

**THE UNIVERSITY OF ZAMBIA
SCHOOL OF LAW**

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Entitled

**APPLICABILITY OF COMPULSORY LICENSE UNDER THE
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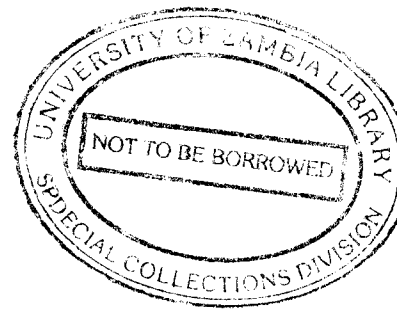
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L410 – Directed Research Paper



APPLICABILITY OF COMPULSORY LICENSE UNDER THE ZAMBIAN PATENT LAW

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A Directed Research Paper submitted to the University of Zambia, Faculty of Law in partial fulfillment of the requirements for the award of the Degree of Bachelor of Laws (LLB).

UNZA

December 2006

DECLARATION

I, Buchisa K Mwalongo, do hereby affirm that the contents of this Directed Research Paper are entirely based on my own research in that I have not in any manner used any person's work without acknowledging the same to be so. This is the first submission of this work and it is not subject to any previously submitted work in this university. I bear absolute responsibility for the errors, defects or any omission therein. I affirm that the contents of this text to be true and correct to the best of my knowledge.

Dated this.....19th.....day of *January*.....2007

Signature:*B K Mwalongo*.....

DEDICATION

To my beloved wife, **Annie**, and our children Bupe and Buchisa Mwila (Jnr) for their sacrifice, patience, understanding and tireless support over the years of my studies. You have made it easy for me to fulfill God's will. Thank you sweetheart, for being the most wonderful "helper suitable" a man could ever hope to have, and for loving me in spite of my feeble attempts to be the husband you deserve.

"Like a lily among the thorns, so is my darling among the maidens" (Song of Solomon 2:2).

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PREFACE

This research is about applicability of compulsory license at the local and international plane. A compulsory license is a mechanism governments use to grant licenses to third parties to exploit an invention. This type of license is granted either by an administrative authority or judicial body. This type of license is granted without the consent of the patent holder. It is also a means of technological transfer of intellectual property rights.

Under the current Zambian patent law regulating compulsory licenses, adequate compensation is not provided for. This may lead to stifling of the advancement of science and technology which is the bedrock of wealth creation. The research will make comparisons of the applicability of compulsory license with other jurisdictions. It will also look at the applicability of compulsory license according to Article 31 of the TRIPS Agreement

Lastly, this paper will also make recommendations about the changes to be made to the current patent legislation in order to include the provisions contained in article 31 of the TRIPS Agreement.

ABBREVIATIONS

ARV	Antiretroviral
AZT	Azidothymidine
CL	Compulsory License
GATT	General Agreement on Tariffs and Trade
HIV	Human immuno-deficiency virus
IP	Industrial Property or Intellectual Property
IPRs	Intellectual Property Rights
LDCs	Least Development Countries
NGO	Non Government organization
NIEO	New International Economic Order
PEIT	Patent Examiner Initial Training
TRIPS	(Agreement on) Trade Related Aspects of Intellectual Property
TWN	Third World Network
UDHR	Universal Declaration of Human Rights
UK	United Kingdom
US	United States
USPTO	United States Patent and Trademarks Office

Organizations

ARIPO	African Regional Intellectual Property Organization
COMESA	Common Market for Eastern and Southern Africa
EC	European Communities
EU	European Union
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Chapter 1

Introduction

Compulsory License

A compulsory License is an authorization given by a national authority to a person, without or against the consent of the title holder, for the exploitation of a subject matter protected by a patent or other intellectual property rights or it is the authorization given by a judicial or administrative authority to a third party for use of a patented invention without the consent of the patentee, on various grounds of general interest (absence of working, public health, anti-competitive practices, emergency, national defense).¹

The concept of Compulsory License (CL) is governed by the *Zambian Patents Act*² of 1st April, 1958. This provision is premised on the United Kingdom (UK) patent law deeply rooted to the Statute of Monopolies of 1623. The birth of compulsory license is anchored to the obligation introduced by the Statute of Monopolies which had influenced many national patent laws during the XIX century to work out a patented invention locally.³ The granting of compulsory licenses appeared as a means of mitigating that drastic measure of direct forfeiture.

A system of compulsory license was adopted in the UK under the Patent Act of 1883 for cases in which, the patent was not being worked out in the UK on the grounds that reasonable requirements of the public were not satisfied, or any person was barred or prevented from exploiting or using an invention.⁴ This provision had greatly influenced patent laws subsequently adopted in many countries besides the UK and this was the beginning of the development of the International Convention for the protection of Industrial Property commonly known as the Paris Convention in 1883.⁵

¹ Integrating Public Health Concerns into Patent Legislation in Developing Countries by Carlos Correa, University of Buenos Aires, Argentina, South Centre 2000.

² Section 37 of the Patents Act, Chapter 400 of the Laws of Zambia.

³ Origins and diffusion of the concept of compulsory licenses: <http://www.southerncentre.org/publications/complicence/complicence-04.htm> , 25th July, 2006.

⁴ Section 22 of the UK Patent Act of 1883.

⁵ Supra note 2.

Our patent law is an extension of the UK patent law. The UK patent law is applicable by way of Section 2 of the English Law (Extent of Application) Act, Chapter 11 of the Laws of Zambia which subjects the provisions of the Zambian Constitution and any other written law, whether common law or the doctrine of equity or the statutes which were in force in England as of April 17, 1911 (being the commencement of Northern Rhodesia, Order in Council of 1911)⁶ and any statute of later date in force in England, now applied to the Republic, or which hereafter shall be applied thereto by any Act or otherwise shall be in force in the Republic.

The Zambian Patents Act under Sections 37, 40 and 41 empowers the government to license to any company, government agency or any party or individual the right to use a patent without the consent of the patent holder in cases of abuse or insufficient use of patent rights (Section 37) and special provisions as in state use during an emergency (Sections 40 and 41) respectively.

A compulsory license may be granted by a competent authority to a designated person who should in turn compensate the patent holder through the payment of remuneration. The provision of compulsory license is a critical element in a health-sensitive sector. Under the patent law such licenses may constitute an important tool to competition and increase affordability or access to drugs⁷ on one hand and on the other hand may after all deter or derail advancement in research and development. The issuance of CL at the same time should ensure that a patent holder is handsomely compensated. Intellectual property has undergone more changes in the last ten years than in the rest of this century.⁸

These new changes in the last ten years have prompted the adoption of the Uruguay Round Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in 1994 which has led to the expansion of intellectual property rights into new fields, for instance, patents on drugs to cure HIV and AIDS. These changes have significantly

⁶ Intellectual Property Law in Zambia by George M Kanja, University of Zambia, 2006

⁷ Supra note 2.

⁸ Intellectual Property Rights, TRIPS Drugs and Public Health issues and proposals by the Third Network, September 2001.

strengthened the legal protection of a patent holder⁹ on one limb and on the other limb have accelerated the issuances of compulsory licenses by the developing countries.

The extension of intellectual property rights to patents on medicines or drugs and the enhanced powers bestowed on the patent holder have generated interesting debates between the north and the south on commercial, public or society on issues concerning public health and consumer protection.

Intellectual Property Rights

There can be no applicability of compulsory licenses without the protection of intellectual property rights. Intellectual property (IP), very broadly, means the legal rights which result from intellectual activity in the industrial, scientific, literary and artistic fields¹⁰ or it is a category of public law that generally includes copyrights and related rights, patents, trademarks, geographical indications, industrial designs, utility models, plant varieties, integrated circuits, trade secrets and sui generis regime for data bases that has also been established in some countries.¹¹ Simply put, IP is the products or creations of the human mind. The aim of intellectual property law is to safeguard creators and other producers of intellectual goods and services by granting them certain time-limited rights to control the use made of those productions. These rights do not apply to the physical objects in which the creations may be embodied but instead they apply to the intellectual creations as such.

Precisely intellectual property is traditionally divided into two branches composing of industrial property and copyright. The Convention establishing the World Intellectual Property Organization (WIPO), concluded in Stockholm on 14th July, 1967 describes intellectual property as rights relating to literary, artistic and scientific works; performances of performing artists, phonograms and broadcasts; inventions in all fields of human endeavor; scientific discoveries; industrial designs; trademarks and commercial names and designations protection against unfair competition and other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.¹² The areas

⁹ Supra note 6.

¹⁰ WIPO Intellectual Property Handbook: Policy, Law and Use, Publication No. 489 (E) WIPO 2004, Second Edition.

¹¹ Supra note 1.

¹² Supra note 10.

stated as literary, artistic and scientific works involve the copyright branch of intellectual property. The areas mentioned as performances of performing artists, phonograms and broadcasts are concerned with related rights or sometimes referred to as rights related to copyright. The areas stated as inventions, industrial designs, trademarks service marks and commercial names and designations constitute the industrial property branch of intellectual property. The area mentioned as protection against unfair competition is covered under Article 1(2) of the Paris Convention for protection of industrial property (Stockholm Act of 1967) (the Paris Convention) includes the repression of unfair competition which belongs to the industrial property branch.¹³

Intellectual Property, in sum, is a legal right to property and the power to exclude others. For Example, the owner of an automobile has the power to bar others from entering or driving it without his consent. In the same sense, the owner of a real estate property may build a wall fence around it to exclude others having access to it. Similarly, IP may operate under the same principles, although IP rights relate to intangible products of the human mind besides their physical embodiment. Intellectual property gives the holders of these rights the same kind of rights other property owners have, the right to exclude others from interfering or having access to the protected subject matter. Simply put, inventions are new solutions to technical problems and industrial designs are aesthetic creations associated with the appearance of industrial products.

Reasons countries enact Intellectual Property Laws

Generally, countries enact laws to protect IP for two many reasons, firstly it is to give statutory expression to the moral and economic rights of creators in their creations and the rights of the public in access to those creations and secondly, it is to promote a deliberate act of government policy, creativity and the dissemination and application of its result in order to encourage fair trading which contributes to economic and social advancement and development¹⁴in a given society.

¹³ Article 10bis (2) that states that “any act of competition contrary to honest practices in industrial and commercial matters constitutes an act of unfair competition.

¹⁴ Supra note 12.

Discoveries

Scientific discoveries are not inventions according to the WIPO Convention. Under the Geneva Treaty on the International Recording of Scientific Discoveries (1978), defines a scientific discovery as the recognition of phenomena, properties or laws of the material universe not hitherto recognized and capable of verification.¹⁵ Inventions are normally new solutions capable of solving specific technical problems.¹⁶ Such solutions must, naturally, rely on the properties or laws of the material universe that are not technically applied. An invention puts to new use and new technical use, the properties or laws whether they are recognized (discovered) simultaneously with the making of the invention or whether they were already recognized (discovered) before, and independently of, the invention.¹⁷ Generally speaking, discoveries are not patentable under many jurisdictions.

Intellectual Property Evolution

The evolution of IP starts with Renaissance Northern Italy which is thought to be the cradle of the IP system. The concept of the IP system is not a new one but dates back to the Venetian law of 1474 that made the first attempt to systematically protect inventions by a form of a patent by granting an exclusive right to an individual.¹⁸ In the same century the invention of movable type and the printing press by Johannes Gutenberg around 1440 contributed to the birth of the first copyright system in the world and towards the end of the 19th century new ways of manufacturing were invented which triggered large scale industrialization.¹⁹ The industrialization was influenced by rapid-city growth, expanding railway networks, the investment of capital, and the growing transoceanic trade. New ideals of industrialism and the emergence of stronger centralized governments and stronger nationalism made contributions to many countries establishing their first modern IP laws.²⁰ It is at this same time that the international IP system started to take form or shape with the two fundamental intellectual property treaties, namely, the

¹⁵ Article 1(1)(i).

¹⁶ Supra note 14.

¹⁷ Supra note 16.

¹⁸ Intellectual Property A Powerful Tool for Economic Growth by Kamil Idris, the current Director General of WIPO, Overview p.1.

¹⁹ Supra note 18.

²⁰ Supra note 19.

Paris Convention for the protection of industrial property established in 1883 and the Berne Convention for the protection of literary and artistic works established in 1886.²¹

The World Intellectual Property Organization (WIPO) is one of the specialized agencies of the United Nations (UN) system of organizations. The Convention Establishing the World Intellectual property organization came into existence in 1967 signed at Stockholm and came into force in 1970. The origin of WIPO dates back to 1883 and 1886 and these are the two treaties that adopted the Paris Convention and the Berne Convention respectively. Both Conventions provided for establishment of international secretariats. These two Conventions were placed under the supervision of the Swiss Federal Government.

The main platform underlying the IP system historically has been to recognize and reward IP ownership of inventions and creative works in order to stimulate further inventive and creative activities that in turn, of course, would boost economic growth. The purpose of the patent system has always been conceived as a compromise between the private interests or private rights of the inventor and the public interest which, in short, constitutes a barter transaction.²²

As such the inventor is granted a right of monopoly from the state, but is obligated to disclose his invention publicly in such a manner that it can be carried out by ordinary persons skilled in the art. The principle of barter expresses the social duty of intellectual property, although little remains of this concept early in the 21st century.²³ The main reason underlying public disclosure of an invention is to ensure that patents stimulate technological progress. Furthermore, it allows basic applied research to be carried out on a patented invention provided that no commercial transactions are advanced.

The weakness of inventions lies on the insufficient disclosure of patented inventions to the public as said by **Friedrich Karl Beier**, a German professor of patent law, who stated that only a small percentage of the inventions being patented were publicly disclosed in

²¹ Supra note 20.

²² Patents and Development Lessons Learnt from the Economic History of Switzerland by Richard Gerster, Intellectual Property Series No. 4, Third World Network (TWN).

²³ Supra note 22.

an insufficiently clear manner. He reiterated that the information contained in current patent specifications frequently fails to provide the practical knowledge of technological advancement or progress that used to be a standard some years ago.²⁴ In addition, micro-organism patenting has contributed to the problem of description more difficult because the duty of disclosure has now been complicated by an additional requirement of deposit. Moreover some experts believe that unrestricted competition is a premise for greater incentives than state grants of monopoly (Hauser/Schanz 1995, p.225).

The other purpose for setting up of a viable patent system is that inventions in nature promote industrialization and provide jobs. The original text of the 1883 version of Article 5 of the International Convention for the protection of Industrial Property (the Paris Convention), an important document of international patent law states that the patent holder has an obligation to exploit a patent and the language of the revised text, as well, has also laid emphasis on the working of a patent as a jurisdiction or matter of national law.²⁵

In today's modern global economy, very few patents are exploited through local production or the granting of licenses. Instead, working the patent through importation is now encouraged and has become the dominating facility extensively being applied.²⁶ A patent not only confers exclusive rights to exploit an invention based on local or licensed production, but it also grants a monopoly on importation of products based on the patent. The patent protection system, therefore, perpetuates the existing inequitable division of labour between the North and the South, rather than overcoming the monopoly aspect bestowed on the patent holder²⁷. In principle, the applicability of compulsory licenses, acts as a bridge or an instrument for advancing the public interest as opposed to the interest of the patent holder.

The conditions applied for legal grant of compulsory licenses administratively is different from country to country. In practice, however, they have proven to be a blatant or ineffective weapon because a license is restricted by time limits and other conditions, and

²⁴ Supra note 23.

²⁵ Supra note 24.

²⁶ Supra note 25.

²⁷ Supra note 26.

in order to protect the patent holder, compulsory licenses both in the north and south are rarely encouraged or granted.²⁸ Notably it is often seen that protection of intellectual property is an important factor affecting the investment climate. But history does not attribute to this view. For instance, countries like Canada and Italy have faced no obstacle in attracting foreign investors, regardless of the fact that they had lacked patent protection for pharmaceutical products at various times. There are many other factors that are more decisive to attract foreign investment. In essence, foreign investors to some extent stake their investments because of the market size in countries such as India, China or Brazil, and surprisingly, this is so even when the conditions are contrary to the textbook descriptions of a market economy. Small countries like Zambia, even when their laws to protect patents are in place and enforceable, and have even created attractive market conditions, but they are still regarded as marginal and unattractive for foreign investment.²⁹

Industrial Property System in Zambia

The patent system in Zambia is administered by the Patents Act, Chapter 400 of the Laws of Zambia. The Zambian patent law is an extension of the UK patent law as already stated above. Industrial property as it is commonly understood is associated with a species of property that cannot be seen by the eye, but yet it is known to exist as it makes its presence felt and its existence is appreciated in several ways that affect our daily living. For instance, on each given day the average person is surrounded by products that are full of intellectual property, ranging from the clothes we wear, books we read, to the cars we drive and the music we listen to. Unfortunately, many of us do not realize that intellectual property envelopes many products or goods everywhere.³⁰

The main aim of setting up the Zambian industrial property office was to establish a balance between on one hand the extent of privileges traditionally granted to the holders of IP rights and on the other hand to ensure a smooth and effective process of transfer of

²⁸ Supra note 27.

²⁹ Supra note 28.

³⁰ Paper by Zambia Patent Office presented to LAZ on Granting and Registration Procedures and Benefits Accrued from the protection of intellectual Property, 4th March, 2005: Intellectual Property Law by George M Kanja, University of Zambia, 2006, p.1.

technology in Zambia.³¹ The legislation on IP in Zambia dates back to 1958 when the first law to protect patents was enacted and the country was still placed under the hands of the Federation of Rhodesia and Nyasaland until its dissolution in 1963. Before the dissolution of the Federation the registration and processing of patents and all other industrial property issues was a federal function regulated by the Federal Central Patents and Trademarks and Designs Registry in Salisbury (now known as Harare).³² Following the recommendations of the Federal Liquidation Agency, the Federal Patents, Trademarks and Design office, including all the records and equipment concerned therewith passed to the jurisdiction of the Government of Rhodesia on the dissolution of the Federation.

The Federal Patents, Trademarks and Designs were a unitary system of records and applied to the three territories constituting the defunct Federation³³. There were no separate records maintained in respect of any of the constituent territories. The records that were placed under the control of the Government of Rhodesia included the Federal Registers which still constitute evidence of title to some of the existing industrial property rights in Zambia.

In 1969 the Government of the Republic of Zambia despite all the disadvantages it experienced decided to establish an independent national patent office capable of affording a high standard of protection for industrial property rights within the frame of the 1949 British Patent Act in order to accommodate its national interest. The office was firmly established in 1969.³⁴ It had to be started from the scratch and the task at hand then included the recruitment of staff, formulation of procedures and acquisition of requisite equipment. It was very difficult to operate independently for a number of years without referring to the Federal records that existed at the time. The trade and industrial property policies were influenced to a large extent by Southern Rhodesia. Zambia at the time was naturally a trade area for manufactured items from the south. In Zambia there were no manufacturing industries worth talking about. This factor contributed to the trend of

³¹ Industrial Property Status in Zambia by J M C Kunkuta, former Registrar of Patents, Trade Marks and Industrial Designs, 2002.

³² Supra note 31.

³³ Supra note 32.

³⁴ Supra note 33.

inventive activities. Generally, in Zambia there is a fair amount of inventions and these inventions are confined to the Copperbelt.³⁵

It was in the 1970s that Zambia's development process began to evolve in different directions by deliberately diversifying the economy. The concept of diversifying the economy was understood to mean lessening the country's dependence on copper by developing the agriculture and manufacturing sectors mainly through import substitution³⁶. The question of finding appropriate technology took the central stage for the Republic to begin to produce the products domestically. As expected, import substitution agenda required industrial processes to evolve technological levels equivalent to the quality of goods previously imported.

For Zambia to begin producing locally what used to be sourced from foreign jurisdictions it had to embark on industrial process rather late because at this time a large part of the world was already industrialized or where in the process of being industrialized.³⁷ Zambia's link to the Federation and the then existing trade patterns naturally caused her to experience a series of draw backs.

The three problems concerning Zambia's technological development had to be tackled. Firstly, the economy needed resources to finance its domestic efforts to recreate the technology already existing somewhere and in this vein, National Council for Scientific Research and other Research and Development institutions or Centers were established with the main object of creating national technology to reduce technology dependence and this was done by placing emphasis on applied research.³⁸

Secondly, the government wanted to tackle the complex structure of corporate entities which had control and access to the technology, technological information, the strength and the scale of operations. In the light of this obstacle, the government took a close control over agreements that provided for patents and trademarks licensing including

³⁵ Supra note 34.

³⁶ Supra note 35.

³⁷ Supra note 36.

³⁸ Supra note 37.

technical know how and to this effect technology transfer was institutionalized through the enactment of the Industrial Development Act of (now repealed) 1977, as a result, industries such as Indeni Refinery, Nitrogen Chemicals Zambia Limited, Kafue Textiles to mention a few were set up as conduit for transfer of technology.³⁹

Thirdly, the issue of competition exerted pressure on import substitution companies by multinational corporations operating in Zambia and this trend had to be rearranged. To this effect, the Zambian Government eliminated competition through the nationalization of industries including the mines belonging to international companies, South Africa Breweries (Anglo American) Lever Brothers etc., were nationalized and the importation of goods that were capable of being produced locally was restricted and strictly monitored by the Control of Goods Acts.⁴⁰

The high financial commitments including the payments to former proprietors of nationalized companies and the economic hardships largely assisted in shaping Zambia's Industrial Property policy. In the past industrial property rights in Zambia were used as a market to lever for privileged imports that virtually turned Zambia into a warehouse economy where everyone including the government itself was engaged in trading.⁴¹ In view of the industrial property policy, this was wrong, because it is envisaged that the basic purpose of a patent is to enhance applied research levels and gradually promote industrial progress for the benefit of society at large.

The problem facing the Zambian patent system is lack of understanding which is attributed mainly to lack of a basic national infrastructure of science and technology. This is further compounded by lack of IP policy. This in itself is an impediment to effective exploitation of industrial property system in the country. The other problem is that the IP portfolios are fragmented, for instance, copyright is under the ambit of the Ministry of Information and Broadcasting whereas industrial property is administered by the Zambia

³⁹ Supra note 38.

⁴⁰ Supra note 39.

⁴¹ Supra note 40.

Patent office, an Executive Agency under the Ministry of Commerce, Trade and Industry. This, to a large extent has made the formulation of IP policy difficult.

The Current Industrial Property legislation

In Zambia intellectual property rights are administered through the following legal instruments: The Patents Act Chapter 400; The Trade Marks Act Chapter 401; The Registered Deigns Act Chapter 402; Merchandise Act Chapter 403; and The Copy Right Act Chapter 406. Save for the Copy Right Act, all other IP laws are administered by the Zambia Patent Office an Executive Agency of the Ministry of Commerce, Trade and Industry (MCTI).

The Patents Act Chapter 400

The Patents Act provides for an independent system of patent protection that includes all fields of technology and the term of a patent is 16 years contrary to the TRIPS requirement of 20 years. Extension of the term is possible for a further period of 4 years depending on the circumstances surrounding the extension request from the patent holder. In the administration of the Patents Act, the Registrar is empowered to refuse the grant of patents in respect of products which are capable of being used as food or medicine (product patents) that extends also to agriculture chemicals (Section 38(1). Granting of patents to plant varieties within the ambit of the existing patent legislation is not possible, even though the Government has fully encouraged the development of plant varieties. It is imperative (own view) that activities of plant breeding are also given protection to encourage food production and in the course of doing so would contribute largely to the national food security.

Trade Marks Act Chapter 401

It provides for the registration system of marks. Registration is only in respect of goods and does not extend to services. Registration is for a term of 7 years initially and can thereafter be renewed for unrestricted periods of 14 years.

The Registered Designs Act Chapter 402

It provides for the registration system of Designs. The term of protection is 5 years subject for renewal for two consecutive periods of five years each.

The Merchandise Act Chapter 403

It provides for the registration system of enforcing industrial property rights and insists on goods being marked and the procedure of denying access to the Zambian market goods that may infringe protected rights.

Patents

A patent is a statutory grant which bestows on an inventor or his or her legal successor the right to exclude others from making, using, offering for sale, selling or importing the claimed invention for a limited period of time.⁴² The inventor can sue anyone who exploits the patented invention without his or her permission. The theory underlying the system is that the financial reward flowing from the exploitation of the patent and disclosing of the inventions for public dissemination and use, would somehow encourage innovation and raises the technical level of a nation's industry in order to promote and encourage fair trade.⁴³

The patent property right is only valid and enforceable in those territories where the patent has acquired protection, in other words, it means patent protection is territorial. The granting of the patent is conditioned on novelty, a minimal degree of inventive ingenuity (inventive step), and the industrial applicability of an invention. The patent as a legal right is not to be confused with a printed specification. A patent describes how to make and use an invention through a written description and drawings.⁴⁴

The patent includes the claims, which set forth the invention that receives patent protection. The patent rights are granted in exchange for the addition of the knowledge to the public domain. In essence, this is a quid-pro-quo⁴⁵ arrangement between the government and an inventive entity.⁴⁶ The government grants property rights of defined tenure in exchange for the consideration or value of public disclosure of inventions.

⁴² United States Patents and Trademarks Office, Introduction to Patent Examining, GIPA Edition, PEIT Manual, Rev. 10th May, 2006.

⁴³ Secrets of Intellectual Property, A guide for small and medium-sized exporters, International trade centre UNCTAD/WTO WIPO, Geneva 2004.

⁴⁴ Supra note 39.

⁴⁵ Latin meaning something for something or an action or thing that is exchanged for another or thing of more or less equal value, a substitute, p1282, Black's Law Dictionary, Eighth Edition by Bryan A Garner.

⁴⁶ Supra note 41.

The grant of the patent produces the following benefits: (i) the immediate benefit that the disclosure of new knowledge or information is that it will inspire others to further improve upon or experiment with the knowledge; (ii) the delayed benefit that comes after the expiration of the patent term is that the public (public domain) may make and use the claimed invention for free, if appropriate; and (iii) The long-term benefit obtained by a valid and enforceable patent is that it encourages the expenditure of capital resources for research and development, thus promoting the progress and development of new technologies.

Novelty

The patent system was conceived to reward the inventor for the contribution to the pool of existing knowledge. The criteria used to define what is new are key determinants of the scope of possible limitations to free access and use of technical knowledge and products in the public domain.⁴⁷ The test of novelty considers how much distance separates one claimed invention from the prior art. An invention is new if it is not anticipated by the prior art. Prior art is, in general, all the knowledge that existed before the relevant lodging or priority date of a patent application, whether it existed by way of written or oral disclosure.⁴⁸

The novelty requirement in modern patent law is generally based on an assessment of the prior art on a universal basis, that is, anywhere in the world. Many times, novelty is destroyed by previous written publication, prior use or other form of public (oral) communication of the invention.⁴⁹ A document will only destroy the novelty of any invention claimed if the subject matter is explicitly contained in the document. The subject matter set forth in a claim of an application under examination is therefore compared element by element with the contents of each individual publication. Lack of novelty can only be established if the publication itself contains all the characteristics of that claim, that is, if it anticipates the subject matter. Within this framework, the legal definition and application of novelty requirement significantly differs from country to

⁴⁷ Integrating Public Health Concerns into Patent Legislation in Developing Countries, by Carlos Correa, University of Buenos Aires, Argentina, South Centre 2000, p.40.

⁴⁸ WIPO Intellectual Handbook: Policy, Law and Use, Chapter 2, WIPO Publication No. 489 (E), WIPO 2000.

⁴⁹ <http://www.southcentre.org/publications//publichealth/publichealth-06htm>, dated July 27, 2006.

country.⁵⁰ In some jurisdictions, a flexible standard is applied, thus allowing the granting of a great number of patents. For example, in the United States (US), disclosure that has taken place outside the US is only made destructive when made in a written form.⁵¹ The US, for instance, requires complete disclosure only in a single application to destroy novelty, despite the fact that a skilled person may have been able to derive the invention without effort from combination of publications.

Inventive Step (Non Obviousness)

Even if it is novel, an invention is not issued if its technical aspect would or could have been discovered in the due course by a person with average skills in the same art or respective field. In the United States practice, for instance, courts applying the non obviousness standard (the US equivalent to inventive step) undertake a three step factual inquiry, examining first; (i) the scope and content of the prior art to which the invention pertains; (ii) second, the differences between the prior art and the claims at issue; (iii) and third, the level of ordinary skill in the pertinent art.⁵²

The expression ordinary skill is intended to exclude the best expert that can be found. It is intended that the person be limited to one having the average level of skill reached in the field in the country concerned. The expression inventive step conveys the idea that it is not enough that the claimed invention is new, that is, different from what exists in the state of the art, but that these differences must have two characteristics. Firstly, it must be inventive that is, the result must be of a creative idea, and it must be a step that must be noticeable.

There must be a clearly identifiable difference between the state of the art and the claimed invention. This is why, in some jurisdictions, there is the concept of an advance or progress over the prior art. Secondly, it is a requirement that this advance or progress be significant and essential to the invention. In most cases, it is useful to assess inventive step in relation to the three aspects, namely: the problem to be solved; the solution to that

⁵⁰ Supra note 48.

⁵¹ Supra note 46: This may permit the patenting in that country of knowledge, including of indigenous communities, used but not published in written form outside the United States, Correa, 1999a.

⁵² Integrating Public Health Concerns into Patent Legislation in Developing Countries by Carlos Correa, University of Buenos Aires, Argentina, South Centre 2000, p. 44.

problem; and the advantage effects, if any, of the invention with reference to the background. In establishing the existence of inventive step, it is generally necessary to consider not only the knowledge derived from a single prior art document but also the combined knowledge of existing literature, patent documents and other prior art.

However, current US practice is against such an approach and holds that the subject matter of a claim is not rendered obvious by the prior art unless there is some specific suggestion or teaching in the prior art that points the way to it.⁵³ However, the Agreement on TRIPS is not specific with the issue of inventive step. Article 27.1 provides that patents shall be granted to protect inventions which involve an inventive step and in a footnote it allows Member countries to interpret inventive step as synonymous with non obviousness.⁵⁴

Industrially Applicable

The third criterion for patentability is in respect of industrial applicability of the invention. Patent law around the world aims at protecting technical solutions to a given problem, and abstract knowledge.⁵⁵ A patent to be accepted must be the type that can be applied for practical purposes and not be purely theoretical. The invention must be a product or part of a product and in real sense it should be possible to make that product. And the invention is that process or part of that process that makes it possible for someone to carry out or use that process in practice.⁵⁶

Applicability and industrial applicability are expressions that reflect the possibility of making and manufacturing in practice and that the invention can be carried out or used in practice. The term industrial in a broader sense, include any kind of industry. In simpler language, industrial activity means a technical activity on a certain scale. The industrial applicability requirement is met as long as the claimed invention can be made in an industry without taking into account the use of the invention.⁵⁷

⁵³ Supra note 47; Dratler, 1999.

⁵⁴ Supra note 48.

⁵⁵ Supra note 49.

⁵⁶ Supra note 45.

⁵⁷ Supra note 51.

Countries differ in their treatment of industrial applicability. Under the US law, certain developments that do not lead to industrial product may be patented. An invention only needs to be operable and capable of satisfying some function of benefit to humanity, for instance, must be (useful)⁵⁸. The usefulness concept is broader than the industrial applicability concept required in Europe and other countries. The US rule permits the patentability of purely experimental inventions that cannot not be made or used in an industry, or that do not produce a technical effect⁵⁹ as demonstrated by the large number of patents granted in United States on methods of doing businesses.⁶⁰

The application of industrial applicability requirements is often complex in the chemical, pharmaceutical, and biotechnology industries, where there are particular problems relating to the acceptable degree of speculative information. Thus, in the US mere speculation about chemical homologues would be insufficient whereas in vitro testing in animal tumor models of products intended for human use may be deemed to be sufficient.⁶¹ The TRIPS Agreement does not define the concept of industrial applicability and therefore leaves countries themselves to consider what is industrially applicable by applying flexibilities under the Agreement. In other words, the Agreement allows a member country to consider industrial application as synonymous with the invention being useful.

Disclosure of the Invention

There is an additional requirement of patentability besides an invention being novel, involving an inventive step and industrially applicable. This requirement relates to sufficient disclosure of the invention in the application. It is obligatory that the inventor discloses an invention in a manner sufficiently clear for an ordinary person skilled in the art to carry out the invention.⁶² It is a requirement that a description sets out the best mode for carrying out the invention claimed. This should be demonstrated by illustrations where appropriate and reference made to the drawings if any. In some

⁵⁸ Chisum and Jacobs, 1992 p.2-50.

⁵⁹ Bainbridge, 1992, p. 270-272.

⁶⁰ The growing flood of Wall Street patents in Patnews (Internet Patent New Services) of 29.9.99.

⁶¹ Supra note 58.

⁶² Supra note 52.

jurisdictions, the description is required to disclose the best mode known to the applicant for carrying out the invention.

The sufficient disclosure of an invention is to allow for an opposition procedure in some jurisdictions instituted before the grant of the patent. An opposition procedure is a process that permits third parties to present objections to the grant of the claimed invention. Having fulfilled the requirements mentioned above, the patent application is denied protection or patentability if it falls under the following:

- (i) Discoveries of materials or substances already existing naturally;
- (ii) Scientific theories or mathematical methods;
- (iii) Plants and animals other than microorganisms. And essentially biological processes for the production of plants and animals, other than non biological and microbiological processes;
- (iv) Schemes, rules or methods, such as those for doing business, performing purely mental acts or playing games;
- (v) Methods of treatment for human humans or animals, or diagnostic methods practiced by on human or animals but this does not extend to products for use in such methods.

Ordre Public and Morality

Under the TRIPS Agreement, Article 27.2 a Member is further allowed to exclude from patenting certain kinds of inventions⁶³ for instance, inventions that contravene public order or morality. The text of the TRIPS Agreement applies the concept of ordre public as one of the grounds for an exception. This concept may be interpreted as being narrower than public order or public interest. Under the Manual for Guidelines for Examination of the European Patent Office, for instance, links ordre public to security reasons, such as riots or public disorder, and inventions that may lead to criminal or other generally offensive behaviour.⁶⁴

⁶³ Article 27.2 states “ Members may exclude from patenting inventions, the prevention within their territory of the commercial of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that exclusion is not made merely because the exploitation is prohibited by domestic law.”

⁶⁴ Part C, Chapter IV. 3.1.

Generally, there is no one accepted notion of ordre public but a WTO Member country has room to apply the flexibilities covered under this Agreement to define in its national legislation what it deems or considers fit to be ordre public depending upon its own national needs to protect the public values. The expression morality is also relative to the values prevailing in one given society. Such values are not the same in different cultures and countries, and such values do change over time.

It is a matter of national public policy to determine when a certain conduct may be deemed contrary to the fundamental values of society.⁶⁵ Article 27.2 in itself does not limit ordre public only to security reasons but it also provides for the protection of human, animal or plant life or health and may even be applied to inventions that may lead to serious prejudice of the environment.

Summary: A compulsory license is a license granted by an administrative or judicial body to a third party to exploit an invention without the authorization of the patent holder. This type of license is commonly known as non-voluntary license connoting the lack of consent by the patent holder. The TRIPS regulations or rules on compulsory license are contained in Article 31.

A compulsory license is one mechanism the government authority may apply as a means of technological transfer Intellectual property rights intellectual property are rights awarded by competent authority to individuals principally over their creative works, namely, inventions, literary works and artistic works, symbols, names, images, and designs used in commerce. Intellectual property gives the owners of creative works the right to prevent others from making unauthorized use of their property for a limited period; for instance, patent protection lasts 20 years universally.

Intellectual property is categorized as industrial property (functional commercial innovations), and Artistic and Literary Property (cultural creations).⁶⁶ A patent is an exclusive right awarded to an inventor to prevent others from making, selling, distributing, importing or using an invention, without license authorization for a fixed period of time (TRIPS 20 years and the Zambian patent law it is still 16 years from the date of filing a patent application). In return to patent protection, society requires that the patent application should disclose the invention in a manner that enables others to work the invention by persons ordinarily skilled in the art and include the best mode of working out the patented invention.

⁶⁵ Intellectual Property Rights, the WTO and Developing Countries, The TRIPS Agreement and Policy Options by Carlos M Correa, 2000 p. 62.

⁶⁶ Integrating Intellectual Property Rights and Development Policy, London September 2002.

Chapter 2

International Applicability of Compulsory License

At the international plane, there are two legal instruments that contain provisions or rules for compulsory licenses. The two legal instruments are the Paris Convention⁶⁷ for the protection of industrial property administered by WIPO and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)⁶⁸ an ambit of the WTO. A compulsory license generally enables a government to license to a third party the right to use a patented invention without the consent or against the will of patent title holder. This type of license is commonly referred to as non-voluntary license connoting the lack of consent from the patent holder.

The TRIPS rules on CL are contained in Article 31. The concept of CL itself, however, has a long history. One of the first legal instruments to incorporate the concept was the United Kingdom (UK) Statute of Monopolies of 1623.⁶⁹ The TRIPS Agreement was adopted in 1994 and since then CL has become the main feature of patent laws around the globe.⁷⁰ Article 31 of TRIPS details the conditions that WTO member states need to apply when it chooses to use compulsory licensing and these include licenses on a case-by-case basis, evidence of unsuccessful prior request for a voluntary license non-exclusivity of the license and the requirement to compensate the patent holder adequately just to mention a few.

Licenses that are provided by obtaining the consent of the title holder are referred to as voluntary as opposed to compulsory or non-voluntary licenses. Voluntary licenses give the right to perform acts covered by the exclusive right under an authorization from the patent title holder. The authorization is generally referred to as license contract in a contract entered between the owner of the patent and the beneficiary of the license in a

⁶⁷ Article 5A(2) of the Paris Convention which provides that, "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent abuses which might result from the exercise of the exclusive rights conferred by the patent , for example, failure to work."

⁶⁸ Article 31 of the Agreement on Trade Related Aspects of intellectual Property Rights (TRIPS).

⁶⁹ Correa (1999a), p. 1.

⁷⁰ Correa (1999a), p. 2.

contract.⁷¹ In opposition, the beneficiary of a non voluntary license has the right to perform acts covered by the exclusive right under an authorization given by the government authority against the will of the owner of the patented invention or patent for invention.

Paris Convention

The discussions that led to the formation of the Paris Convention reflected conflicting views on the issue of working a patent locally and this is the premise that assisted in compulsory licenses being generated at the end of the century. The Conference of 1883 that led to the birth of Paris convention adopted the concept of working of a patent locally, an obligation that generated sharp opposition from the United States and other countries.⁷² After a turbulent process of negotiations the concept of compulsory license was adopted in The Hague in 1925 as the main means or feature of ensuring the exploitation of a patented invention.

The forfeiture of the patent would only apply where a compulsory license proved to be ineffective as a means of addressing the non-working condition of a patent (Article 5A), forfeiture as it is became a subsidiary measure only applicable if a compulsory license had failed to remedy non-exploitation.⁷³ The Paris Convention which relates to patents for inventions, utility models, industrial designs, trademarks and trade names, in short industrial property, has a wider provision to recognize the right of a member state to establish compulsory licenses but under certain limitations. The limitations are as follows:

- (i) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example failure to work (Article 5A(2));
- (ii) Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the

⁷¹ WIPO Intellectual Property Handbook: Policy, Law and Use, WIPO Publication No. 489, Second Edition, 2004, p. 34.

⁷² <http://www.southcentre.org/publications/complicence/complicence-04htm> , p.4, dated July 25, 2006.

⁷³ Supra note 61.

said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license (Article 5A(3));

- (iii) A compulsory license may not be applied for on the ground of failure to work out or insufficient working before the expiration of four years from the date of filing the patent application or three years from the date of the grant of the patent, whichever period expires last: it shall not be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license (Article 5A (4)); and
- (iv) The foregoing provisions shall be applicable, *mutatis mutandis*, to utility models only (Article 5A (5)).

Article 5A (2) of the Paris Convention, in particular, provides for countries to grant non-voluntary licenses to prevent abuses resulting from the exercise of patent rights such as failure to work the patent locally whereas Article 5A (4) of the said Convention specifically provides for compulsory licenses for failure to work or insufficient working of the patent and may not be requested before a certain period of time of non-working or insufficient working has lapsed. The stipulated time limit expires either four years from the date of filing the patent application or three years from the date of sealing the patent for invention. However, the applicable time is the one that, in an individual case, expires last or deems fit.

The time limits of three or four years usually take into consideration that, it may take quite some time for the patent holder to commence the working of the patented invention in each country where he had obtained patent protection. The rationale behind this provision is to give the patent holder ample or longer time limit especially where the patent holder justifies his inaction by proving legitimate reasons for not working the patent locally, may be it is because of legal, economic or technical obstacles that have made it impossible to work the patented invention and if this request by any chance is not proven, then the request for compulsory license is turned down at least for the time being.

This limit time of three to four years is a minimum time limit provided under the Paris union but that does not limit the national laws to provide for a longer time limit period.⁷⁴ Article 5A(4) further provides compulsory licenses for non-working or insufficient working and can only be transferred together with the part of the enterprise benefiting from the compulsory license. The patent holder must remain with the right to grant other non-exclusive licenses and to work the invention himself. These limitations are provided or intended to prevent a compulsory licensee from obtaining a stronger position on the market than is warranted by the purpose of the compulsory license, for example, to ensure sufficient working of the invention in the country locally.⁷⁵

The grant of non-voluntary license does not prohibit or exclude the licensee from paying royalties but on the contrary national laws dealing with this issue generally require that the licensee make payments to the patent holder on the premise of working the patented invention. Whereas it is expected that the grant of compulsory licenses would, in many instances, sufficient to correct the anti-practices or abuses, Article 5A (3) provides for the forfeiture or revocation of the patent in cases where the grant of such licenses is not sufficient. This paragraph or provision further permits that, no proceedings for the forfeiture of or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory licensee.

Compulsory License in Favor of Private Parties

Some jurisdictions provide compulsory license even where there has been no abuse of the patent right and they do so to protect public interest. Generally, compulsory licenses granted on the basis of public interest can be divided into two branches, namely, licenses that are granted in favor of private parties and those that favor the government itself or the one that favors a person acting on behalf the government. One example of a compulsory license that favors a private party is in relation with dependent patents and this is granted to remedy the situation that arises when it is impossible to work a patent because it is dependent on another patent belonging to a different patent holder.⁷⁶

⁷⁴ Supra note 62.

⁷⁵ Supra note 63.

⁷⁶ Supra note 64.

Compulsory License in Favor of the Government

In many cases, patent laws provide for the government to exploit inventions without or against the consent of the patent holder or to have third parties use the invention on its behalf to meet the interest of the public. There are three instances in which this may occur, namely, national defense, national economy and public health. These situations are more concerned with cases that involve national emergencies, for instance, if the government is faced with HIV and AIDS problem, and the owner is not willing to increase the production of that drug for the treatment of HIV and AIDS fearing that mass production of that drug would lower the price or stifle competition, then the government has no choice but to acquire the patented drug or medicine against the will of the patent holder to satisfy the interest of the public under Article 5A (2).⁷⁷

Compulsory License under TRIPS

Article 31 administers what is commonly known as compulsory license or non-voluntary license. The patent itself is a charter from a government in recognition of particular work that gives that person certain rights. In other words, it is a contractual obligation between the patent holder and the public that normally carries a period of 20 years from the date of filing the application. The compulsory license in real sense mainly acts to restrain the exercise of those private rights in the public interest. The compulsory license is one mechanism through which governments limit the private power that resides in having technical knowledge by patent holders and make that technical knowledge immediately accessible for public use. The limitation should take precedence over patent interests.

Article 31 of the TRIPS allows a member country to exploit a patent without the consent of the patent holder, including the use by the government or third parties authorized by the government. WTO members may provide different forms of compulsory licenses in respect to patents which are explicitly provided for under this Agreement (Article 31) as long as they are not repugnant to the provisions of the Treaty. Article 31 of the TRIPS Agreement specifically lays down the conditions regulating the issuance of compulsory license but leaves much room to each WTO member state to decide the premises for the granting of licenses in cases of emergency and extreme urgency; remedying a practice

⁷⁷ Supra note 65

determined after administrative or judicial process to be anti-competitive practices; enabling the use of dependent patents and cases that involve public, non-commercial use. The TRIPS Agreement does not restrict member states to use other grounds besides the ones mentioned in the foregoing paragraph but can extend to other areas of public interest. Article 31 refers to public, non-commercial use on the basis of using a patent without the authorization of the patent holder.⁷⁸ In other words, public or non-commercial use may be applied as a specific ground to grant a compulsory license. However, public and non-commercial use of a patent can also be in the form of the government's right to utilize patents without the need to obtain a compulsory license.

The Agreement, in addition, contains a set of provisions to be referred to whenever member states want to grant compulsory licenses and these provisions are contained in Article 31 (a) to (j). Subject to certain conditions, Article 31 explicitly permits other use without the authorization of the patent holder. Such cases may include decisions made on case by case basis; only after seeking voluntary license first; national emergency; circumstances of extreme urgency; public non-commercial use (but right holder must be informed); scope and duration specified; non exclusive; predominantly for supply of domestic market (not in case of adjudicated and anti-competitive practices; and adequate remuneration paid to the patent owner.⁷⁹

Article 31 does not limit or attempt to specify any way the grounds upon which such licenses may be granted but a member state can extent to other situations that it considers beneficial to its local needs. This freedom to determine the grounds for granting CL has been re-affirmed under paragraph 6(b) of the Doha Declaration on the TRIPS Agreement and Public Health. This provision states that “(e) ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted”.

Paragraph 6(c) of the Doha Declaration provides freedom to WTO member states to freely determine appropriate grounds upon which compulsory licenses can be applicable

⁷⁸ Manual on Good Practices in Public-Health-Sensitive Policy Measures and Patent Laws, Third World Network, pp. 89 – 93, 2nd Printing 2005.

⁷⁹WTO Workshop on TRIPS and Public Health, held from 26 to 28 September, 2005, Geneva, Switzerland.

to protect public health and ensure access to affordable medicines.⁸⁰ For instance, a member country is allowed to apply for public non-commercial use under Article 31.b to authorize a third party to use a patented invention without negotiating with or without a license. The only obligation under this provision is that the patentee or patent holder must be adequately remunerated (Article 31.h). This approach is commonly used in situations of emergencies that also include public health emergencies (Article 31.b). When such an authorization is given to remedy anti-competition practices such as high practices from exercise of monopoly power, the products can even be allowed to be exported (Article 31.K).⁸¹

The TRIPS Agreement does not limit the grounds for the concession of compulsory license to be granted. The conditions applicable for granting such licenses may include, namely, case-by-case evaluation and decision; prior request to the patentee for a voluntary license; determination of scope and duration of the compulsory license; non-exclusivity; non-assignability; preferably for the domestic market; and remuneration.⁸² On remuneration, considerable room is left at the national⁸³ plane to determine when remuneration is deemed adequate. It must be determined based on each individual case, taking into account the circumstances of the licensee and of the market where it operates as well as the purpose of the license. A standard mainly applicable to determine the royalty base rate is the average rate paid in voluntary licenses in a given sector.

History of the provision

Before the TRIPS Agreement came into existence, countries through out the world enacted laws to authorize compulsory licenses. The terms in these legislations differed from country to country considerably.⁸⁴ A number of countries such as Canada and India incorporated in their patent laws licenses of right concerning certain subject matter areas in relation to food and pharmaceutical patents based on the time limit provided by the

⁸⁰ Supra note 76.

⁸¹ Compulsory License: Models for State Practices in Developing Countries, Access to Medicines and Compliance with the WTO TRIPS Accord by James Love, Third World Network (TWN).

⁸² Supra note 78.

⁸³ Supra note 80.

⁸⁴ Resource Book on TRIPS and Development, UNCTAD-ICTSD 2005 p. 462.

Paris Convention. This gave a right to any person interested after the time limit period has expired automatically entitled to a compulsory license. Patent laws in many jurisdictions include other grounds of public interest on which compulsory licenses are to be applicable.⁸⁵ For instance, in the South Africa, a large number of compulsory licenses have been granted in order to remedy anti-competitive practices.

The Paris Convention recognizes member states to grant compulsory license to remedy abuses of patent rights that include failure to work the patent (Article 5A). Although the Paris Convention prescribes a minimum period of time before a compulsory license is applicable (3 or 4 years depending on the circumstances), it does not otherwise limit the granting of such licenses in a sense, the only problem is that it does not establish a right of compensation on behalf patent holders.⁸⁶ For instance, the USA government proposed that “governments shall not generally grant compulsory license to patents and should also not grant patents where there is a legitimate reason for not practicing the invention such as government regulatory review.

If a government grants a compulsory license, it shall not discriminate against inventions in particular fields of technology and it should pay full compensation to the patentee for the license and that no compulsory license shall be exclusive.⁸⁷ Controversy over the issuance of appropriate scope of compulsory licensing is cited as one of the reasons the TRIPS negotiations were initiated.⁸⁸ In the late 1970s and early 1980s, developing countries demands for a New International Economic Order (NIEO) included greater access to technology.

The developed countries increasingly expressed that the treaty system governed by WIPO failed to adequately protect the interests of their technology-based and expressive industries. The major concerns were that WIPO treaties did not in some cases establish adequate substantive standards of IPR protection and further, that the WIPO System did

⁸⁵ Supra note 69.

⁸⁶ Resource Book on TRIPS and Development, Cambridge University Press p.463.

⁸⁷ Suggestion by the US for achieving the Negotiating Objective, US Proposal for Negotiations on TRIPS, Negotiating Group on TRIPS, including Trade in Counterfeit Goods, MTN.GNG/NG11/W/14, 20 October, 1987, November 3, 1987.

⁸⁸ By Frederick Abbot, Thomas Cottier and Francis Gurry, *The International Intellectual Property System: Commentary and Materials*, Kluwer Law 1998, pp.717-718.

not provide adequate mechanisms for enforcing obligations.⁸⁹ These demands laid a platform for the negotiations on the revision of the Paris Convention. These negotiations broke down in 1992, significantly because of competing demands concerning compulsory licensing.⁹⁰ The failure of these negotiations convinced industry interests that they would not succeed in solving what they viewed as the intellectual property problem at WIPO and this perception led to refocusing of IPR efforts to GATT. In the lead-up to negotiations on a mandate for the Uruguay Round, developing countries industry groups successfully created a coalition of government that would pursue the objective of IPRs regulations from WIPO and transferred to the GATT.

The dual objectives of the GATT were mainly to establish high standards of IPR protection and a strong multilateral enforcement mechanism. The GATT was founded in 1994 with the aim of liberalizing world trade and was actually not concerned with IPR as such. From the outset of the Uruguay Round negotiations in 1986, and until early 1989, developing countries were opposed to incorporating substantive standards of IPR protection in the GATT⁹¹ (although there was sympathy for affording basic protection against trademark counterfeiting and copyright piracy).⁹² The resistance of developing countries, however, was somehow overcome by a combination of concessions offered by the developed countries in other areas (principally agriculture and textiles) and by threats of trade sanctions and implicitly led to the dismantling of the GATT.⁹³

The Doha Declaration

Paragraph 6 of the Doha on TRIPS Agreement and Public Health,⁹⁴ adopted at the Fourth Ministerial Conference (9-14 November 2001), instructed the WTO Council for TRIPS to address issues affecting members lacking or with insufficient manufacturing capacities in pharmaceuticals and how they can make effective use of compulsory license. This came about because many developing countries and (LDCs) cannot produce either active

⁸⁹ Supra note 76.

⁹⁰ Supra note 77

⁹¹ Supra note 78

⁹² Frederick M Abbott, *Protecting first World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework*.

⁹³ UNCTAD-ICTSD, *Policy Discussion Paper; Intellectual Property Rights; Implications for Development* (2003), Geneva (hereinafter UNCTAD-ICTSD Policy Discussion Paper).

⁹⁴ WT/MIN(01)/DEC/2, 20 November 2001, hereinafter “the Doha Declarations.”

ingredients or formulations due to lack of technology, equipment, human resources or economic viability of domestic production.⁹⁵ If a product is deemed covered in an exporting country by the exclusive rights granted to the patent owner, production for export could take place under a compulsory license.⁹⁶

However, the TRIPS Agreement establishes that, unless a compulsory license is granted to remedy anti-competitive practices (Article 31(k)) it must “predominantly” supply the licensee’s domestic market (Article 31(f)). This simply illustrates that if a company received a request to manufacture and export a product that is covered in the manufacturing country by a third party’s patent, then it would not be able to do so (in the absence of the patent owner’s authorization), to the extent that production was predominantly for export and not for the manufacturer’s domestic market. However, this obligation is not applicable where the compulsory license has been issued to cure a practice determined by a judicial or administrative process deemed to be an anti-competitive practice.⁹⁷

Parallel Imports

Besides compulsory licenses, parallel imports are applicable to a WTO member. Parallel imports are permitted or legally justified under the TRIPS Agreement. Article 6 of the TRIPS Agreement provides for the application of doctrine of exhaustion of rights and this concept is not a matter of dispute settlement. The members are left to decide how this concept of exhaustion should be applicable in their jurisdictions. They may either adopt the international exhaustion of patent rights or regional exhaustion of patent rights or third option of national exhaustion of patent. The doctrine of exhaustion of rights was first developed in the USA by case law and Europe as an expression of the free-trade ideas prevailing at the end of the 19th Century.⁹⁸

⁹⁵ Implementation of WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, by Carlos M. Correa, University of Buenos Aires, April 2004 p.1.

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⁹⁷ WTO Document WT/L?540, 2 September 2003; Utilizing TRIPS Flexibilities for Public Health Protection South to South Regional Frameworks, South Centre, April 2004.

⁹⁸ Intellectual Property Rights, the WTO and Developing Countries, The TRIPS Agreement and Policy Options by Carlos M. Correa 2000 p.81.

This doctrine is applicable under patents on the basis that the patentee has no right to control the use or resale of goods once they are legitimately put in the market place by the patent holder or the licensee. In other words, parallel imports involve the importation or the resale of patented goods in a country without the authorization of the patent holder which has been put on the market legally of the exporting country by the title holder or in another legitimate manner. For example, a company may buy patented goods sold in Zambia and then resell them in Zimbabwe where the same patent is in force without the permission of the patent holder. The rationale underlying parallel imports is that since the inventor has been rewarded through the first sale or distribution of the product, he has no right to control the use or resale of goods put on the market with his consent or in authorized form. In other words, it means the inventor's rights have been exhausted.⁹⁹

Parallel imports are only allowed to cover legitimate products and not counterfeit products. In some instances, however, parallel imports have been applicable (on a regional scale) even when originating in a country where the product was not protected.¹⁰⁰ In economic sense, parallel imports are applicable to curb market segmentation and price discrimination by patent holders on a regional or international scale. In other words, parallel imports allow consumers to effectively shop on the world market for the lowest price concerning a patented good.¹⁰¹

Parallel imports are of paramount importance in the health sector, since the pharmaceutical industry generally sets prices differently through out the world for the same or similar medicines. Importation of a patented medicine from a country where it is sold at a lowest price will give access to more patients in the importing country to a

⁹⁹ Integrating Public Health Concerns Into Patent Legislation in Developing Countries By Carlos Correa, University of Buenos Aires, Argentina, South Centre 2000 p.72; The Doctrine of "exhaustion of rights" may be applicable at the national plane (rights are deemed exhausted domestically and the commercialization in foreign countries is not deemed to have exhausted the rights of the patentee), at the regional plane, as in the case of the European Community (exhaustion is deemed to have occurred if the commercialization took place in a country member of a regional agreement), or at the international plane.

¹⁰⁰ See the decisions of the European Court of Justice in *Stephar*, *Merck v Primecrown*, and *Beechan v Europharm*.

¹⁰¹ *Supra* note 93.

patented medicine without preventing the patent owner from receiving the remuneration for the patented invention in the country where the product was first sold.¹⁰²

The doctrine of exhaustion rights was originally limited to the domestic market. In the European Communities (EC), however, the doctrine has been extended by the decisions of the European Court of Justice to the entire common market, in order to avoid the market fragmentation that the application of import bans in each jurisdiction may create. The EC's exhaustion doctrine is applicable with respect to different types of intellectual property rights, including copyright. In relation to patents, the validity of the doctrine has been held even in cases where the exporting EC country did not provide for patent protection (see in particular, the decision of the European Court of Justice in **Merck v Stephar, case 187/80**, and the more recent decision in **Merck v Primecrown and Beecham v Europharm**).¹⁰³

Summary: At the international plane, there are two legal instruments that regulate compulsory licenses, namely, the Paris Convention for the protection of industrial property widely covers the applicability of compulsory license under Article 5A(2) which provides for the grant of non-voluntary licenses commonly referred to as compulsory license and further provides for the grant of compulsory licenses for non-working or insufficient working under Article 5A(4). The other is the TRIPS Agreement under Article 31 allows WTO members to authorize third persons to exploit a patented invention against the will of the patent holder provided certain conditions are adhered to, for instance, treating each case on merit and adequately remunerating the patent holder.

Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health is applicable to address WTO member states lacking or with insufficient manufacturing capacities in pharmaceuticals to utilize compulsory license effectively. Article 31(f) of the TRIPS requires that the production of drugs under government use or compulsory license be predominantly for the supply of the domestic market but this condition is not extended to instances where the government is trying to remedy anti-competitive practices (Article 31(k)).

Besides applying the provisions available under Article 31 of the TRIPS Agreement, WTO member states are authorized to apply Article 6 of the TRIPS that permits parallel imports which is based on the doctrine of exhaustion of rights. Exhaustion of rights simply means that a patent holder exhausts his rights after the first legitimate sale of the patented product in a country, region or on the international market. In simpler terms, it is a legal justification for the administration of parallel imports.

¹⁰² Supra note 95p.73.

¹⁰³ Supra note 92 p. 82.

Chapter 3

Local Applicability of Compulsory License

Compulsory license is applicable under sections 37, 40 and 42 in relation to the Zambian patent law.¹⁰⁴ Section 37(1)¹⁰⁵ specifically provides for the applicability of compulsory license in cases involving abuse or insufficient use of patent rights and it is mainly premised on Article 5A(4) of the Paris Convention of 1967 for protection of industrial property, which enables members to authorize third parties to exploit a patented invention against the will of the patent holder.

The Paris Convention on which our patent law draws its strength on compulsory licensing does not provide for adequate compensation, a new feature incorporated under Article 31 of TRIPS to remedy the mischief previously permitted under the Paris Convention. The draw back or insufficiency concerning the Zambian patent law is that Article 31 of TRIPS has not been incorporated or domesticated in the current Zambian Patents Act to be precise (Sections 37 and 41). In other words, Zambia is not yet TRIPS compliant though it is a party to World Trade Organization. The current patent law in Zambia lacks rules or regulations that are contained in Article 31, a common feature now being included or to be included in many jurisdictions on compulsory license in future.

Grounds for granting compulsory license

The TRIPS Agreement refers mainly to five possible specific grounds for the granting of a compulsory license. The main grounds are: refusal to deal; emergency and extreme emergency; anti-competitive practices; non-commercial use; and dependent patents. These grounds have already been referred to or covered in Chapter two. Article 31 of the TRIPS Agreement which contains rules on compulsory license does not provide an exhaustive list of grounds for the applicability of such licenses, but allows a WTO member to extend to other grounds on the basis of public interest. The usefulness of

¹⁰⁴ Chapter 400 of the Laws of Zambia.

¹⁰⁵ “Any person interested who can show that he has been unable to obtain a license under a patent on reasonable terms may, after the expiration of a period of three years subsequent to the date on which that patent was sealed or four years subsequent to the date on which the application in respect thereof was lodged, whichever period last expires, apply to the Registrar in the prescribed manner for compulsory license on the ground that reasonable requirements of the with respect to the invention in question have not been or will not be satisfied.”

Article 31 as a provision is to provide a balance against broad patent rights that hinder access to affordable medicines that will be unnecessarily limited if other grounds (besides the five possible ones specifically referred to therein) cannot be accommodated.¹⁰⁶ These are not the only grounds applicable under Article 31 but can extend to other areas of public interest by a WTO member as it deems fit to accommodate its public interest.

Conditions applicable for granting compulsory license

Besides the grounds on which WTO members are allowed to issue the grant of compulsory licensing, Article 31 further approves conditions on which each WTO member must adhere to when applying the concept of compulsory license. These conditions are listed hereunder and mainly include the following:

Individual merits

Section 37 provides a blanket application of issuance of CL and does not take into consideration the reasonableness of looking at each license on its individual merit as provided for under Article 31(a) of the TRIPS. In other words, governments should not attempt to grant blanket authorization of compulsory licenses pertaining to certain types of technologies or enterprises, but in opposition must require each application for a license to undergo a process of review to establish whether it meets the established rules or criteria for the granting of such a license.¹⁰⁷

Under the US practice, for instance, authorization use of patents by government under which language Article 31 of the TRIPS was drawn from or premised on requires interpretation flexibility on the reviewing of individual cases. Under the US law, the government may use any patented invention (or authorize its contractor to use such invention) without providing prior notification to the patent holder, subject only to the patent holder's right to initiate a proceeding before the Court of Claims for compensation.¹⁰⁸ Under the US patent law, a patent holder is not allowed to obtain an injunction against such government use. This means that in cases of government use of a

¹⁰⁶ TRIPS, Drugs and Public Health: Issues and Proposals by Third World Network, 2001.

¹⁰⁷ Resource Book on TRIPS and Development, UNCTAD-ICTSD PROJECT and Sustainable Development: 2005, p.468.

¹⁰⁸ Supra note 107.

patent the consideration of individual merits can take place after the license is granted and relates only to the question of compensation.¹⁰⁹

The requirement that licenses be determined on their individual merits does not necessarily mean that presumptions may not be established in favour of granting licenses, in particular to contexts that would mean placing the burden on patent holders to overcome the presumptions. For instance, a compulsory licensing statute might provide that the absence of supply on the local market of a patented product at an affordable price justifies the granting of a compulsory license thus placing the burden on the patent holder to demonstrate that there are adequate supplies of products on the local market at affordable prices.¹¹⁰

Section 40 (1)¹¹¹ of the Zambian Patents Act has a provision to authorize any government department or any third person or party to exploit a patented invention with a written permission from the Minister, to make, use or exercise any invention disclosed in any specification lodged at the patent Office in matters that involve use of the patented invention for servicing of the State.

This provision is an extension of Article 5A of the Paris Convention but does not place the patent holder to be compensated adequately for his creative work after the acquisition of government use or authorization based on public interest or cases of extreme emergency as provided for under Article 31 of the TRIPS Agreement. Unfortunately, this provision is vague because it just mentions that the Minister gives a written permission for issuance of compulsory license, but it is not clear which Minister is charged with this responsibility. In Malaysia for instance, it is clear because the Minister of Health has been given this responsibility to authorize the grant of compulsory licenses.¹¹²

¹⁰⁹ Supra note 108.

¹¹⁰ Supra note 109.

¹¹¹ “Notwithstanding anything in this Act, any Government department or any person authorized in writing by the Minister may make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the state in accordance with the provision of this section.”

¹¹² Malaysia’s Experience in Increasing Access to Antiretroviral drugs: Exercising the Government Use’ Option by Chee Yoke Ling, Third world network2006.

Prior Negotiations

Section 41(2)¹¹³ allows applicability of compulsory license on the ground of special provisions as to state use during emergency or any purpose as mentioned under this section. Concerning prior negotiations under Article 31(b) of the TRIPS, and accordingly, such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have been unsuccessful within a reasonable period of time.

This requirement may be waived by a WTO member in cases involving a national emergency or other circumstances of extreme urgency or cases of public non-commercial use. This provision has not been extended to grounds applicable under the patent law and has shown a lot of inadequacy in relation with the current Zambian patent law as provided for under Article 31 and it promptly needs these sections on the applicability of CL to be replaced completely by incorporating the rules contained in Article 31 of the TRIPS Agreement.

In addition, matters concerning national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, should be notified as soon as reasonably practicable.¹¹⁴ In situations of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable ground to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly (Article 31(b)).

Article 31, in general, requires that a party seeking a compulsory license must first undertake negotiations with the patent holder for a voluntary license on sensible commercial terms and conditions and that, such efforts have not been successful within a reasonable period of time. This condition is inherently flexible since the concept of reasonable terms and period of time will depend on context.¹¹⁵ As already stated our patent law is inadequately represented on these matters bordering on public interest.

¹¹³“During any period of emergency the powers exercisable in relation to an invention by a government department or a person authorized by the Minister under section forty, shall include power to make, use exercise and vend the invention for any purpose which appears to the Minister necessary or expedient.”

¹¹⁴ Supra note 110.

¹¹⁵ Supra note 114.

Royalties

Patent licenses usually involve the payment of royalties from licensees to make payment to the patent holders. A royalty is a usage fee the amount of which may be calculated on different bases. For instance, a royalty may be payable based on the licensee's net income from sales of the product or it may be a fixed amount payable at periodic intervals. The traditional application of royalties for licensing of patented products or processes will vary from industry to industry, and within each given industry, depending on the value of a particular technology involved.¹¹⁶ Finally the level of royalty will also generally depend on either the proven or anticipated success of the product in the market place. This aspect of royalties should be reflected in our patent legislation during the review of IP legislations and the royalty rate be clearly outlined.

Reasonable period of time

Concerning reasonable period of time, a patent holder that does not wish to license its technology, but also does not wish to see a compulsory license granted may as well attempt to prolong negotiations using a variety of tactics. Such tactics may include engaging in grave negotiations over unnecessarily detailed terms and conditions that do not appear to reach a conclusion. Negotiations that are seeking licenses on reasonable commercial terms are perfectly justified in setting an outer limit for successfully concluding licenses, and refusing to negotiate beyond that point.¹¹⁷ This type of behaviour should be curtailed by introducing a new provision in the patent law provision that discourages this negative notion of negotiating for the sake of prolonging the negotiations to avoid the issuance of CL on behalf of the patent holder.

Waiver of prior negotiations

Issues concerning waiver of prior negotiations do not require prior negotiations under certain conditions with the patent holder. These conditions include national emergency; other circumstances of extreme urgency; or public non-commercial use (Article 31(b)). In matters of national public interest this provision will apply for the government to acquire CL without necessarily engaging in prior negotiations but does not exclude the government to adequately compensate or pay the patent holder in remunerations.

¹¹⁶ Supra note 115.

¹¹⁷ Supra note 116.

Notification

Further, in cases of national emergency or extreme urgency, the government is obliged to notify the patent holder of the grant of compulsory license as soon as reasonably practicable. Reasonable practicability will entirely depend on the circumstances of each individual case and need not precede the grant of a license (Article 31(b)).¹¹⁸ This provision should be included in our patent law to curb abuse on the part of the authority granting compulsory licensing.

Scope and duration

Article 31© provides that the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology it shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive. In this respect, the purpose of the authorization is applicable or intended to determine the scope of the license. This means that compulsory licenses do not actually provide the licensee with an unencumbered field of application.¹¹⁹

A compulsory license granted to an aircraft parts supplier regarding military aircraft components might not, for example, authorize the supplier to sell the same patented parts for use in civilian aircraft. The duration of the license should also be limited in terms of purpose, but this does not bar a compulsory licensee from obtaining a grant that is of sufficiently long duration to justify its investment in production from a commercial point of view. A license grant should in that manner be long enough to provide adequate incentives for production, otherwise the rules contained in Article 31© will be frustrated.¹²⁰ This provision is sufficient to prevent or deter authorities in charge of issuance of compulsory licenses not to continue using the authorization when the purpose for which it was authorized expires.

¹¹⁸ Supra note 117.

¹¹⁹ Supra note 118.

¹²⁰ Supra note 119.

Non-exclusivity

In normal circumstances, when a patent holder grants a license for a particular territory, he may agree to refrain from conferring marketing rights over the product covered by the licensee in that territory to other parties, for example, if it grants an exclusive license.

Adequate compensation

In matters involving adequate compensation (Article 31(h)), it is envisaged that the right holder shall be paid adequate remuneration in the circumstances of each case, taking into consideration the economic value of the authorization. The requirement of payment of adequate compensation was not included in the Paris Convention regulations on compulsory license on which our national patent law on compulsory license stems from. This requirement is in relation with the government use as well as private party use of the patented invention.

The TRIPS Agreement rules on compensation applies substantial flexibility as a consequence of the use of the terms in circumstances of each individual case (Article 31(h), indicating that factors relating to the underlying reasons for the grant of license may be taken into account in establishing the level of compensation. Granting authorities are instructed to consider the economic value of authorization, but are not required to base the royalty payable to the patent holder on that value.¹²¹ The term adequate signifies to indicate something that is sufficient or meets the revocation of a patent. Compulsory licenses in nature are simply non-exclusive, and the grant of a compulsory license to a third party (including the government) should not preclude the patent holder from exploiting the national market or exporting the patented product (Article 31(f)).

Review by judicial or Distinct Higher Authority

Article 31 (i) of the TRIPS Agreement provides for legal validity of any decision relating to the authorization of such use and shall be subject to judicial review or other independent review by a distinct higher authority in that WTO member; and Article 31(j) provides that any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher

¹²¹ Supra note 120.

authority in that member state. The interpretation is that the requirements for judicial review are set out in general terms to provide substantial discretion to countries implementing the requirements on the grounds that legal institutions and procedures vary in different nations. The review of grant and remuneration decisions may either be undertaken by a court or may be undertaken as an independent review by a distinct higher authority.¹²²

Article 31 does not give discourse on the nature of the authority that may initially grant a CL or determine the level of compensation. This decision is left in the hands of an executive administrator. Article 31(i) and (j) also provides for independent review by a distinct higher authority. In other words, the word independent in this context means that the reviewing person or body should not be controlled or be subjected to control by a person or body that initially grants the license or determines the payment.

Independence means that the reviewer should be able to modify or reverse the initial decision without undue threat of the political or economic reprisal.¹²³ The term, higher authority, simply refers to a more senior level government person or body than the granting person or body whereas the term distinct could mean a person or body within the same government agency that initially grants licenses, provided there is adequate separation of personnel and functions among the two persons or bodies.¹²⁴

Remedies for anticompetitive practices

A WTO member under Article 31(k) is not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur.¹²⁵ OAs alluded to earlier on, when a compulsory license is applicable on the basis of a judicial or administrative finding of anti-competitive practices, the

¹²² Supra note 121; Resource Book on TRIPS and Development p. 478

¹²³ Supra note 122.

¹²⁴ Supra note 123.

¹²⁵ Supra note 124.

applicable requirements, namely, of prior negotiations, notice and limiting the license to predominant supply of the domestic market do not apply in this case. In addition, the finding may be reflected in the manner of payment to the patent holder. Finally, it is likely that the anti-competitive conditions that led to the initial granting of CL will recur. In this sense or circumstance the competent authorities may refuse to terminate the license.¹²⁶

Dependent patents

Under Article 31(l) where such use is applicable to permit the exploitation of a patent (“the second patent”) which cannot be exploited without infringing another patent (“the first patent”) the following conditions are applicable: (i) 31(j) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent; (ii) the owner of the first patent shall be entitled to a cross license on reasonable terms to use the invention claimed in the second patent; (iii) and the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent. Article 31(l) takes into consideration in which the CL is applicable to allow the exploitation of a second patented invention that depends upon rights to use an already existing patented invention.¹²⁷

Having both looked at the grounds for issuance of CL and conditions to be adhered to under Article 31, I will attempt to establish arguments for or against non-voluntary licenses popularly referred to as compulsory license. Patents disclose per nature information that is useful to one skilled in the art to work out the invention. It is on this premise that patents are considered to be beneficial to the industry as publications of patents contain the latest state-of-the-art that becomes a cushion to inspire future generations by rewarding the inventors for their innovative and creative work besides working out the invention locally. Moreover, after the expiration of a patent term, it automatically falls into the public domain and can be exploited freely by anyone without

¹²⁶ Supra note 125.

¹²⁷ Supra note 126.

obtaining consent from the patent holder.¹²⁸The principal aim of ensuring working the patented invention locally is to provide a means of transfer of technology and this is one way of effective and efficient accomplishment of the transfer of technology.¹²⁹

The working of a patented invention in a particular country provides two arguments. Firstly, compulsory working of inventions may work against the goal of transfer of technology and secondly, it may not be economically viable to do so. By nature, compulsory licensing is less effective than voluntary licensing in so far as encouraging transfer of technology is understood, and to a large extent may even be counter-productive to that same goal. In other words, voluntary licensing clearly offers a means whereby the transfer of technology can be conveyed. CL should not be seen as playing such role but be seen as means to correct abuses which may be committed in the exercising of the patent rights (anti-competitive practices).¹³⁰

The transfer of technology would be best applicable in an atmosphere of co-operation between the transferee and transferor (between the patent holder and the licensee) of that given technology. The cooperation generally leads to the disclosure of technical know how which is not included in the patent specification but comes about through the working of the invention which is a crucial process in making a commercial product viable. In compulsory licensing, the cooperative atmosphere and the technical know how is absent. Thus the grant of CL under a patent only results in the bare right of working the patented invention which in true sense is an insufficient vehicle for the full transfer of technology.¹³¹

Compulsory license coupled with inadequate compensation to patent holders also acts a conduit against innovation and creativity because inventors and would be creators of works will be discouraged to venture into this important field of art where there is inadequate or no compensation.¹³² It is also not viable economically for the patent holder to work his invention in every jurisdiction he had sought protection because in one

¹²⁸ WIPO Intellectual Property Handbook; Policy, Law and Use WIPO publication No. 489(E) 2004 p. 35.

¹²⁹ Supra note 125.

¹³⁰ Supra note 126.

¹³¹ Supra note 127.

¹³² Own.

country production of the same products would be cheaper due to the availability of raw materials whereas it would be a huge production expense in another environment due to non availability of raw materials.¹³³ But this position does not exclude the patent holder from working the patent locally.

In addition, a number of people interviewed were of a general view that mandatory acquirement of a patented invention may lead to stifling of the advancement of science and technology which is the bedrock of wealth creation. A counterview was expressed that, while it may deter progress in research and development, but this should be weighed against the broader public interest, for instance, the mitigation and treatment of HIV and AIDS.

Summary: Sections 37, 40 and 42 provide for compulsory licensing under the *Zambian patent law*. Under the current patent law on compulsory license, adequate remuneration is not provided for because these sections were drafted or drawn on the basis of the Paris Convention of 1967 for the protection of industrial property which has no provision for adequate remuneration to the patent holder upon issuance of a license. Under Article 31 of TRIPS Agreement, the grounds on which compulsory license is applicable have been stretched beyond provisions contained in the Paris Convention (Article 5A) and in addition, there are conditions obtaining under this Article that require a WTO member to follow whenever the issuance of compulsory license is applicable.

The grounds under Article 31 provided for compulsory license are refusal to deal; emergency and extreme emergency; anti-competitive practices; non-commercial use; and dependent patents. To these grounds there are conditions to be followed, namely, individual merits; prior negotiations (commercial terms and conditions, reasonable period of time, waiver of prior negotiations, notifications, and competition law remedy); scope and duration; and conditions; non-exclusivity; non-assignable; termination; adequate remuneration; review by judicial or distinct higher authority; remedies for anticompetitive practices; and depend patents.

These conditions are provided under Article 31(a) to (l) of the TRIPS Agreement. Unfortunately, our patent law has not been domesticated to incorporate these conditions. It is only when these conditions are provided for under the *Zambian patent law*, patent holders will not be adequately remunerated in matters relating to issuance of compulsory licenses. This has adverse effect on the promotion of innovative and creative activities to increase the pool of technological knowledge.¹³⁴

¹³³ Own.

¹³⁴ Own.

Chapter 4

Comparisons between Local and International Applicability of Compulsory License
Sections 37, 40 and 42 were drafted on the basis of the Paris Convention for the protection of industrial property. To be precise, they are a product of Article 5A (2) and (4) of the Paris Union. This article provides for CL to prevent the abuses which might result from the exclusive rights bestowed upon the patent holder based on failure to work the patented invention, but it is only applicable pursuant to a request filed after three or four years of failure to work or insufficient working of the patented invention. Compulsory licensing may not be granted in the circumstance where the patentee gives legitimate reasons for his inaction.

In so far as the TRIPS Agreement is concerned, it has expanded the grounds for granting of CL beyond the provisions contained in the Paris Convention. Section 31 of the TRIPS Agreement, for instance, it refers to five grounds upon which CL is applicable, namely, refusal to deal, emergency and extreme urgency, anti-competitive practices, non-commercial practices and dependent patents. Besides these grounds, Article 31 also provides for conditions to be adhered to when issuance of CL is applicable. The Zambian patent law is inappropriately and incompatible with the provisions of the TRIPS Agreement and thus, needs to be aligned to the provisions of Article 31 of the TRIPS Agreement on compulsory license.

Parallel imports

The current Zambian patent law does not provide for parallel imports. Parallel imports are allowed under Article 6 of the TRIPS Agreement and member states are free to incorporate this principle of international exhaustion of rights in their national patent legislations. The Zambian patent legislation does not have this provision that has become a common feature in many national patent laws besides the applicability of compulsory

licensing. This provision is not subjected to the WTO dispute settlement system for disputes relating to exhaustion of rights. Parallel imports serve a good purpose in the health sector because medicines can be sourced or imported from cheaper sources and this can provide access to many HIV and AIDS patients who can not afford expensive patented drugs. It is very clear and necessary for Zambia to incorporate parallel imports in its domestic patent law because they are permitted within the framework of the TRIPS Agreement. It will be necessary to amend our national patent legislation to incorporate article 31(f) of the TRIPS that allows the applicability of compulsory licensing of production of drugs predominantly for domestic market as provided for under paragraph 6 of the Doha Declaration.

The Zambian government using this provision granted a compulsory License No. CL 01/2004 to Parco Limited, a company incorporated in Zambia using sections 40 and 41 of the Patents Act and Statutory Instrument No. 83 of 2004 to manufacture antiretroviral under the names of Norvavir 30 and Norvarvir 40 patented drugs. In my view there was no need to grant a compulsory license to Parco Limited because these patented drugs are not protected in Zambia. It is settled knowledge that patent protection is territorial and it is improper rather inaccurate to grant a compulsory license where the patents have not sought protection in that jurisdiction.

The issuance of compulsory license was inappropriate because the patented drugs are not protected in Zambia. Nevertheless, the government would have used Section 38(1) of the Zambian patent law to use the patented drugs because this section prohibits protection of product patents, namely, a substance capable of being used as food or medicine; or in the production of food or medicine; or a process for producing a substance as aforesaid; and any invention capable of being used as or part of a surgical or curative device (product patents).

United States

The United States has attached much importance to intellectual property and to this effect the protection of intellectual property is entrenched in Article 1, Section 8 of the

Constitution. Section 8 provides that¹³⁵ **“The congress shall have power....to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”** It must be understood that in sense science refers to authors and writings, and whereas useful arts refer to inventions. The exclusive right concept is derived from the British or European concept that the ruling monarch or government had the power to grant to an individual an exclusive right (patent) upon petition of the individual for the services to be rendered within a defined area by that individual to the exclusion of all others who might be capable of rendering that service (**Patent Examiner Initial Training (PEIT) Manual, p. 1-1, Rev 10/5/2006**).

Service is used in the broad sense of providing goods, services and technological advancements or advantages whereas the patent grant is reserved strictly for inventors, technological advancements in the arts and sciences. We can learn from the Americans and try to insert the IP protection clause in our Constitution. Apparently our Constitution only provides for the protection against deprivation of property under Article 16 but this only refers to tangible property excluding intangible property (intellectual property). It is time we lobbied the government to include the advancement of science in the highest law of the land, the Constitution to show our commitment to the importance of intangible property and its economic value.

Although there is no provision for compulsory licensing provided for under the US, compulsory licenses are applicable under special legislation¹³⁶ and the anti-trust laws. The US government has created these legislations when the country’s public interest was at stake. The Atomic Energy Act and Clean Air Act set out particular circumstances where a private party could demand a license from a US patent holder. Anti-trust authorities in the US have recently ordered compulsory licenses in the Ciba-Geigy and Sandoz merger (1997) in relation to cytokine products.

¹³⁵ USPTO Global Intellectual Property Academy, Introduction to Patent Examination, PEIT Manual, REV 5/10/2006.

¹³⁶ US Clean Air Act 1988 (42 USC Section 7608 and Atomic Energy Act (42USC Section 2183)

In the Dow acquisition, the Federal Trade Commission required Dow to license to a potential entrant intangible, dicyclomine assets and issues concerning public interest as provided under the TRIPS Agreement. And in comparison, including all formulations, patents, trade secrets, technology, technical know-how, specifications, designs, drawings, processes, quality control data, research materials, technical information systems, software, the Drug Master File, and all information relating to the US Food and Drug Administration Approvals that are not part of the acquired company's physical facilities or other tangible assets.¹³⁷ Though the USA has not provided for CL in their patent laws there are other statutes that have been enacted to take care of licensing. There is need in this respect to align our patent law to the TRIPS Agreement in order to take care of public health concerns (Article 31).

United Kingdom

The British Patents Act 1977 Chapter 37 (as amended by the Copyright, Designs and Patent Act 1988), Section 55(1) provides that "Notwithstanding anything in this Act, any government department may, for the services of the Crown and in accordance with this section, do any of the following acts in the United kingdom in relation to a patented invention without the consent of the proprietor." This may include;

- (a) where the invention is a product, may-
 - (i) make, use import or keep the product, or sell or offer to sell it where to do so would be incidental or ancillary to making, using, importing or keeping it; or
 - (ii) in any event, sell or offer to sell it for foreign defense purposes or for the production or supply of specified drugs and medicines, or dispose or offer to dispose of it (otherwise than by selling it for any purpose whatever;
- (b) where the invention is a process, may use it or do in relation to any product obtained directly by means of the process anything mentioned in paragraph (a) above;
- © without prejudice to the foregoing, where the invention or any product obtained directly by means of the invention is a specified field drug or medicine, may sell or offer to sell the drug or medicine;..."¹³⁸

¹³⁷ Integrating Public Health Concerns into Patent Legislation in Developing Countries, by Carlos Correa, University of Buenos Aires, Argentina, South Centre 2000.

¹³⁸ Manual on Good Practices in Public-Health-Sensitive Policy measures and Patent Laws, Third World Network, 2003.

From the British point of view, it is very clear that provisions of Article 31 of the TRIPS Agreement has taken care of the aspect of state practice as far as drugs are concerned for the sake of public health interest. Including Article 31 in our national patent legislation will take care of public health interests that are very close to the heart of government.

Austria

The Patent Law (Federal of 1970, as amended by the Law of May 23, 1984, amending the Patent Law Introducing Patent Treaties) provides for CL under Section 29 and the provision reads as follows, “ if the interest of armed forces or public welfare or any other compelling federal interest requires an invention in respect of which a patent has been applied for or granted to be used in whole or in part by the federal authorities or to be made accessible for general use, the federal authorities may expropriate either such patent or the right to the use of the invention in whole or in part pursuant to a decision of the competent Landeshauptmann and on payment of fair compensation.” This provision is similar to the provision of the Zambian Patents Act, except that the Austrian patent law provides for adequate compensation after the expropriation of the patented invention.

India

The latest amendments to the Patents Act of 1970 are found in the Patents (Amendment) Act 2005, which received Presidential assent on 4 April 2005. The objective of 2005 Act was intended to bring India in compliance with the TRIPS Agreement after the end of transitional period in 2005 (for those countries without product patent protection) and thus, the majority of the amendments are deemed to have come into force on 1 January, 2005. Before India amended its patent law it was in the same position as Zambia.

The Zambian patent law does not offer protection for product patents but it is advisable for Zambia to learn from India’s experience and revise its national patent law on product patents before 2016 which is a deadline for Least Developed Countries to align their laws according to the TRIPS Agreement on the protection of product patents.¹³⁹

¹³⁹ The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines, South Centre, April, 2006.

Malaysia

Malaysia in 2003 became the first country to issue a compulsory license following the adoption of the Doha Declaration on the TRIPS Agreement and Public-Health by the 2001 Ministerial Conference of the World Trade Organization. The Government Use or public non-commercial use option can be described as a special type of CL, whereby there is no need to have prior unsuccessful negotiations with the patent holder before obtaining authorization to import or manufacture the subject matter of a patent. Thus, for ensuring smooth access to medicines, a government can import or third party (contractor) authorized by the government can import or manufacture a generic version of a patented drug for public non-commercial use.

This is permitted in respect of those drugs or medicines to be used in public hospitals and clinics.¹⁴⁰The Malaysian Patents Act 1983, Sections 48 to 50 provides for compulsory licenses. Sections 37 and 58A provide for parallel import based on the international exhaustion of rights principle. Section 84 provides for the Rights of Government, the term commonly used for Government Use, in the patent law sphere. Specifically, Section 84 (1) provides for the Rights of Government and the provisions are as follows:

Notwithstanding anything contained in this Act –

- (a) where there is national emergency or where the public interest, in particular; national security, nutrition, health or the development of other vital sectors of economy as determined by the government, so requires; or
- (b) where a judicial or relevant authority has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive, the Minister may decide that, even without the agreement of the owner of the patent, a government agency or third person designated by the Minister may exploit a patented invention. The patent owner shall be notified of the Minister's decision as soon as reasonably practicable.

¹⁴⁰ Malaysia's Experience in Increasing Access to Antiretroviral Drugs: Exercising the Government Use Option, by Chee Yoke Ling, Third World Network 2006.

Section 84 (3) provides for the payment to the patent holder adequate remuneration.¹⁴¹ We can import and incorporate the elaborative experience of Malaysia on exercising government use under the TRIPS Agreement into our patent law provisions such as parallel import, exhaustion of rights and Rights of Government use in a concise manner as contained in Section 84 (1) of the Malaysian Patents Act.

Sub-Saharan Experience

Zimbabwe

Section 34 of the Patents Act empowers the Minister to authorize the use of patented inventions by any government department or third party, for the service of the State. Section 35 clarifies that an authorization by the Minister under Section 34 during a period of emergency “shall include power to make, use, exercise and vend the invention for any purpose which appears to the Minister necessary or expedient.

Section 34 (2) further provides that the uses of inventions are to be on terms and conditions which the Minister and the patent holder may agree upon. Looking at the provisions contained in the above mentioned sections, it is clear that the Zimbabwean patent law has embraced Article 31 of the TRIPS Agreement and the Zimbabwean experience can also provide as a means for revising our patent law.

Kenya

With regard to parallel import, the Kenyan Intellectual Property Act 2001 has adopted the international exhaustion of rights. Section 58 (2) of the Intellectual Property Act on limitations of rights now provides that; “The rights under the patent shall not extend to acts in respect of Articles which have been put on the market in Kenya or in any other country or imported into Kenya.”

In my view, the Zambian patent law should adopt the route that Kenya has embraced or taken to provide for the principle of international exhaustion of rights in their patent legislation. I am of the view that the objective for Kenya to include this principle in their

¹⁴¹ Supra Note 140.

patent legislation was premised on the fact that patent innovation and creative activities on drugs are concentrated more in the developed world (North) rather than the developing world (South). The South is just being used as a market outlet for the North.

Summary: From the comparisons provided above it is imperative that the Zambian patent law should be revised to expand the provision for government use or rights of government (non-commercial use), parallel import and compulsory licenses based on Article 31 of the TRIPS Agreement and Paragraph of the Doha Declarations.

The experience of Malaysia demonstrates that when health officials and Ministers are sensitized about the rights and flexibilities under the TRIPS Agreement and national patent laws are designed appropriately, access to affordable drugs can become a reality. This can be achieved despite the mounting pressures from the patent holders and even misgivings from other government agencies. The challenge is to continue to exercise the rights and flexibilities provided under the TRIPS Agreement to ensure access to treatment for HIV and AIDS, malaria and tuberculosis for all, as well as to take these rights to treat other diseases of importance to developing countries.¹⁴²

¹⁴² Supra Note 141.

Chapter 5

Recommendations and Conclusion

This chapter will focus on recommendations and the conclusion. Some of the recommendations are based on the comments by the Secretariat of WIPO and others are my own. The recommendations are as follows:

Article 16 of the Constitution

The patent law in Zambia is very old and has not been revised for many years to align it with the emerging changes in the field science and technology at international level and locally. First of all, we must lobby for insertion of the promotion of science and technology to be included in our Constitution to show our commitment and the importance attached to intellectual property. This insertion will be the initial means or basis for promoting the progress of science and useful arts.

Unfortunately the Zambian Constitution only provides for the protection from deprivation of physical property under Article 16, excluding the most important rights (intangible rights) commonly referred to as intellectual property. There is need to include or insert the protection of IP in our Constitution as is the case in the United States. The promotion of IP in the US is contained in Article 1, section 8 and it reads “The congress shall have power.....to promote the progress of science and useful arts, by securing for limited times to authors and inventors the right to their respective writings and discoveries.”

The Patents Act

Section 28(4): The rights conferred by a patent under the current national patent legislation are not clear as contained in Article 28 of the TRIPS Agreement. The Patents Act contains no provisions on exceptions to rights granted, such as under Article 30 of the TRIPS Agreement (for instance, the use of patented invention for experimental purposes; the use for the purpose of obtaining marketing approval of goods under government control). In addition, the Act excludes the exhaustion of rights, which Zambia under Article 6 of the TRIPS Agreement and paragraph 6 of the Doha Declaration, is free to establish either national exhaustion, or regional exhaustion or

international exhaustion. The Act needs to include these additional provisions on these issues (WIPO).

Section 29

The term of the patent protection should be increased from 16 to 20 years from the date of lodging the complete specification at the Patent Office.

Section 37

The entire section should be overhauled so as to reflect the spirit of Article 31 of the TRIPS Agreement and the WTO General Council Decision of August 30, on the implementation of paragraph 6 of the Doha Declaration. The reason is that the insertion of these two provisions will expand the list of grounds of minimum and mandatory conditions that compulsory license must respect in order to protect the rights of patent holders (WIPO).

Section 37(3)

The provision shall not be applicable in cases of extreme urgency or where the compulsory license is granted to remedy a practice deemed anti-practice after judicial or administration proceedings (Article 31(k)) of the TRIPS Agreement.

Section 37(6)(a)

This provision is not in line with Article 27.1 of the TRIPS Agreement and Sections III.4 and XI of the General Agreement on Tariffs and Trade (GATT) 1947. Zambia as a member of WTO is entitled to require the patent holder to exploit the invention and make the products readily available to the public in sufficient quantities, quality and at reasonable price.

This can also be obtained through importation (Article 6, exhaustion of rights, commonly known as parallel import) of the TRIPS Agreement. In order to provide evidence of compliance of this obligation to exploit the invention (meaning that the patented products or products manufactured with the patented process must be made available to the Zambian public) the patent owner is entitled to do so by means of local manufacturing or through importation (WIPO).

Section 37(6) (d)

This provision should be rewritten because it is the natural right for the patent holder to decline issuing a license to his rivals or competitors. Patent rights are essentially an exclusive right and this provides a premise for the patent holder the right to say “no” to granting licenses to competitors. The patent holder is only not allowed to decline issuance of a license where there is public interest involved or where the refusal is intrinsically anti-competitive (when, for instance, if it emanates from collusion).

Section 37(7)

Both under the Paris Convention of 1967 for the protection of industrial property (Article 5A) and the TRIPS Agreement (Article 31), compulsory licenses may be applicable for importing (WIPO).

Section 37(8)

The phrase “patent monopoly” should be substituted by “exclusive patent right.” Property rights and monopoly is not one and the same thing, even if property rights are per definition exclusive. To be a monopolist it calls for one to be a sole vendor in the market where consumers will have no access to alternative products. In case of patented products there is room enough to compete with other patented products, with non-patented products that are already available on the market and with the prospect of new inventions. In addition, all compulsory licenses applicable under Article 31(d) the TRIPS Agreement must be non-exclusive (WIPO).

Section 37(9)(a)

This provision is repugnant to the definition of the phrase “adequate remuneration under Article 31(h) of the TRIPS Agreement which reads that the right holder shall be paid adequate remuneration in the circumstance or merit of each case, taking into consideration the economic value of the authorization. This section lacks the provision under the TRIPS Agreement.

Section 37(11)

This provision should be changed to exclude exclusive compulsory licenses because they are permitted under Article 31(d) of the TRIPS Agreement.

Section 37(15)

This provision should be revised. Articles made by patented processes are not unique if there are other alternative processes for making it. Such articles, therefore, should not be considered as they were patented. Therefore, the phrase “and while an alternative process is not developed” should be added to this provision.

Section 40(2)

The state or any of its agencies have no immunity from liability in cases of infringement. Under Articles 31(h) and 42.2 of the TRIPS Agreement, adequate remuneration must be paid to the patent holder in all cases of the use of the invention. This section should provide for no injunction to be instituted against the state or its authorized agents. Here stops the favored treatment of the State vis-à-vis private citizens. This provision should be added to this section.

Section 41

The cases under section 41 should be treated as “security exceptions to make this provision compatible with Article 73 of the TRIPS Agreement. The present language in this provision tends to refer to the grounds for compulsory licenses which are subject to special regime covered under Article 31 of the TRIPS Agreement. This provision needs to be changed to make it TRIPS compliant.

Section 53

The compulsory licensee should also be permitted to sue others on infringement grounds. One, in normal circumstances, should not expect the patent owner to cooperate with the licensee. In addition, the non-exclusive licensee should also be entitled to protect the patented invention against the infringement if the patent holder, requested him to take measures, fails to do so within two to three months. This section does not provide for reversal of the Burden of Proof as provided for under Article 34 of the TRIPS Agreement.

Review by Judicial or Distinct Higher Authority

There is need to incorporate this provision contained under Article 31 into our patent law. The Article provides for the legal validity of any decision relating to the authorization of

such use should be subject to judicial review or other independent review by a distinct higher authority in that member state (Article 31(i)) and second, that any decision relating to the remuneration provided in respect of such use should be subject to judicial review or independent review by a distinct higher authority in that member country (Article 31(j)). This provision, in my view, was included in the TRIPS Agreement to detect and deter arbitrary compensation by authority responsible for issuances of compulsory licenses and also as a matter of permitting fair or adequate compensation to the patent holder on one hand and on the other hand to encourage innovative activities in the areas of science and technology for the well being of mankind at large.

Parallel imports

Parallel imports are allowed under Article 6 of the TRIPS Agreement that provides for the concept of exhaustion of rights and this concept is not a matter of dispute settlement. Thus, TRIPS leaves this option to member states to decide how this principle may be applicable within the national legal framework or territory.

The member state may either go by way of national exhaustion of patent rights or by way of regional exhaustion of patent rights or by way of international exhaustion of patent rights. Adoption of this principle in the Zambian patent law would permit the importation of a patented product into the country without the consent of the patent holder where or when the said patented product has been placed on the market of another country.¹⁴³

Royalty guidelines

In order to determine compensation and royalties to be applicable to the patent holder the Minister should appoint a compensation committee to determine compensation for patent holders in cases where third parties are authorized to use the patented products or inventions without the consent of the patent holders.

¹⁴³ Manual on Goods Practices in Public-Health-Sensitive Policy Measures and Patent Laws, Third World Network, 2003 p.40.

The Minister, in addition, should also appoint an independent authority to be known as compensation appeals committee and this committee's purpose shall be reviewing the determination of compensation by the compensation committee or appeal by any interested party on the ground that the compensation committee has failed to comply with the terms and criteria for determining compensation as outlined hereunder.¹⁴⁴

Where the invention involves a pharmaceutical or medical device that is relevant to public health and developed by using private funds, the royalty percentage proposed should be 4% of the selling price being charged by the third party authorized by the government to exploit the patent.¹⁴⁵

Where it is certainly established that a particular product has high therapeutic value or where there is proof that the cost of the development of pharmaceutical product or other invention is particularly costly when compared to other products, an additional of one percent (1%) to two percent (2%) should be awarded as a royalty.¹⁴⁶ Where it is clearly established that the research and Development was materially supported by public or donor funds, the royalty to accrue should be one percent (1%) to percent (2%) less.¹⁴⁷

In cases where the patent or patents cover only a minor component of the invention, a pro rata share of the royalty should be paid, based upon the relative importance of the invention to the development of the product and in cases where there are several patents comprising one product, the compensation committee should set a product royalty based upon the criteria in the preceding paragraphs above.

And the person who sells the product shall pay the royalty into an escrow fund until such time that the patent owners can resolve disputes over the division of the royalty payment to the different patent holders. In the absence of an agreement between the parties, the

¹⁴⁴ Supra note 143.

¹⁴⁵ Supra note 144.

¹⁴⁶ Supra note 145.

¹⁴⁷ Supra note 146.

compensation committee should determine the appropriate division, or order the patent holders to enter into binding arbitration to determine allocations.¹⁴⁸

Review and revision of compensation guidelines

The Minister(s) responsible for intellectual property should from time to time review the guidelines for the determination of compensation on a periodic basis, and should revise the guidelines, where new circumstances or information call for revision where it deems necessary and appropriate.

TRIPS-Compliance/ Domestication

In order to be TRIPS compliant we must internationalize or domesticate the TRIPS rules and regulations in our municipal law on patents to enjoy the rights and flexibilities under the TRIPS Agreement. Zambia follows the dualism theory as far as treaties are concerned. The dualist stresses that the rules of the international systems of international law and municipal law are distinct and cannot be said to have effect on, or overrule, the other.¹⁴⁹

The dualist theory in short, regards international law as separate systems so that the municipal courts can only apply international law either when it has been incorporated into municipal law or when the courts incorporate international law on their own.¹⁵⁰ The dualist theory requires an enabling act to be passed by parliament for it to be applicable or effective domestically.

CONCLUSION

A compulsory license is a license granted by an administrative or judicial body to a third party to exploit an invention without the authority or the consent or authorization of the patent holder. At the local plane compulsory licensing is applicable under sections 37, 40 and 41 of the Patents Act.

¹⁴⁸ Supra note 147.

¹⁴⁹ Introduction to Human Rights and International Humanitarian Law, by Carlson Anyangwe, The University of Zambia Press 2004.

¹⁵⁰ Zambia Sugar Company Plc v Fellow Nanzaluka Appeal No. 82/2001 Unreported; Unity Dow v Attorney General for Botswana.

At the international plane compulsory license is applicable under the Paris Convention for the protection of industrial property (Article 5A (2) and the TRIPS Agreement (Article 31). Zambia is a member since inception and is therefore entitled to grant compulsory licenses under Article 31 of the TRIPS Agreement so long the issuances of such licenses are within the confines or the framework of the provisions of TRIPS Agreement.

In order to be TRIPS compliant there is need to internalize or domesticate the TRIPS Agreement into our municipal patent legislation to make TRIPS have direct effect and enforceable by the municipal courts. The Zambian patent legislation on compulsory license should be completely overhauled and replace it with Article 31 of the TRIPS Agreement. Issues such as expanded grounds and conditions on compulsory licenses (Article 31 of the TRIPS Agreement), and parallel imports, exhaustion of patent rights and paragraph 6 of the Doha Declaration should be included at the time of the revision of the patent law legislation.

Lastly, the elaborative Malaysian experience as referred to above should be our initial basis for revising our patent law legislation. The Malaysian experience illustrates that when health officials and ministers are informed of the rights and flexibilities under the TRIPS Agreement, and national patent laws are designed appropriately, access to affordable drugs can become a reality. This is despite the pressures being exerted from the patent holders and even misgivings from other government agencies. The challenge is to continue to exercise these rights and flexibilities to ensure and attain access to treatment for HIV and AIDS, malaria, tuberculosis and other related diseases of importance to developing countries.¹⁵¹

¹⁵¹ **Malaysia's** Experience in Increasing Access to Antiretroviral Drugs: Exercising the 'Government Use' Option by Chee Yoke Ling, Third World Network 2006.

GLOSSARY

Best Mode: The best way known by the inventor at the time of filing a patent application for carrying out or practicing the invention.

Claim: One or more statements in a patent or application that precisely define the specific features of the invention for which patent protection is granted or sought.

Compulsory license: The authorization given by a judicial or administrative authority to third party for use of a patented invention, without the consent of the patentee, on various grounds of general interest (absence of working, public health, anti-competitive practices, emergency and national defense).

Disclosure: A description or revelation of an invention made by the inventor. It also applies to acts of divulgation, including those made third parties, that may destroy the novelty of an invention.

Essential drugs: Drugs selected for their efficacy and safety to meet the priority health needs in a given country or region. The essential drugs concept has been the basis of WHO's drug in the WHO list of essential drugs also includes price considerations.

Exhaustion of intellectual property rights: Doctrine according to which the patent holder "exhausts" his/her rights after the first legitimate sale of the patented product in a country, region or on the international market. It provides a legal justification for the admission of parallel imports.

Generic drug: A pharmaceutical product which is not protected by a patent in force, and which is commercialized under a non-proprietary name or brand name.

Infringement: The unauthorized making, using, or selling of a product or process that uses an invention protected by a patent. The determination of an infringement allows the right-holder to recover civil remedies against the infringer. Some infringements are also criminal offences.

Intellectual property: A category of public law that generally includes copyrights, patents, trademarks, geographical indications, industrial designs, utility models, plant breeder's rights, integrated circuits and trade secrets. A sui generis regime for data bases has also been established in some countries.

License (voluntary): Authorization given by a right-holder (licensor) to someone (licensee) to exercise acts that only the licensor can legally do.

Novelty: Requirement of patentability. It exists when an invention was not made publicly available (generally anywhere in the world) before the date of application of the patent.

Obviousness/inventive step: Requirement of patentability. It is generally met when invention is not obvious to a person normally skilled in the relevant field of technology.

Parallel import: The importation, without the authorization of the owner of an intellectual property right, of a protected product marketed abroad by the patentee or by an authorized party.

Patent: A title granted to protect an invention, generally for a twenty-year period.

Patentee: The owner or order of a patent.

Patent application: A legal petition that describes an invention and specifies the claims.

Prior art: All of the pertinent and applicable knowledge in the public domain at the time a patent application is filed.

Priority right: The right to acquire an intellectual property right where competing applications are filed based on the priority in the date of application.

Right-holder/title-holder: Terms used to indicate anyone with a proprietary interest in an intellectual property right.

Sui generis: A term meaning a specialized regime of intellectual property rights, separate from copyright, patents and other chapters of intellectual property rights.

Working: The use of an invention in a commercial context, such as manufacturing of a patented product, use of a patented process and commercialization of a protected product. In some cases, it is also the importation of a patented product.

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