DOES THE COMPULSORY LICENSE JUSTIFY DEVELOPING COUNTRIES' VIOLATION OF INTERNATIONAL PATENT LAWS? AN ANALYSIS BASED ON PHARMACEUTICAL DRUGS

By

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University of Zambia
Lusaka
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"your job is to find justice no matter how hard she may try to hide from you"

A Time to Kill- John Grisham.

THE UNIVERSITY OF ZAMBIA

SCHOOL OF LAW

I recommend that the obligatory essay prepared under my supervision by **CHONGO CHITUPILA**

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Be accepted for examination. I have checked it carefully and I am satisfied that it fulfills the requirements relating to format as laid down in the regulations governing obligatory essays.

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DR. P. MATIBINI

Supervisor

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Date

Obligatory Essay on

DOES THE COMPULSORY LICENSE JUSTIFY DEVELOPING COUNTRIES' VIOLATION OF INTERNATIONAL PATENT LAWS? AN ANALYSIS BASED ON PHARMACUTICAL DRUGS

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COMPUTER No. 21019916

Submitted to the University of Zambia in partial fulfillment of the requirements of the Bachelor of Laws (LLB) Degree programme.

School of Law

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DECLARATION

I, **CHONGO CHITUPILA,** do hereby declare that this essay is my authentic work and that to the best of my knowledge, information and belief, no similar piece of work has previously been produced at the University of Zambia or any other institution for the award of a Bachelor of Laws degree. All other works referred to in this essay have been duly acknowledged.

Made this ...18th..... Day of January 2007

By the said **CHONGO CHITUPILA**

At Lusaka.

DEDICATION

This essay is dedicated to my mother; my strength, my shield, my angel-my mom. For encouraging my love for books, expanding my horizons and encouraging me to be a better person.

The essay is also dedicated to all those afflicted by HIV/AIDS especially one particular person- justice is paramount above all.

ACKNOWLEDGEMENTS

Firstly I'd like to thank my heavenly FATHER, for all the love, blessings and miracles. For getting me through all the tears and tough times, especially when I thought I could not do it. To you are the praise, glory and greatest thanks.

Dr. Matibini, thank you for supervising my work and sacrificing your time to read through and make corrections- obviously a tedious task, but I am grateful to you and consider myself privileged to have been under your renowned experience and supervision.

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I'd like to thank my mother, for teaching me the value of education and independence, for introducing me to the wonderful world of books and encouraging me to read, as well as supporting me. For loving me despite all my faults and being a great guide and teacher. For being the best mom in the world. Love you! **May your soul forever breathe.**

I'd like to thank my granma, for being the pillar of strength that holds us all together, for being there when you were needed the most and putting up with my growing pains. Thanks for the love and encouragement. Love you!

Kateule, my big sister and friend, thanks for paving the way and showing not only that it can be done, but how it can be done. You're the best sister in the world and thanks for the encouragement and love. Love you!

To ma two baby brothers, Mowa and Muleba, (you're all grown up now) you guys are my inspiration and motivation, thanks for loving me unconditionally and being there through it all. When I'm finally rich we can attend a World Cup final! Love you!

Aunt Sharon, for being ma second momma, 'thank you' isn't really enough for how you've blessed my life and I know a large part of all this would not have been possible without you. God bless you!

Ngosa, ma baby sister, thanks for always showing me that the world owes me nothing and to stand up for myself. Now its your turn! Love you kid!

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To dad; thank you for introducing me to the legal world and fuelling my life long love affair with the legal profession. **May your soul rest in peace**.

Finally, I wish to state that any imperfection and errors that may be in this essay are entirely my own.

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CHAPTER ONE

HISTORY AND BACKGROUND OF THE COMPULSORY LICENSE

1.0 Introduction

When patent rights are granted, they enable the patent holder to prevent a third party from exploiting his invention. However, in some instances reasons of public interest arise which justify national authorities decision to allow the exploitation of the patent by a third party, without the patent holders consent or authorization.[1]

In he field of patents, the issue of government authorization to use a patent without the permission of the patent owner is represented by the term, compulsory license. 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.[2]

Alternatively, it 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.[3] This type of license is commonly referred to as a non-voluntary license because, it connotes the lack of consent by the patent holder. The non-voluntary license is distinguished from the voluntary license, which is a license granted by the owner of the patent and there is consent by the patent holder.

The concept of compulsory licensing has a long history in both national and international law. In national, the birth of the concept of compulsory license can be traced to the United Kingdom, Statute of Monopolies of 1623. Later in 1883, the Patent Act adopted a provision for the granting of compulsory licenses for cases in which the patent was not

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[1] Musungu & Oh.2006. The use of flexibilities in TRIPs by developing countries: can they promote access to medicines?p27

[2] S. Musungu, Villanueva & Blasetti. 2004. Utilizing TRIPs flexibilities for public health protection through south-south regional frameworks. p12

[3] http://www.southcentre.org/publications/complicence

being worked in the United Kingdom.[4] In French law, the compulsory license was granted as a method of mitigating the drastic measure of direct forfeiture of a patent in cases where the patent was not being worked.[5]

1.1 Paris Convention 1883

At the international level, compulsory licensing can be traced to the International Convention for the Protection of Industrial Property (Paris Convention) of 1883. This convention applies to patents on inventions, utility models, industrial designs, trademarks and trade names. During negotiations at the Paris Convention, there were conflicting views as to the issue of local working, that is, the industrial use of the invention in the country of registration of the patent,[6] and compulsory licensing. In 1925, further negotiations at a conference held at The Hague, led to the adoption of compulsory licensing as principal means to ensure the exploitation of a patent.

The Paris Convention recognizes the right of member countries to establish compulsory licenses, but this is with specific limitations under the convention. Article 5A 1-4 stipulates:

1. Member states may provide for the grant of compulsory licenses to prevent abuses of the exclusive rights conferred by the patent, for example, non-working of the patent.
2. Forfeiture of the patent will not be provided for, except where the grant of compulsory licenses is not sufficient to prevent abuses. Forfeiture or revocation of a patent will not be instituted before the expiration of three years from the grant of the first compulsory license.

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[4] ibid
[5] http://www.southcentre.org/publications/complicence
[6] ibid

3. A compulsory license may not be applied for, on the ground of failure to work or insufficient working, before the expiration of four years from the date of application for the patent or three years from the date of the grant of the patent, whichever period expires last.
4. A compulsory license shall be non-exclusive and shall not be transferable.

Compulsory licensing became a characteristic feature in patent laws worldwide, at the beginning of the 1990s, around one hundred countries recognised such licenses.[7] The incorporation of compulsory licenses into national laws, took place parallel to the broadening of the grounds under which compulsory licenses may be granted.

1.2 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs)

Prior to TRIPs, countries throughout the world maintained legislation authorizing the grant of compulsory licenses. The terms of this legislation varied considerably.[8] In the late 1970s and early 1980s, developing countries demanded for a new international economic order including access to technology, their demands were manifest in the negotiations.[9] As a result of the inability of countries to agree as to the appropriate scope of compulsory licensing, TRIPs negotiations were initiated.

Article 31 of the TRIPs Agreement, refers to the compulsory license as "other use without the authorization of the right holder".

This Article regulates the practice of compulsory licensing, it addresses the interests of patent holders in particular cases, and this is because a compulsory license is directed at an identified patent and authorized party.[10] The article does not attempt to specify or

[7] http://www.southcentre.org/publications/complicence
[8] UNCTAD-ICTSD.2005. Resource book on TRIPs and Development.
[9] Ibid...p463
[10] op. cit. p462

limit in anyway the grounds upon which such licenses may be granted, instead it sets up procedures that Governments are expected to follow when they grant a license and describes certain terms tat compulsory licenses should embody. The procedures and terms vary depending on the contexts in which the compulsory license is employed.[11]

In effect, Article 31 acts as a guide for countries. The TRIPs Agreement refers to various grounds for the granting of compulsory licenses, there are five specific grounds:

a) Emergency and extreme urgency;

b) Anti-competitive practices;

c) Public non-commercial use (also known as governmental use);

d) Dependent patents; and

e) Refusal to deal.

The agreement does not limit the members' right to establish compulsory licenses on grounds other than those expressly mentioned.

While Article 31 does not restrict the grounds for granting compulsory licenses, it contains a detailed set of conditions, including the need to grant them on a case by case basis, the requirement of a prior request to the patent holder on reasonable commercial terms, the exclusive character of the licenses, the stipulation of compensation based on the economic value of the license, and the conditions for the termination of he authorization. Article 31 (g) in particular, imposes a serious burden on the compulsory licensing system, as it opens up the possibility that a compulsory license be terminated as soon as the circumstances which led to its granting have ceased to exist.[12] All significant patent systems, comply with the requirements of the agreement on Trade Related Aspects

[11] UNCTAD-ICSTD.2005. Resource book on TRIPs and Development. p462
[12] http://www.southcentre.org/publications/complicence

of Intellectual Property.

1.3 Doha Declarations

The November 2001 Doha Declarations on the TRIPs Agreement and Public Health, was adopted by the World Trade Organization (WTO) Ministerial Conference of 2001 in Doha on November 14, 2001, it reaffirmed the flexibility of TRIPs member states in circumventing intellectual property rights for better access to essential medicines.

Paragraph 5(b) states '*each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted*'[13]

The Doha Declaration recognizes the compulsory license and that countries have the right to grant compulsory licenses.

1.3.1 Grounds for granting Compulsory Licenses

Compulsory licenses may be granted on varied grounds subject to determination by national laws.

There are a number of grounds, the basis on which Governments the world over grant compulsory licenses.

1. **Refusal to deal;** In principle, a patent owner has the right to give or not give a license to a third party. This is considered a fundamental element of intellectual property rights in some jurisdictions. Refusal to deal is the refusal to grant a license on reasonable terms.[14] An example of how a compulsory license can be based on 'refusal to deal' is provided by a decision of the European Court of Justice of 6th April 1995 in the Magill case.[15] IN its judgment, the court stated that

[13] Declaration on TRIPs and Public Health, WTO Ministerial Conference. 4th session, Doha, 9-14 November, 2001. WT/MTN (01)/DEC/W/2

[14] http://www.southcentre.org

[15] Radio Telefis Eireann and Independent Television Publications Ltd v. Commission [1995] 4 CMLR 718

Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP), who were the only sources of basic information on programme scheduling, which is an indispensable raw material for compiling a weekly television guide, could not rely on national copyright provisions to refuse to provide that information to third parties. Such refusal in this case constituted the exercise of an intellectual property right beyond its specific subject matter and thus was an abuse of its dominant position (RTE and ITP held a dominant position because they were the only source in Ireland of the basic information, necessary to produce weekly television programming guides) and an intellectual property right. In this case, the two companies had refused to grant a license to Magill to enable it produce a weekly television guide, this prevented the appearance of a new product on the market, which RTE and ITP did not offer. Their refusal was considered unreasonable.

2. **Non-working and inadequate supply;** the origin of compulsory licenses is linked to the obligation to work a patent. Compulsory licensing can be established for lack of or insufficient working of a patent, following the Paris Convention, a large number of countries established compulsory licenses for lack of or insufficient working. Working was generally understood as the *industrial* use of the invention but has now come to be understood as the *commercial* use of the invention. This term incorporates the fact that the obligation to work the patent could be satisfied by the importation of the patented product.

Compulsory licenses can also be granted for inadequate supply of the patented product. For example, national laws on 'breeders rights' in Argentina (1973) and

Poland (1987) provide that, if the supply of the cultivar is not adequate in terms of quantity, quality and price, a compulsory license will be granted.[16]

3. **Public Interest;** In many countries, this is established as a ground for granting a compulsory license. The notion of what constitutes public interest varies over time and from country to country, it is the duty of the courts or administrative authorities to decide when the interests of the public are to be ensured or to be protected by the grant of a compulsory license. Therefore, in certain jurisdictions such as the United States of America, it has been argued that insufficient working, the dependency of the patents, or the interests of consumers in obtaining a protected product, at the lowest possible price, do not constitute a sufficient basis for the granting of compulsory licenses on the ground of public interest. However, in countries with limited industrial development, public interest may be deemed to include the opportunity to develop a national industry.[17]

4. **Governmental Use (Public non-commercial use);** a government may use patented inventions without the consent of or compensation to the patentee, although *ex gratia* rewards may be given. A license obtained in his manner may be used by any person authorized by a Government department.

   When a license is issued for Governmental use, the government cannot commit the tort of patent infringement, but it can be held liable to pay reasonable compensation. The US Government has made extensive use of compulsory licenses for Governmental use. The Governmental use of a patent is regarded as based on 'eminent domain'. Article 31 of the TRIPs Agreement introduces a

[16] http://www.southcentre.org
[17] ibid

requirement to inform promptly a right holder about government use of his or her patent.[18]

5. **Facilitate the use of Dependent Patents;** the TRIPs Agreement, as well as a number of national laws permitting the granting of compulsory licenses when the use of an invention-a dependent invention, is not possible without infringing another-the principal invention. The Agreement does however set out a number of conditions that have to be met if such licenses are to be granted. There is some flexibility in the interpretation of these provisions, especially with regard to the evaluation of the economic and technical importance of the dependent invention. With such compulsory licenses, the owner of the principal patent benefits, not only from the compensation paid for the use of his or her patent, but also from the right to use the dependent patent.[19]
6. **Anti-competitive practices;** compulsory licenses are issued in order to counter practices that aim at disposing, hindering or undermining fellow competitors. Such compulsory licenses may be issued to force a patentee to make readily available to other industry members, research results, or to transfer the know-how actually used in production.[20]
7. **Compulsory licenses for medicines;** In some countries such as Brazil, Argentina and India, compulsory licenses have been provided for specific products such as pharmaceuticals and food. In principle, the TRIPs Agreement prohibits this type

[18] http://www.southcentre.org
[19] ibid
[20] http://www.southcentre.org

of license, based on Article 27.1[21] of the TRIPs Agreement. The argument against it is that, national laws cannot discriminate in the exercise of patent rights on the basis of the field of technology. Licenses of this type, however, have proven to be an important tool in the promotion of competition and lowering the prices of protected products.[22]

Compulsory licenses limit the exercise of patent rights, they allow the use of an invention, but only by the person that has been so permitted by an authority, after the determination that certain requirements established by the law are met. The request for a compulsory license and its use may be subject to time restrictions, as well as payment of compensation to the patent holder.

A patent is a charter from a Government in favour of a particular person that gives that person certain rights, but patent rights are not absolute. The compulsory license attempts to restrict the use of those exclusive rights in the interest of the public.[23] Governments use compulsory licenses as an instrument through which they harness the power that resides in the grant of patents so as to ensure that in the interest of the public, easier access to technical knowledge takes precedence over other patent interests.

In relation to the compulsory license, there has been a fierce debate as to the production of drugs for treating serious diseases such as malaria, HIV and AIDS, using compulsory licenses. Drugs made under patents are widely available in developed countries and would tremendously help in the management of epidemic diseases in developing and least developed countries. However, these drugs are largely expensive and well protected

[21] Article 27.1 reads'...patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced'
[22] http://www.southcentre.org
[23] UNCTAD-ICTSD.2005. Resource book on TRIPs and Development.

y patents. The prices of the drugs are far beyond the reach of the majority of people in he third world countries, despite the fact that they are the worst affected by diseases such is HIV/AIDS, tuberculosis and malaria. It is on this basis that Governments in third world countries had asked pharmaceutical companies to reduce prices, a request that was urned down on numerous occasions. In some cases only slight reductions were made by the pharmaceutical companies that own mot of the patents. It is from this background that developing countries such as India issued compulsory licenses that enabled the production of life-saving drugs and has enabled millions of people in developing countries who need them, to access them. Brazil testifies that the rate of deaths caused by HIV/AIDS has plummeted in the period following the Brazilian Governments offer of free treatment using generic drugs, manufactured under compulsory license.[24] This has definitely not gone down well with the patent holders such as pharmaceutical companies and the United States Government, which has been supporting the intellectual property rights of US drug manufacturers, who do not want foreign countries manufacturing or importing, cheaper generic drugs. The US Government has gone to the extent of threatening trade sanctions on countries that have dared to use the compulsory licensing system to obtain generic drugs, countries such as Thailand and South Africa. A number of countries have bowed to the pressure, but countries like Brazil remained defiant in the face of American pressure. The US Government deemed this a violation of patent laws, but countries such as Brazil and India argue that they are looking out for the interests of their citizens and ensuring access to life saving drugs for all-especially the poor.

[24] http://www.southcentre.org

CHAPTER TWO

THE EFFECTS OF COMPULSORY LICENSING ON HEALTHCARE; AN ANALYSIS OF COMPULSORY LICENSING, INNOVATION AND ACCESS TO LIFE SAVING DRUGS

2.0 Introduction

> *When a new medicine or drug comes on to the market, it is often marketed under a brand. When the patent on the branded product expires, other drug producers can produce the same drug but they may not use the 'brand' name for the drugs. These producers therefore have to market the drug by its chemical name or 'generic' name. A* **generic drug** *is a pharmaceutical product intended to be interchangeable with the original branded product (which is often patented), in that the generic drug contains the same active substances as the branded product and thus confers the same health benefits.*[25]

Drugs have been singled out for special treatment both in terms of patenting and compulsory licensing primarily because of their role in promoting public health. There is a health crisis in developing countries. About 14 million people die each year from infectious diseases, many of which are preventable or treatable.[26] This health crisis is caused by several interlinked factors-poverty, and lack of access to health services, water and sanitation are a few. But the supply of effective and affordable medicines and people's access to such medicines and treatment is the most important factor in the promotion of public health.[27]

Public interest has been aroused around the world, by the health crisis in developing countries, caused by the exorbitant prices of drug treatments. HIV/AIDS medicines are a high profile example, but there are many cases of medicines for other life-threatening diseases being made unaffordable, simply

[25] Manual on good practices in public-health-sensitive policy measures and the patent laws. 2003. p1
[26] Oh. C. 2001. TRIPS, Drugs and Public health: Issues and proposals. p4
[27] Oh. C. 2001. TRIPS, Drugs and Public health: Issues and proposals

because companies owning or controlling patents on the medicines have been able to block competition from other firms and other products.[28]

Patent rights have been extended around the world through the provisions of the World Trade Organisation (WTO) Agreement on Trade-Related Aspects on Intellectual Property Rights (TRIPs). Proponents of the TRIPs Agreement argue that patents and other intellectual property rights are essential for promoting research and development, as well as stimulating innovation. [29] However, there is minimal evidence to support the view that the introduction of TRIPs-compliant standards of intellectual property rights has promoted transfer of technology, research and development or innovation in developing countries.[30]

In setting the price of pharmaceutical products, patents play a key role. States issue patents on drugs in order to grant research-based pharmaceutical companies a monopoly over the exploitation of their products for a limited period of time. Thus, investments in research and development will be recovered through a temporarily limited opportunity to set prices above marginal costs of production. This allows a fair reward for the financial effort in developing new drugs and encourages further innovation. Patent holders argue that the compulsory license infringes their exclusive rights, as there is no need to obtain the patent holders permission to manufacture or export the patented product.

2.1 Opponents view

Western pharmaceutical companies argue that patent protection is necessary to ensure they make adequate returns to encourage future research and development

[28] Ibid...p6
[29] Oh. C. 2001. TRIPS, Drugs and Public health: Issues and proposals. p5
[30] Ibid...p5

of drugs.[31] But, according to them, compulsory licensing hinders research and development. They also argue that in the poorest countries most affected by AIDS, they have made great efforts to help, offering discounted prices and *waiving or not enforcing patents.*[32]

Richard Rozek,[33] argues that although access to health care is a major concern for people throughout the world, it is incorrect to suggest that access to health care is a problem that should be examined solely in terms of pharmaceuticals, especially in relation to the impact of the TRIPs Agreement. He states that there are other barriers primarily responsible for access problems. These barriers include:

i) certain military, social and political conditions;

ii) financial hurdles;

iii) physical factors;

iv) damaging economic policies;

v) information asymmetries; and

vi) costs and prices of health care goods and services

He further dismisses claims by representatives of developing countries and a number of non-governmental organisations, who express concerns that protecting intellectual property rights will inhibit access to essential pharmaceutical products. Rozek contends that compulsory licensing does not improve access to essential drugs or medicines, rather it provides opportunities for firms pursuing their own economic interests to obtain access to the most profitable products. He

[31] http://www.corpwatch.org
[32] http://www.corpwatch.org
[33] A critic of compulsory licensing in his article 'The effect of compulsory licensing on Innovation and Access to Healthcare.

further contends that even when essential medicines are available to people in developing countries, the prescribing and consumer use of the drugs is often, ineffective, wasteful or even harmful. According to Rozek, compulsory licensing paves the way for poor quality drugs and counterfeit medicines that are a health hazard. He insists that quality problems are consequences of the compulsory licensing regime because generic products are not the equivalent of the brand product. Rozek states that, protection of intellectual property rights encourages firms to adhere to good manufacturing practices, otherwise without the protection, other firms would free ride on the investments made by innovators.

Compulsory licensing, Rozek argues, will only serve to make pharmaceutical firms reluctant to introduce products in countries with compulsory licensing laws. As a consequence, such countries will receive new medications later than countries without compulsory licensing, since innovators do not want to create additional sources of supply of products in a given country. This is so especially if that country has the potential to export to other countries. Moreover, intellectual property rights are not the sources of access problems for healthcare in developing countries, Rozek argues. Political, informational, financial, physical, social or ethnic problems unrelated to the pharmaceutical industry inhibit access, Rozek contends. He points out that, lack of protection of intellectual property rights is the likely cause of reduced access to healthcare because of the reluctance of pharmaceutical firms to introduce products in those countries with compulsory licensing laws.

He insists that compulsory licensing impedes access to healthcare by reducing the incentives of innovators to invest in developing and disseminating new medicines. Local governments also have problems in regulating the quality of licensed products, gathering data on adverse events and enforcing product recalls as well as disseminating information about proper use of products.

Rozek also assesses the impact of compulsory licensing on prices of essential drugs. According to his research, sellers of patented drugs do not necessarily enjoy monopoly or the power to raise prices. Rozek and Berkowitz studied prices at the manufacturer level and price movements of the pharmaceutical products in six therapeutic categories for nine countries, they found that protecting intellectual property rights does not result in an increase of real or nominal prices of existing products.[34]

There is a contention that protection of intellectual property rights in developing countries is likely to cause a decline in the local pharmaceutical firms, who will not be able to survive and compete, if they have to wait until the patent expires, to copy a protected product. Rozek states that in actuality, patent laws stimulate local firms to devote more resources to research and development and new products will emerge and there will be new opportunities for the local firms. Rozek states that this is not possible in a compulsory licensing system.

[34] Rozek and Berkowitz. 1998. The effects of patent protection on the prices of pharmaceutical products: is intellectual property protection raising the drug bill in developing countries? I.J.W.I.P 2 March pp179-243

Lois Boland states, "compulsory licensing diminishes the exclusivity of the patent grant and undermines the incentive for the innovation and investment that is a critical component of technological progress."[35]

Rozek concurs with Boland and adds that compulsory licensing will not improve access to pharmaceutical technologies or medicines, in fact it actually harms consumers and local firms.

2.2 Proponents view

Proponents of compulsory licensing completely disagree with critics such as Rozek. They argue that access to medicines and healthcare could save the lives of many people. Although there are many factors that prevent equal access to healthcare, the price of medicines is one of the most significant obstacles to healthcare in both the public and private sectors.[36] They further argue that actually, compulsory licensing improves access to life-saving drugs with little or no impact on innovation. Collen Chien,[37] whose article was based on research done on drug patents that had compulsory licenses issued over them, reports that she observed no uniform decline in innovation by the companies affected by the compulsory licenses. She further states that she found very little negative impact.[38] Her findings suggest that the assertion that compulsory licensing harms innovation is probably wrong.

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[35] Lois Boland. 1999. US Government position on compulsory licensing of patents. 26th March. www.haiweb.org

[36] http://www.tac.org

[37] Fenwick & West J.D. Associate, University of California at Berkeley School of Law

[38] Chien. C. 2003. Cheap drugs at what price to innovation? Does the compulsory licensing of pharmaceuticals hurt innovation?

Proponents of compulsory licensing ague that patents favour drug companies to the detriment of poor people who need them. Chien contends that compulsory licensing has long provided an antidote to the ills of the patent system.

In a study that focused on Canada's extensive compulsory licensing program, it was concluded that Canada's program had no negative impact on pharmaceutical innovation. And following legislation[39] authorizing compulsory licensing for drugs, a domestic generic industry developed.[40] This led to a wide choice of drugs on the market and the reduction of drug prices.

Balasubramaniam,[41] states that although compulsory licensing improves access to essential medicines, it does not enable the strengthening of the pharmaceutical industry in developing countries and is not a permanent sustainable solution.[42] This is debatable because countries such as Brazil and India have developed viable industries through compulsory licensing, however the author tends to agree with Balasubramaniam, that compulsory licensing is not a permanent sustainable *solution.*

Proponents of compulsory licensing in South Africa, for example Treatment Action Campaign (TAC), argue that compulsory licensing enables third parties, usually local industries to produce drugs, especially those that are patent protected. This brings about an increase of drugs on the market, creates choice and lowers drug prices. If local industries are granted licenses, it creates an environment that will enable the development of a generic drug industry.

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[39] Canadian Patent Act s. 4 (1) & 39 (4)
[40] Op. cit note 14
[41] D.K. Balasubramaniam. 2002. Access to medicines & public policy safeguards under TRIPS
[42] Ibid...p13

Most importantly, proponents argue that, compulsory licensing enables access to drugs for poor people in developing countries.[43] This is because compulsory licensing enables the licensee to produce drugs at a cheaper price. Drugs can be sold at cheaper and more reasonable prices because compulsory licensing enables the licensee to produce the drugs without incurring the costs that come with research and development. Most pharmaceutical companies claim research and development makes their patented protected drugs expensive. However, licensees do not obtain the licence to use a patented product freely, they must pay royalties to the right holder.[44] In effect right holders are paid for the use by a third party of their patented product even if it is obtained without their authorization.

The cheaper drugs are then sold to those who can afford them, alternatively some governments, for example Brazil and South Africa, produce or buy the cheap drugs and provide them for free to registered patients who are too poor to afford them. Zambia buys and imports the cheaper generic drugs and provides them for free, under similar programs like Brazil and South Africa. Without compulsory licensing this would not have been possible.

In Brazil for instance, use of generic drugs produced under compulsory license, meant that in 2001, the government was able to provide free treatment to 90,000 poor patients in Brazil.[45] This was possible because of the cheaper prices of generic drugs. Brazils HIV/AIDS program is widely regarded as one of the most successful in the world.

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[43] http://www.tac.org
[44] http://www.southcentre.org
[45] http://ww.bbcworldservice.com

Although it is contended that most drugs produced under compulsory license are of poor quality or counterfeit, this has been argued not to be so. The charity Medicins Sans Frontieres (MSF) says there is no evidence that generic drugs produced under compulsory licenses in developing countries are any less effective than branded versions produced in the west.[46] MSF says, "as a medical organisation, it is the first to ensure the absolute quality guaranteed on generic drugs."[47] World Health Organisation (WHO), in March 2002, also included products from generic drug manufacturers in its list of products and manufacturers which meet WHO quality standards as suppliers to the UN agencies. This initiative was prompted by the need to ensure the availability and affordability of HIV/AIDS medicines.[48]

The question arises-how much cheaper are generic drugs when compared to brand versions? Generally, they are around 70 to 90 percent cheaper, according to MSF. For instance, fluconazole, a drug which manages cryptococcal meningitis, an infection affecting one in five AIDS sufferers, was supplied exclusively by the US company Pfizer until 1998. Since cheaper generic alternatives became available, branded version which was more expensive became cheaper. Generic versions of the drug are sold at $0.64 in India, $0.29 in Thailand compared to $10.50, which is the price of the branded version in Kenya and $27 in Guatemala. Before the introduction of generic version in South Africa, the drug cost $8.25.[49] In Brazil when the government began producing generic AIDS drugs, the prices of

[46] http://www.bbworldservice.com
[47] ibid
[48] Manual on good practices in public health-sensitive policy measures & Patent laws.2003. p4
[49] Oh. C. 2001. TRIPs, Drugs and public health: Issues and proposals. p3

equivalent branded products dropped by 79%.[50] Domestic production of AIDS drugs has enabled the Brazilian government to halve the AIDS death rate through the universal free treatment program and it saves $472 million from averted hospitalizations.[51]

Another contention by proponents of compulsory licensing is that, although pharmaceutical companies claim that huge investments in research and development warrant the high prices for their products, this is debatable. A number of medicines were in fact discovered by public funded institutions and universities.[52] For instance, the National Institute of Health (NIH) was instrumental in the discovery of a number of AIDS medicines. Some 70% of drugs with therapeutic gains were produced with government involvement, yet it is the pharmaceutical industry that reaps most of the profits from the sale of medicines.

From the preceding arguments, the following conclusions can be made:

Those in opposition of compulsory licensing argue that in the long run it does not improve access to life-saving drugs because pharmaceutical firms will be reluctant to introduce products in countries with compulsory licensing laws. Such countries will as a result receive new medications later than other countries without compulsory licensing laws. Opponents also contend that pharmaceutical firms will be unwilling to invest in developing and disseminating new medicines, if their rights will be abrogated by compulsory licensing.

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[50] Ibid...p14
[51] ibid
[52] Oh. C. 2001. TRIPs, Drugs and public health: Issues and proposals. p13

They also contend that compulsory licensing inhibits local firms from developing their innovative capabilities and leads to a flood of poor quality products on the market.

Proponents of compulsory licensing argue that compulsory licensing actually improves access to healthcare. They say it enables either the local manufacturer or the importation of generic medicines equivalent to their brand counterparts. The effect of this is that there will be a wide choice of drugs competing on the market. The competition will lead to reasonable prices of generic drugs and reduced prices of brand drugs. This makes them affordable to those who cannot afford the exorbitant prices of brand drugs. Compulsory licensing also enables governments in developing countries to make available for free, HIV/AIDS drugs to poor patients. This is most notable in Brazil and Zambia.

As to the quality of the drugs, MSF and WHO, have guaranteed that the generic drugs are of high quality. Where the compulsory license is issued for local manufacture, it has the effect of in the long run strengthening local capacity and the potential of developing a local industry as occurred in India.

In essence compulsory licensing does have an effect on access to life-saving drugs. It enables the manufacture or importation of life-saving drugs for a number of diseases, but most notably HIV/AIDS. In countries where licenses have been issued, there has been an increase of drugs available to consumers. This has led to competition not only between brand and generic drugs, but also competition between different generic drugs. The effect has been lower prices. This places life-saving drugs within the reach of the worlds poor who need them most.

The effect of compulsory licensing on healthcare has been that, with the availability of reasonably priced generic drugs and lower priced brand drugs, governments are able to put in place policies and programs that enable them to provide cheaper and in some cases free access to life-saving treatment. This has been most prominent in the area of HIV/AIDS.

The effect of compulsory licensing on innovation is debatable, according to opponents, incentives for innovation decline and so does investment in research and development. However, proponents have counter argued that compulsory licensing has very little negative impact on innovation.

The pharmaceutical industry is a lucrative business coupled with the fact that not many countries have been bold enough to issue compulsory licenses. The result is that innovation has not been negatively affected. Innovators will not stop inventing medicines because it is a lucrative business and very few countries use compulsory licensing. The potential profits and legal protections already in place far outweigh the threats of compulsory licensing.

CHAPTER THREE

ANALYSIS OF THE TRIPS AGREEMENT AND THE DOHA DECLARATION

In international law, countries can use compulsory licenses on patents for a variety of purposes. The legal basis for that is the Paris Convention but most importantly, the TRIPs Agreement. The Uruguay Round introduced multilateral negotiations on trade-related intellectual property rights. Under immense pressure from industrialized countries, a specific agreement on the availability and enforcement of such rights became part of the final act of the Round referred to as the Agreement on Trade-Related Aspects of Intellectual Property (hereinafter referred to as the TRIPs Agreement).[53]

The TRIPs Agreement is the most comprehensive international instrument on intellectual property (IPRs), dealing with all types of IPRs.[54]

The Agreement establishes minimum standards on copyright and related rights, trademarks, patents and industrial designs to mention but a few. The Agreement is based on and supplements the Paris, Berne, Rome and Washington Conventions.[55]

The standards of protection set forth relate to both the availability of rights as well as to their enforcement.[56] This means that member countries in certain areas covered by the TRIPs Agreement cannot confer a lower level of protection than that set out in the Agreement. However, member countries are not obliged to provide comprehensive protection.

3.0 The TRIPs Agreement: Article 31

Article 31 of the TRIPs Agreement entitled 'other use without the authorization of the

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[53] Correa. C.2000. Intellectual Property Rights, the WTO & Developing countries.
[54] Ibid...p1
[55] op. cit. note 1
[56] Correa. C. 2000. Intellectual Property Rights, the WTO & Developing countries. p2

right-holder', regulates the practice of compulsory licensing.

The compulsory license acts to restrain the exercise of private rights in the public interest.[57] It is one of the methods through which government limits the private power that resides in the grant of patents. It acknowledges that in various contexts the public interest should take precedence over other patent interests.[58]

The Agreement contains a detailed set of conditions for the granting of compulsory licenses. There are five specific grounds for the granting of compulsory licenses, extreme emergency, anti-competitive practices, non-commercial use, dependent patents and non-working or insufficiency of working.

The TRIPs Agreement does not restrain members from establishing compulsory licenses on other grounds not explicitly mentioned in the Agreement. The Agreement does not limit the grounds for the grant of compulsory licenses, but it contains comprehensive conditions under which a compulsory license can be granted.

The manner in which the conditions are applied will determine the effectiveness of the compulsory licensing system.

3.1 The Provisions of Article 31

(a) authorization of such use shall be considered on its individual merits.

Governments should require each application for a license to undergo a process of review to determine whether it meets the established criteria for the granting of a license.[59]

(b) 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 not been successful within a reasonable period of time. This requirement may be waived by a member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In

[57] UNCTAD-ICTSD.Resource book on TRIPs and Development. 2005.p461
[58] ibid
[59] op. cit note 5

situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds 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 generally requires that a party seeking a compulsory license must first engage in negotiations with the patent holder for a voluntary license based on reasonable commercial terms and conditions. These efforts must prove unsuccessful for a reasonable period of time.[60] This provision is flexible because the concept of reasonable terms and conditions and period of time depend on a particular context at a particular time. What amounts to reasonable period of time depends on the purpose for which the license is required.[61] For instance, negotiations for life-saving pharmaceutical drugs would be more rapid than negotiations for computer hardware.

There are certain conditions under which prior negotiation with the patent holder does not have to be pursued. These include instances where there is a national emergency, circumstances of extreme urgency and public non-commercial use. The language used in the Agreement is such that, it leaves room for countries to interpret. Each country therefore, may decide what situation amounts to national emergency or extreme urgency. Public non-commercial use is a flexible concept and governments have considerable latitude in granting compulsory licenses without requiring commercial negotiations in advance based on it. It may refer to government use or use for public benefit.[62] The government has an obligation to notify the patent holder of the grant of compulsory license as soon as reasonably practicable.

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[60] UNCTAD-ICTSD. 2005. Resource book on TRIPs and Development. p468
[61] ibid...p478
[62] UNCTAD-ICTSD. 2005. Resource book on TRIPs and Development. p471

c) The scope and duration of such use shall be limited to the purpose for which it was authorized.

Compulsory licenses are not intended to provide the licensee with an unlimited field of application. The license should be used solely for the purpose it was intended.

Although it is preferable that the duration of the license be limited in terms of purpose, a long duration may be granted. A license grant should be long enough to provide adequate incentive for production, otherwise the entire Article would be pointless.[63]

d) Such use shall be non-exclusive;

This provision implies that, where a patent holder grants a license, it may still confer marketing rights over the licensed product to other parties in the same territory.[64] This however, creates problems for prospective licensees as they face the possibility of competition from not only the patent owner, but other licensees as well.

e) Such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

The objective of this provision is to prevent the development of a market in compulsory licenses as instruments with independent value. The creation of such a market would generally enhance the value of compulsory license and may encourage parties to seek them.[65]

f) Any such use shall be authorized predominantly for the supply of the domestic market of the member authorizing such use;

The use of the word 'predominantly' would generally suggest that more than fifty percent of the production by a compulsory licensee should be intended for the supply of the domestic market.[66]

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[63] UNCTAD-ICTSD.2005. Resource book on TRIPs and Development.
[64] Ibid...p473
[65] ibid
[66] UNCTAD-ICTSD. 2005. Resource book on TRIPs and Development. p474

Therefore, a government may authorize a compulsory licensee to produce for export as long as the licensee undertakes to produce for the domestic market.[67]

g) Authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur.

The licensee must have their legitimate interests adequately protected in the event of the termination of a license.

Countries may put in place mechanisms for the protection of licensees, this is because for compulsory licenses to be successful, they must provide sufficient economic incentive for the licensee.[68]

h) The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

This provision on compensation is substantially flexible because of the use of the term 'in the circumstances of each case, this indicates that factors relating to the reasons for the grant of the license may be taken into account in establishing the level of compensation.[69]

This requirement applies to government as well as private party use of the patent.[70]

i) The legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that member;

j) 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 authority in that member;

The procedures that each country adopts for the review of decisions are likely to play a critical role in determining whether compulsory licenses will applied for and used.[71]

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[67] UNCTAD-ICTSD. 2005. Resource book on TRIPs and Development.
[68] Ibid...p474
[69] op. cit. note 15.p475
[70] UNCTAD-ICTSD. 2005. Resource book on TRIPs and Development. p475
[71] ibid...p477

The requirements for review are set out in general terms and countries can use their discretion in implementation, this is because the legal institutions and procedures of the various nations differ.

The Article does not specify the type of authority that may grant a compulsory license, however, governments should develop and make public, regulatory procedures as the basis in which compulsory licenses will be granted. These procedures may have exceptions as is necessary if a compulsory license is to be granted in an extreme emergency.

The Article does not suggest a preference for the character of the court to review decisions for example a specialized court such as a patent court.[72]

'a distinct higher authority' refers to a more senior level government person or body than the granting person or body.[73]

k) Members are not allowed 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.

When a compulsory license is granted based on a judicial or administrative finding of anti-competitive practices, the requirements of prior negotiations, notice and limiting the license to predominant supply of the domestic market do not apply.[74]

A finding of anti-competitive conduct on the part of the patent holder provides flexibility regarding the potential terms of a compulsory license.[75]

These were the relevant provisions of the Agreement. Article 31 narrows the grounds under the compulsory licensing system and sets out safeguards, but it is framed in a

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[72] UNCTAD-ICTSD. 2005. Resource book on TRIPs and Development. p478
[73] ibid...p478
[74] ibid...p479
[75] UNCTAD-ICTSD. 2005. Resource book on TRIPs and Development.

general manner that allows flexibility. Zimbabwe declared a period of emergency on HIV/AIDS in 2002. In accordance with Article 31, this was to enable it make or use any patented drug in the treatment of persons suffering HV/AIDS or HIV/AIDS related conditions.[76]

In 2003, the Malaysian government in accordance with Article 31, authorized a local company to import three anti-retroviral medicines. The medicines to be imported were generic versions and were for the sole purpose of supplying government hospitals.[77] This falls in line with the 'government use option' as found in Article 31.

Article 31 sets out the conditions to be met in the granting of compulsory licenses, it does not limit a country to the specifically stated grounds. Since the permissible grounds are not explicitly defined in the Agreement, it leaves developing countries with wide discretion when determining public health sensitive compulsory licensing policies and law.[78] This flexibility is affirmed in paragraph five (b) of the Doha Declaration which states; "each member state has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."

3.2 The Decision on the implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health.

Paragraph 6 of the Doha Declaration recognized that there was a problem of insufficient or no manufacturing capacity in the pharmaceutical sector in many developing countries. Many developing countries and least developed countries cannot produce either active ingredients or formulations, this is due to lack of technology, equipment, human

[76] Musungu. S. & Oh. C. 2006. The use of flexibilities in TRIPs by developing countries: Can they promote access to medicines? p. 38
[77] ibid...p42
[78] op. cit. note 24

resources and economic viability of domestic production.[79] This meant that they had difficulties in making effective use of compulsory licensing.

This decision was adopted on 30th August, 2003.[80]

The decision is intended to allow countries with manufacturing capacity to make and export pharmaceutical products to countries with public health needs, notwithstanding Article 31 (f) of TRIPs that limits compulsory licensing predominantly to the supply of the domestic market. This means that those products may be legally exported freely to other countries.

It does this by establishing a mechanism under which the restriction of Article 31(f) is waived for the exporting country and Article 31(h) remuneration, is waived for the importing country.[81]

Paragraph one defines 'pharmaceutical product' in broad terms. It requires members (except least developed countries) to submit a notification of their intention to use the system in whole or in part, the notification can be modified at any time. The notification establishes the member as an "eligible importing member".[82] Eligible importing members include any least developed countries (LDC) as long as the LDC is a member of WTO and any other member that has made a notification to the Council for TRIPs of its intention.[83] A number of developed countries have agreed to opt out of using the system

[79] Correa. C. 2004. Implementation of the WTO General Council Decision on paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health. p1
[80] WT/L/540
[81] UNCTAD-ICTSD. 2005. Resource book on TRIPs and Development. p484
[82] ibid
[83] Correa. C. 2004. Implementation of the WTO General Council Decision on paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health. p11

as importers, for example France, the United Kingdom and the United States of America.[84]

Paragraph two of the Doha Declaration establishes conditions for the use of the waiver. The importing member must notify the TRIPs Council of its needs and must indicate that it has determined that it has insufficient or no manufacturing capacity for the products in question. If there is a patent in the importing member, it must indicate that it has issued or intends to issue a compulsory license. The exporting member must notify the TRIPs Council of the terms of the export license it issues.[85]

Paragraph three provides for a waiver of the remuneration requirement for the importing country. The importing country does not have to pay royalties to the patent holder.

Paragraph four has a requirement; importing members have to implement measures proportionate to their means so as to prevent the diversion of products imported under this system. The paragraph does not specify the nature of the means. They may include mechanisms under which patent holders can obtain remedies.[86]

Paragraph five requires other members to put in place measures that prevent the importation of diverted products into their territories.

Paragraph six provides a waiver of Article 31 (f) for regional trading arrangements in Africa. On the basis of this waiver, a member country can export to countries throughout the region under a single compulsory license.

The main benefit of the waiver in this paragraph is to allow importation and exportation throughout the African region.[87]

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[84] WT/L/540
[85] UNCTAD-ICTSD. 2005. Resource book on TRIPs and Development.p484
[86] UNCTAD-ICTSD. 2005. Resource book on TRIPs and Development.
[87] Ibid...p485

Paragraph eight states that the waiver does not require annual renewal.

Paragraph nine indicates that the Decision is without prejudice to rights that members may otherwise have under TRIPs.

Paragraph 11 states that will remain effective for each member until an amendment comes into effect to replace it.

The Decision applies when a required pharmaceutical product is subject to one or more patents validly in force in the exporting country. Also, it applies when the relevant patents are not subject in the exporting country to a compulsory license to remedy anti-competitive practices.[88]

The system under the Doha Declaration can be used, especially by developing and LDCs to import pharmaceutical products under a compulsory license granted according to any of the grounds authorized by their national laws. Members are free to determine what those grounds are.

There is an understanding that the Decision "should be used in good faith to protect public health...and not to be an instrument to pursue industrial or commercial policy objectives".[89]

A number of countries have used the compulsory licensing system to address their public health emergencies, despite the basis for such licenses being the two aforementioned instruments, a number of developed countries particularly the United States of America have strongly objected and taken unilateral action. The effect has been that a number of developing countries and LDCs are reluctant to implement the compulsory licensing system despite its legality and benefits.

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[88] Correa. C. 2004. Implementation of the WTO General Council Decision on paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health. p9

[89] Statement by the Chair of the WTO General Council in adopting the Decision.

Compulsory licensing is not a violation of patent laws as contended by the United States Government. It has its basis in two recognised international instruments which both specifically provide for and deal with the issue of compulsory licensing. Therefore, it is legal and developing countries are entitled to use the compulsory licensing system to address their public health needs especially when dealing with infectious diseases and endemic diseases such as HIV/AIDS.

CHAPTER FOUR

DEVELOPING COUNTRIES THAT HAVE ALLEGEDLY DEFIED PATENT LAWS IN THEIR PHARMACEUTICAL INDUSTRIES AND ITS EFFECT

Ideally, under the TRIPs Agreement, developing countries can rely on Article 31 to invoke compulsory licensing. In practice however, governments are reluctant to exercise the provision in Article 31 due to the political and economic ramifications, most notably in the area of trade sanctions.

The exercise of provisions in Article 31 has been met with considerable resistance and the threat of trade sanctions as well as retaliation by developed countries.[90] Prominent among the resisting countries is the United States of America. Despite the threats, a number of countries have persisted with and used the compulsory licensing system to enable the manufacture or importation of cheaper generic drugs. Brazil, Malaysia and India are some notable examples.

The United States Government in particular has been accused of stopping the developing world from producing generic drugs. It insists that they import American made drugs at Western prices. However, the TRIPs Agreement allows for compulsory licensing. This allows developing countries to produce drugs that are under patent.

The government of United States of America contends that any action that contravenes the protection of intellectual property rights is a violation of the TRIPs Agreement and trade law. The US Government watches out for countries that they think do not provide adequate and effective patent protection for pharmaceutical products. Countries such as

[90] Islam. R. the Generic Drug Deal of the WTO from Doha to Cancun. J.W.I.P Sept. 2004 vol.7 No. 5 p677

Thailand fell under this group for attempting to use compulsory licensing to ensure the availability of affordable HIV/AID medicines.

The US Government considers measures for the control of patent abuses as trade barriers and requires the abolishment of such measures.

The US Government has insisted that developing countries implement the TRIPs Agreement provisions especially those that strengthen the protection of intellectual property rights, this US campaign is backed by some of the most powerful drug companies.[91] Countries that do not do this are declared defiant and placed on the 'priority watch list' also referred to as super 301. This is section 301 of the Omnibus Trade and Competitiveness Act 1988, which empowers the United States to unilaterally designate specific countries as unfair traders and to threaten them with retaliatory action.[92]

When developing countries agreed to accept the TRIPs Agreement, they expected that such unilateral action by the US Government be removed. However, this has not been the case.

4.0 Defiant Countries

4.1 India

India was one of the countries whose patent laws were not TRIPs compliant. It therefore made use of compulsory licensing to enable the production of cheaper generic drugs and the emergence of a local pharmaceutical industry.

The Patents Act 1970, of India only covered the process to make medicines, not the products themselves. It stated:

"The following are not inventions within the meaning of this Act:

[91] http://www.corpwatch.org
[92] Op. cit note 1

i) any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings ...to render them free of disease..."[93]

Based on this Act anyone could produce and sell generic drugs as long as they used different processes for its production.[94] Indian companies took advantage and legally produced generic versions of medicines that were under patent elsewhere. The government issued compulsory licenses to Indian firms to produce generic medicines.[95] The effect has been that, India's medicine prices are amongst the lowest in the world. They are comparatively cheap and affordable.[96]

Furthermore, India developed a thriving generic drug industry that produces drugs for patients across the world. Medicins Sans Frontieres (MSF) said more than a third of the anti-retroviral (ARV) Aids drugs it uses come from India.[97]

Indian pharmaceutical firms have been instrumental in producing cheap drugs, especially for HIV/AIDS sufferers in developing countries-the majority of whom cannot afford the drugs they need.

Some of the recipient countries of cheap generic drugs for diseases such as tuberculosis, malaria and HIV/AIDS are: countries in Africa e.g. Zambia, China, South Korea, Indonesia, France and Malaysia.[98]

Though India was a staunch opponent of international patent regimes, the Indian Parliament passed a Patent Bill on the 22nd of March, 2005. This law changed the patent regime in India drastically.

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[93] Patents Act 1970 (39 of 1970) as amended by the Patents Amendment Act 1999 s. 3(1)
[94] http://www.pww.org: Indian patent law threatens low-cost drugs
[95] http://www.pww.org: Indian patent law threatens low-cost drugs.
[96] ibid
[97] ibid
[98] http://www.pww.org: Indian patent law threatens low-cost drugs.

This Act now provides for patent protection of products as well as processes. The Indian government states that the country has developed a strong pharmaceutical industry and it stands to gain more than it would lose from strengthened patent protection.[99] The law introduced patent protection for big corporations and pharmaceutical products. Consequently, it is now illegal for domestic companies to produce generic copies of patented drugs.[100]

The legislation now brings India into compliance with the TRIPs Agreement. The Indian government maintains that the law will not lead to an increase in drug prices. However, civil society groups are skeptical about the legislation, insisting that it is too ambiguous and could be misused by multinational companies. They further state that drug prices will rise and that the procedures in the new Indian legislation are far from adequate.[101]

The legislation prevents the manufacturing, selling, distribution or importation of medicines without authorization.

4.2 Malaysia

The Patents Act 1983 of Malaysia provides for compulsory licensing.[102] The government in Malaysia uses the option of 'government use' which is a form of compulsory license. Under this option, the government issues a license for the importation of generic drugs. This has been particularly used for the importation of generic ARV drugs. The drugs concerned are patented in Malaysia.[103] This move was as a result of unsuccessful

[99] http://www.ictsd.org
[100] http://www.icstd.org
[101] ibid
[102] s.48-54
[103] Chee Yoke Ling. Malaysia's experience in increasing access to antiretroviral drugs. Exercising the "government use" option. p4

negotiations with drug companies, requesting them to reduce prices. The reductions were inadequate and prices remained out of reach for the majority.[104]

The government decided to purchase generic drugs from the Indian company Cipla. It was then that opposition arose. Glaxo-Smith-Kline (GSK), one of the companies with which negotiations had been unsuccessful, offered to drop the prices of a number of their drugs. The government however decided to push through with the importation from India.[105] This enabled the Ministry of Health to supply the ARVs free.

GSK and Bristol-Myers Squibb lodged complaints against the Malaysian governments move. The companies' threatened reduced foreign investment in the country.[106]

The government proceeded to issue a license to a local Malaysian company to import generic ARVs. The effect was phenomenal. The average cost of Ministry of Health treatment per month per patient dropped from USD$315 to USD$58, an 81% reduction when generic drugs were used. There was also an increase in the number of patients who could be treated at government hospitals and clinics.[107]

The effect on the pharmaceutical firms was that they dropped their prices.[108]

4.3 Brazil

Brazil is one of the countries that has been embroiled in confrontations with the United States Government over compulsory licensing.

The Brazilian government disagrees with the US Government over the high cost of drugs used to treat people with HIV/AIDS. Brazil uses compulsory licensing, it has built a

[104] Ibid...p3
[105] Ibid...p5
[106] Ibid
[107] ibid
[108] ibid

successful AIDS program based on the local manufacture and free distribution of generic versions of AIDS drugs. The country produces seven of the fourteen drugs it distributes.[109]

Brazil is considered a pioneer in the treatment and prevention of AIDS, it is the only large developing country that distributes AIDS drugs to those who need them.

In 2001, Brazil threatened to produce at a local laboratory, copies of the two most expensive AIDS drugs. This was because the makers of the drugs, Roche (a pharmaceutical firm in Switzerland) had refused to lower their prices.[110] The US argued that copying the drugs violated patent rules and they complained to the WTO, their contention was that Brazilian law permits a local company to manufacture a product made by a foreign firm, if that firm fails to initiate production within Brazil within three years. The US complained that the Brazilian law was a protectionist measure and discriminatory.[111] They also threatened to impose trade sanctions on Brazil. They however eventually dropped the complaint and Brazil did not issue the license as Roche reduced their prices by half.[112] However, in 2003, Brazil contended that it could produce the drug Nelfinavir, for even less and it threatened a decree to that effect.[113]

The Brazilian government threatened to issue a compulsory license for Kaletra, a drug developed by Abbott Laboratories of the USA. The license was never issued because Abbott offered to substantially reduce its prices.[114]

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[109] http://www.accessmed-msf.org
[110] http://www.accessmed-msf.org
[111] http://www.bbcworldsrvice.com
[112] ibid
[113] http://www.accessmed-msf.org
[114] ibid

The effect is that compulsory licensing is a weapon which enables developing countries to bargain with pharmaceutical firms and force them to reduce their prices.

The Brazilian government has a state owned pharmaceutical company called Far-Manguinhos Laboratory. It produces generic versions of popular drugs.

Although Brazil locally produces most of the drugs it needs, it was not able to produce them in sufficient quantities to meet demand and sustain the AIDS drugs program. In 2003, it introduced a new policy in which a decree was signed which enabled Brazil to acquire AIDS medications that it did not produce itself, from countries such as India and China. This decree was issued based on the fact that Brazil could no longer afford to buy patented AIDS drugs from multinational pharmaceutical firms.[115] Despite negotiations with the firms, the parties reached no conclusion.

Brazil's defiance in the continued use of its compulsory licensing system in the face of pressure from the USA is vigorously defended. Brazil insists that its laws permitting production of generic drugs is "an important instrument" in battling HIV/AIDS.[116] Reports indicate that the Brazilian law permitting production of generic drugs has halved annual deaths from HV/AIDS since 1995, this is due to the free distribution of mainly Brazilian produced AIDS drugs.

Brazil's AIDS program would be threatened if the government had to pay higher prices for imported drugs. It is widely regarded as one of the most successful in the world. In contrast with many other countries, the number of infections in Brazil has dropped and the government is able to provide free treatment to thousands of people suffering from HIV/AIDS.

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[115] http://www.accessmed-msf.org

[116] http://www.bbcworldservice.com

Brazil is considered a leader in the treatment of HIV/AIDS, although its epidemic is not on the same scale as that in Africa and nor is it as poor.

The United States Government staunchly opposes the Brazilian policy of compulsory licensing to combat its AIDS crisis. It views Brazil's persistent pursuit of lower prices on AIDS drugs as a threat to pharmaceutical companies' profit margins. It also views Brazil's generic industry as a patent pirate and a rebellion against patent protection and its free distribution of HIV medicines as being a breach of TRIPs obligations.[117]

4.4 Bowing to pressure

4.5 Republic of South Africa

South Africa is one of the countries hardest hit by the AIDS epidemic, in an attempt to come to terms with the situation, the South African Government in 1997, passed the Medicines and Related Substances Control Amendment Act.[118] The aim of the Act was to provide several methods to improve access to HIV/AIDS drugs. The Act permits compulsory licensing without giving the pharmaceutical firms industry the right to appeal.[119] The Pharmaceutical Manufacturers Association of South Africa (PMA), and 39 multinational drug companies took legal action against the government at the Pretoria High Court in February 1998, to annul the legislation.[120] The case received intense national and international media coverage. This led to an international public outcry against the court case. The PMA and the drug companies due to international pressure dropped the case in 2001. However, the multinational drug companies requested the US

[117] Islam. R. The Generic Drug Deal of the WTO from Doha to Cancun. J.W.I.P VOL.7 No.5 Sept 2004
[118] The Medicines and Related Substances Control Amendment Act No. 90 of 1997
[119] http://www.cosatu.org.za: HIV/AIDS. The PMA court case
[120] Case No. 4183/98 of 18 February 1998

Government to use its Special 301 and place South Africa on the "watch list" of countries that lack adequate intellectual property protection and threaten trade sanctions.[121]

The Act introduces a legal framework to make medicines more available and affordable in the public sector. The legal framework introduces three important elements;

1. Generic substitution of medicines-manufacturing or importing cheaper generic drugs of the same quality and containing the same or similar active ingredients as those contained in branded drugs
2. A pricing committee- to set up a transparent pricing mechanism and force drug companies to justify their prices.
3. Parallel Importation-to allow the government to import the same medicines sold by the same companies or its licensee at a lower price in another country.[122]

Section 15 (c) of the Act provides for compulsory licensing. Compulsory licensing allows South Africa to manufacture its own AIDS drugs and to distribute them within South Africa at affordable prices. Use of compulsory licensing makes it possible to reduce the price of a drug by 90%. For South Africa, that is a substantial step as it is subject to the highest priced pharmaceuticals in the world.[123]

The Act gives the Minister of Health broad powers and grants the same Minister the authority to Act outside the boundaries of existing South African patent law. For example, the patents Act 1978, precludes parallel importation, the 1997 Act reverses that position by stating that 'a medicine which is imported by a person other than the person who is the holder of the registration certificate...may be imported.'

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[121] Islam. R. The Generic Drug Deal of the WTO from Doha to Cancun. J.W.I.P Sept 2004 Vol. 7 No.5
[122] http://www.cosatu.org :HIV/AIDS: The PMA court case
[123] http://www.academic.dayton : The South African Medicines and Related Substances Control Amendment Bill and TRIPs

The Act attempts to improve the healthcare system by lowering the prices of essential medicines. This is of great importance to people living with HIV/AIDS.

When the court action was instigated the implementation of the Act was suspended for three years, and in those three years thousands of people unable to afford AIDS drugs died.[124] On 20th February 2001, the association of US pharmaceutical companies called on the US government to threaten South Africa, with trade sanctions due to their violation of intellectual property rights.[125]

South Africa did not invoke this Act to justify its compulsory licensing amidst fears of incurring sanctions from United States and other western trading partners.[126]

4.6 Thailand

The Thai government uses compulsory licensing under Thai law as a remedy for abuse of monopoly rights especially.[127]

The US Government considers measures for the control of patent abuses as a trade barrier and has requested Thailand to abolish those measures.

Since 1993, the US Government has limited Thai production of generic drugs because of a bilateral program between the two countries that allowed medicines into Thailand, that were not patented in Thailand with exclusive rights for 5 to 6 years. The effect was that generic versions of these products were not put on the market during this time.[128] The Thai Government was also forced to amend the Thai Patent Act in 1992, to protect product patents and extend patent protection from 15 to 20

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[124] http://www.cosatu.org

[125] ibid. the US Government also put South Africa on the 301 watch list for its decision to authorise generic versions of Taxol, a cancer drug.

[126] Islam. R. the Generic Drug deal of the WTO from Doha to Cancun. J.W.I.P Sept 2004 Vol. 7 No. 5 p678

[127] http://www.thailawforum.com

[128] http://www.focusweb.org : Dying for free trade: U.S or us?

years. Furthermore, in 1993 the Thai government was pressured to implement a safety monitoring program (SMP), whereby any new drug patented outside Thailand between 1986 and 1991, would be given two years minimum protection under SMP. While on the SMP list, no generic versions could be registered in the country.[129]

Thailand has been faced with an HIV/AIDS crisis with thousands dying. The government health budget cannot cover the cost of treating large numbers of infected people, this has been further aggravated by strong patent protection and the SMP program. The effect was increased government medical expenditure and the suppression of competition. In essence this led to the decline of its local pharmaceutical industry and high prices of original drugs.

Thailand however began to defy the United States government-though to a limited extent.

In order to deal with the AIDS crisis and high costs of treatment, the Thai government passed a resolution in January 2001, to allow the production of generic drugs within a shorter time after the release of branded versions.[130] The SMP was amended. Prominent among these changes was that the release period of generic versions was made shorter.

Although the changes were minor, they evoked fiery opposition from the US Government. They threatened to place Thailand on their priority watch list and threatened trade sanctions against Thai exports.[131]

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[129] ibid
[130] http://www.focusweb.org
[131] ibid

The changes introduced, greatly lowered the government's medical expenditure and placed cheaper products on the market, meaning increased access to drugs for poor patients.

Thailand declined to conform to US requirements and pressure to tighten laws on patent protection such as elimination of price controls. The US trade representative placed and is still keeping Thailand on the list of nations deemed to be among the worst violators of US innovations.

However, Thailand still remains in a precarious situation. It offers a high degree of patent protection, similar to that found in developed countries. But it is doubtful whether this type of patent regime is appropriate to Thailand and in encouraging the development of a local industry.[132] However, in its attempt to combat the HIV/AIDS epidemic, it made minor changes that put it at loggerheads with the US government, despite its attempts to appease the same government.

US trade officials are accused of being more concerned about lobbying for their pharmaceutical companies' commercial interests rather than addressing the public health crisis of infectious diseases raging in developing countries and the lack of access to medicines by the poor who need them but cannot afford them.

"The US government is seemingly oblivious to terrible disparities in access to modern technologies..."[133]

Countries that have defied patent laws seem to have developed their local industries and have available on their markets cheaper versions of branded drugs and enable access for large numbers of poor people, otherwise unable to afford them. In the case

[132] http://www.thailawforum.com

[133] http://www.bkkpost.samart.co.th :interview with James Love, economist with Consumer Project on Technology

of Brazil it not only produces drugs, but supplies them freely to patients. Whereas India is one of the largest producers and suppliers of generic drugs to the developing world.

As for the countries that have bowed to threats, they need to acknowledge that it is well accepted in international law that countries can use compulsory licenses on patents and there is a very good legal basis, which is the Paris Convention and TRIPs Article 31. They should be able to implement compulsory licensing without unilateral threats.

CHAPTER FIVE

CONCLUSION AND RECOMMENDATIONS

The TRIPs Agreement and the Doha declaration offer sufficient legal ground to use compulsory licensing to address the public health concerns of developing and least developed countries, especially if they have strong national patent laws.

5.0 Conclusion

Many developing countries are reluctant to use compulsory licensing for a number of reasons such as administrative and financial difficulties, most notably though, developing countries are reluctant to use compulsory licensing due to fierce opposition from developed countries as was shown in chapter four. However, compulsory licensing is a policy option which is clearly allowed under the TRIPs Agreement and this was set out in chapter three. As can be derived from chapters two and four, a number of countries have invoked compulsory licensing to address their public health concerns-with encouraging results in most cases. Brazil has a successful program that entails the free distribution of generic anti-retroviral drugs to thousands of poor patients.

Developing and least developed countries are facing a major health crisis in the form of the HIV/AIDS pandemic, exorbitant drug prices only compound the situation because most people cannot afford them. To deal with the crisis, countries such as Brazil and South Africa have made attempts to use parallel importation to enable them obtain cheap drugs. However, many developing countries are reluctant to use parallel importation, this is especially due to drug companies' threats of single price charges to all countries (regardless of whether a country is developed or developing). However, drug prices in many developing and least developed countries are amongst some of the highest in the

world, this is shown in chapter two. Article 6 of the TRIPs Agreement specifically allows parallel importation and developing and least developed countries should use it.

Many developing and least developed countries are willing to negotiate for lower prices of branded drugs with pharmaceutical companies, however, the reduction in prices is usually not substantial. Drug prices still remain too high and as such drugs are not affordable.

Chapter four shows that in their efforts to provide cheaper medicines to address public health concerns, developing and least developed countries face stiff opposition from western governments. This opposition is present despite the fact that most of the attempts are legitimately done based on the TRIPs Agreement. To address the opposition posed by western countries, developing countries need to mobilize international support in their cause against major pharmaceutical companies and the United States government. It is pertinent that the international community takes a step to strongly condemn unilateral sanctions, such as the 'special 301 watch list' imposed on developing countries that invoke the compulsory license, by the US Government. The same chapter also shows that international outcry and pressure on western nations, can yield positive results in favour of the developing and least developed countries.

One of the major shortcomings of the domestic laws of developing and least developed countries is that, they have not domesticated the provisions of the TRIPs Agreement. Chapter four shows that South Africa has a domestic law that incorporates compulsory licensing and parallel importation-both are found in the TRIPs Agreement, South Africa is however reluctant to invoke the Act. In order to effectively utilize the provisions of the

TRIPs Agreement, especially to their advantage, developing and least developed countries need to domesticate the provisions of the TRIPs Agreement.

The majority of developing countries lack the financial capacity and infrastructure to produce generic medicines. The solution to this is, importation of generic drugs from countries that have the manufacturing and export capacity.

5.1 RECOMMENDATIONS

5.1.1 Compulsory licensing

Compulsory licensing can be used either for local pharmaceutical production or importation.

Brazil successfully used the threat of compulsory licensing to obtain significant discounts of up to 65% on antiretroviral drugs from Roche and Merck. The World Health Organization (WHO) also explicitly supports developing countries in the use of TRIPs safeguards to promote access to medicines.

For a country to effectively make use of compulsory licensing, a number of barriers must be addressed and requirements must be fulfilled; to effectively implement compulsory licensing, there is a need for knowledge and administrative infrastructure. However, many developing countries lack this capacity. Article 67 of the TRIPs Agreement requires developed countries to provide technical assistance '*on request and on mutually agreed terms and conditions*' to developing and least developed countries to help address such gaps. Developing countries should use this provision and approach developed countries and international organizations for assistance.

Compulsory licensing is useful for local production and as a negotiating instrument. However, its usefulness depends to a large extent on whether the appropriate technology and production capacity exist and whether the necessary human resources are available.

5.1.2 Parallel Importation

Parallel importation is the import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of an exporting country under a parallel patent.[134] Parallel importation is allowed under the TRIPs Agreement Article 6. Parallel imports are of great importance in meeting public health needs especially enabling access to affordable medicines because there are substantial price differences for pharmaceutical products in different markets.[135] Therefore, Parallel importation of patented medicines from a country where they are sold at a lower price will enable more patients in the importing country access cheaper drugs.

5.1.3 Importation pursuant to paragraph 6 of the Doha Declaration

Countries can opt to import generic medicines as provided under paragraph 6 of the Doha Declaration, instead of using their local industry for production of generic medicines. The decision allows countries with manufacturing capacity, to make and export pharmaceutical products to other countries with public health concerns. It also enables countries to import generic pharmaceutical products. The paragraph provides a series of waivers for the restriction on exports in Article 31 (f), a waiver of restrictions on re-export and a waiver for the requirement of payment of remuneration to the patent holder. This paragraph addresses the problem faced by countries unable to use the compulsory licensing system. The domestic laws of developing countries should be amended to allow

[134] Musungu. F. & Oh. C. 2006. The use of flexibilities in TRIPs by developing countries: Can they promote access to medicines? P. 47
[135] http://www.globalizationandhealth.com

the production and export, as well as the importation of generic medicines under compulsory license. Furthermore, the domestic laws should provide broad grounds for granting compulsory licenses and include importation, set definite time limitations for voluntary license negotiations that will enable grants of compulsory licenses without delay in the event that the time limit is deemed satisfied and no consensus is reached. Domestic laws of developing countries should not place limitations in the implementation of the paragraph, as it is phrased in a broad manner. For example, there should be no restrictions on the types of medicines to be imported.

5.1.4 Voluntary Differential Pricing Arrangements

Developing countries may enter into agreements with specific pharmaceutical companies, in which the developing countries agree to buy drugs from those pharmaceutical companies at prices that are lower than those which wealthy countries are paying. The prices are usually reduced, as long as the developing countries fulfill certain agreed conditions. The countries and pharmaceutical firms may enter into what are known as supply agreements. The essence of differential pricing is that prices are adapted to the purchasing power of governments in developing and least developed countries.

Voluntary differential pricing can be an important tool in insuring access to essential drugs at affordable prices in developing countries, while at the same time allowing the patent system to continue its role of providing incentives for research and development into new drugs. However, this option may not lead to adequate price reductions.

5.1.5 National laws

Developing countries need to incorporate the provisions of the TRIPs Agreement into their domestic legislation on patents, because in the hierarchy of laws, domestic law is

superior to international law, and forms a strong foundational basis. They can then use the TRIPs Agreement and the Doha Declarations as their second line legal basis. The TRIPS Agreement sets out minimum standards of protection to be incorporated into national laws. Members are not obliged to grant 'more extensive' protection than that provided in the Agreement (as stipulated in Article 1). Developing countries can opt to regard the protections provided in the TRIPs Agreement as being maximum standards of protection as well. Developing countries should furthermore, put in place administrative procedures, civil and criminal procedures in the courts and enlist where necessary, the intervention of the police, in order to ensure the enforcement of the rights, while at the same time creating a balance between the protection of intellectual property rights and developing countries' need to address their public health crisis.

5.1.6 International mobilization

In order to put and end to unilateral action such as that of the United States Government, developing countries should raise international awareness about their cause and at the international level mobilize support against the pharmaceutical companies and the United States Government. International support and condemnation, was to a large extent responsible for the withdrawal of the pharmaceutical companies' case against the South African government. Strategies of pressure and intimidation against countries that undertake measures to protect public health and promote access to drugs should be discouraged. Discouragement would be most effective if it is implemented by trade organizations such as the World Trade Organization (WTO).

Affordable and available antiretroviral drugs were possible because there were no pharmaceutical patents in key producing countries like Brazil and India, this enabled

them to develop local industries. But with the implementation of the TRIPs Agreement, access to cheaper drugs is becoming, once again, difficult and patent protection is stifling the generic industry and generic competition. Furthermore, developing countries face fierce opposition from the governments of developed countries such as the United States Government in relation to use of compulsory licensing. The following recommendations;

a) Compulsory licensing;

b) Parallel importation;

c) Importation pursuant to paragraph 6 of the Doha Declaration;

d) Voluntary differential pricing;

e) National laws; and

f) International mobilization

are the legitimate options available to developing countries and are the effective tools, which enable access to affordable medicines.

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