyright Treaty (WCT).

B. 'OF LITERARY OR ARTISTIC WORKS'

Article 10(2) also specifies that only 'literary or artistic works' may be used under the copyright exception for the purpose of teaching. A very wide and broad definition of the term 'literary and artistic works' is found in Article 2(1) of the Berne Convention, where it includes 'every production in the literary, scientific and artistic domain, whatever may be the mode or form of its expression'.

Although digital technology may pose greater risks to authors' interests compared to works used in face-to-face teaching²⁸, it has been well accepted that digital technologies are also covered under the exception.²⁹ The reason behind all the subsequent Berne Convention revisions³⁰ show that such wording was to enable educators 'to take full advantage of the new means of dissemination provided by modern technology'³¹, and that it should extend to digital fixations of works.³² Acceptance for the exceptions to be applied to digital technology can also be seen in the Agreed Statement concerning Article 10 of the WCT, where member states may '... appropriately extend into the digital environment limitations and exceptions in their national laws ... [and] devise new exceptions and limitations that are appropriate in the digital networked environment.'³³ Thus, the law made it clear that whatever mode of literary, scientific and artistic works that may be used in MOOCs, it will still be covered under the specific exceptions for teaching purposes.

²⁸ Sam Ricketson and Jane C Ginsburg, *International Copyright and Neighbouring Rights: The Berne Convention and Beyond* (Second, Oxford University Press 2006) 794.

²⁹ Raquel Xalabarder, 'The Liability of Internet Service Providers (ISP) for the Infringements Committed by Their Clients and Users' [2006] IDP. Internet, Law and Politics E-Journal 378–379 <<http://journals.uoc.edu/index.php/idp/article/view/n2-xalabarder>> accessed 27 October 2015.

³⁰ That provides for 'publications destined for educational or scientific purposes' as in the Berne Act 1886, 'educational or scientific publications' as in the Brussels Act 1948, 'publications intended for teaching or having a scientific character or in chrestomathies' as proposed in the Programme for the Stockholm Conference 1967, and the current text which added 'recordings and broadcasts'.

³¹ Raquel Xalabarder, 'Study on Copyright Limitations and Exceptions for Educational Activities in North America, Europe, Caucasus, Central Asia and Israel' (World Intellectual Property Organization 2009) 14 <http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=130393>. accessed 27 October 2015

³² Sam Ricketson and Jane C Ginsburg, *International Copyright and Neighbouring Rights: The Berne Convention and Beyond* (Second, Oxford University Press 2006) 793.

³³ WIPO, *Records of the Intellectual Property Conference of Stockholm* (1971) 112.

C. 'BY WAY OF ILLUSTRATION'

Article 10(2) uses the phrase 'by way of illustration', whose ordinary meaning refers to:

The action or fact of illustrating, (1) Lighting up, illumination, enlightenment; (2) The action of making or fact of being made illustrious, brilliant, or distinguished; distinction. Also, an example, means or cause of distinction; (3)(a) The action or fact of making clear or evident to the mind; setting forth clearly or pictorially; elucidation; explanation; exemplification; (b) That which serves to illustrate or make clear, evident, etc.; an elucidation, explanation; an example, instance; (4)(a) The pictorial elucidation of any subject; the elucidation or embellishment of a literary or scientific article, book, etc., by pictorial representations; (b) An illustrative picture; a drawing, plate, engraving, cut, or the like, illustrating or embellishing a literary article, a book, etc.³⁴

Based on the Proposal of the Working Group on Excerpts from Protected Works, 'by way of illustration,' was to be understood 'in the sense of subsidiary reproduction'.³⁵ On this basis the exception only applies when the copyright work is used for supplementing other work and is only regarded as secondary or of lesser importance.³⁶ For instance, a short video used in a MOOC to illustrate the conflict happening in Syria for its International Law students may fall under the Article 10(2) exception since the video is simply reproduced to support or demonstrate the lesson. Similarly, a journal article is reproduced for students' further reading so as to provide further clarification in the lesson.

The word 'illustration' refers to works that could make things clearer or evident to the mind, not just by giving a mere example, but also including setting forth clearly or pictorially, elucidating or explaining a matter in question, which can commonly be done by posting journal articles or chapters that better define, clarify or explain the subject matter in detail. Moreover, the Working Group dealing with Article 10(2) describes 'by way of illustration' to be understood only 'in the sense of subsidiary

³⁴ *Oxford English Dictionary* (Second, University Press 1989).

³⁵ WIPO, *Records of the Intellectual Property Conference of Stockholm* (1971) 885.

³⁶ Ratnaria Wahid, 'Exploring Flexibilities within the International Copyright System for Teaching, Research and Study' (DPhil thesis, University of East Anglia 2011).

reproduction', which means that the copyright work is used to assist or supplement the main teaching material, which is normally the lecturer's notes.³⁷

Moreover, the phrase 'by way of illustration' was not intended to restrict the term 'educational purposes' previously used in the earlier version of the Berne Convention, but to ensure that the reproductions used are indeed 'illustrating' the teaching.³⁸ However, when a journal article is reproduced for students to analyse and comment in a MOOCs' online forum, this may arguably not constitute mere 'illustration'. However, such argument is not valid because the work will be at the centre of discussion and thus becomes primary in ensuring success of the teaching activities, and therefore would not surpass the requirement of 'by way of illustration' under Article 10(2).

It was also accepted at the Stockholm Conference that the words 'by way of illustration' do impose some limitation on the size of the borrowing, but would not exclude the use of the whole of a work in appropriate circumstances.³⁹ For example, it may be necessary to reproduce a short literary work or artistic work such as case summaries or photographs in order for it to be properly utilized for teaching purposes.

D. 'PUBLICATIONS, BROADCASTS OR SOUND OR VISUAL RECORDINGS'

Article 10(2) further specifies that utilization is permitted by way of illustration 'in publications, broadcasts or sound or visual recordings for teaching'. These expressions were not meant to exhaust the full range of permissible utilizations, but instead to accommodate new technology.⁴⁰ Hence,

³⁷ WIPO, *Records of the Intellectual Property Conference of Stockholm* (1971) 885.

³⁸ Raquel Xalabarder, Study on Copyright Limitations and Exceptions for Educational Activities in North America, Europe, Caucasus, Central Asia and Israel (World Intellectual Property Organization 2009) 15 <http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=130393>. accessed 27 October 2015.

³⁹ Lucie Guibault, *The Nature and Scope of Limitations and Exceptions to Copyright and Neighbouring Rights with Regard to General Interest Missions for the Transmission of Knowledge: Prospects for their Adaptation to the Digital Environment* [2003] e-Copyright Bulletin 1, 15; Sam Ricketson and Jane C Ginsburg, *International Copyright and Neighbouring Rights: The Berne Convention and Beyond* (Second, Oxford University Press 2006) 791.

⁴⁰ Raquel Xalabarder, 'The Liability of Internet Service Providers (ISP) for the Infringements Committed by Their Clients and Users' [2006] IDP. Internet, Law and Politics E-Journal 378 <<http://journals.uoc.edu/index.php/idp/article/view/n2-xalabarder>>. accessed 27 October 2015

'distance learning', correspondence courses, 'teaching on demand' or 'broadcasting'⁴¹ or any kind of teaching and learning conducted online⁴², which are very common in MOOCs environment, are all covered under the Article 10(2) provision. By including the term 'broadcasts' it also shows that Article 10(2) includes wire transmission. Based on the records of the Brussels Conference, the delegates have accepted that broadcast was one means of wireless communication to the public, as interpreted in the Rome Convention Article 3(f) to be 'the wireless transmission for public reception of sounds or images and sounds of the representations'.⁴³

When utilizing copyright works in broadcast, it may be difficult to ensure that the utilization is used for teaching purposes only, since it is not easy to control the destination when a work is broadcasted. Hence, an educational broadcast may be made to a larger group of people other than those for whom the instruction is intended. This approach is acceptable when the Study Group rejected a proposal that seeks to limit the scope of the teaching exception to only educational broadcasts carried out within teaching establishments or inside schools.⁴⁴ Moreover, Article 10(2) encompasses not only the making of broadcasts but also the performances of broadcasts in schoolrooms or lecture theatres.⁴⁵ The phrase 'by way of illustration in publications, broadcasts or sound or visual recordings for teaching' does not constitute an exhaustive list.⁴⁶ Based on these

⁴¹ Daniel Seng, WIPO Study on the Copyright Exceptions for the Benefit of Educational Activities for Asia and Australia (World Intellectual Property Organization 2009) 10 <http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=130249> accessed 27 October 2015

⁴² Raquel Xalabarder, 'Study on Copyright Limitations and Exceptions for Educational Activities in North America, Europe, Caucasus, Central Asia and Israel' (World Intellectual Property Organization 2009) 14 <http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=130393> accessed 27 October 2015.

⁴³ Sam Ricketson and Jane C Ginsburg, *International Copyright and Neighbouring Rights: The Berne Convention and Beyond* (Second, Oxford University Press 2006) 732; Raquel Xalabarder, 'Study on Copyright Limitations and Exceptions for Educational Activities in North America, Europe, Caucasus, Central Asia and Israel' (World Intellectual Property Organization 2009) 9 <http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=130393>. accessed 27 October 2015.

⁴⁴ WIPO, *Records of the Intellectual Property Conference of Stockholm* (1971) 886.

⁴⁵ Claude Masouye, *Guide to the Berne Convention for the Protection of Literary and Artistic Works (Paris Act 1971)* (World Intellectual Property Organization 1978) 60.

⁴⁶ Raquel Xalabarder, 'Study on Copyright Limitations and Exceptions for Educational Activities in North America, Europe, Caucasus, Central Asia and Israel' (World Intellectual Property Organization 2009) 14

arguments, wireless transmission of works to public as adopted in MOOCs is covered under the teaching exception of Article 10(2).

It is debatable whether Article 10(2) facilitates the use of teaching compilations under the exception. Digital educational compilations, which are fundamental in online teaching, consisting part of the instruction itself compiled on a web page, may pose far greater risks against the legitimate interests of authors compared to non-digital educational compilations.⁴⁷ The application of Article 10(2) to teaching compilations was derived from its reference to 'publication' as well as the express reference to 'chrestomathies'⁴⁸ which might be rendered as 'educational compilations'⁴⁹ in the earlier version of the Berne Convention. This is particularly provided for in Article 8 of the Berne Act of 1886, which was later reorganized into Article 10(2) of the Brussels Act 1948.⁵⁰ The Working Group, however, recommended deleting the word 'chrestomathies' on the ground that it was no longer necessary due to the number of exceptions to the right of reproduction already available in the Convention.⁵¹

Ricketson in his early edition rationalizes that chrestomathies and anthologies, in many instances, would naturally fall within the scope of publications for teaching purposes under Article 10(2).⁵² This position was later altered, stating that it is unlikely that chrestomathies and anthologies would fall within the scope of publications intended for teaching purposes under Article 10(2), as 'it will be a distortion of language to describe an anthology of poetry (with the complete texts of the poems) or a 'course pack' consisting of chapters taken from various books about the subject to be covered in the course, as being used 'by way of illustration [...] for

teaching' .⁵³ Australia, for instance, has subjected its compilation of copyright materials to voluntary licensing arrangement or compulsory licensing schemes.⁵⁴

Others, however, contended that Article 10(2) did refer to 'publications' (as well as the original reference to 'chrestomathies' in the Berne Act), which favours the acceptance of teaching compilations provided that it fulfils further conditions i.e. 'to the extent justified by the purpose' and that 'such utilization is compatible with fair practice'.⁵⁵ Hence, it is not a straightforward case but should be decided on a case-by-case basis.

E. 'FOR TEACHING'

Article 10(2) specifically allows copyright exceptions for 'teaching', which includes 'teaching at all levels - in educational institutions and universities, municipal and State schools and private schools'.⁵⁶ The Stockholm Report however excludes education outside these institutions, for instance, general teaching available to the general public.⁵⁷ Thus, Article 10(2) only refers to formal education at elementary, intermediate and tertiary institutions of learning, or something that is of an 'official' degree.⁵⁸ Nevertheless it could be argued that such a view may be disadvantageous to informal educational setting, since the development of technology has opened up the opportunities for anyone to pursue distance learning. Applying this to the context of MOOCs, teaching can still be considered as classroom-based since it will comprise the same registered students, studying a subject matter provided by trained lecturers, guided by a specified curriculum that lasts for a certain period of time. MOOC students still need to register, follow a certain syllabus within a certain time frame, complete certain activities and are also expected to participate and contribute to forums and online discussions. Thus, MOOCs should also be considered as falling

<http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=130393>. accessed 27 October 2015.

⁴⁷ *ibid.*

⁴⁸ According to the Oxford English Dictionary, the term 'chrestomathy' refers to 'a collection of choice passages from an author or authors, esp. one compiled to assist in the acquirement of a language'.

⁴⁹ Sam Ricketson and Jane C Ginsburg, *International Copyright and Neighbouring Rights: The Berne Convention and Beyond* (Second, Oxford University Press 2006) 784.

⁵⁰ Article 10(2) of the Brussels Act 1948 provides as follows: 'The right to include excerpts from literary or artistic works in educational or scientific publications or in chrestomathies, in so far as this inclusion is justified by its purpose, shall be a matter for legislation in the countries of the Union, and for special Arrangements existing or to be concluded between them.'

⁵¹ WIPO, *Records of the Intellectual Property Conference of Stockholm* (1971) 885.

⁵² Samuel Ricketson, 'The Berne Convention for the Protection of Literary and Artistic Works: 1886-1986' (Kluwer 1987) 499.

⁵³ Sam Ricketson and Jane C Ginsburg, *International Copyright and Neighbouring Rights: The Berne Convention and Beyond* (Second, Oxford University Press 2006) 794.

⁵⁴ *ibid.*

⁵⁵ Raquel Xalabarder, 'Study on Copyright Limitations and Exceptions for Educational Activities in North America, Europe, Caucasus, Central Asia and Israel' (World Intellectual Property Organization 2009) 14 <http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=130393>. accessed 27 October 2015

⁵⁶ WIPO, 'Records of the Intellectual Property Conference of Stockholm' (1971) 293.

⁵⁷ *ibid.*

⁵⁸ Raquel Xalabarder, 'On-Line Teaching and Copyright: Any Hopes for an EU Harmonized Playground?' in P Torremans (ed), *Copyright Law: A Handbook of Contemporary Research* (Edward Elgar Publishing 2007) 378.

under the scope of formal education that could benefit from the teaching exceptions.

The word 'teaching' should not be interpreted restrictively⁵⁹, since it will exclude adult education programmes⁶⁰ which are beneficial for a country's development. In interpreting the scope of 'teaching', the focus should be on the nature of the instruction, not just on the award itself.⁶¹ It is important that in this information technology era different modes of teaching and learning are acknowledged and recognized. There is no reason to limit the scope of 'teaching' to the classroom only for the purposes of Article 10(2), and the word 'teaching' should extend to correspondence courses or Web-based courses where students receive no face-to-face instruction from a teacher.⁶²

F. 'TO THE EXTENT JUSTIFIED BY THE PURPOSE' AND 'UTILIZATION IS COMPATIBLE WITH FAIR PRACTICE'

Article 10(2) requires that the use of copyright works under the teaching exception must be justified and compatible with fair practice. At this point, commentators differ as to whether Article 10(2) as a special rule, which comes much earlier, should exist in an unqualified form or need to be applied cumulatively with the three-step test⁶³, which specifies three conditions that need to be fulfilled in order to qualify as exceptions to the reproduction right, namely that: (a) it must be a certain special

case; (b) that it does not conflict with a normal exploitation of the work; and (c) that it does not unreasonably prejudice the legitimate interest of the author.

The first possibility is that the three-step test does not need to be applied to the exception for teaching purposes. In interpreting the text of the Berne Convention, the Main Committee I⁶⁴ remarked as follows:

The Drafting Committee was unanimous in adopting, in the drafting of new texts, as well as in the revision of the wording of certain provisions, the principle *lex specialis legi generali derogat*: special texts are applicable, in their restricted domain, exclusive of texts that are universal in scope. For instance, it was considered superfluous to insert in Article 9, dealing with some general exceptions affecting authors' rights, express references to Articles 10, 10*bis*, 11*bis* and 13 establishing special exceptions.

This line of interpretation demonstrates that the operation of the specific teaching exception within its specific sphere is unaffected by the more general provision contained in Article 9(2).⁶⁵ The uses allowed under the teaching exception are thus not bound by the requirement of the three-step test.⁶⁶ Applying the principle of *lex specialis legi generali derogat*, which means that specialized law prevails over general law, the teaching exception continues to exist in an unqualified form because it provides, in effect, a special rule, where the three-step test would not be applicable.⁶⁷

Thus, although the three-step test appears to apply to all types of exceptions, there is a general rule of interpretation that where there is a specific rule in an earlier treaty, then that earlier treaty continues and is not replaced by the general provision of a later treaty. Moreover, in discussing Article 9(2) of the Berne Convention, the study group pointed out that 'the provisions already existing for certain special purposes (Articles 10, 10*bis* and 11*bis*, paragraph (3) must be regarded as rules exercising

⁵⁹ WIPO, *Records of the Intellectual Property Conference of Stockholm* (1971) 886.

⁶⁰ Sam Ricketson and Jane C Ginsburg, *International Copyright and Neighbouring Rights: The Berne Convention and Beyond* (Second, Oxford University Press 2006) 792; Raquel Xalabarder, 'Study on Copyright Limitations and Exceptions for Educational Activities in North America, Europe, Caucasus, Central Asia and Israel' (World Intellectual Property Organization 2009) 14 <http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=130393> accessed 27 October 2015.

⁶¹ Daniel Seng, 'WIPO Study on the Copyright Exceptions for the Benefit of Educational Activities for Asia and Australia' (World Intellectual Property Organization 2009) 8 <http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=130249> accessed 27 October 2015.

⁶² Sam Ricketson and Jane C Ginsburg, *International Copyright and Neighbouring Rights: The Berne Convention and Beyond* (Second, Oxford University Press 2006) 793.

⁶³ The three-step test is provided for in Article 9(2) of the Berne Convention and Article 13 of the TRIPS Agreement, which bears the same three conditions. Article 9(2) of the Berne Convention provides that: 'It shall be a matter for legislation in the countries of the [Berne] Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.'

⁶⁴ WIPO, *Records of the Intellectual Property Conference of Stockholm* (1971) 1134.

⁶⁵ Richard K Gardiner, *Treaty Interpretation* (Oxford University Press 2008) 297–298.

⁶⁶ Samuel Ricketson, 'WIPO Study on Limitations and Exceptions of Copyright and Related Rights in the Digital Environment' (World Intellectual Property Organization 2003) 21.

⁶⁷ Richard K Gardiner, *Treaty Interpretation* (Oxford University Press 2008) 297–298.

limits on the questions with which they deal'.⁶⁸ On this basis, the teaching purposes exception continues to exist in an unqualified form because it provides, in effect, a special rule, and thus the three-step test does not need to be applied in this particular situation.

Based on this structure of the Berne Convention, states may freely enact legislation on subjects covered under the specific exceptions without the restrictions of the three-step test.⁶⁹ Hence, it is up to member countries to consider what is regarded as 'fair practice' and 'justified by the underlying purpose'.⁷⁰ The expression 'fair practice' implies that 'the uses in question can only be accepted after an objective appreciation'.⁷¹ The requirement of 'fair practice' is essentially a question for national tribunals to determine in each particular instance. Using copyright works without permission or not paying compensation for work used for the purpose of teaching in a private university, may not be considered 'justified by the purpose'. Similarly, utilizing a substantial amount of copyright works, even for the purpose of teaching, may not be considered as fulfilling the condition of 'compatible with fair practice'.

Despite these two conditions, an analysis of the specific teaching exception provision in the Berne Convention shows that it is quite an open, flexible and technology-neutral exception, in the sense that it does not limit copying to any specific quantitative or qualitative restrictions on exempted uses.⁷² The provision also does not require any payment of remuneration; it is up to member states to implement it either as a free exception or limitation, as a remunerated legal licence, or as a combination of both.⁷³ Such flexibilities certainly provide an opportunity for member countries to find the right balance between the public interest (education) and that of the author, according to their different circumstances.

⁶⁸ WIPO, *Records of the Intellectual Property Conference of Stockholm* (1971) 112.

⁶⁹ Ruth L Okediji, *The International Copyright System: Limitations, Exceptions and Public Interest Considerations to Developing Countries* (UNCTAD-ICTSD 2006) 14.

⁷⁰ Raquel Xalabarder, 'On-Line Teaching and Copyright: Any Hopes for an EU Harmonized Playground?' in P Torremans (ed), *Copyright Law: A Handbook of Contemporary Research* (Edward Elgar Publishing 2007) 380.

⁷¹ WIPO, *Records of the Intellectual Property Conference of Stockholm* (1971) 117.

⁷² Raquel Xalabarder, 'On-Line Teaching and Copyright: Any Hopes for an EU Harmonized Playground?' in P Torremans (ed), *Copyright Law: A Handbook of Contemporary Research* (Edward Elgar Publishing 2007) 378.

⁷³ Raquel Xalabarder, 'On-Line Teaching and Copyright: Any Hopes for an EU Harmonized Playground?' in P Torremans (ed), *Copyright Law: A Handbook of Contemporary Research* (Edward Elgar Publishing 2007) 380

The second possibility is where Article 13 of the TRIPS Agreement applies the three-step test to all exceptions to exclusive rights, as it is clearly expressed, and thus should be applied in addition to the exception for teaching purposes. It was viewed that the specific exceptions are supported by the open-formulated three-step test, which acts as an additional safeguard.⁷⁴

Thus, a national legislature that wants to exempt the utilization of a work by way of illustration for teaching must fulfil not only the conditions under Article 10(2) of the Berne Convention, but also the abstract criteria of the three-step test. The exception must also be limited to certain special cases, not conflict with the normal exploitation of a work, and not unreasonably prejudice the legitimate interests of the right holder. All specific limitations provided under the Berne Convention, including teaching exceptions, can automatically be regarded as a 'special case'.⁷⁵ In terms of the application of the two conditions to MOOCs, it depends on the facts and circumstances of the case.

Without clear interpretation and in the context of the TRIPS Agreement, WCT and WPPT, it was viewed as advisable to employ the proportionality test inherent in the three-step test in determining whether the use of certain copyright work is 'fair'.⁷⁶ To this extent, one may need to consider the kind and amount of work used, the quantity of copies made, and the specific implications of the technology, in order to find the right balance between the copyright owners' and the users' interest.

It may well be that when a person applies the three-step test in addition to the teaching purposes exception, he may find himself going through the same exercise twice because he is only considering the same factors in relation to the teaching purposes exception and the three-step test, but in a different

⁷⁴ Martin Senftleben, 'Copyright, Limitations and the Three-Step Test: An Analysis of the Three-Step Test in International and EC Copyright Law' (Kluwer Law International 2004) 155.

⁷⁵ *ibid.* 157.

⁷⁶ Sam Ricketson and Jane C Ginsburg, *International Copyright and Neighbouring Rights: The Berne Convention and Beyond* (Second, Oxford University Press 2006) 793; Martin Senftleben, 'Copyright, Limitations and the Three-Step Test: An Analysis of the Three-Step Test in International and EC Copyright Law' (Kluwer Law International 2004); Raquel Xalabarder, 'On-Line Teaching and Copyright: Any Hopes for an EU Harmonized Playground?' in P Torremans (ed), *Copyright Law: A Handbook of Contemporary Research* (Edward Elgar Publishing 2007)

language.⁷⁷ Bringing the teaching purposes exception and the three-step test together, it can be seen that although the two exceptions are not identical, there are compromises between those.⁷⁸ Article 10(2) reiterates factors that are similar to the three-step test, which are thus not likely to yield a different outcome in normal circumstances; both exceptions seem to have similar philosophies.

When the three-step test and the inherent requirement of the teaching purposes exceptions are applied cumulatively, in effect the TRIPS Agreement may conceivably narrow the scope of the teaching purposes exception under the Berne Convention. This may occur based on a narrow reading of TRIPS on the assumption that Article 10(2) of the Berne Convention does not oblige States to comply, but leaves it to countries to decide as a matter of national legislation.⁷⁹

G. ACKNOWLEDGEMENT

Article 10(2) is further subject to the requirement in Article 10(3) of the Berne Convention which requires that the source and the name of the author be mentioned when copyright works are used for teaching purposes. The attribution of the source and authorship is consistent with common practice in educational scholarship.⁸⁰

However, there are inconsistent views regarding the question of whether the right of integrity or moral rights as referred in Article 6*bis* of the Berne Convention also applies.⁸¹ Ricketson initially viewed

that the moral right under Article 6*bis* does not apply in respect of Article 10, as for practical reasons, there is a need for flexibility to modify and alter a work where necessary when it is quoted or utilized for teaching purposes.⁸² However, on the basis of the report of the Main Committee I, which notes that delegates generally agreed that Article 6*bis* applied in respect of exceptions authorized by the Convention, including Article 10⁸³, it was later viewed that 'while modifications within reason may be required when works are utilized for teaching purposes, this should not give *carte blanche* to educators to make deleterious, reputation-damaging alterations'.⁸⁴

V. CONCLUSION

In short, Article 10(2) of the Berne Convention can facilitate the teaching of courses in universities via MOOCs provided that it is flexibly interpreted. The wording under Article 10(2) is purposely couched to be open and flexible, so as to allow national lawmakers to take advantage of its flexibility and to apply the scope of the teaching exception according to their circumstances. The rights cover a broad use of works for teaching exceptions. Based on a flexible interpretation, the exception may apply when a work is copied, reproduced, translated, adapted or performed for the purpose of teaching. The exception may also apply when the copyright work is communicated or made available to the public. Thus, flexibly interpreted, Article 10(2) seems to support various activities conducted on copyright works, which are commonly undertaken by lecturers when teaching their students and this includes MOOC as a new form of delivery in teaching and learning.

The phrase 'justified by the purpose' and 'compatible with fair practice' under Article 10(2) was also worded in general terms and necessitates further

⁷⁷ Ratnaria Wahid, 'Exploring Flexibilities within the International Copyright System for Teaching, Research and Study' (DPhil thesis, University of East Anglia 2011).

⁷⁸ *ibid.*

⁷⁹ *ibid.*

⁸⁰ Daniel Seng, 'WIPO Study on the Copyright Exceptions for the Benefit of Educational Activities for Asia and Australia' (World Intellectual Property Organization 2009) 11 <http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=130249>. accessed 27 October 2015.

⁸¹ Article 6*bis* of the Berne Convention reads:

(1) Independently of the author's economic rights, and even after the transfer of the said rights, the author shall have the right to claim authorship of the work and to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, the said work, which would be prejudicial to his honor or reputation.

(2) The rights granted to the author in accordance with the preceding paragraph shall, after his death, be maintained, at least until the expiry of the economic rights, and shall be exercisable by the persons or institutions authorized by the legislation of the country where protection is claimed. However, those

countries whose legislation, at the moment of their ratification of or accession to this Act, does not provide for the protection after the death of the author of all the rights set out in the preceding paragraph may provide that some of these rights may, after his death, cease to be maintained.

(3) The means of redress for safeguarding the rights granted by this Article shall be governed by the legislation of the country where protection is claimed.

⁸² Samuel Ricketson, 'WIPO Study on Limitations and Exceptions of Copyright and Related Rights in the Digital Environment' (World Intellectual Property Organization 2003) 16.

⁸³ WIPO, *Records of the Intellectual Property Conference of Stockholm (1971)* 1165.

⁸⁴ Sam Ricketson and Jane C Ginsburg, *International Copyright and Neighbouring Rights: The Berne Convention and Beyond* (Second, Oxford University Press 2006) 796.

interpretation by the courts. Hence, the provision still allows for national law to take advantage of the inherent flexibilities. Arguably, the three-step test may or may not necessarily be employed. It is for the national law to determine the exempted use of works for teaching purposes, within the limits of Article 10(2).⁸⁵ The exceptions provided under international agreements are purposely couched in general terms, so as to pose as guidance and as a yardstick for member countries to make laws that suit their needs and circumstances.

The teaching exception is important since it is based on major public interest considerations, such as the promotion of education and culture.⁸⁶ Copyright exceptions also prevent monopoly control⁸⁷ and exploitation not just by authors or inventors, whose creativity are supposed to be rewarded, but by large information-based corporations.⁸⁸ In rapid technological development, various works can easily be made available, benefiting the public by way of reducing costs for innovation, encouraging the exchange of ideas as well as enhancing networking, public funding and support.⁸⁹ Often, it is in the interest of authors to disseminate and make known his or her creations. Copyright exceptions play an important role as a mechanism of access and

contribute to the dissemination of knowledge, which in turn is essential for a variety of human activities and values, including liberty, the exercise of political power, and economic, social and personal advancement ... open up rapid advances in information and communication technologies that are fundamentally transforming the processes of production, dissemination and storage of information.⁹⁰

⁸⁵ Raquel Xalabarder, 'On-Line Teaching and Copyright: Any Hopes for an EU Harmonized Playground?' in P Torremans (ed), *Copyright Law: A Handbook of Contemporary Research* (Edward Elgar Publishing 2007) 380.

⁸⁶ Lucie Guibault, 'Contracts and Copyright Exemptions' in PB Hugenholtz (ed), *Copyright and Electronic Commerce: Legal Aspects of Electronic Copyright Management* (Kluwer Law International 2000) 137.

⁸⁷ Adrian Sterling, *World Copyright Law* (Sweet & Maxwell 2003).

⁸⁸ S Picciotto, 'Defending the Public Interest in TRIPS and the WTO' in Peter Drahos and R Mayne (eds), *Global Intellectual Property Rights: Knowledge, Access and Development* (Palgrave 2002) 1–2.

⁸⁹ *ibid.* 1.

⁹⁰ PB Hugenholtz and Ruth L Okediji, 'Conceiving an International Instrument on Limitations and Exceptions to Copyright' (2008) 10–11. <<https://www.opensocietyfoundations.org/reports/conceiving-international-instrument-limitations-and-exceptions-copyright>> accessed 27 October 2015.

A successful implementation of MOOCs will only materialize through sufficient understanding of the role of copyright law and utilizing the flexibilities permitted under the copyright exceptions, taking into consideration the need of the people. It is important for every country to address the issue of access and sharing of information for the purpose of education that considers the interests of both copyright owners and users. However, public interest in education should be given more weight, as education is not a luxury, nor a mortgage nor a business, but a right to be upheld. In a time when education could be delivered across borders instantly with minimal costs, copyright law should not be seen as posing a risk or a hindrance. While some aim to profit from education by means of technology, one should not take for granted the shared responsibility in supporting education, which is considered a basic human right for all.

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7 ESTABLISHMENT OF SPECIALIZED IP COURTS IN PAKISTAN FOR THE EFFICIENT ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

Saad Nusrullah*

ABSTRACT

In the last few years intellectual property has been gaining ever increasing recognition in Pakistan. The Government of Pakistan is concerned about the impact of infringement, counterfeiting and piracy on Pakistan's economy, and is taking steps to curb infringing activities and ensure effective enforcement of intellectual property rights in the country. One such step is the establishment of separate intellectual property courts, as required under the Intellectual Property Organization of Pakistan Act, 2012. This paper examines the previous judicial regime for the enforcement of intellectual property rights in Pakistan, and highlights issues relating to the present system and the need for improvement. In addition, it considers the advantages and drawbacks of establishing separate intellectual property courts in Pakistan, and examines the experience of several other countries.

Keywords: *Intellectual property rights (IPRs), enforcement, infringement, counterfeiting, piracy, special courts, and judicial system*

I. INTRODUCTION

The enforcement of intellectual property rights (IPRs) is a controversial issue among developing¹ and developed countries. Intellectual property rights are the rights which are given to persons over the creation of their minds. They usually give the creator an exclusive right over the use of his or her creation for a certain period of time.² The Paris Convention was the first treaty regarding IPRs and was signed in 1883³. The Convention was revised at Brussels in

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¹ Instead of using the term 'developing countries' and 'least developed countries' separately, 'developing countries' will be used for both.

² http://www.wto.org/english/tratop_e/trips_e/intel1_e.htm (last visited 15 January 2016).

³ International agreements concerning IPRs occurred in the later part of the 19th Century. In 1873, the Austrian Government held an international exhibition of inventions at Vienna, many inventors were hesitant to exhibit. They feared that in the absence of protection their inventions might be copied. In response, several diplomatic

conferences were held. These culminated in 1883, when 11 States signed the Paris Convention for the protection of Industrial Property. The convention established rules between the Member States concerning patents, trademarks and industrial designs.⁴ Simon Walker, 'The TRIPS Agreement, Sustainable Development and the Public Interest, Environmental Policy and Law' Paper No. 41, IUCN-The World Conservation Union, 2011, pp5-6.

⁴ http://www.wipo.int/treaties/en/ip/parish/summaries/_paris.html (last visited 15 January 2016).

⁵ *ibid.*

⁶ Simon Walker, *The TRIPS Agreement, Sustainable Development and the Public Interest, Environmental Policy and Law Paper No. 41*, IUCN-The World Conservation Union, 2011, pg.6

⁷ Berne Convention for the Protection of Literary and Artistic works.

⁸ https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited 15 January 2016).

⁹ https://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm#Who%27sSigned (ast visited 15 January 2016)

¹⁰ Preamble of the TRIPS Agreement 1995.

¹¹ Article 41(1) Section 1. General Obligations. Part III.

II. SPECIALIZED IP COURTS

Since the TRIPS Agreement is an Annex to the Marrakesh Agreement Establishing the World Trade Organization, all WTO Members are bound by it. However different time frames were granted to states according to their status as developed and developing countries⁹, after which states had to start incorporating the standards and laws governing IPRs under the TRIPS Agreement.¹⁰

The agreement generally obliged Member States to comply with the standards for the protection of IPRs and to prevent infringements by enacting laws by providing remedies and taking further steps to promote protection.¹¹ Under the Agreement, Members were obliged to implement a fair, speedy and improved system of IPR enforcement, just like

any other legal system.¹² States were not required to create a separate specialized system or courts in order to deal with IPR disputes distinct from the existing system dealing with the other laws in general. However, states have established separate IPR courts at their own discretion.¹³ Most of the Member States have established separate specialized Tribunals or Courts in order to resolve IPR-related disputes in order to make the system more efficient. These courts are established with different names in different states such as the Specialized Intellectual Property Court¹⁴, the Intellectual Property Court¹⁵, the Patents Court, a specialist court within the Chancery Division of the High Court of Justice of England and Wales¹⁶, the central Intellectual Property and International Trade Court (IP&IT Court),¹⁷ and the Court for Intellectual Property Disputes¹⁸, to name a few. The purpose of all these Tribunals is basically to arbitrate on issues concerning IPRs.

This establishment of separate systems for the protection of IPRs has been highly appreciated by forums such as the International Intellectual Property Institute (IIPi) and the United States Patent and Trademark Office (USPTO) for a variety of reasons. Such specialized judicial systems develop a better understanding and awareness of IPR-related matters, which ultimately reduces litigation and judicial errors, and brings coherency and certainty making the system effective overall with an increased predictability of case outcomes. There are different models of courts with different names adopted by the various states but having an identical purpose. Some states have one kind of court only and some have more than one for intellectual property-related disputes. These different courts in the various countries are as follows:

Specialized IPR Trial Court;¹⁹

Specialized IPR Appeals Court;²⁰

Specialized IPR Trial Division;²¹

Specialized IPR Appeals Division;²²
Commercial Trial Court;²³

Commercial Appeals Court;²⁴

Trial Court that exclusively hears IP;²⁵

Appeals Court that exclusively hears IPR cases;²⁶

Administrative Tribunal;²⁷

Specialized Judges on Courts of General Jurisdiction;²⁸

Considering Specialized IPR Court, Division, or Tribunal;²⁹ and

Considering Commercial Court.³⁰

In the United States there is one specialized IPR court, the United States Court of Appeals for the Federal Circuit.³¹ It is an appellate court which has jurisdiction over matters related to patents, trademarks, appeals from the United States Court of International Trade, the US Trademark Trial and Appeals Board, the US Patent Trial and Appeal Board and issues, including issues arising from the US International Trade Commission. The court mainly provides guidance to the lower courts concerning IPR cases.³²

As regards specialized courts in China, the government has established a court of general jurisdiction with a specialized division that hears IPR disputes. The Chinese judicial system essentially consists of Basic People's Courts, Intermediate People's Courts, High People's Courts and the

¹² Article 41(2) Section 1.General Obligations. Part III.

¹³ Article 41(5) Section 1.General Obligations. Part III.

¹⁴ Malaysia names its court the 'Intellectual Property Session Court'.

¹⁵ Singapore's 'Intellectual Property Court' is one of the specialist commercial court established under the High Court of Singapore.

¹⁶ United Kingdom

¹⁷ Thailand

¹⁸ The Intellectual Property Court, Russian Federation.

¹⁹ First instance court that only hears IPR disputes.

²⁰ Second instance court that only hears IPR disputes.

²¹ Specialized division of a first instance court of general jurisdiction that only hears IPR disputes.

²² Specialized division of a second instance court of general jurisdiction that only hears IPR disputes.

²³ First instance court that hears IPR matters in addition to other commercial, economic, business disputes.

²⁴ Second instance court that hears IPR matters in addition to other commercial, economic, business disputes.

²⁵ First instance court of general jurisdiction that exclusively hears IPR matters.

²⁶ Second instance court of general jurisdiction that exclusively hears IPR matters.

²⁷ Specialized tribunal that is part of an administrative agency and hears IPRs matters.

²⁸ Judges sitting on courts of general jurisdiction who have training or experience in IPR matters.

²⁹ The state is considering implementing a specialized IPR trial or appeals court, a specialized IPR trial or appeals division, or a specialized IPR administrative tribunal.

³⁰ The state is considering implementing a commercial trial or appeals court.

³¹ The court was established under Article III of the Constitution by the Congress on 1 October 1982.

³² <<http://www.caft.uscourts.gov/the-court/court-jurisdiction>> (last visited 15 January 2016).

Supreme People's Court.³³ All High People's Courts, Intermediated People's Courts and Basic People's Courts have specialized IPR divisions with civil jurisdiction to hear IPR cases. There is also a specialized division in the Supreme People's Court to hear cases related to IPRs. There are specialized IPR judges in these specialized divisions.³⁴ A specialized IPR tribunal, the Chinese Intellectual Property Organization's Re-examination Board, conducts the proceedings of annulment. The People's Courts has the jurisdiction to hear appeals from the board.³⁵ The victims of infringements can also seek reliefs from the administrative organization which enforces quickly.³⁶

Similarly, Japan has also established a separate system for IPR-related issues, comprising a specialized appeals court, specialized divisions of district and appeals court to hear cases regarding IP disputes. Appeals from district courts on patent actions, suits against decisions of the Japan Patent Office, and IPR cases of first instance can be filed before the Intellectual Property High Court. Further, one specialized division of the Osaka High Court, four divisions of the Tokyo District Court and two divisions of the Osaka District Court have been established to hear IPR cases.³⁷

India, as a developing country, has established a specialized administrative tribunal, which hears appeals regarding IPRs. The decisions of the Register Trademarks can be appealed to the Indian Intellectual Property Appeals Board, established in 1999. There must be at least one technical and one judicial member on the board.³⁸ It sits in Ahmedabad, Chennai, Delhi, Kolkata and Mumbai. Trials regarding infringement are under the jurisdiction of the High Court.³⁹

³³ The Supreme People's Court of the People's Republic of China, Intellectual Property Protection by Chinese Courts in 2009, <http://www.court.gov.cn/zscq/znsq/201004/t20100426_4545.html> (Last visited 15 January 2016).

³⁴ *ibid.*

³⁵ Patent Law of the People's Republic of China, Adopted at the 4th Session of the Standing Committee of the Sixth National People's Congress, 12 March 1984, Amended 27th Session of the Standing Committee of the Seventh National People's Congress, 4 September 1992.

³⁶ United Kingdom Intellectual Property Office, Intellectual Property Rights Primer For China 24 (2008).

³⁷ The International Intellectual Property Institute (IPI) and the United States Patent and Trademark Office (USPTO), *Study on Specialized Intellectual Property Courts* (2012)

³⁸ Peter Oller, 'Academics Challenge India's IP Appeals Board' *Managing Intellectual Property* (11 February 2011).

³⁹ Intellectual Property Appeals Board, <<http://www.ipab.tn.nic.in/>> (last visited 15 January 2016).

III. ESTABLISHMENT OF SPECIAL IP COURTS IN PAKISTAN

Pakistan, being a member of WTO since 1 January 1995, is also a developing country and as such the provisions of the TRIPS Agreement and all the obligations regarding IPR enforcement are applicable.⁴⁰ The TRIPS Agreement granted its members classified as developing economies like Pakistan a period of five years, i.e. until 2000, to bring laws governing IPRs in conformity with the obligations required by the Agreement.⁴¹ Formerly, the protection of IPRs was not well developed in Pakistan. The laws governing IPRs in Pakistan can be divided into two regimes: Pre-2000 and Post-2000.

The existence of these two regimes is obvious for the reason that after 2000 Pakistan was obliged to replace its outdated and archaic IP-related laws, in order to comply with the global standards and the requirements of the TRIPS Agreement.⁴² The pre-2000 legislation⁴³ included:

- The Patents and Designs Act 1911 and the Patent Rules 1933;
- The Patents and Designs Act 1911 and Design Rules 1933;
- The Trademarks Act 1940 and the Trademark Rules 1963; and
- The Copyright Ordinance 1962 and the Copyright Rules 1967.

The foregoing laws were replaced with new laws i.e. post-2000 legislation⁴⁴, including:

- The Patent Ordinance 2000 and the Patent Rules 2003;
- The Registered Designs Ordinance 2000;
- The Registered Layout-Designs of Integrated Circuits Ordinance 2000;

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<https://www.wto.org/english/thewto_e/countries_e/pakistan_e.htm> (last visited 15 January 2016).

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<https://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm#Who%27sSigned> (Last visited 15 January 2016).

⁴² *Id.*

⁴³ <<http://supremecourt.gov.pk/jjc/Articles/19/2.pdf>> (last visited 15 January 2016).

⁴⁴ *ibid.*

- The Trademarks Ordinance 2001 and the Trademark Rules 2004;
- The Copyright Ordinance 1962, as amended in 2000; and
- The Copyright Rules 1967, as amended in 2002.

The two aforementioned regimes with different legislations highlight the impact of the TRIPS Agreement, which resulted in significant changes in the laws related to IPRs. The Intellectual Property Organization of Pakistan (IPO-Pakistan) established on 8 April 2005 under the cabinet division is the main institution in Pakistan that deals with the management and enforcement of IPRs, creating awareness about their great importance in a modern and digitalized society. It deals with the administration of IPRs, including patents, trademarks, designs and copyrights and promotes protection by taking various steps and proposes legislation.⁴⁵

The concept of specialized courts or tribunals having exclusive jurisdiction over particular subject matters is not novel or without examples in the context of Pakistan.⁴⁶ The constitution of Pakistan allows the establishment of such specialized courts.⁴⁷ Therefore, in order to further strengthen IPR enforcement and to increase efficiency, separate IPR Tribunals having exclusive jurisdiction regarding IPR-disputes have been established in Pakistan, based on modern IP judicial models. However the number of such tribunals is determined by the federal government, according to judicial necessity. At present three courts have been established: one in Punjab, in Sindh and the last in the federal capital territory of Islamabad; the courts became functional on 1 October 2015 after the appointment of presiding officers.⁴⁸ The Tribunals have the exclusive jurisdiction to hear cases regarding the infringement of IPRs or any other offence related to IP.⁴⁹ Then any

⁴⁵ <<http://ipo.gov.pk/Contents/AboutIPO.aspx>>(last visited 15 January 2016).

⁴⁶ Anti-Terrorism courts, Accountability Courts, Banking Courts, Consumer Courts, Child Protection Court, Drug Courts, Environmental Protection Tribunals, Labour Courts to name a few are currently working in Pakistan.

⁴⁷ Article 175. The Judicature. Part VII. The Courts. Chapter 1 of the Constitution of the Islamic Republic of Pakistan.

⁴⁸ <<http://ipo.gov.pk/Common/NewsDetails.aspx?NewsID=253>> (last visited 15 January 2106).

⁴⁹ Section 18(1) and (2) of the Intellectual Property Organization of Pakistan Act, 2012.

High Court having territorial jurisdiction over the tribunal can hear the appeals from the tribunals.⁵⁰

IV. ADVANTAGES AND DRAWBACKS OF SPECIALIZED IP COURTS

A state stands to gain numerous benefits by establishing a specialized IP judicial system as exemplified in some of the systems of developed countries. The establishment of a specialized IP enables governments to legislate according to issues and challenges in this particular area of litigation, in which legislation may include regulations, procedures or laws. Specialized IP courts in Pakistan would give judges of the courts an opportunity to develop expertise in IP law. Such expertise in this area would enable the judges to decide IP cases more efficiently and effectively. The impact of such expertise would be that the judges and advocates would be able to diagnose patterns, intricacies and issues arising from cases, rendering the overall system more effective.⁵¹

Intellectual property-related Issues are becoming more complicated than ever as a result of changing technologies and the rise in the number of innovations. Hence a specialized system with expert and competent professionals would contribute to an incessant development in this legal arena, required to tackle these issues effectively. The establishment of a specialized IP system would ensure protection of IPRs and encourage business and commercial communities to invest. Weak enforcement of IPRs in some developing countries like Pakistan might discourage multinational companies to invest and start business in such countries due to the possibility of loss of their valuable rights. The establishment of specialized IP courts would improve the protection of IPRs and encourage multinational companies to invest more in Pakistan; hence its economy would grow further.

Though there can be many benefits of a specialized IP system, still the hypothesis may not stand equally true and beneficial for every state. There must be a contextualized analysis of the particulars of the given country, taking into consideration the advantages and drawbacks in order to measure the overall efficacy. If a specific model is effective in a particular country, it does not necessarily mean that such a model would be appropriate in any other country. Every state should adopt a model for the protection of IPRs, customized and tailored to its own

⁵⁰ Section 19 of the Intellectual Property Organization of Pakistan Act, 2012.

⁵¹ The International Intellectual Property Institute (IPI) and the United States Patent and Trademark Office (USPTO), *Study on Specialized Intellectual Property Courts* (2012).

conditions, context, requirements and pattern or nature of the issues. These considerations should be taken into account by every government and are crucial, especially for a developing country with quite limited resources like Pakistan. Accordingly, it must be evaluated if the cost is justifiable, because a great deal would be spent on infrastructure and the establishment of such a specialized system.

Another aspect to take into account is that there should be sufficient litigation for a separate system in order to justify this cost. Thus the cost must be weighed against the benefits, otherwise it would be merely the misuse of resources and it would be more pragmatic to spend the resources to resolve a number of other issues that a country like Pakistan is facing such as poverty and terrorism. In a country like Pakistan the focus should be on promoting IP education by arranging special courses and training on IPRs for small and medium-sized enterprises (SMEs), lawyers, judges and the business communities. This would be a more pragmatic approach, as it would not only reduce litigation by bringing awareness, but also reduce the need for such tribunals and would save resources for other issues.⁵²

The countries having modern IP judicial systems models have IP expertise in the specialized courts for the IPR matters as exemplified in the aforementioned case-studies. The establishment of a separate IP court system seems logical and justified only if it has the judges who have special knowledge in IPRs, otherwise there is no point in creating a separate system if it lacks this requirement because there will be no novelty, and instead of bringing the intended consistency, certainty and efficiency, it will inevitably lead to various problems.

As regards the situation in Pakistan at present, separate tribunals have been established, but the qualification for presiding officers does not include any expertise in IP. A person who has been judge of the High Court or has been a District and Sessions Judge or an advocate who is qualified to be appointed as a Judge of High Court can be a presiding officer in the IP tribunal, so technically there is no one specialized in the IP tribunals.⁵³

The other issue with the specialized IP tribunals in Pakistan is that only three courts have been

⁵² The International Intellectual Property Institute (IIPi) and the United States Patent and Trademark Office (USPTO), *Study on Specialized Intellectual Property Courts* (2012)

⁵³ Section. 16(4) of the Intellectual Property Organization of Pakistan Act, 2012.

established in the province of Sindh, Punjab and in the federal capital territory Islamabad but no tribunal has been established in *Khyber Pakhtunkhwa* and the province of Baluchistan.⁵⁴ So it has become difficult for litigants to access the tribunals as there are many commercial centres in major cities and this has further worsened the situation, because before the establishment of the aforementioned tribunals, the proceedings regarding IPRs could be initiated in any district court. This is a very important factor which must be considered for tribunals should be easily accessible to the litigants, whether by increasing the number of tribunals or analysing the locations of commercial centres, and the locations of the tribunals should be decided accordingly.⁵⁵

The other issue concerning the establishment of specialized IP tribunals is that, as the judges would remain the same and only a limited number of judges would preside, there is a probability that judges may become prejudiced. As in Pakistan there would be one judge in each IP tribunal and this legal arena is still developing, only a limited number of lawyers are experts on IP-related issues, and they would be frequently appearing before the same judge with the possibility that the judge may become biased, which is detrimental to the essence of the independence of the judiciary i.e. impartiality, and may lead to corruption.⁵⁶

Establishing specialized IP courts dealing with particular IP matters may narrow the vision and the mentality of the judges confined to IP matters and may lead to ignorance of other legal causes of action and matters involved in a case. This would affect cases which involve multiple interlinking issues, need to be resolved collectively.⁵⁷

V. CONCLUSION

Having specialized intellectual property courts may represent both benefits and issues and challenges. Pakistan, being a developing country with limited resources, should focus on bringing awareness to lawyers and judges with special training. Public

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<<http://ipo.gov.pk/Common/NewsDetails.aspx?NewsID=253>>(last visited 21 February 2016).

⁵⁵ The International Intellectual Property Institute (IIPi) and the United States Patent and Trademark Office (USPTO), *Study on Specialized Intellectual Property Courts* (2012).

⁵⁶ The International Intellectual Property Institute (IIPi) and the United States Patent and Trademark Office (USPTO), *Study on Specialized Intellectual Property Courts* (2012).

⁵⁷ *ibid.*

awareness of intellectual property compliance also needs to be enhanced, keeping in view factors such as poverty, corruption, nepotism, lack of expertise and lack of IP education. Thus instead of establishing separate intellectual property tribunals, leading to various issues in the context of Pakistan, a more pragmatic middle ground would be to improve the existing legal system for IP matters by reforming the overall judicial system and diagnosing the root causes of the issues rendering the overall system inefficient. It could be more justifiable in terms of cost and benefits. However, as the specialized intellectual property tribunals have now been established by the Government of Pakistan and are now functional, such tribunals would only serve the purpose if judges receive suitable training on the subject matter and other steps, necessary to maximize the benefits and minimize the issues and challenges related to specialized IP courts, are urgently taken, keeping in view the limited resources and other constraints being faced by the country.

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8 PARALLEL IMPORTS, TRADEMARK LAW, AND AGENCY REGULATIONS: LEGAL UNCERTAINTY IN UAE JURISPRUDENCE

Dr Bashar Malkawi*

ABSTRACT

Parallel importation is one of the most enigmatic issues in the laws of the United Arab Emirates (UAE). This article addresses the merits and demerits of parallel importation from the perspective of the UAE. It reviews the relevant provisions in its trademark and agency laws, as well as relevant case law. The article also examines the options available to the UAE legislature to reform its laws and then provides a set of conclusions and recommendations.

Keywords: trademarks law, agency law, parallel imports, exhaustion, trade

I. INTRODUCTION

Trademarks are among the most precious assets of enterprises. The value of a trademark amounts to billions of dollars. Each year the Best Global Brands Report generates increasing interest from companies and practitioners associated with brands and the Report lists the top 100 most valuable brands worldwide.¹ Emirates Airline, headquartered in the UAE, is the most valuable airline brand worldwide valued at US\$7.5 billion.²

The UAE encounters cases of parallel importation because it is a high-priced economy. Parallel imports can occur on account of the non-availability of a product in the market or of sourcing low-priced products from other countries, thus making it possible to make profits through price differences.³ Generally parallel import

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¹ See Best Global Brands Ranking, *Interband Ranking* (2014), available at <<http://www.bestglobalbrands.com/2014/ranking/>>

² Emirates finished 171 out of the 500 evaluated global brands. See *Emirates Soars as World's Most Valuable Airline*, Gulf News (2 February 2016).

³ See Triska Hamid, 'UAE Tech Fans Forced to Dig Deep for Microsoft Surface' *The National* (11 November 2012) (In September the iPhone 5 reached Dh6,000 before dropping almost Dh2,000 only a few weeks later). The main reason why parallel imports have emerged is price differentials between the same products sold in different markets. See also Christopher Stothers, *Parallel trade in Europe: Intellectual Property, Competition and Regulatory Law 2* (2008).

products are cheaper, depending on the nature of the product, owing to the absence of customer care and warranties.⁴ In exceptional circumstances however, prices can soar and fluctuate. Retailers are tempted to opt for parallel imports when manufacturers fail to launch a product. Low prices for parallel imported products may affect the domestic sales of the trademarked products, giving rise to the question as to whether parallel imports should be restricted or prohibited.

UAE is a party to several treaties and international organizations. For example, UAE is a member of the Gulf Cooperation Council (GCC).⁵ In addition, UAE is a Member of the World Trade Organization (WTO).⁶ Although UAE has made many efforts to bring its intellectual property laws into compliance with the international legal standards set forth in the WTO's Agreement on Trade-Related Intellectual Property Rights (TRIPS) and other international treaties, the UAE has not taken a clear stance on many intellectual property issues such as trade secrets, and trademark exhaustion and parallel imports of trademarked goods. Trademarks have been the form of intellectual property most familiar to the business community in the UAE. Yet, neither trademarks law nor agency law or practice addresses clearly parallel importation.⁷

Parallel imports or grey market goods are genuine goods and not counterfeits, whereby trademark is misappropriated. Parallel imports involve the importation of genuine goods outside the authorized distribution channels. In other words, parallel import is the importation of these goods from a foreign source by bypassing the authorized local distributor and trademark licensee, thereby allowing the sale of goods directly to

⁴ For example, grey market pharmaceutical products in the United States can be as much as 80 per cent cheaper. See Elin Dugan, 'United States of America, Home of the Cheap and the Grey: A Comparison of Recent Court Decisions Affecting the US and European Grey Markets' (2001) 33 *Geo. Wash. Int'l L. Rev.* 397,410.

⁵ The GCC is generally regarded as a success story for economic integration in Arab countries. The GCC was established in May 1981. The GCC consists of six member states: (1) United Arab Emirates; (2) Bahrain; (3) Saudi Arabia; (4) Oman; (5) Kuwait; and (6) Qatar. See the Cooperation Council Charter, List of Member States (1981) available at <<http://www.gccsg.org/eng/index.php?action=Sec-Show&ID=1>> (last visited 12 February 2016).

⁶ UAE has been a Member of the WTO since 10 April 1996. See World Trade Organization, *Members and Observers*, available at:

<https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm> (last visited 11 February 2016).

⁷ The paper is concerned mainly with parallel importation development in the UAE in the context of trademarks laws and agency regulation. However, trademarks law shall not be regarded as the only instrument of regulating parallel importation. Competition law, which is outside the scope of this paper, is an indirect instrument that can be used to address the issue of parallel importation. Parallel import restrictions can distort competition and thus may breach competition law.

retailers or consumers.⁸ In most cases, the manufacturer establishes an exclusive territory or conditions of resale through some contractual agreement or agreements, by which the manufacturer, distributor or trademark registrant generally agrees to sell only to particular entities and not to other entities that may compete with the authorized channel.⁹

The paper will examine these competing interests in further detail, analyse why the courts in UAE have been reluctant to adopt a clear position on parallel imports, and explain why a legislative amendment to the Trademarks Law and Agency regulation is likely to be necessary before UAE's position on parallel imports is made clear.

II. THE UAE COMMERCIAL AGENCIES LAW

The Commercial Agencies Law (Federal Law No. 18 of 1981, as amended by Federal Law No. 14 of 1988) defines a commercial agency as any arrangement, whereby a foreign company is represented by an agent to distribute, sell, offer, or provide goods or services within the UAE for a commission or profit.

Trading is at the core of the UAE's commercial heritage, and consequently the UAE has special laws and practices encouraging foreign suppliers to use local sales agents.¹⁰ The following conditions highlight this stance:

- Commercial agents must be UAE nationals or companies incorporated in the UAE and owned entirely by UAE nationals.¹¹
- Commercial agents must be registered with the UAE Ministry of Economy and Commerce to engage in commercial agency activities. However, if the agency is not registered, no action can be taken against parallel importation.
- The agency agreement must be registered in order for the agent to avail himself of the protections afforded under the law and to have the agency relationship recognized under UAE law.

⁸ See Keith E Maskus, 'Parallel Imports', (2000).23 World Econ. 1269.

⁹ See Robert J Staaf, 'The Law and Economics of the International Grey Market: Quality Assurance, Free-Riding and Passing Off' (1988) 4 Intell. Prop. J. 191, 192.

¹⁰ See Alisha Ansari, 'What is the Scope of Competition Law in the UAE? A Comparative Study with Developed and Developing Nations 131-137 (Master Thesis, University of Western Ontario 2013).

¹¹ See Federal Commercial Agencies Law No. 18 of 1981, Article 2.

- Commercial agents are entitled to an exclusive territory encompassing at least one emirate for the specified products. (Article 5.1 of the Commercial Agencies Law). However, an exclusivity agreement does not change the source of the product.
- Unless otherwise agreed, commercial agents are entitled to receive commissions on sales of the products in their designated territory, irrespective of whether such sales are made by or through the agent. (Article 7 of the Commercial Agencies Law)
- Commercial agents are entitled to prevent products subject to their agency from being imported into the UAE if the agent is not the consignee. A corollary dimension that arises in relation to the application of this article is the controversial subject of parallel importation. For example, the president of Samsung Gulf Electronics has called on the UAE Government to implement tougher restrictions on the parallel importation of branded consumer electronics goods. Retailers are selling Samsung products outside of regulated distribution channels.¹² The language of the commercial agency law effectively acts as a ban on parallel imports of that product. However, companies operating in free trade zones in the UAE can import such products and resell them within a free zone.
- Commercial agents are entitled to receive compensation from the principal if the agency is terminated without substantial justification or if the agency is not renewed by the foreign principal and the agent may be able to preclude the foreign party from appointing a replacement agent in such circumstance.

On the basis of these conditions, a sales agent is given the exclusive right to import the relevant product, to receive compensation for any parallel import of the product by others and even to block the foreign supplier's direct import of the product into the sales agent's territory. In other words, the local commercial agent is given a monopoly right and serves as the main instrumentality for protecting trademarks.

III. TRADEMARKS LAW: THE GENERAL FRAMEWORK

Trademarks identify the source from which the goods originate and guarantee the quality of the goods bearing

¹² See Ronan Shields, 'Samsung Warns UAE over Parallel Imports' Arabian Business (14 November 2006).

that trademark.¹³ The UAE Trademarks Law of 2002 emphasizes the function a trademark plays in distinguishing the goods and protecting the interests of consumers.¹⁴

The Trademarks Law of 2002 (Trademarks Law) describes a trademark in the broadest language as any visually perceptible sign. The Trademarks Law defines a trademark as any visually perceptible mark used or available to any person to distinguish his goods or services from the goods or services of others. This is in compliance with Article 15 of the TRIPs Agreement which states that a Member may require, as a condition of registration, that a sign be visually perceptible. For instance, a trademark could be a word, logo, numeral, letter, slogan, or a colour.¹⁵ As such, the Trademarks Law does not apply to non-traditional trademarks such as sound or smell. For example, a fragrance trademark can never be registered.¹⁶ In order to receive protection, a trademark does not need to be original, but it must be distinctive and be able to represent to consumers the source of goods or service identified. The UAE adopts a system of first-to-file. When there are two or more applications for registration of marks identical with or confusingly similar to each other, or for identical or similar goods or services, legal protection may only be granted to the valid application with the earliest priority or filing date amongst all applications.¹⁷ Article 19 of the Trademarks Law grants protection in renewable ten-year portions. Specifically, Article 19 states, in part, that:

The period of protection resulting from the registration of a trade mark shall be 10 years. The mark owner may secure the continuance of such protection for successive periods of 10 years each if he applies for renewal of such mark's registration within the last year of the

¹³ See William Cornish and David Llewelyn, *Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights* 620 (6th ed., 2007).

¹⁴ See Trademarks Law No. 8 of 2002, Article 3. Presumably the law does not permit registration through the Madrid System Concerning the International Registration of Marks under the Madrid Protocol, since UAE is not a party. This is the trademark registration system used by the nearly 100 countries. Although it is not directly relevant to grey market goods it would facilitate trademark protection for global companies operating in the UAE and their agents. See World Intellectual Property Organization, *Madrid – The International Trademark System*, available at: <<http://www.wipo.int/madrid/en/>>.

¹⁵ See Article 2 of Trademarks Law No. 8 of 2002, In respect of colours, it is to be noted that limitation of a trademark to a colour(s) may be a basis for establishment of distinctiveness. As to whether colours themselves, such as the colour orange, can be treated as trademarks, the answer is not clear.

¹⁶ The registration of fragrances or sounds would present complex challenges for trademark examiners in the UAE. It is unclear how they would be categorized, catalogued, preserved during the registration period, or searched and tested for confusing similarity.

¹⁷ *ibid.* Article 17.

valid protection period according to the terms and conditions provided for in this Law and its Executive Regulations.

The Trademarks Law provides penalties against offenders who misrepresent goods or use counterfeit trademarks. These penalties include fines and/or imprisonment.¹⁸ Article 37 of the law states:

Shall be sentenced to imprisonment and a fine of at least Dh. 5000 (Five Thousand) or either:
1. Any person who forges a trade mark registered according to law or imitates same in a way misleading the public and any person who uses with bad faith a forged or imitated trade mark.
2. Any person who places with bad faith on his products a registered trade mark owned by a third party, or uses such mark without right.
3. Any person who deliberately sells, offers for sale or negotiation or acquires for sale products having a forged, imitated or illegally placed trade mark, the same applies to any person who deliberately provides or offers the provision of services under a forged, imitated or illegally placed trade mark.

Moreover, Article 39 states:

Any person who repeats one of the offenses stated in Articles 37 and 38 hereof, shall be punished with the same penalty in addition to closing the commercial premises or the exploitation project for a period of no less than 15 days and no more than 6 months and publishing the judgment at the cost of the party adjudged pursuant to the procedures indicated in the Executive Regulations.

The Law does not state if the owner of an infringed trademark may obtain an accounting of profits. Moreover, Article 41 of the Law provides for a cease and desist order. It also provides for an interlocutory seizure of goods. The seizure is to take place at the request of the owner of a trademark. The Law provides for the destruction or disposal of materials or tools used in infringement of trademarks. Article 43 states that:

The competent court may rule the confiscation of the object attached or to be attached later and the deduction of its price from the fines or compensations or disposition thereof in any other way deemed expedient by the court. The court may also order to destroy the illegal marks or, when necessary, to destroy the products, envelopes, packing, tools and any such other objects bearing such marks or illegal data, as well as, the machines and tools

¹⁸ *ibid.* Article 37.

used specifically in the forging operation. It may likewise order all the foregoing even in case of acquittal. The court may further order that the judgment be published in the bulletin or in an Arabic daily at the cost of the judgement debtor.

An owner of a trademark will have to register the trademark for using it.¹⁹ This is in line with the doctrine that trademark rights are territorial.²⁰ Registration of a trademark gives certain rights which include the exclusive right to use the mark, licensing, and enforceability.²¹ For example, Article 10 of the Trademarks Law provides that:

Subject to the provisions of Article 26 hereof, no trade mark identical or similar to an already registered mark may be registered for the same categories of products or services, or different goods or services, if the use of the requested trademark would generate an impression that such goods or services are linked to the goods or services of the owner of the registered mark or prejudicing his interests. Should one or more persons apply simultaneously for the registration of the same mark or close or similar marks for one category of products or services, the Ministry shall suspend the registration of all applications until an attested waiver is submitted by the opponents in favour of one of them or a final judgment is awarded in favour of one of them.

In addition, Article 17 states:

Any person who registers a mark shall be deemed its sole owner. The ownership of such mark may not be disputed if the person who registers it, uses it uninterruptedly for at least 5 years from the date of registration without an action being lodged against him ruling for its validity. The owner of a registered trademark may prevent others from using a similar or identical trademark, to distinguish products or services that are identical, similar

¹⁹ *ibid.* Article 7.

²⁰ Registered trademark rights extend nationwide within a country. For instance, for the purpose of trademarks law, only registration -and in some cases use - in UAE is relevant. If a company desires to extend its trademark rights outside the national borders of a particular country, then that company must register its trademark in every country. See Edouard Treppoz, 'International Choice of Law in Trademark Disputes From a Territorial Approach to a Global Approach' (2014). 37 *Colum. J.L. and Arts* 557, 559

²¹ See Trademarks Law No. 8 of 2002, Articles 10, 17, 30, 31, and 37.

or correlated for which the mark has been registered, in such a way that confuses the consumers.

Article 30 provides that:

The owner of a trade mark may, by a written and attested contract, licence one or more persons to use such mark for all or part of the products or services for which the mark is registered. The mark owner may use it himself unless otherwise agreed. The period for licensing the use of a mark may not exceed that prescribed for its protection.

Also, Article 31 of the law states:

A contract licensing the use of a trade mark shall be recorded in the Trade Marks Register of marks. Such licensing shall have no effect vis-à-vis third parties except after being recorded in the register and announced in the manner determined in the Executive Regulations.

Article 37 provides that:

Shall be sentenced to imprisonment and a fine of at least Dh. 5000 (Five Thousand) or either:

1. Any person who forges a trade mark registered according to law or imitates same in a way misleading the public and any person who uses with bad faith a forged or imitated trade mark;
2. Any person who places with bad faith on his products a registered trade mark owned by a third party, or uses such mark without right;
3. Any person who deliberately sells, offers for sale or negotiation or acquires for sale products having a forged, imitated or illegally placed trade mark, the same applies to any person who deliberately provides or offers the provision of services under a forged, imitated or illegally placed trade mark.

The Trademarks Law provides for a registry of trademarks.²² The registry helps inform applicants what marks have been registered, and provides a description of their goods, products and services, changes, and licence of the mark.

²² *ibid.* Article 5.

IV. UAE LAW AND EXHAUSTION OF RIGHTS

The theory of trademark exhaustion is used to justify the importation of grey market products. Under this theory, once the first sale of a marked product takes place after the product has entered the stream of commerce in the trademark owner's territory, the trademark owner's rights are exhausted, that is to say, the trademark owner can no longer control sales of the trademarked products.²³ It has also been argued that the trademark owner loses the right to control subsequent sales of trademarked products even once these products have been sold abroad.²⁴

There is no international agreement that addresses national, regional, or international exhaustion. The Paris Convention does not regulate this issue and the TRIPS Agreement takes a neutral position in dealing with this concept.²⁵ As negotiators of TRIPS could not agree on how to deal with grey market goods, the issue of exhaustion and parallel importation is left to national legislations and court decisions.

Whether or not the owner or licensee of the registered trademark can block the importation of the grey market goods depends on what position the UAE adopts on trademark exhaustion and parallel imports. The Trademarks Law fails to address clearly whether parallel imports infringe trademark rights and whether it adopts a national or international exhaustion of rights. Additionally, UAE customs authorities, even in developed countries such as the United States and the European Union, in general can be somewhat lax when it comes to checking whether the products are authorized for sale by the manufacturer or rights holder at the point of entry, unless the lawful trademark holder advises customs regarding the likelihood of shipments of grey market goods.²⁶ It just is not a high priority for most customs services.

The most pertinent legislative provisions provide in relevant parts:

- The trademark owner who registered his mark in UAE has the exclusive right to use such trademark for the product that it has been registered.²⁷ However, the Trademarks Law

does not provide examples of 'use' of the holder of a trademark right such as subsequent sale, displaying or distributing trademarked products.

- It shall not be permissible to cause prejudice to the exclusive right of another person to use a registered trademark. This language can provide protection against parallel imports on the basis that such imports can cause prejudice to the exclusive right to a trademark.
- Registration of any trademark which is identical or similar to a trademark previously registered for the same classes of products or services, or non-similar class of goods and services, is not permitted if using the trademark may generate the impression of a connection between the goods and services to be registered and those of the owner of the registered mark, or if using the trademark to be registered may damage his interests.²⁸ This Article can be used to block import goods that bear any marks confusingly similar to registered trademarks.
- The trademark owner may, by a written notarized contract, grant to any person a licence to use the trademark in accordance with the agreed agreement and quality guidelines. The trademark licence agreement may specify the range of the geographical area for marketing products or services bearing the trademark; and to prevent all actions, which may lead to lower the value of or cause harm to the products or services bearing the trademark.²⁹ Thus, a trademark owner can use the licence to restrict the sale or distribution of products bearing his mark when these products are manufactured abroad. The licensee could argue that the imported products are manufactured in breach of the licence agreement lacking the quality of the genuine products.
- It is an infringement of the exclusive right to use a registered trademark to sell goods that the owner knows bear a counterfeited registered trademark.³⁰

V. UAE CASE LAW

The influx of grey market goods has generated a few court cases that have seen trademark holders and their authorized distributors pitted against retail dealers who

²³ See Ryan L Vinelli, 'Bringing Down the Walls: How Technology is being Used to Thwart Parallel Importers Amid the International Confusion Concerning Exhaustion of Rights' (2009) 17 *Cardozo J. Int'l and Comp. L.* 135, 149.

²⁴ Lazaros G Grigoriadis, *Trade Marks and Free Trade: A Global Analysis* 59-60 (2014).

²⁵ Article 6 of the TRIPS Agreement provides that nothing in the agreement shall be used to address the issue of the exhaustion of intellectual property rights.

²⁶ See James Whymark, *Policing Parallel Imports around the World, in Anti-Counterfeiting – A Global Guide* (2014) 32

²⁷ See Trademarks Law No. 8 of 2002, Article 17.

²⁸ *ibid.* Article 10.

²⁹ *ibid.* Article 34.

³⁰ *ibid.* Article 37.

have profited from their sales of grey market products. The legal theories under which a plaintiff can file a trademark infringement suit include the Trademarks Law, unfair competition, unjust enrichment, and breach of contractual relations in agency agreements.³¹ This is explained in the following typical cases.

A case concerning parallel imports was decided in 2009.³² It is generally considered the most significant case because for the first time in the UAE it resulted in imprisonment of the defendants.³³ However, closer examination of the case reveals that the court treated the case as one involving counterfeit goods and thus imposed the jail sentences.³⁴ By definition grey market goods are genuine, not counterfeit. If the imported products are counterfeit, the exclusive importer can prevent the sale of these products by filing a trademark infringement claim in the court. Moreover, the court ruled – in part – that the importation of goods must go through approval procedures by government entities before importation is allowed. One wonders whether the defendant in that case had obtained the necessary governmental approval would the products still have been permitted to enter the country. The court did not provide clear guidance under what circumstances parallel imports may be permitted, and what if appropriate government permits were obtained. Therefore, the jurisprudential value of that case can be limited.

The case concerns a UAE company, UAE Mechanical, acting as an agent and distributor of 'Maggi' chicken stock cubes which is a product of Nestle.³⁵ It came to the knowledge of UAE Mechanical that some traders

imported boxes of Maggi cubes (product of Egypt). As stated by the plaintiff, these products did not conform to the required specifications. The High Federal Court found that UAE Mechanical was entitled to preserve its rights as the authorized agent of the manufacturing company for marketing certain goods.³⁶ Also, the court accepted UAE Mechanical's arguments that it was entitled to protect its rights in the trademark that is registered for Maggi cubes and that unauthorized importation and sale of these goods was an infringement of the exclusive rights.

As the facts of the case show, some parallel importers imported genuine goods that are subject to an agency agreement with the purpose of circumventing the agent. The effect of the Court's decision is that while Nestle could not enjoin sales of grey market goods in the UAE, its agent/distributor succeeded in obtaining remedies by having the goods of the parallel importers impounded, destroyed, or re-exported, or by requesting compensation. Apparently, the quality of Maggi (product of Egypt) differs from Maggi cubes designed for the UAE market. Maggi of Egypt cubes may not be designed to comply with consumer specifications in UAE. By bringing the case, the agent/distributor sought to protect regular trade channels. In this context, it raised possible violations of the agency law. Trademark infringement cases focus on the protection of the rights of the commercial agent and the elimination of the threat to monopoly rather than the recognition and protection of trademark rights.³⁷ Unfortunately, the court in that case did not address the issue of parallel importation in greater detail.

In another case, the trademark owner entered into a licensing agreement with a UAE distributor.³⁸ Then a third party in the UAE attempted to import the goods. That case presented an opportunity for the courts to rule directly on the legality of importing parallel imports without the prior authorization of the trademarks owner or its licensee. In that case, however, the trademark was not registered in the UAE, so the plaintiff could not proceed under the Trademarks Law which is applicable only to national registered trademarks (unless the mark is well known), and had to proceed under unfair

³¹ Courts in other countries considered various theories in their analyses of parallel importations. For example, some courts focussed on the function of the trademark which serves to identify the source of the goods, while in some cases the focus was upon deception or consumer confusion. Other courts focussed on material differences between the goods. See Christine Haight Farley, 'Territorial Exclusivity in US Copyright and Trademark Law' (2014) Washington College of Law Research Paper No. 2014-30, 51-52.

³² See Praveen Menon, 'Shopkeeper jailed over illegal DVDs' *The National* (13 October 2009).

³³ *ibid.*

³⁴ Trademark laws afford various types of relief to owners of registered marks. These include seizure, confiscation or destruction of infringing goods. Damages may also be awarded. In addition, infringement constitutes a criminal offence punishable by imprisonment or fines. Therefore, a criminal case may be filed simultaneously with a civil action for damages. See Amir H Houry, 'The Development of Modern Trademark Legislation and Protection in Arab Countries of the Middle East' (2003) 16 *Transnat'l Law* 249, 263, 275. See also Bradley J Olson, 'The 10 Things Every Practitioner should Know about Anti-Counterfeiting and Anti-Piracy Protection' (2007) 7 *J. High Tech. L.* 106, 125

³⁵ See *Journal of Bar Association*, Decision No. 10/1418, p 957 (2010).

³⁶ In the UAE, cases decided by courts do not have precedential value, as they provide an indication of how courts approach issues and are of some value in predicting how future cases might be decided. The sole exceptions are decisions by the High Federal Court, the highest court in UAE, which is highly influential and asserts wide powers.

³⁷ For example the *Brylcreem* case in the UAE was lodged under the commercial transaction law, but not under the trademarks law. See David Price, *The Development of Intellectual Property Regimes in the Arabian Gulf States: Infidels at the Gates* (2009) 36.

³⁸ See *Journal of Bar Association*, Decision No. 13/786, (2013).page 147.

competition provisions of the Commercial Code.³⁹ Therefore, the court did not address whether the licensee or trademark owner's rights were exhausted. The court considered the claim based upon the need to prevent consumer confusion as to the source of goods.

The approach taken by courts in the UAE demonstrates that the judiciary is not the proper vehicle for a final determination of the parallel importation issue. Courts were presented with specific facts that differed on a case-by-case basis. Those court decisions do not settle the matter in a satisfactory matter. Sometimes conflicting court cases have definitely muddied the waters. Customs authorities may not be able to seize grey market goods at the borders as a result of practical administrative difficulties. An authorized agent or distributor should bring a private action in court against the importer of grey market goods, a task that could prove difficult as the distributor must identify the parallel importer and engage in a time-consuming process.⁴⁰ Modification in legislations and holistic policy changes are needed.

VI. THE DEBATE OVER PARALLEL IMPORTS IN THE UAE

The debate over whether to permit parallel imports of trademarked goods in the UAE raises important and sensitive political, economic and legal issues. The broader policy question concerns a conflict between the importance of permitting free competition and the need for protecting the rights of the trademark holder.

Some in the UAE may argue that agents/distributors would abuse the market because of the exclusive agency.⁴¹ Parallel imports would not be sold in competition with goods subject to an exclusive agency agreement. Those agents/distributors are strong merchants.⁴² They may desire to protect themselves from the interference of small competitors or merchants since they do not have to lower their prices to compete with parallel imports.⁴³ Small merchants may not be able to benefit from price discrimination among

different markets. Closed distribution channels would impede free trade, competition, and consumer choice in terms of product and price.

Those with opposing views may counter that local agents/distributors/wholesalers have built the goodwill of imported products through their time consuming and expensive marketing plans, promotional efforts, and by providing a product warranty through after-sale servicing.⁴⁴ The purpose of all these programmes is to maintain clients and increase the sale of goods. Agents provide services and incur costs that parallel importers do not provide or incur.⁴⁵ Thus, parallel importers enjoy a free ride at the expense of authorized distributors. In addition, parallel imports may damage product quality control.⁴⁶ The quality of product frequently varies from region to region.⁴⁷ Poor quality in parallel imports could cause consumer confusion and diminish the reputation of the manufacturer and agent. In analysing the language of the Commercial Agency Law, one can find a protectionist flavour in protecting domestic interests. This is obvious when reading the language in the Commercial Agency law which states that commercial agents are entitled to prevent products subject to their agency from being imported into the UAE if the agent is not the consignee.

VII. CONCLUSION

Parallel importation represents a thorny issue as it is intertwined with the economic, political, and legal conditions in a particular country. Many intellectual property scholars and experts have studied merits and demerits of parallel importation. The UAE faces the difficult path of choosing the appropriate path in addressing parallel importation.

There is no definitive solution for the issue of parallel importation in the UAE. Nevertheless, the UAE cannot maintain the *status quo*. The Trademarks Law does not address clearly whether parallel imports infringe trademark rights and whether it adopts a national or

³⁹ See The Federal Commercial Transactions Law No. 18 of 1993, Articles 64-66.

⁴⁰ To avoid any administrative difficulty, some large companies in the UAE, who act as agent or distributor for foreign corporations, appoint a parallel import coordinator.

⁴¹ There are six commercial agents who control more than 40 per cent of the UAE commodity market. See 'Inflation and Price Hike in the UAE; Effects and Solutions' available at <<http://www.albayan.ae/across-the-uae/1186581628317-2007-08-12-1.781298>> (12 August 2002).

⁴² See Bernard M Hoekman and Jamel Zarrouk, *Catching Up with the Competition: Trade Opportunities and Challenges for Arab Countries* 239 (2000).

⁴³ See 'MEA Consumables Market Continues to Grow but Faces Mounting Pressure from Parallel Imports' available at <<http://idc-cema.com/eng/about-idc/press-center/58276-mea-consumables-market-continues-to-grow-but-faces-mounting-pressure-from-parallel-imports>> (27 April 2014).

⁴⁴ See Sarmad Hasan Manto, 'The Perils of Grey Market Trade' (October 2014), available at <<http://www.theoath-me.com/s/the-perils-of-grey-market-trade>> (last visited 14 February 2016).

⁴⁵ The agent/distributor is required to provide spare parts and other items which are necessary and sufficient for maintenance of the imported goods. See Commercial Agency Law, Article 11.

⁴⁶ See Manoj Nair, 'UAE's Auto Market Sees Flare up in Grey Imports' Gulf News (24 March 2014).

⁴⁷ See International Trademark Association, 'Position Paper on Parallel Import' (July 2007) 10 (Goods may have been formulated or packaged for a particular jurisdiction, and then are imported into a different jurisdiction from that intended by the brand owner. Motor lubrication oils are radically different for the Middle East and Scandinavia. This is to the detriment of the consumer and erodes the brand owner's value in the brand).

international exhaustion of rights. Further, UAE case law does not provide clear guidance under what circumstances parallel imports may be permitted, and what if appropriate government permits are obtained. Trademark owners and their agents use the UAE agency law to prevent parallel importation. The UAE agency law should not be used as a backdoor – through exclusive agreements – to ban parallel importation and replace the role of trademarks law. Trademarks law should play a central stage in addressing the issue of parallel importation in the UAE.

Although placing a total ban on parallel imports in the UAE seems the easiest way, it is unrealistic. This will even exacerbate the current situation where the authorized agent enjoys monopolistic position. As long as there are differences in market conditions among countries, parallel imports will exist. A total ban on parallel imports will lead to further legal uncertainty and may even encourage counterfeit trade. Therefore, the question that needs to be answered is how to balance the interests of stakeholders i.e. trademark owner and commercial agent, and those of the consumers.

As a first step, the UAE should consider the costs and benefits of allowing parallel imports. Parallel importation promotes free and healthy competition in both price and service. The source of supplying and distributing products for UAE's market would be diversified. Then, the UAE needs to modify its trademarks law and other regulations in a way to address parallel importation in an orderly fashion. For example, parallel importation could be allowed where there is no evidence consumer confusion. The burden of proof for consumer confusion – which could be a very substantial – falls upon the importer/agent for the genuine goods. In most parallel importation cases, there are no guarantees and after-sales services. Therefore, the UAE may want to require a labelling system to inform consumers that parallel products are not subject to guarantees and other services. The UAE, through the Ministry of Economy, could even require retailers to market their products as parallel importation. In addition, the UAE should keep the door open for trademark owners and their licensees to challenge parallel importers. This allows the courts to be proactive in addressing the issues not covered by the law and create guidelines under which the various parties involved can bring an action to protect their interests.

Now UAE has a good opportunity more than at any previous time to learn from the experience of other countries that have decided to regulate and not totally ban parallel importation, instead of following our own restrictive model. It is important for any future trademarks law in the UAE to be flexible no matter which approach the country decides to adopt.

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9 WHY SOUTH AFRICA SHOULD INTRODUCE PATENT SEARCHES AND SUBSTANTIVE EXAMINATIONS TO IMPROVE ACCESS TO ESSENTIAL MEDICINES

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ABSTRACT

This paper provides an overview of South Africa's current patent search and substantive examination regime and argues that the current legal regime is inadequate and requires a serious overhaul. The paper further highlights the importance of patent searches and substantive examinations, while providing a comparative analysis of applicable legal provisions. Although South Africa has recently acknowledged that the law should be changed to introduce patent searches and substantive examinations, this paper nonetheless highlights possible impediments to this proposed law reform. This paper concludes that patent searches and substantive examinations should be introduced alongside other patent law reforms such as the introduction of pre and post-grant patent opposition.

Keywords: Patent searches, substantive examination, access to medicines, TRIPS flexibilities, essential medicines, generics

I. INTRODUCTION

At present, South Africa is confronted with several epidemics such as 'HIV/AIDS, other infectious diseases, violence and injuries, and non-communicable diseases'.¹ In the context of public health, the country is faced with ongoing health-related challenges such as HIV/AIDS, tuberculosis, malaria, heart disease, cancer, hepatitis and a host of other ailments. Although state-driven treatment programmes have seen HIV/AIDS infection rates decline, there has been no such decline in

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¹ Yusuf A Vawda, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing Country Case Study: South Africa' IDCR, (Toronto 2011) 2.

diseases in other areas, especially tuberculosis and lifestyle diseases such as heart disease. It has been reported that South Africa has the largest antiretroviral treatment programme globally and these efforts have been largely financed from its own domestic resources.² The country now invests more than US\$ 1 billion annually to run its HIV/AIDS programmes.³

South Africa largely depends on imported patented medicines to deal with the burgeoning disease burden. However these medicines are expensive.⁴ Although some Southern African Development Community (SADC) members, such as South Africa, Zimbabwe and Mozambique, have limited pharmaceutical manufacturing capacity, the volumes of locally produced drugs are inadequate to deal with the disease burden. As members of the World Trade Organization (WTO), SADC members can take advantage of the flexibilities introduced by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and override patent rights in some specified instances in order to access affordable essential medicines.

The TRIPS Agreement does not prescribe how patent laws should be drafted in Member countries, but provides for the basic tenets of patentability. Therefore, it is up to individual countries to decide, within the confines of their laws, what amounts to patentable subject matter and how its patentability may be determined. One way of ensuring that only high quality patents are registered would be to require that trained experts examine all patent applications for technical quality, after the existing database has been searched for possible conflicting patents. Patent searches and substantive examinations are important and this paper makes the case for their inclusion or clarity in South African patent law in order to improve access to essential medicines. Patent searches and substantive examinations were recently identified as an important area of IP law requiring urgent reform in South Africa.⁵

II. BASIC CONCEPTS AND DISTINCTIONS

Essentially, a patent search may be regarded as the process by which prior inventions or ideas are examined, with a view to finding information that bears close

² John Maurice, 'South Africa's Battle against HIV/AIDS Gains Momentum' (The Lancet 2014), 1535-1536.

³ Maurice above mentioned at 1535.

⁴ South Africa's total health budget is estimated to be R178 billion in 2017/18 (Former Finance Minister Nhlanhla Nene's budget Speech delivered on 25 February 2015 at <<http://www.medioclubsouthafrica.com/economy/4165-south-africa-s-budget-2015-the-full-text>>. This figure includes the annual cost of procuring medicines for public sector hospitals and clinics, a figure which is unsustainable when one factors in other demands, such as provisioning for higher education on the fiscus.

⁵ For these and other IP law reform priority areas, see generally South Africa's Draft National Policy on Intellectual Property, 2013 available at: <http://groundup.org.za/sites/default/files/36816_gen918.pdf> (3 December 2014).

similarity to a given patent application, in order to determine whether the claimed invention is novel and inventive. Information relevant to the prior art of a pharmaceutical patent application may be widely sought by a number of third parties such as the Ministry of Health, generic drug producers, research institutions, academics and civil society groups interested in health matters.⁶ These searches would supplement prior art disclosures in patent applications, and patent searches undertaken through more traditional databases. Patent searches for relevant prior art in patent applications can be undertaken via the South African Companies and Intellectual Commission (CIPC) online facility, European or US Patent Office databases, or the WIPO database. In order for deserving patent applications to be registered, an up-to-date and reliable patent database is a prerequisite.

In practice, in the South African context, a prior art search is ordinarily undertaken by the applicant inventor or by his patent attorney/agent. This is undertaken to ensure that no existing patents are being infringed and that the invention is new/novel. Although this initial search is not essential, it is advisable.

In South Africa, Section 34 of the Patents Act⁷ authorizes the examination of patent applications, but at present no such examination is conducted.

On the other hand, where patent applications are examined by qualified examiners, the patent examination entails an analysis of the patent application for technical quality, adequate disclosure, unity of claims, and whether the prior art signifies that the claimed invention is new and involves an inventive step. Such an examination also seeks to establish the potential industrial applicability of a patent application. As stated above, South African law mandates patent examinations although in practice these are not carried out.⁸

In summary, a patent search and substantive examination system will essentially involve an examination of the quality of the invention.⁹ This will

entail a consideration of a number of prerequisites, such as the subject matter of the invention which must be patentable, the industrial applicability aspect of the patent, and the novelty and inventive step aspects.¹⁰ In the context of pharmaceuticals, properly stringent patentability criteria would therefore examine, among other things, the absolute novelty of the invention and a significant degree of inventiveness shown, for instance, whether there is a significant technological or therapeutic advance. This may entail revisiting the new use provisions provided for by the Patents Act.¹¹ South Africa would do well to require the patent office to undertake a thorough technical and scientific examination of the validity of the claims of every patent application filed.¹² For reasons outlined immediately below, patent searches and examinations are important for South Africa.

III. WHY ARE PATENT SEARCHES AND EXAMINATIONS IMPORTANT FOR SOUTH AFRICA?

From the perspective of an applicant, undertaking a patent search prior to applying for a patent is crucial, as it helps the applicant to¹³:

- Determine whether the intellectual property may be protected as an invention i.e. whether the invention meets the various requirements for the successful grant of a patent¹⁴;
- determine whether or not he or she is infringing someone else's intellectual property right;¹⁵
- learn about competition or to direct research and innovation;
- determine who owns an IPR; and

[Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf](#)>

¹⁰ Wen and Matsaneng, above, at 9.

¹¹ Section 25(9) of the Act provides for the patenting of novel uses of known substances.

¹² Treatment Action Campaign, 'Why South Africa Should Examine Pharmaceutical Patents' (2013), Policy Brief 60, 5.

¹³ This information was taken from the website of the South African Companies and Intellectual Property Commission (CIPC), 'Online Transacting', available at: <http://www.cipc.co.za/index.php/trade-marks-patents-designs-copyright/patents/how-app/> (last accessed 6 March 2016).

¹⁴ These requirements are set out in TRIPS Article 27 and Section 25(1) of the South African Patents Act.

¹⁵ The various grounds for the possible infringement of patents and the possible remedies are spelt out in Sections 65 to 71 of the South African Patents Act.

⁶ MSF, Treatment Action Campaign (TAC) and Section 27 recommendations to the South African Department of Trade and Industry (DTI) on the Draft IP Policy, entitled, 'Joint Submission on the Draft National Intellectual Property Policy' (2013), 30 (hereafter TAC, MSF and Section 27 recommendations).

⁷ Patents Act 57 of 1978 as amended.

⁸ Section 34 of the Patents Act.

⁹ Yu-Fang Wen and Thapi Matsaneng 'Patents, Pharmaceuticals and Competition: Benefiting from an Effective Patent Examination System' (2013) 8 available at: [http://www.compcom.co.za/wp-content/uploads/2014/09/Patents-Pharmaceuticals-and-](http://www.compcom.co.za/wp-content/uploads/2014/09/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf)

- check that their IPR in question is not being infringed.

By contrast, as will be further emphasized below, while it is advisable for applicants for patents to undertake patent searches as advocated above, it is unfortunate that South Africa's existing patent database is incomplete and not all patent documents are included. The applicant will need to resort to the use of the *Paper Based Patent Disclosure Office* (emphasis added) for the missing information.¹⁶

The importance of a patent search and examination system for the South African legal system may further be broadly further highlighted as follows:

- Introducing patent searches and examinations will make life-long saving medicines and drugs available and accessible to South Africans, because pharmaceutical companies will no longer be able to file multiple patents for the same drug.
- Since patent searches and examinations will be used to determine whether a 'new' drug is novel and inventive, the likelihood of granting evergreen patents will be reduced if the Act is amended to include, for example, enhanced efficacy.¹⁷
- From the perspective of competition law, introducing patent searches and examinations will ensure that big pharmaceutical companies do not file patents for minor improvements to drugs. This will allow more genuine pharmaceutical innovators to enter the market and drug prices are likely to stabilize once there are many pharmaceutical players who will compete against each other with positive results for consumers.
- It is common cause that in the absence of a patent search and substantive examination system, multiple patents filed by large pharmaceutical companies defer the expiry of patents by extending their lifespans. The entry of generic drugs onto the market will be delayed since generic manufacturers must wait for these multiple patents to expire. A patent search and substantive examination will therefore allow for the early entry of

generic drugs and promote the establishment of more generic manufacturers, thus improving the availability of essential drugs and introducing much needed competition, which will, in turn, lead to a lowering of drug prices.

The introduction of patent searches and examinations will ensure that South Africa complies with its own national law and makes full use of flexibilities allowed under the TRIPS Agreement. In the absence of a patent search and examination system, South Africa can in no way grant patents that are novel, involve an inventive step and are useful in industry, trade and agriculture. Similarly, in the absence of a functional patent search and examination system, South Africa can in no way effectively comply with her obligations spelt out in Article 27 of the TRIPS Agreement.

Finally, through the introduction of patent searches and examinations, South Africa will be able to provide stronger protection and achieve enhanced fulfilment of its human right to health obligations.

It is important not to lose sight of the fact that patent searches and examinations do not guarantee non-infringement of existing patents. This observation does not, however, diminish the importance of patent searches and examinations as highlighted earlier.

IV. NOTABLE GAPS IN THE RELEVANT LAW

The main issue relating to patent searches and examinations in South Africa is that patent applications are accepted and patents are granted as long as administrative and financial requirements are met.¹⁸

While the South African Patents Act provides for the registrar to 'examine', in the prescribed manner, every application for a patent and every complete specification accompanying such application¹⁹, in practice this examination does not look beyond the formal requirements. This is confirmed by the Patent Regulations, which clearly spell out that any application accompanied by a provisional specification must be examined to ensure that the documents lodged are legible and capable of reproduction.²⁰ For complete specifications, it is provided that the registrar shall examine them in order to ensure compliance with the prescribed formalities.²¹

¹⁶ Since South Africa is regarded as one of the most technologically advanced nations in Africa, the incomplete electronic database is a serious indictment of the country's status as a leader and beacon of economic hope in Africa.

¹⁷ On this and other possible solutions, see Yusuf A Vawda, 'After the Novartis judgment – "Evergreening" Will Never be the Same Again!' (2014) 18 Law, Democracy and Development 3015-316 at 315.

¹⁸ TAC 'Why South Africa Should Examine Pharmaceutical Patents' (2013), Policy Brief, Treatment Action Campaign, Pretoria 60, 2.

¹⁹ Section 34 of the Act.

²⁰ Regulation 40 of the Patents Act.

²¹ Regulation 41 of the Patents Act.

A patent is therefore granted once all the required documents are accepted without any enquiry into the technical and other requirements for patentability spelt out in the Patents Act.²²

South African Patent law does not expressly provide for a compulsory prior art search, and as previously stated, where such a search is not compulsory, the satisfaction of patentability criteria cannot be achieved.²³

It has been reported that the current South African Companies and Intellectual Property Commission (CIPC) online search facility leaves a lot to be desired, since the only functional search fields are the title of the invention, the name of the inventor and the South African patent number, while a number of other search fields return no results.²⁴

This is compounded by the fact that none of the patent claims or specifications can be viewed and the status of the patent is not always available or up-to-date.²⁵

If the patent search database is improved and access to accurate information on patents is made available to stakeholders, this will complement the recommendations that are made here about the introduction of patent searches and examinations.

The gaps in the legal regime are summarized in the following table:

| Legal provision and content: Patents Act and Regulations (paraphrased or actual) | Non-legal summary of provision | Commentary and suggested improvement |
|---|--|---|
| S34 'The registrar shall examine in the prescribed manner every application for a patent and every complete specification accompanying such application or lodged at the patent office in pursuance of such application and if it complies with the requirements of this Act, he shall accept it.' | The registrar is required to examine in the prescribed manner every application for a patent and the accompanying descriptive account of the patent and if the application complies with the Act, accept it. | It should be mandatory for the registrar to examine all patents 'in the prescribed manner'. The prescribed manner is usually the one prescribed by the Act and clarified by the Regulations, if any. The Regulations (see immediately below) should provide that the registrar 'must' examine patents and specifications in order to ascertain compliance with section 25(1) of the Act. Alternatively, there could be a provision mandating examination for <i>priority patents</i> (emphasis added), including those related to pharmaceutical, biological, and other medical or health technologies. |
| Regulation 40 of the South African Patents Act 'Any application accompanied by a provisional specification shall be examined to ensure that the documents lodged are legible and capable of reproduction.' | For a provisional application specification, the examination will aim at ensuring that lodged documents are legible and capable of being reproduced. | This kind of examination does not aid the one contemplated by Section 34 of the Act. Indeed, it takes away the gains made by Section 34. This Regulation must be amended to add unequivocally an examination of the technical quality of the patent in addition to what is expected of the documents. This will give Section 34 its implementing teeth. |
| Regulation 41 The registrar shall examine the application accompanied by a complete specification in order to ensure that it complies with the prescribed formalities. | Complete specifications must be examined by the registrar to check if they comply with the prescribed formalities. | This regulation is ambiguous and must be amended to state clearly that the examination will look at the quality of the documentation and the technical merits of the final specification. This will then actualize the provision in Section 34. |

²² The general and specific requirements for patentability and exceptions thereto are set out in Section 25 of the Patents Act.

²³ Section 25(1) of the South African Patents Act 57 (1978) sets out the patentability criteria: novelty, involvement of an inventive step and usefulness in trade, industry and agriculture.

²⁴ MSF, TAC, Section 27 Recommendations at 30.

²⁵ MSF, TAC, Section 27 Recommendations at 31.

V. WHAT CAN SOUTH AFRICA LEARN FROM OTHER JURISDICTIONS?

When one looks at both the African and international legal contexts of patent searches and examinations, South Africa does not compare favourably. South Africa can therefore learn a number of useful lessons from other jurisdictions in order to improve its current patent law through timely legislative reform. The jurisdictions outlined below can indeed offer significant lessons for IP law reform for South Africa. The selected laws of select countries, together with a commentary on the relevance of the law in the context of South Africa, are outlined in tabular form below.

| Country and legal provision | Content of legal provision | Comments in the context of South Africa |
|--|---|---|
| <i>Argentina Pharmaceutical Guidelines: Joint Regulation Nos. 118/2012, 546/2012 and 107/2012 issued on 2 May 2012 by the Argentine Patent Office, together with the Ministries of Industry and of Health.</i> | The new Guidelines ambitiously restrict the patentability of several categories of inventions in the pharmaceutical field, in particular polymorphs and pseudo polymorphs, enantiomers, Markush claims, selection patents, Salts, esters and other derivatives of known substances, Active metabolites, prodrugs, formulations and compositions, combinations, second medical use and dosage regimes and manufacturing processes. | Although these guidelines are conceived as general instructions addressed to the patent examiners, in practice, they operate as very specific legal provisions which must be adhered to. South Africa does not need to adopt a similar radical approach; after all, South Africa has no patent examiners at the moment. However, the specific substances excluded from patentability are quite informative, notably the exclusion of derivatives of known substances. |
| <i>Botswana Industrial Property Act of 2012</i> | Section 22 Provides for the examination of patents for technical quality | Such a provision is long overdue for South Africa, which provides for such in Section 34 of the Patents Act, but negates it through wrong regulations and contrary practice at the patents office. |
| <i>India Patents Act of 1970, as severally amended</i> | Section 11B(1) 'No application for a patent shall be examined unless the applicant or any other interested person makes a request in the prescribed manner for such examination within the prescribed period.' Section 12(1) 'the application and specification and other documents related thereto shall be referred at the earliest by the Controller to an examiner for making a report to him in respect of the following matters, namely; "—whether the application is in accordance with the Act, whether there is a legal ground for any objection ...".' | While India has generally been lauded as having progressive provisions in its legislation, making examinations conditional upon requests reduces such an important activity to being optional. South Africa should not follow this route. It must act in accordance with the prescriptions of Section 34. This provision spells out very clearly the targeted outcomes of the examination process. This clear language must be adopted by South Africa in order to improve Section 34. |
| <i>Kenya Industrial Property Act of 2001</i> | Section 27 – Minister may direct that applications for patents relating to a specified field or specified technical fields shall be the subject of an examination as to substance. | While this provision is worthier than its South African counterpart, it is not truly progressive because only selected inventions will be subject to this 'examination as to substance'. All inventions irrespective of the field of technology should be subjected to 'an examination as to substance'. South Africa may be advised to consider the option of prioritizing certain fields or important technologies, like medicines and other medical products to examination first while examination capacity is expanded in other areas. |

| Country and legal provision | Content of legal provision | Comments in the context of South Africa |
|--|---|---|
| <i>Japan Patent Act (Act No. 121 of 1959) as amended in 2006</i> | Article 47 – The Commissioner of the Patent Office shall direct the examination of patent applications by an examiner and the qualifications of examiners shall be as prescribed by Cabinet Order. | This self-explanatory provision goes a step further and directs how examiners' qualifications shall be determined. South Africa must consider adopting something similar. |
| <i>Thailand Thai Patent Act BE 2522 (1979) as amended by Patent Act (No 2) BE 2535 (1992) and Patent Act (No 3) BE 2542 (1999)</i> | Section 24 – 'Before granting a patent to the applicant, the competent officer shall: examine the application as to its conformity with Section 5, in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulations.' [section 5 deals with requirements for patentability, namely novelty, inventive step and utility] | This is another very clear provision dealing with what must be examined. This should illuminate South Africa's law reform path in the appropriate context. |
| <i>Zimbabwe Patents Act (Chapter 26:03, as amended by Act No. 14/2002)</i> | Section 11(1)(a) – 11(2) Provides for the formal examination of patent applications by an examiner in order to establish compliance with the provisions of the Act and to check if there is congruence between the final specification, the provisional specification and the Patent Cooperation Treaty specification. | Again, like the similar provisions commented on above, this provision also clearly points out what will be examined. South Africa must expressly provide for patent examination in order to effectively use exemptions and stringent standards of patentability allowed under the TRIPS Agreement and the Patents Act of 1978 as amended. |

VI. CONCLUSION

It is heartening to report that, on 9 February 2015, the South African Department of Trade and Industry (DTI) and the South African Companies and Intellectual Property Commission (CIPC) hosted an important meeting with relevant stakeholders and announced that patent searches and substantive examinations would be introduced in the country, perhaps as early as 2017.²⁶ The idea is to fully examine domestic applications in selected fields and to partially recognize the substantive examination outcomes of other jurisdictions²⁷ in respect of foreign applicants.²⁸ This is welcome news, although at the time of writing South African Patent Law practice did not cater for patent searches and substantive examination.

²⁶ This information was taken from the website of the South African premier IP law firm, *Adams and Adams*, going by the title 'Roundtable Discussion: Substantive Search and Examination' <http://www.adamsadams.com/index.php/media_centre/news/roundtable_discussion_substantive_search_and_examination/> (accessed 6 March 2016). The report is dated 25 February 2015.

²⁷ For a comparative note on other jurisdictions in the patent examination context of South Africa specifically, see Caroline B Ncube, 'The Draft National Intellectual Property Policy Proposals for Improving South Africa's Patent Registration System: a Review' (2014) 9 *Journal of Intellectual Property Law and Practice*, 822-829.

²⁸ Adams and Adams, note 26 above. The selected fields are not mentioned, the only hint given being, 'the selection of technology sectors to be made on the basis of the South African economic priorities'.

It is worth reiterating that the current lack of substantive examination and the absence of opposition proceedings has resulted in 'invalid' patents being granted, including patents for inventions with only 'marginal inventive steps', thereby permitting the 'blocking' of further innovation and development in certain market sectors by powerful companies.²⁹

The drug that was involved in the dispute between Novartis and the Republic of India³⁰, Imatinib Mesylate, starkly illustrates the need for patent search and examination in South Africa.³¹

Imatinib Mesylate was patented in South Africa with no litigation ensuing.³² The most likely reason why this drug and its new-use variants have been patented in South Africa since 1993 is the fact that South African patent law does not provide for mandatory patent searches and examinations.³³ The Mesylate version of Imatinib was

²⁹ *ibid* 28.

³⁰ See *Novartis AG v. Union Of India and Ors*, Supreme Court of India, Civil Appellate Division, 1 April, 2013, available at <<http://indiankanoon.org/doc/165776436/>> (last accessed 5 March 2016).

³¹ See generally Emmanuel K Oke, 'Exploring the Flexibilities in TRIPS: Lessons from India's Pharmaceutical Patent Law' (2015) 41 *Commonwealth Law Bulletin*, 82-106; specifically Lonias Ndlovu, 'Lessons for the SADC from the *Indian Case of Novartis AG v. Union of India*' 18 *Potchefstroom Electronic Law Journal*, 2015, 783-815.

³² See Companies and Intellectual Property Commission of South Africa (CIPC), 'Patent Search Results for Imatinib', at <<http://patentsearch.cipc.co.za/patents/patentresult.aspx>> (last accessed 6/03/2016).

³³ See Section 34 of the Patents Act 57 of 1978 and Regulations 40 and 41 to the same Act.

patented in South Africa in 1997 and is due to expire in 2017, while in 2002, a new use patent for the same drug was granted, and the patent is due to expire in 2022.³⁴ In 2013 and 2014, Novartis applied and was granted a process patent for the *Process for the Preparation of Alpha Form Imatinib Mesylate*³⁵ and a product patent for the *Pharmaceutical Granulate Comprising Imatinib Mesylate*.³⁶

It is doubtful if such minor additions to Imatinib would have been patented in a legal system with a robust patent examination model. A patent search and substantive examination system will essentially involve an examination of the quality of the invention.³⁷ This will entail a consideration of a number of prerequisites such as the subject matter of the invention which must be patentable; the industrial applicability aspect of the patent; and the novelty and inventive step aspects.³⁸

In the SADC region, Botswana's Industrial Property Act of 2010 may be regarded as model legislation for patent examinations.³⁹ The relevant law provides for an examination of a patent application in order to comply with the requirements of the Act⁴⁰, and also grants the Minister responsible for patents the discretion to designate certain patent applications as exempt from an examination covering the requirements for novelty and inventive step.⁴¹ Although Botswana's law in the specific context could have been better drafted, it is a good example of a deliberate step that will limit the abuse of the patent system and curb patent evergreening.

That South Africa has taken a bold step to introduce patent searches and substantive examinations is a welcome step in the right direction of relevant law reform. Some controversies may arise when one factors in the state of the economy and some geopolitical realities on the ground. For instance, although South Africa has now affirmed that the law will change to

accommodate patent examiners, the reality is that local patent examiners will have to be trained and an appropriate jurisdiction or entity to conduct the training needs to be identified. Argentina, Brazil and India would appear to be attractive candidate countries for such training from a developing country perspective. However, it is also possible that some developed countries, such as Japan or even the United States, may be willing to offer the training gratuitously. The choice of the appropriate institution to offer the training will in all likelihood depend on the ideological congruence between the chosen country/institution and South Africa. Developed country jurisdictions, which traditionally favour patent rights, are likely to fashion the examination regime in such a manner that the valuable TRIPS exceptions may be seriously circumscribed. The choice of the patent examination training provider really faces the danger of becoming a politically value-laden exercise.

The other important consideration will be the cost of training patent examiners and overhauling the current database in order to modernize it for the contemporary IP landscape. South Africa indeed faces economic challenges at this moment including the prospect of a sovereign downgrade from rating agencies like Moody and Standard & Poor's.⁴² These economic challenges imply two possible occurrences:

- The postponement of the implementation of patent searches and substantive examination; and
- examination or the implementation of a compromised regime for same.

While the nation waits for the process to unfold fully until 2017, life has to be lived in the interim and it is suggested that the Patent Regulations be amended to cater for substantive examination, while the law is being amended.⁴³ The introduction of patent searches and substantive examination without anything further will be inadequate. To improve access to essential medicines, other aspects of South African patent law, such as the cumbersome regime for compulsory licences, the absence of pre and post-grant opposition and the reluctance of the government to fully implement its regime for parallel imports, must also be revisited.

³⁴ According to Baccarrani et al, 'Chronic Myeloid Leukemia: An Update of Concepts and Management Recommendations of European Leukemia Net' *Journal of Clinical Oncology*, 2009, at 6044, there are no major therapeutic differences between Imatinib Mesylate and its new use counterpart.

³⁵ South African Patent number 2013/00872, granted on 30 April 2013.

³⁶ South African patent number 2014/06139, granted on 27 May 2015.

³⁷ Wen and Matsaneng (2013) 'Patents, Pharmaceuticals and Competition: Benefiting from an effective patent examination system' available at: <<http://www.compcom.co.za/wp-content/uploads/2014/09/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf>> at 8 (last accessed 6 July 2016).

³⁸ Wen and Matsaneng, above 9.

³⁹ See specifically Section 22 of the Industrial Property Act (Botswana Act).

⁴⁰ Section 22(1) of the Botswana Act legislation.

⁴¹ Section 22 (2) of the Botswana Act legislation.

⁴² See for instance, Mail and Guardian 'SA Placed on Review for Downgrade' (10 March 2016), available at: <<http://mg.co.za/article/2016-03-09-sa-placed-on-review-for-downgrade>>

⁴³ It is common cause that the Patents Act provides for substantive examination of patents in Section 34 thereof. However, the regulations negate the good effect of the law by requiring only formal examinations.

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