COMPULSORY LICENSING OF PATENTS: IMPLEMENTATION GAPS BETWEEN THEORY AND PRACTICE

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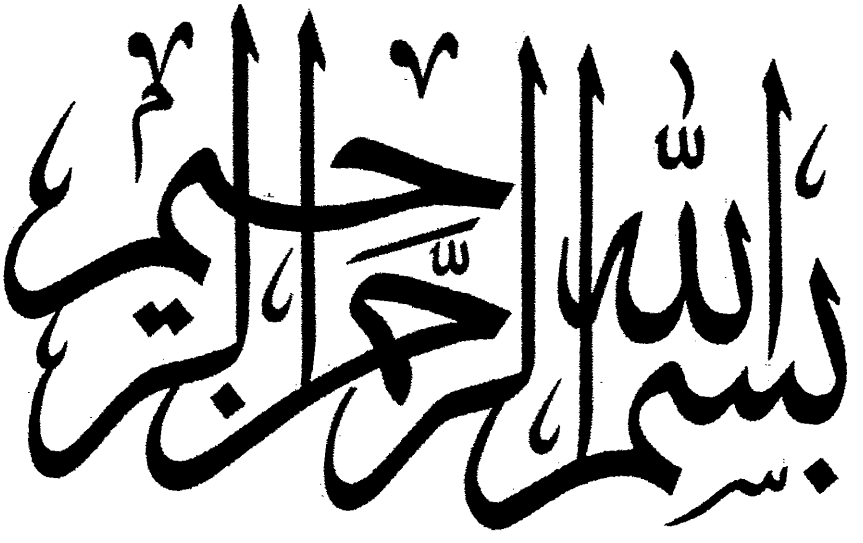
بسم الله الرحمن الرحيم

Dedication

Dedicated to the Developing World, praying that may Allah exalted provide them the strength, sustenance, and vision to compose themselves into a homogeneous being, out classing geographical variation and difference in level of development, forming a core group in the WTO, from where they can raise a common voice and thrive to safeguard their interests.

INTERNATIONAL ISLAMIC UNIVERSITY

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Approval Sheet

This is certified that we evaluated the thesis titled "Compulsory Licencing Of Patents: Implementation Gaps between Theory and Practice" submitted by Mr. Muhammad Zaheer Abbas, Registration No. 145-FSL/LLMIL/F10 in partial fulfillment of the award of the degree of LLM International Law. The thesis fulfills the requirements in its core and quality for the award of the degree.

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DECLARATION

I, **Muhammad Zaheer Abbas**, hereby declare that this dissertation is original and has never been presented in any other institution. I, moreover, declare that any secondary information used in this dissertation has been duly acknowledged.

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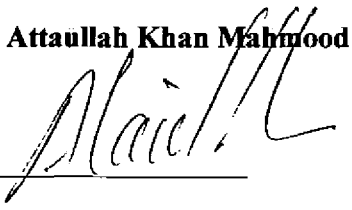
Signature: 

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ACRONYMS

ACTA	Anti-Counterfeiting Trade Agreement
AIDS	Acquired Immune Deficiency Syndrome
CEDAW	Convention on Elimination of all forms of Discrimination Against Women
CGPDTM	Controller General of Patents, Designs and Trademarks
DSB	Dispute Settlement Body
FDI	Foreign Direct Investment
GATT	General Agreement on Tariffs and Trade
HIV	Human Immunodeficiency Virus
ICERD	International Convention on the Elimination of All Forms of Racial Discrimination
ICESCR	International Covenant on Economic, Social and Cultural Rights
IFPMA	International Federation of Pharmaceutical Manufacturers Association
IPAB	Intellectual Property Appellate Board
IPRs	Intellectual Property Rights
LDCs	Least Developed Countries
MNCs	Multi-National Corporations
NGOs	Non-Governmental Organizations
NITD	Novartis Institute for Tropical Diseases
PhRMA	Pharmaceutical Research and Manufacturers Association of America
R&D	Research and Development
TRIPS	Trade-Related Aspects of Intellectual Property Rights

UDHR	Universal Declaration of Human Rights
UN	United Nations
US	United States
USTR	United States Trade Representatives
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	The World Trade Organization

TABLE OF CASES

1. Bayer Corporation v. Natco Pharma Limited
2. City of Milwaukee v. Activated Sludge
3. Foster v. American Machine and Foundry Company
4. Nerney v. New York, New Haven And Hartford Railroad Company
5. Roche Pharmaceuticals v. Natco Pharma Limited

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I consider myself deeply indebted to a few people without whose assistance and guidance this dissertation would have been impossible to complete. I owe a debt of gratitude to my supervisor, Mr. Attaullah Khan Mahmood, Assistant Professor, for his patience and his thorough and insightful guidance, initially and throughout in writing this dissertation. My earnest gratitude is also due to Dr. Hafiz Aziz-ur-Rehman, Assistant Professor, for his invaluable comments, suggestions and insights. I highly appreciate his intellect that became a source of inspiration for me in carrying out this work. I acknowledge his valuable consistent long distance research assistance throughout my work on this dissertation.

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ABSTRACT

Compulsory license is a non-voluntary license issued by the state to a third party without authorization of the patent holder on the condition of payment of a reasonable royalty to the patentee. The concept, though in conflict with the exclusive right of the patent holder, was introduced in the U.K in the Statute of Monopolies 1623 as a safeguard to prevent abuses of monopoly rights. Since then, this concept has been endorsed by all important international conventions and treaties on the subject.

Importance of compulsory licensing increased manifolds after TRIPS made patent protection for pharmaceuticals mandatory for all WTO member states. Access to drugs in the third world emerged as an international issue especially after the outbreak of epidemics and pandemics like HIV/AIDS. The condition of 'supply to the domestic market', initially put under TRIPS, had to be waived in 2003 in the wake of outcry at the global level to protect lives of patients in LDCs having no drug manufacturing capacity of their own.

Now, theoretically, the flexibility is available to WTO member states but it is seldom used by the underprivileged countries because not only the procedure for availing the flexibility is unnecessarily cumbersome and expensive but also there are various practical implications which bar poorer countries from availing the flexibility.

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INTRODUCTION

Intellectual property is "a category of intangible rights protecting commercially valuable products of the human intellect".[1] Primarily, there are three types of intangible property namely, patents, copyrights, and trademarks. Intellectual property rights also include trade secret rights and publicity rights.[2] The notion of Intellectual Property Rights is based on the principle that the person who made an intellectual contribution must have an exclusive right to enjoy the fruits of his labor. A person who comes with an original creation carrying a utility must be provided an exclusive right to commercially exploit their creation not only to reimburse their costs incurred on research but also to have an incentive for further research and innovation. It sounds quite logical, but the monopoly right provided to the inventor is not only in direct conflict with the competition laws but also has implications with regards to human rights law. Thus, there is a need to provide safeguards to ensure that this exclusive right of the patent holder is not misused.

Compulsory licensing of patents is one such safeguard under which government of the state that granted the patent could allow a third party to use the patent without consent of the patent holder on payment of a reasonable royalty or remuneration to the patent holder. It is "a statutorily created license that allows certain people to pay a royalty

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[1] Bryan A. Garner, *Black's Law Dictionary*, 8th Edition, (Thomson West, 2004), 824.
[2] Farzana Noshab, "Intellectual Property Rights: Issues And Implications For Pakistan", *The Institute of Strategic Studies, Islamabad*, last accessed date June 4, 2012, doi: http://www.issi.org.pk/old-site/ss_Detail.php?dataId=178.

and use an invention without the patentee's permission".[3] This safeguard is particularly useful with regards to pharmaceuticals especially in the instances of public health crisis when underprivileged states have no other option but to dilute the patent in order to improve access to affordable essential medicines to their poor citizens with limited purchasing power.

After the industrial revolution in the West, the technologically advanced countries felt the need for international standards regarding protection of intellectual property rights. Their efforts could not bear the desired fruits until the end of the cold war between the capitalist and communist blocks. Towards the end of the twentieth century, they linked trade with IPRs protection and succeeded in negotiating an international treaty which was imposed on the third world subject to the provision of an extended period for implementation of the treaty obligations. The primary objective of TRIPS Agreement was to provide stringent intellectual property protection to protect the interests of the multinationals in the technologically advanced world. Problems of the third world were therefore not given due consideration. Though compulsory licensing and parallel importation were included as safeguards, but these were just exceptions to the general stringent patent protection for all products including pharmaceuticals.

[3] Garner, *Black's Law*, 2004, 938.

Compulsory licensing safeguard initially provided under TRIPS had no practical significance for least developed countries (hereinafter LDCs) which lacked manufacturing capacity of their own because the pharmaceutical products manufactured under compulsory license could only be used for domestic use. With the outbreak of epidemics and pandemics like HIV/AIDS in Africa, the outcry by NGOs and human rights activists succeeded to draw attention of the world community towards practical problems faced by the LDCs (lacking manufacturing capacity) despite the flexibilities provided in the TRIPS. Changes were made in the existing system under Doha Declaration 2001, and WTO Waiver Decision 2003 to address the problems of the LDCs by allowing export of generics produced under compulsory licensing to these countries.

Now, theoretically, safeguards are available to the poorer countries and WTO member states have included the compulsory licensing provisions in their municipal laws. But practically, these provisions are seldom used owing to numerous implications including economic and political pressure. Poor countries dependent on economic and political support of the advanced countries cannot withstand such pressure and normally do not even dare to think about invoking the compulsory licensing provisions. If they decide to use the flexibilities, they have to face costly patent litigation which multinational pharmaceuticals can easily afford, but the poor countries see no economic incentive in bearing such enormous costs.

This couple of problems mentioned here is just tip of the ice burg. There are numerous other implications for third world countries which bar them from availing the legitimate flexibilities provided under TRIPS. Purpose of this work is to explore the practical implications faced by the poorer countries in availing the legitimate flexibilities provided under TRIPS and to discuss the implementation gaps between theory and practice of compulsory licensing. Moreover, an analysis of Indian compulsory licensing provisions would be made in the light of practical Indian cases on compulsory licensing.

Literature Review

Many states have raised voice for human rights violations as a result of stringent patent protection of pharmaceuticals and inefficacy of the existing flexibilities to deal with the health crisis. A lot is being written on the subject, but intensely minute literature is present in subcontinent especially in India and Pakistan. Much work is still to be done to enforce the safeguards provided under TRIPS Agreements to protect rights of individuals. The literature to be reviewed shortly highlights the nexus between protection of intellectual property rights and access to medicines in the developing countries. It evaluates the effectiveness of compulsory licensing as a safeguard to improve access to essential medicines in countries with low per capita income. Here, is some work of eminent scholars who worked on compulsory licensing, particularly on the right to health.

Ebenezer Durojaye, in *Compulsory Licensing and Access to Medicines in Post Doha Era: What Hope for Africa?* argues that right to health is guaranteed in so many international instruments. He further added that the TRIPS Agreement most significantly has serious implications for access to lifesaving medications in Africa. This article also highlights the causes and effects of Doha Declaration and the change in the existing

system after Doha Declaration. It is concluded with some suggestions which are necessary for the development of a better compulsory licensing regime.[4]

In his article *Intellectual Property and Access to Essential Medicines: Options for Developing Countries,* Jakkrit Kuanpoth has highlighted some key issues relating to intellectual property and pharmaceuticals in order to find ways to increase or improve access to essential medicines for developing countries. He has suggested in his article that developing countries should take positive steps to review and amend the existing law and policy relating to patents and pharmaceuticals.[5]

Tarun Jain, in *Compulsory Licenses under TRIPS and Its Obligations for Member Countries,* argues that the present status of compulsory licensing has been reached after a long struggle by third world countries. He has briefly explained historical basis of compulsory licensing. His main focus is on specific conditions, duration of license and obligations of member states with regards to grant and use of compulsory licensing.[6]

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[4] Ebenezer Durojaye, "Compulsory Licensing And Access To Medicines In Post Doha Era: What Hope For Africa?", *Journal of Intellectual Property Law, Vol. 18 Issue 2,*(Spring2011), last accessed date February 13, 2012,doi:http://web.ebscohost.com/ehost/results?sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13&vid=19&hid=122&bquery=(compulsory+licensing)&bdata=JmRiPWE5aCZ0eXBlPTAmc2l0ZT1laG9zdC1saXZl.

[5] Jakkrit Kuanpoth, "Intellectual property and access to essential medicines: Options for developing countries", *Journal of Generic Medicines, Vol. 2 Issue 1,* (Oct2004), last accessed date February 13, 2012,doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=34&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

[6] Tarun Jain, "Compulsory Licenses Under Trips and Its Obligations for Member Countries", *Journal of Intellectual Property Rights, Vol. 8 Issue 1,* (Feb2009), last accessed date February 13, 2012,doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=34&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

Gianna Julian-Arnold, with collaboration of PTC Research Foundation of the Franklin Pierce Law Center, has written an article *International Compulsory Licensing: The Rationale and the Reality*. In this article, he explained the concept and scope of compulsory licensing. Further, he has examined differences in the approach of developing and developed nations with regards to protection of intellectual property rights. He further examined relevant provisions of the Trade Related Aspects of Intellectual Property (TRIPS) draft agreement and proposed some suggestions for additions to the draft.[7]

Jakkrit Kuanpoth, in another article entitled *Give the Poor Patients a Chance: Enhancing Access to Essential Medicines through Compulsory Licensing,* has highlighted pivotal relationship between pharmaceutical patents and problem of inaccessibility of medicines faced by poor nations. He has quoted examples of experiences of developing countries in Asia in this respect. Thailand is taken as a special case to highlight the problem of inaccessibility of medicines due to implications in invoking compulsory licensing provisions.[8] Carlos Maria Correa, in *Compulsory Licensing: How to Gain Access to Patented Technology,* argued that it is difficult for institutions in developing

[7] Gianna Julian-Arnold, "International Compulsory Licensing: The Rationales And The Reality", *PTC Research Foundation of the Franklin Pierce Law Center, IDEA: The Journal of Law and Technology,* (1993), last accessed date February 13, 2012,doi:http://ipmall.org/hosted_resources/IDEA/33_IDEA/33-2_IDEA_349_Arnold.pdf.

[8] Jakkrit Kuanpoth, "Give The Poor Patients A Chance: Enhancing Access To Essential Medicines Through Compulsory Licensing", *Journal of Generic Medicines, Vol. 6 Issue 1,* (Nov2008,last accessed date February 13, 2012,doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=27&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

countries to obtain voluntary patent license. This article further discusses why, how, and by whom compulsory patent licenses may be obtained and used. Carlos mainly focused on patented research tools rather than patented end products.[9]

Kevin Outterson argued that disease-based limitations would be unwise, as the developing world is undergoing a demographic transition, with increasing shares of its disease burden coming from noninfectious diseases. In his article *Disease-Based Limitations on Compulsory Licenses under Articles 31 and 31bis,* he further added that TRIPS flexibilities must be limited to certain infectious diseases, namely AIDS, tuberculosis, and malaria. He has explained legal provisions contained in article 31 and 31 bis of TRIPS Agreement.[10]

Compulsory Licensing: A Major IP Issue in International Business Today? is basically about the issue of compulsory licensing in the context of the TRIPS Agreement, the Doha Declaration, and in connection with practices and ground realities in several developing nations. The article considers the genesis of compulsory licensing and its application to the pharmaceutical industry.[11]

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[9] Carlos María Correa, "Compulsory Licensing: How to Gain Access to Patented Technology" , *Handbook Of Best Practices*,last accessed date February 13, 2012, doi:http://www.iphandbook.org/handbook/chPDFs/ch03/ipHandbook-Ch%2003%2010%20Correa%20Compulsory%20Licensing.pdf.

[10] Kevin Outterson, "Disease-Based Limitations On Compulsory Licenses Under Articles 31 And 31BIS", *Boston University School of Law*, last accessed date February 13, 2012, doi:http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1407522.

[11] Richard J. Hunter: Hector R. Lozada: Frank Giarratano and Daniel Jenkins, "Compulsory Licensing: A Major IP Issue in International Business Today?", *European Journal of Social Sciences – Volume 11, Number 3* (2009), last accessed date March 21, 2012, doi:http://www.eurojournals.com/ejss_11_3_03.pdf.

William Ebomoy, in *Impact of Globalization on HIV/AIDS Pandemics and the Challenges of Compulsory Licensing and Parallel Importation,* examined the impact of globalization on HIV pandemics specifically, in the developing and the least-developed nations. He has critically examined the legal ramifications of compulsory licensing and parallel importation and their effectiveness to deal with public health crisis.[12]

Joseph a. Yosick, in his article *Compulsory Patent Licensing for Efficient Use of Inventions,* has discussed compulsory patent licensing provisions in the United States (US) and other foreign states. He further provides US patent law and its limited use of compulsory licensing in certain cases. He has briefly highlighted proposals for the expansion of compulsory licensing and criticism on the proposals has been addressed.[13]

Philippe Cullet, in *Patents and Medicines: The Relationship between TRIPS and the Human Right to Health,* has argued on access to drugs and the international intellectual property rights regime. He seems to be more concerned about right to health

[12] William Ebomoyi, "Impact Of Globalization on Hiv/Aids Pandemics and the Challenges of Compulsory Licensing and Parallel Importation", *Journal of Applied Global Research, Vol. 3 Issue 7,* (2010), last accessed date February 13,2012, doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=26&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

[13] Joseph a. Yosick, "Compulsory Patent Licensing For Efficient Use Of Inventions", *University Of Illinois Law Review,*(2001), last accessed date March 29, 2012, doi:http://www.brinkshofer.com/files/107.pdf.

which is not given due consideration in the existing intellectual property rights system. He has highlighted TRIPS Agreement with special reference to human right to health.[14]

Hans Morten Haugen has analyzed the relationship between patent rights and human rights on the basis of conflict in international law, namely incompatible treaty obligations of states which are signatory to both intellectual property rights and human rights treaties at the same time. In his article *Patent Rights and Human Rights: Exploring their Relationships,* he has further expressed his concerns regarding practical implementation of TRIPS obligations.[15]

W. R. Cornish in his book, *"Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights"* highlights the importance of intellectual property rights. He has covered law of patents, trademarks, copyrights and allied rights in one volume. His 1st landmark book covering all issues in one volume was published in 1981. He has argued the impact of intellectual property law. He has discussed IP laws from the socio-legal perspective. After his edition, many other scholars explored different areas of intellectual property rights and followed his footsteps. From1981 to till date, his book is used as a leading textbook in the area of intellectual property rights law. He has rewritten many editions of this book to update the issue to reflect the rapid evolution of IP in recent

[14] Philippe Cullet, "Patents and medicines: the relationship between TRIPS and the human right to health", *International Affairs 79,* (2003), last accessed date February 13,2012, doi:http://onlinelibrary.wiley.com/doi/10.1111/1468-2346.00299/pdf>,

[15] Hans Morten Haugen, "Patent Rights and Human Rights: Exploring their Relationships", *Journal of World Intellectual Property Vol. 10, Issue. 2,* (2007), last accessed date February 23,2012, doi: http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2007.00316.x/pdf.

years. In his recent edition published in 2003, he explored patents, biotechnology and genomics, implementation of the directives affecting copyright on the internet, the rapidly developing case-law on community and national trade marks. He further added a new chapter on IPRs in Digital Technology and Biotechnology. His book provides a comprehensive and authoritative coverage of the whole spectrum of intellectual property law, but it applies in the UK only. There is a need to explore all such areas in Pakistan according to the evolution of IP laws in recent years.[16]

Frederick M. Abbott, in his book "*Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*", has addressed an extremely complex issue of 2003. He has highlighted the importance of WTO's decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. He has explained the decision and has highlighted difficulties for the developing countries in making effective use of compulsory licensing under the TRIP's Agreement. He has suggested a framework for developing countries to amend their patent laws and to fulfill the legal requirements

[16] W R Cornish and D Llewelyn, *Intellectual Property: Patents, Copyright, Trade Marks And Allied Rights*, 5th edition, (London: Sweet and Maxwell, 2003).

under TRIPS agreement. His book is indeed an excellent addition to the existing literature and provides a base to this study.[17]

Recently, M. B. Rao and Manjula Guru have published their book *"Patent Laws in India"*. They have argued what is exactly meant by incremental innovation? And how does the amended Indian Patent Act of 2005 alters the legal definition of patentable subject matter and restructure the essential criteria - utility, novelty, no prior publication, and nonobviousness - around which patent law revolves.

This masterful analysis of patent law in India, by two of India's most distinguished jurists, investigates thoroughly the scope of the possible answers to these crucial questions. Recognizing the character of the revolution taking place in patent law globally under the regime of multinational corporations and India's central role in its development, Dr. Rao and Dr. Manjula Guru's analysis focuses on the patenting of substances arising out of advances in biotechnology, genetically engineered products, and computer-related devices. But they do not neglect the practical details of application, registration, and proceedings as constituted under the amended law; in fact, this book is the most detailed and insightful procedural and practice guide to the subject we have. The publishers conclude with the following boast:

[17] Frederick M. Abbott, *Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*, (Quaker United Nations Office,Geneva, 2002).

> No legal, administrative, or business professional in any of the many areas touched by patent law - not only in India, and elsewhere - can afford to bypass this deeply-informed study of a topic of huge global significance. Corporate counsel seeking an Indian patent will find no better guide.[18]

Almost all these writings of well known scholars are a substantial contribution to the existing legal scholarship but some critical issues related to compulsory licensing deserve a more detailed analysis. Most of the existing literature either supports stringent patent protection under TRIPS or highlights violations of human rights resulting from protection of intellectual property rights. Moreover, there is no dearth of literature on compulsory licensing as a safeguard provided under TRIPS to cater for public health crisis in the WTO member states. What is lacking in the existing literature is a detailed analysis of practical implications for third world countries in using the flexibilities available under TRIPS Agreement. These practical implications bar member states from availing the legitimate flexibilities and this results in human rights violations. Therefore, there is a dire need to give due consideration to the implementation gaps between theory and practice of compulsory licensing and to recommend solutions not only to WTO but also to member states to make the existing system of IPR protection more practicable and acceptable to the third world.

[18] M. B. Rao and Manjula Guru, *Patent Laws in India*, (Kluwer Law International,Law & Business: 2010).

Secondly, most of the existing literature is Western base literature and very few scholars from third world have written on this issue. Consequently, concerns of the poor countries about the existing system have not been adequately addressed, and their interests have not been fairly considered in most of the existing literature. Moreover, the compulsory licensing provisions have been rarely invoked in the subcontinent resulting in a dearth of case law on the issue. This study would be unique because it analyses Indian compulsory licensing provisions in the light of two practical Indian cases -Roche v. Natco and Bayer v. Natco. This study is therefore a humble contribution to emerging legal scholarship on the issue.

Outline of the Thesis

The WTO and TRIPS provide safeguards, exceptions to the stringent patent protection in the form of compulsory licensing and parallel importation. However, third world countries are unable to utilize the safeguards provided in the WTO's TRIPS Agreement. These states are even reluctant to use full flexibilities provided in TRIPS and unable to enact national laws to cater for public health emergencies. The monopoly right provided under the patent system is considered a key reason behind exorbitant prices of drugs rendering them unaffordable for poor citizens of underprivileged states who normally pay out of their pocket for medication. Under the WTO-TRIPS Agreement, developing

countries, in certain exceptional circumstances, can use the option of compulsory licensing to dilute the patents and ensure availability of much cheaper generic versions of patented drugs to their citizens. Compulsory licensing provisions are based on the logic that corporate interest cannot be given priority over public interest in situations where stringent patent protection means denial of the right to life to the masses. To study all the debatable issues, the thesis has been divided into four main chapters.

Chapter 1 explains the concept of compulsory licensing and its historical basis from pre-WTO period till to date. Chapter 2 examines flexibilities provided under TRIPS and WTO and their practical implications for third world countries. Chapter 3 focuses on the case study of Roche v. Natco (Erlotinib Controversy) and Bayer v. Natco. The study concludes with recommendations and suggestions not only for WTO but also for member states especially for third world countries.

Methodology

The study is library based and explanatory as well as analytical, partially based on case study. Furthermore, most of the data is collected from books, articles, research papers, law journals, magazines, conferences, reports of international organizations and Non-Governmental Organizations (NGOs), national and international instruments, and electronic media.

CHAPTER 1

COMPULSORY LICENSING OF PATENTS

1.1 Introduction

The notion of Intellectual Property Rights (hereinafter IPRs) is based on the principle that the person who made an intellectual contribution must have an exclusive right to enjoy the fruits of his labor. A person who comes with an original creation carrying a utility has an exclusive right to exploit their creation. IPRs protection is therefore a tool that can be used to foster innovation by providing temporary monopoly to the IPRs holders as a reward of their effort. As a result, consumers get improved goods and services. Competition law, on the other hand, is meant to ensure fair prices by preventing monopoly. There is a complex relationship between intellectual property rights and competition law, and it has always been a challenge to strike a proper balance between competition and innovation protection.[19]

Though common purpose of both IPRs and competition law is to enhance consumer welfare and promote innovation, the goals of intellectual property laws and competition law are often convergent. There is a conflict between the two because the former creates legal monopolies and the latter eliminates monopolies and anticompetitive practices.[20] There are two forms of competition: product competition and research competition. The first ensures consumer welfare by providing products at market prices;

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[19] *Compulsory Licensing And The Anti-Competitive Effects of Patents for Pharmaceutical Products: From A Developing Countries' Perspective,* 2,last accessed date February 13, 2012,doi:http://www.idra.it/garnetpapers/C14A_Kaushik_A_Jaktar.pdf.

[20] Arutyunyan, Arutyun. "Proceedings of the Institute for European Studies", *International University Audentes, Tallinn University of Technology, Vol. 4* (2008),168 ,last accessed date February 13,2012, doi: http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=28&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

the second is also essential for consumer welfare because it produces better products and new technologies.[21]

Patent[22] protection, despite being contradictory to competition law, has been accepted worldwide as a necessary evil in order to foster innovation. However, such situations may arise when this exclusive right to exploit the creation may not stand the test of public interest and may be required to be breached to serve a greater good. For instance, a patent on a life saving drug may be diluted to the detriment of the patent holder in case of an outbreak of an epidemic. The philosophy underlying compulsory licensing is therefore based on an often repeated saying "Necessity is the mother of invention".[23]

1.2 Meaning of Compulsory Licensing

"Compulsory licensing[24] is a license issued by a state authority to a government agency, a company or other party to use a patent without the patent holder's consent".[25] In simple

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[21] *Ibid* 173.

[22] A grant of right to exclude others from making, using or selling one's invention and includes right to license others to make, use or sell it. Black's Law Dictionary 1125 (6th ed. 1990).
A patent is a form of intellectual property. It consists of a set of exclusive rights granted by a sovereign state to an inventor or their assignee for a limited period of time in exchange for the public disclosure of an invention.

[23] Tarun Jain, "Compulsory Licenses Under Trips and Its Obligations for Member Countries", *ICFAI Journal of Intellectual Property Rights, Vol. 8 Issue 1,* (Feb2009),1,last accessed date February 13, 2012 doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=34&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

[24] The birth of the concept of compulsory licenses is linked to the obligation, introduced by the United Kingdom (UK) Statute of Monopolies in 1623. Compulsory licensing has been reported to be popular in Britain as early as 1850s. Later it was recognized by the international community through Paris Convention of 1883.
For details visit doi: http://www.legislation.gov.uk/aep/Ja1/21/3/contents, (last accessed date February 13, 2012).

[25] Ebenezer Durojaye, "Compulsory Licensing And Access To Medicines In Post Doha Era: What Hope For Africa?", *Journal of Intellectual Property Law, Vol. 18 Issue 2,*35, (Spring2011), last accessed date February 13, 2012,
doi:http://web.ebscohost.com/ehost/results?sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13&vid=19&hid=122&bquery=(compulsory+licensing)&bdata=JmRiPWE5aCZ0eXBlPTAmc2l0ZT1laG9zdC1saXZl.

words, "compulsory license is an action of a government forcing an exclusive holder of a right to grant the use of that right to other upon the terms decided by the government."[26] The government, however, pays a royalty to the patent holder in order to compensate them for the use of their patent without their consent.[27] In other words, "Compulsory licensing means a non-voluntary license issued by the state to a third party, without the authorization of the patent holder, on the condition that the licensee pays reasonable remuneration to the right holder in return".[28] The licensee enjoys the right to manufacture, sell or import the patented product.

These acts are otherwise covered by the exclusive rights of the patent holder.[29] The state must, however, ensure that the licensee manufactures, sells or imports only approved generics.[30] If unapproved generics become widely available, it may raise safety concerns for the state that granted compulsory license.[31] A compulsory license or a non-voluntary license may also be defined as "an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state."[32]

No doubt, patents are necessary to promote innovation. If the government does not ensure patent protection, no firm would have an incentive to develop new products. If

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[26] Jain, "Compulsory Licenses Under Trips and Its Obligations for Member Countries", 28.

[27] Durojaye, "Compulsory Licensing And Access To Medicines In Post Doha Era: What Hope For Africa?", 35.

[28] Jakkrit Kuanpoth, "Intellectual property and access to essential medicines: Options for developing countries", *Journal of Generic Medicines, Vol. 2 Issue 1*, (Oct2004),56,last accessed date February 13, 2012,http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=34&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

[29] *Ibid.*

[30] A medication sold under its generic name: - usually legal only after the patent has expired, or if no patent was issued for the substance. Generic drugs are usually less expensive than proprietary medications.

[31] Ed Lamb, "Compulsory Licensing: A Necessary Evil?", *Pharmacy Times*, (Jun2007), 57, last accessed date February 13, 2012, doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=34&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

[32] Gianna Julian-Arnold, "International Compulsory Licensing: The Rationales And The Reality", *Journal of Law and Technology*, (1993), 1, last accessed date February 13, 2012, doi:http://ipmall.org/hosted_resources/IDEA/33_IDEA/33-2_IDEA_349_Arnold.pdf.

other firms are allowed to copy the same products, there would be no monopoly and prices would automatically come down. But this price control is at the cost of innovation. Patent is therefore an imperfect but necessary instrument to encourage innovation.[33] But when monopolistic patent rights are conferred on the products which are essential for human life, they can have adverse effects on the socio-economic development of the country that grants patents. An obvious result of patents may be an increase in price and decrease in supply of the patented products as the patent holder enjoys monopoly.[34]

World Trade Organization[35] (hereinafter WTO), in its Doha Declaration[36], recognizes the right of access to affordable medicines. Life saving medicines may be beyond the purchasing power of common masses in many developing and underdeveloped countries due to patent protection enjoyed by the pharmaceutical products. The availability of life saving medicines becomes even more uncertain in case of national emergency. In such situations, the national governments may avail the flexibility provided under WTO regulations by using the provision of compulsory licensing. It may, however, be noted that a national emergency is not the only ground for the issuance of compulsory license. Doha Declaration on Public Health 2001 provides

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[33] Aidan Hollis, "The Link Between Publicly Funded Health Care And Compulsory Licensing", *CMAJ: Canadian Medical Association Journal, Vol. 167 Issue 7*, (2002),756, last accessed date February 13, 2012 , doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=28&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

[34] Jakkrit Kuanpoth, "Give The Poor Patients A Chance: Enhancing Access To Essential Medicines Through Compulsory Licensing", *Journal of Generic Medicines, Vol. 6 Issue 1*, (Nov2008), 1,last accessed date February 13, 2012, doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=27&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

[35] The World Trade Organization (WTO) is the only global international organization dealing with the rules of trade between nations. It intends to supervise and liberalize international trade. The organization officially commenced on January 1, 1995 under the Marrakech Agreement, replacing the General Agreement on Tariffs and Trade (GATT).

[36] The November 2001 Doha Declaration on the TRIPS Agreement and Public Health was adopted by the WTO Ministerial Conference of 2001 in Doha on November 14, 2001. It reaffirmed flexibility of TRIPS member states in circumventing patent rights for better access to essential medicines.

freedom to member states to determine grounds of compulsory licensing.[37] In the absence of international norms and standards for this practice, the grounds for granting compulsory licensing vary from country to country depending on laws of each state.

Compulsory licensing obviously involves breaking of the exclusive right of the patent holder. The purpose behind breaking of the patent right is to change the terms of bargaining between the buyer and the seller. For instance, if the government is a buyer and the patent holder is a seller, and the parties fail to negotiate a reasonable price of the product, compulsory licensing provisions provide for an arrangement using which the government may dilute exclusive patent right of the patent holder and license some other firm to sell the same product. Thus, compulsory licensing, by stimulating generic competition, strengthens the bargaining position of the government resulting in lowering of prices. [38]

1.3 Rationale of Compulsory Licensing

Professor Graham Dutfield[39]- a Professor of International Governance who is also associated with the Oxford Intellectual Property Research Centre at Oxford University-, notes that:

> In international law, compulsory licensing provisions arose in the late nineteenth century as a compromise between those countries that preferred to have patents revoked in cases of non-working, and other nations that were less

[37] Janodia, Manthan, Rao, J. Venkata & Udupa, N., "Correspondence", *Current Science, Vol. 91 Issue 8,* (2006),998,last accessed date February 13, 2012, doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=28&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

[38] Hollis, "The Link Between Publicly Funded Health Care And Compulsory Licensing", 765.

[39] Graham Dutfield is a Professor of International Governance at Leeds University School of Law. He is also associated with the Oxford Intellectual Property Research Centre at Oxford University.

keen to interfere with the freedom of patent holders to set up manufacturing facilities where they pleased.[40]

As regards concern for protection of IPRs, keeping in view the above statement, the countries can be divided into two groups whose behavior is totally different depending on interests of each group. It is a common observation that developing and under developed countries are not so much concerned about protection of IPRs and are not willing to spend on development of a costly administrative mechanism to enforce the protection of intellectual property rights. There are various reasons behind this intentional casual approach towards protection of IPRs.

- Firstly, by allowing piracy, developing and underdeveloped countries can ensure availability of needed goods and services to their citizens at affordable prices.
- Secondly, the local industries which produce counterfeit goods employee thousands of workers and therefore reduce unemployment.
- Thirdly, in order to advance in science and technology, third world countries need maximum access to intellectual property of advanced nations.
- Fourthly, more than 80% patents in developing and underdeveloped countries are owned by citizens of technologically advanced countries. Consequently, the governments of third world countries are not willing to

[40] Dutfield, Graham, "Delivering Drugs to the Poor: Will the TRIPS Amendment Help?", *American Journal of Law and Medicine*, *vol.34* (2008), 107-124.

spend huge amounts in developing effective administrative mechanism to enforce IPRs of citizens of advanced states.[41]

Developed countries, on the contrary, are very much concerned about protection of intellectual property rights because their progress and economic growth, to a great extent, depends on investment in research and development. Their patent system provides incentives to speed up their technological progress, enhance their productivity, and improve their world trade position by strengthening their economy.[42] In Italy, for instance, pharmaceutical research and development increased by more than 600 percent in a decade after Italy approved drug patent law in 1978.[43] A limited exclusive right must be given to the patent owner to enable them to use the invention to recover the cost of their invention and have an incentive for further inventive research. Anything that interferes with the exclusive right of the patentee would certainly discourage investment in the field of research. As the progress of advanced countries is mainly due to extensive inventive research, they are concerned about the protection of IPRs, and they oppose any interference in the exclusive rights of the patentee of the invention. [44]

As mentioned earlier, compulsory license is interference in the exclusive rights of the patentee of the invention. Incentive to innovate and create new works may be diminished as a result of compulsory licensing.[45] There must be an incentive to invent

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[41] Arnold, International Compulsory Licensing. 5.

[42] Robert Gottschalk, "Vital Speeches of the Day", 21, last accessed date February 13,2012,doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=28&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

[43] Richard J. Hunter: Hector R. Lozada: Frank Giarratano and Daniel Jenkins, "Compulsory Licensing: A Major IP Issue in International Business Today?", *European Journal of Social Sciences – Volume 11, Number 3* (2009), 376, last accessed date March 21, 2012, doi:http://www.eurojournals.com/ejss_11_3_03.pdf.,

[44] *Ibid.*

[45] *Ibid.*

because commercialization of new ideas involves money and effort.[46] The amount of royalties set by the state granting a compulsory license cannot be considered as an incentive for further research; it is no way near the potential financial benefit which the patent owner would have enjoyed on an exclusive basis.[47] Compulsory licensing is therefore opposed by many developed countries. In the United States[48], for instance, compulsory licensing is severely criticized. The countries which implement compulsory licensing provisions are criticized by the United States and the foreign multinational firms because the licensee reaps the benefits of other's research without contributing their fair share to the costs incurred on research and development.[49] If developing and underdeveloped countries do not strengthen their patent laws, pharmaceutical giants like Pfizer and Merck, and developed countries like the United States may be required to bear the cost of research and development for the rest of the world.[50]

Critics of compulsory licensing further argue that over 90 percent of the drugs included in the Essential Drugs List published by the World Health Organization (hereinafter WHO) are not protected by United States patents. Moreover, compulsory

[46] Gottschalk, "Vital Speeches of the Day",21.
[47] *Ibid* 22.
[48] United States, however, has compulsory licensing provisions in the Clean Air Act of 1970, Plant Variety Protection Act of 1970, and the Atomic Energy Act 0f 1954 and provides the remedy of compulsory licensing in antitrust cases. American courts have actually granted compulsory licenses on medical technologies in the following cases: Voda v. Cordis Corporation (2006), Innogenetics, N.V. v. Abbott Labs (2007), Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates (2009), Medtronic Somafor Danek USA, Inc. v. Globus Med., Inc. (2009), Johnson & Johnson Vision Care, Inc., v. Ciba Vision Corp., 712 F. Supp. 2d 1285 (M.D. Florida 2010), Edwards Lifesciences AG and Edwards Lifesciences LLC (2011), Plaintiffs, v. CoreValve, Inc. and, Medtronic CoreValve, LLC, Defendants. C.A. No. 08-91-GMS. United States District Court, D. Delaware, (February 7, 2011).
For details visit doi: http://www.huffingtonpost.com/james-love/open-letter-to-patent-off_b_1545232.html>, last accessed date February 13, 2012.
[49] Arnold, International Compulsory Licensing, 5.
[50] Jenkins, Compulsory Licensing, 376.

licenses may raise safety concerns[51]; the consumers of counterfeit products are at risk because the inferior quality unapproved generics may contain many dangerous impurities. Furthermore, there are many diseases which are unique to the third world countries. If patent protection is ensured in these countries, it would provide an incentive to multinationals to invest in the research to investigate these diseases which would otherwise remain incurable; multinational pharmaceutical companies carry out investment on research and development after considering the potential financial gain. Uncertainty about patent protection may halt search for new drugs much needed by third world countries. Whereas compulsory licensing has an adverse effect in this regard because it, by eroding patent rights, reduces research and development activities in the third world countries. Absence of business friendly legal climate may discourage patent owning firms to start any new ventures in a country that makes use of compulsory licensing provisions.[52]

In addition to this, use of compulsory license may cause trade friction with the countries which produce patented drugs. Actual occurrence of compulsory licensing is not necessary to cause this loss; sometimes even the fear of compulsory licensing has an adverse effect on trade relations between countries.[53] Moreover, the decision of a

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[51] Lamb, "Compulsory Licensing: A Necessary Evil?", *Pharmacy Times*, (2007), 57, last accessed date February 13,2012,doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=34&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

[52] Robert C. Bird, "Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effects", *Journal of Law, Medicine & Ethics, Vol. 37 Issue 2*, (2009), 210,last accessed date February 13,2012, doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=29&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

[53] Richard Holbrooke & Alan F. Holmer, "Applying U.S. Antitrust's "Rule of Reason" to TRIP's Compulsory Licensing Provision", *New England Law Review, Vol. 36:3*, 697, last accessed date February 13, 2012,doi:http://www.nesl.edu/userfiles/file/lawreview/vol36/3/kripapuri.pdf.

government to grant compulsory licenses may lead to the loss of foreign direct investment. In order to protect their products from compulsory licensing, the pharmaceutical companies may find a different venue for their clinical trials. As a result of weak intellectual property regime, a country becomes less competitive, and brain drain is an obvious result. It becomes nearly impossible for such countries to retain their human capital; the talented scientists and researchers leave the country in search of better opportunities elsewhere in the world.[54]

Another important argument against compulsory licensing of pharmaceuticals is that the pharmaceutical companies normally lower prices, even to the extent of mere cost of production, of their much needed products in the least developed countries on humanitarian considerations.[55] Thus, in the opinion of developed countries, compulsory licensing is neither an effective nor necessary cost controlling measure.

This does not mean that there are no arguments in favor of compulsory licensing. Some are as under;

- Firstly, patents, especially on pharmaceuticals, are harmful to developing and underdeveloped countries lacking their own domestic and technical infrastructure; patents may become an impediment in economic growth of such countries and availability of necessities to population of such countries. Threat of non-voluntary licensing may be helpful in negotiating a reasonable price of the needed drug acceptable to both the patent owner and the government.[56]

[54] Jakkrit Kuanpoth, "Proceed With Caution On Compulsory Licensing", (2011), 1, last accessed date February 13, 2012,doi:http://www.tilleke.com/sites/default/files/informed_counsel_vol2_no1_p3.pdf.
[55] Lamb, "Compulsory Licensing: A Necessary Evil?", 57.
[56] Kuanpoth, "Give The Poor Patients A Chance",, 26.

- Secondly, opposition of compulsory licensing by advanced countries may raise thoughts of 'neocolonialism'[57] because patent protection disproportionately favors advanced countries as developing countries have much fewer patents to protect.
- Thirdly, compulsory licensing of pharmaceutical patents sometimes becomes inevitable to save lives of the populace by ensuring accessibility of drugs at affordable prices; it can be used to break up monopolies and cartels, which are some of the abuses of patent rights.[58]
- Fourthly, apart from economic arguments, use of compulsory licensing to protect the public interest can be defended on social justice grounds; strict adherence to patent protection can hardly be recommended at the cost of human lives.
- Fifthly, compulsory licensing becomes inevitable to deal with the situations of 'patent suppression'[59]. By incorporating an effective mechanism of compulsory licensing, governments of developing countries may pressurize the patent holders to work the patent to maximum national advantage.[60]
- Sixthly, compulsory licensing might be necessary in situations where its refusal may prevent utilization of another important invention which can be significant for technological advancement or economic growth.

[57] Neocolonialism is the practice of using capitalism, globalization, and cultural forces to control a country (usually former European colonies in Africa or Asia) in lieu of direct military or political control. Such control can be economic, cultural, or linguistic.
For details visit doi:http://en.wikipedia.org/wiki/Neocolonialism, (Last accessed date April 10, 2012).
[58] Jenkins, "Compulsory Licensing: A Major IP Issue in International Business Today?", 371.
[59] Patent suppression is a situation in which a patent owner is unwilling to work his invention
[60] Kuanpoth, "Intellectual property and access to essential medicines: Options for developing countries",58.

- Seventhly, the proponents of compulsory licensing argue that compulsory licensing does not discourage research and development because the costs incurred on research are recovered from sales of the patented products in the advanced states of the world having stringent patent protection.[61]
- Eighthly, it is argued that compulsory licensing plays a vital role in developing and fostering a local generic pharmaceutical industry.
- Ninthly, sometimes delay in development of important technology is caused due to deadlocks between the improver and the original patentee. For instance, "holdup problems"[62] occurred in the Wright Brothers[63] and Marconi[64] cases. Similarly, the broad Edison lamp patent[65] slowed down progress in the incandescent lighting field. Compulsory licensing can be used as an effective tool to resolve these deadlocks by pressurizing the original patentee to come to the terms of an agreement with the improver.[66] It can therefore help in generating rapid technical progress.[67]

Despite criticism and drawbacks of compulsory licensing, the right of sovereign states to grant a compulsory license has been effectively recognized at international level. Since patent is a privilege granted to the patent holder by the state, government of the

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[61] Jain, "Compulsory Licenses Under Trips and Its Obligations for Member Countries", 47.

[62] In economics, the hold-up problem is a situation where two parties (such as a supplier and a manufacturer or the owner of capital and workers) may be able to work most efficiently by cooperating, but refrain from doing so due to concerns that they may give the other party increased bargaining power, and thereby reduce their own profits.
For details visit doi:http://en.wikipedia.org/wiki/Hold-up_problem, (Last accessed date April 10, 2012)

[63] U.S Centennial of Flight Commission, "Glenn Curtiss and the Wright Patent Battles".

[64] Guglielmo Marconi, "Patent Disputes", For details visit doi:http://sciencep613.blogspot.com/2007/10/patent-disputes.html, (Last accessed date April 10, 2012).

[65] "U.S. Supreme Court Centre, The Incandescent Lamp Patent", *159 U.S. 465 (1895)*, For details visit doi:http://supreme.justia.com/cases/federal/us/159/465/, (Last accessed date April 10, 2012)

[66] Joseph a. Yosick, "Compulsory Patent Licensing For Efficient Use Of Inventions", *University Of Illinois Law Review*, (2001),1298, last accessed date March 29, 2012, doi:http://www.brinkshofer.com/files/107.pdf.,

[67] Arnold, "International Compulsory Licensing: The Rationales And The Reality", 11.

state can therefore limit that privilege in certain situations. This is the basic rationale for compulsory licensing.[68] The Paris Convention 1883[69] provides:

> Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.[70]

More than 170 countries have ratified this treaty. The United States -a proponent of strong patent protection and a long-time critic of compulsory licensing- is also a party to this treaty. Apart from this theoretical approval of compulsory licensing at international level, practically it has been used even in the United States[71] in a wide variety of areas. In the bio-tech industry, for instance, the United States government has diluted many key patents by granting compulsory licenses to other bio-tech and pharmaceutical companies. The United States Army also makes use of compulsory licensing in such areas as satellite technology and night vision glasses. 'Public policy' or 'national security' is normally cited as ground for grant of these compulsory licenses.[72]

Similarly, in October 2001, in the wake of terrorism attack, the USA, in order to ensure availability of ciprofloxacin for anthrax patients, was forced to use the threat of

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[68] *Ibid* 28.

[69] The Paris Convention for the Protection of Industrial Property, signed in Paris, France, on March 20, 1883, was one of the first intellectual property treaties. It established a Union for the protection of industrial property. The Convention is still in force as of 2011.

[70] Jenkins, "Compulsory Licensing: A Major IP Issue in International Business Today?", 371.

[71] Foster v. American Machine and Foundry Company, 492 F. 2d 1317, (2d Cir. 1974),
City of Milwaukee v. Activated Sludge, 69 F. 2d 577 (7th Cir. 1934),
Nemey v. New York, New Haven. And Hartford Railroad Company, 83 F. 2d 409 (2d Cir. 1936),
There are some of the cases in which US Courts granted compulsory licenses. (Nemey and Activated Sludge are public interest cases)
For details visit doi: http://law.justia.com/cases/federal/appellate-courts/F2/492/1317/321829/, (Last accessed date April 10, 2012).

[72] *Ibid.*

compulsory licensing against Bayer[73]. Prior to Bayer's deal with the U.S. government for supplies of its Ciprofloxacin anthrax antibiotic, Canada had decided to break Bayer's patent and buy the drug from a generic drug manufacturer. Though Canada suddenly reversed its decision yet Bayer could anticipate the use of compulsory license by the US government in case of failure to supply the needed antibiotic.[74]

National laws of the majority of states provide for compulsory licensing in certain conditions. Municipal laws govern the substantive and procedural requirements with regards to non-voluntary licensing. Normally, the authority to grant a compulsory license lies with the executive branch in most of the countries; in some countries, it lies with the judiciary. Municipal laws normally permit companies, research institutions and non-governmental organizations to apply for compulsory licensing. The applicant is required, in some countries, to prove that they are economically and technically competent enough to utilize the compulsory if it is issued. The applicant should mention specific grounds for the issuance of non-voluntary license in order to convince the authorities that the compulsory license is justified in the given conditions. Furthermore, the application should specify the legal provision under which non-voluntary license is being sought. [75]

1.4 Grounds for the Issuance of Compulsory License

As regards grounds for the issuance of non-voluntary license, as mentioned earlier, Article 5 of the Paris Convention stipulates:

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[73] Bayer AG is a chemical and pharmaceutical company founded in Barmen, Germany in 1863. It is well known for its original brand of aspirin.

[74] Durojaye, "Compulsory Licensing And Access To Medicines In Post Doha Era: What Hope For Africa?", 49.

[75] Carlos María Correa, "Compulsory Licensing: How to Gain Access to Patented Technology", *Handbook Of Best Practices, 275*,last accessed date February 13, 2012, doi:http://www.iphandbook.org/handbook/chPDFs/ch03/ipHandbook-Ch%2003%2010%20Correa%20Compulsory%20Licensing.pdf.

> Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.[76]

Therefore, under Article 5 of the Paris Convention, there is only one ground for the issuance of non-voluntary license i.e. to prevent the misuse of exclusive rights enjoyed by the patent holder. Whereas, Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter TRIPS[77]) has not confined itself to just one ground for the issuance of non-voluntary license. Article 31 of the TRIPS Agreement leaves it to states to decide grounds for issuance of non-voluntary licenses in their municipal patent laws. Grounds for grant of compulsory licensing therefore vary from state to state. Article 31 (b) of TRIPS Agreement refers to conditions for the grant of non-voluntary license. Article 31 (b) of TRIPS Agreement reads as:

> 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 national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In 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

[76] Jenkins, "Compulsory Licensing: A Major IP Issue in International Business Today?", 371.
[77] The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the World Trade Organization (WTO) that sets down minimum standards for many forms of intellectual property (IP) regulation as applied to nationals of other WTO Members. It was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994.

or will be used by or for the government, the right holder shall be informed promptly.[78]

Generally, a WTO member country is required to negotiate with the owner of the patent on rational and practical business terms in order to reach an agreement. But Article 31 (b) dispenses with this procedural requirement of negotiation with the patent holder before invoking compulsory licensing provisions. The WTO member country may dispense with this procedural requirement in certain cases namely "national emergency or other circumstances of extreme urgency or in case of public non-commercial use".[79]

TRIPS Agreement does not define national emergency and other circumstances of extreme urgency. Member states have been given latitude to decide what constitutes a national emergency or other circumstances of extreme urgency. Normally, public health crisis like inadequate access to HIV[80]/AIDS[81] vaccines and/or outbreak of epidemics like malaria and tuberculosis and the like or emerging diseases like bird flue constitute such circumstances in which compulsory licensing may be used. But states may interpret 'national emergency' broadly. US, for instance, may grant compulsory licenses for pollution control; Russia may grant a compulsory license for any invention of special importance to the state; Switzerland may grant a compulsory license simply to control prices.

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[78] Article 31 (b) of the TRIPS Agreement, available online on WTO website <http://www.wto.org/english/tratop_e/trips_e/t_agm3_e.htm>, (last accessed date March 18, 2012)

[79] Kevin Outterson, "Disease-Based Limitations On Compulsory Licenses Under Articles 31 And 31BIS", *Boston University School of Law, 3*,last accessed date February 13, 2012, doi:http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1407522,

[80] HIV (human immunodeficiency virus) is the virus that causes AIDS. This virus is passed from one person to another through blood-to-blood and sexual contact. In addition, infected pregnant women can pass HIV to their baby during pregnancy or delivery, as well as through breast-feeding.

[81] AIDS (acquired immune deficiency syndrome) is the final stage of HIV disease, which causes severe damage to the immune system.

As a result of this broad interpretation of 'national emergency' states use compulsory licensing as a tool to compel the owner of the patent to dilute his exclusive right if the state that had granted the patent does not approve of the use of that patent. However, states normally take into account different factors while granting a compulsory license. There are economic and social justice issues that must be considered; unnecessary use of compulsory licensing may aggravate the situation and 'national emergency' may convert into even deeper emergency.[82]

TRIPS Agreement is criticized by many commentators because its language is vague concerning the meaning of the word reasonable. Moreover, it allows the individual nation to decide what constitutes a national emergency. By not involving any third party fact-finder in the determination of a national emergency, the TRIPS Agreement provides the signatory states an opportunity to interpret Article 31 broadly. As a result, the relaxations provided by the Agreement may not always be used in good faith for attainment of a public good as intended by the Agreement. States may even use these relaxations as a tool to circumvent the patent law to expand their industry and business in certain new fields like generic pharmaceutical industry. [83]

Similarly, the term public non-commercial use is fairly vague and it has no standard meaning in patent law. The term public non-commercial use, if read in isolation, appears open ended. But a careful reading of the Article 31 (b) of the TRIPS Agreement establishes that the term public non-commercial use can be best defined as 'use by the government' or 'government use' because Article 31 (b) itself describes public non-

[82] Holmer, "Applying U.S. Antitrust's "Rule of Reason" to TRIP's Compulsory Licensing Provision", 692.
[83] Jenkins, "Compulsory Licensing: A Major IP Issue in International Business Today?", 373.

commercial use as use by the government or contractor.[84] A state may authorize a government or a private enterprise to manufacture or import or supply essential pharmaceuticals on a no profit no loss basis to meet the public needs.[85]

In the absence of uniform international norms and standards, the grounds for grant of a compulsory licensing vary from country to country. Apart from the aforementioned situations, countries may grant a compulsory license on various other grounds. For instance, non-working or inadequate working or misuse of the exclusive rights by the owner of the patent may be used as a ground for the issuance of non-voluntary license; it is an obligation of the owner of the patent to work the patented innovation in the state which granted patent and ensure availability of sufficient quantities of the patented product at a reasonable price to meet the domestic demands of the country which granted the patent. If he fails to carry out his obligation, the granting state may dilute his patent.[86]

Moreover, if the patent holder engages in anti-competitive practices, like abuse of monopoly rights to fix unreasonable prices, entering into collusive agreements with enterprises, forming cartels and the like, that the state may dispense with the procedural requirement of prior negotiation with the patent owner before grant of non-voluntary license.[87]

It must be noted that, under Article 31(g) of the TRIPS Agreement, a non-voluntary license may be terminated as soon as the excuse which was used by the granting state to issue a compulsory license no longer exists. A compulsory license is

[84] Pier De Roo, "Public Non-Commercial Use Compulsory Licensing For Pharmaceutical Drugs In Government Health Care Programs", *Michigan Journal of International Law, Vol. 32:347,* (2011),389, last accessed date March 29, 2012,*doi:* http://students.law.umich.edu/mjil/uploads/articles/v32n2-deroo.pdf.
[85] Kuanpoth"Intellectual property and access to essential medicines: Options for developing countries", 57.
[86] This provision is in accordance with Article 8 of the TRIPS Agreement and Article 5 of the Paris Convention.
[87] Kuanpoth, "Intellectual property and access to essential medicines: Options for developing countries", 57.

therefore not permanent and is exposed to termination on end of circumstances which led to its granting.[88]

1.5 Historical Background of Compulsory Licensing

1.5.1 Pre-WTO Period

Patents have been an important part of intellectual property even before the eighteenth century. However, traditionally, for most of the states enforcement of patent laws was not a priority and consequently they had weak patent regimes. In the 1980s, when the technology-focused industries grew in the advanced world, intellectual property emerged as a trade concern and states started to realize the importance of enhanced global intellectual property protection.[89]

Prior to international conventions and in the absence of any centralized international agency to govern intellectual property rights, the inventors would disclose their inventions to foreign countries upon patenting them in their own country and had to comply with different procedural rules of each country to protect their use in the foreign countries. Patent holders had to maintain their patent agents in each country to protect their interests. Therefore need of international conventions on this subject was felt. Vienna Congress of 1873 was the first international patent convention. The convention not only endorsed the principle of patent protection but also allowed compulsory licensing in situations where the public interest should require it. However, this convention, prescribing only minimum standards, was not popularly accepted.[90]

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[88] Durojaye, "Compulsory Licensing And Access To Medicines In Post Doha Era: What Hope For Africa?", 49.
[89] Bird, "Developing Nations and the Compulsory License", 210.
[90] Holmer, "Applying U.S. Antitrust's "Rule of Reason" to TRIP's Compulsory Licensing Provision", 674.

Prior to World Trade Organization (WTO), World Intellectual Property Organization (hereinafter WIPO[91]), established in 1967 with an aim to protect intellectual property and to encourage the creative activity, was sole centralized international agency that governed intellectual property rights. The WIPO's aim is to bring harmony in intellectual property legislation and procedures of member states.[92] Under the WIPO regime, not only various new treaties were concluded but also some old treaties were revised keeping in view the advancements in technology. Paris Convention for the Protection of Industrial Property[93] and Berne Convention for the Protection of Literary and Artistic Works are the most notable out of these treaties. Former was originally concluded in 1883 and the latter was originally concluded in 1886. The primary objective of the Paris Convention was to develop a system at international level using which inventors could protect their innovations globally. Article 5(A)(2) of the Paris Convention provided for involuntary licensing in order to prevent abuse of exclusive patent rights.[94] On a similar footing, Article 11 of the Berne Convention provided for compulsory licensing in case of broadcasting and related rights. Similarly, Article 13 of the Berne Convention provided for compulsory licensing in case of recording of musical works.[95]

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[91] World Intellectual Property Organization, "The Global IP Recource", available online doi: http://www.wipo.int/portal/index.html.en.(Last accessed date April 1, 2012).

[92] Joseph a. Yosick, "Compulsory Patent Licensing For Efficient Use Of Inventions", *University Of Illinois Law Review,* (2001), 1248, last accessed date March 29, 2012,doi:http://www.brinkshofer.com/files/107.pdf.

[93] Full text of Paris Convention is available online at doi:http://www.wipo.int/export/sites/www/treaties/en/ip/paris/pdf/trtdocs_wo020.pdf. (last accessed date March 29, 2012)

[94] "Is Article 31BIS Enough? The Need To Promote Economies Of Scale In The International Compulsory Licensing System", *Temple Int'l & Comp. L.J.,* (2008), 166, Last accessed date April 1, 2012,doi: http://www.temple.edu/law/ticlj/ticlj22-1Gumbel.pdf.

[95] Jain, "Compulsory Licenses Under Trips and Its Obligations for Member Countries", 31.

Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations 1961 is another important treaty in this regard. Rome Convention recognizes the grant of compulsory licensing without mentioning any conditions for the grant thereof. Article 15 of the Convention merely states that "Compulsory licenses may be provided only to the extent to which they are compatible with this Convention"[96] Although ambiguities are there in these conventions yet they show that the concept of compulsory licensing was recognized in the intellectual property rights conventions well before TRIPS Agreement.[97]

In order to centralize international trade issues, the General Agreement on Trade and Tariffs was created in the 1940s. The GATT is an international agreement with 92 states as contracting parties. These states participate in multilateral trade negotiations with an aim to expand international trade, raise world welfare by reducing uncertainty associated with commercial transactions between different states, and to prevent economic discrimination between nations.[98] Under GATT, further trade negotiations were held in Uruguay between 1986 and 1994. As a result of these rounds, World Trade Organization was established as a separate and viable organization with members from developed, developing and least developed nations. GATT deals with trade in goods, whereas WTO deals with trade in services and intellectual property related to trade and investment issues.[99]

[96] Article 15(2) of the Rome Convention
[97] Jain, "Compulsory Licenses", 32.
[98] Arnold, "International Compulsory Licensing", 14.
[99] Holmer, "Applying U.S. Antitrust's Rule of Reason", 675.

1.5.2 Post-WTO Period

Post-WTO period saw much more rapid progress with regards to intellectual property laws in general and compulsory licensing in particular. Some of the important developments are briefly discussed as under:

1.5.2.1 TRIPS Agreement

The WTO, in December 1994, approved an important treaty the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) which came into effect on January 1, 1995. Primary objective of TRIPS Agreement was to minimize the distortions and impediments to global trade by giving due importance to protection of IPRs.[100] It provided for minimum standards to harmonize divergent domestic laws of the WTO member countries and provided mandatory rights for right holders.[101] It required all WTO member states to adopt regulations relating to IPRs as laid down in the treaty.[102]

The TRIPS Agreement, under Article 27(1), provides that the signatory states are obliged to protect any innovations, whether products or processes, in all fields of technology. Before 1995, when TRIPS Agreement was not concluded, almost 50 countries had excluded drugs from patentability.[103] But TRIPS Agreement prohibited any such exclusion.[104] To enjoy protection, the invention must fulfill three conditions namely,

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[100] Arnold, "International Compulsory Licensing", 14.
[101] Kuanpoth, "Give The Poor Patients A Chance", 17.
[102] Jenkins, "Compulsory Licensing", 371.
[103] William Ebomoyi, "Impact Of Globalization on Hiv/Aids Pandemics and the Challenges of Compulsory Licensing and Parallel Importation", *Journal of Applied Global Research, Vol. 3 Issue 7,* (2010), 36, last accessed date February 13,2012,doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=26&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13>,
[104] John H. Barton, "TRIPS And The Global Pharmaceutical Market Health Affairs", *Vol. 23 Issue 3,* (2004),147, last accessed date February 13,2012,doi:

"it must be new, it involves an inventive step, and it is capable of industrial application"[105]. Moreover, TRIPS Agreement, under Article 28, provides the patent holders exclusive rights to prevent third parties from making, using, offering for sale, selling or importing patented products without consent of the patent holder.[106] These monopoly rights are provided to the patent holders for a period of twenty years.[107]

Keeping in view the practical implications of patent protection in third world countries, TRIPS Agreement provides mechanisms to poorer countries to override patents through legitimate means. It contains arrangements such as 'parallel importation'[108] and 'compulsory licensing' which are exceptions to the stringent patent protection.[109] Even though the word 'compulsory license' has never been used in the TRIPS Agreement, the exclusive rights to the owner of patents are specifically subject to compulsory licensing under the Agreement. Article 30 of the TRIPS Agreement provides:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably prejudice the

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http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=34&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

[105] Benjapol Kongsombut, "Patent search options for technology firms", *Bangkok Post*, (May, 2012),last accessed date May 21, 2012,doi: http://www.tilleke.com/sites/default/files/2012-may18-patent-search-options.pdf.

[106] Article 28(1)(a) of the TRIPS Agreement

[107] Jain, "Compulsory Licenses", 33.

[108] A parallel import is a non-counterfeit product imported from another country without the permission of the intellectual property owner. Parallel imports are often referred to as 'grey product'. The practice of parallel importing is often advocated in case of software, music, printed texts, and electronic products and occurs for several reasons. It involves bringing in products from a third party in another country at relatively inexpensive price. The companies set different prices for the same product in different countries. The purchaser from a third party other than the manufacturer can take advantage from this fact. For instance, according to a study in 1998, the price of Smithkline Beechman's version of Armoxil was $8 in Pakistan, $14 in Canada, $16 in Italy, $22 in New Zealand, $29 in the Philippines, $36 in Malaysia, $40 in Indonesia, and $50 in Germany. Certainly, the actual production cost is same for any market but the logic of price difference is to allow an elevated price to recover costs of research and development from the developed world. There may be various other reasons for price difference in different countries.
For more details, visit <http://en.wikipedia.org/wiki/Parallel_import> (Last accessed date April 11, 2012)

[109] Durojaye, "Compulsory Licensing And Access To Medicines", 35.

legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[110]

Under Article 31, TRIPS Agreement provides an exception to the monopoly rights of patent owners.[111] Instead of listing or defining situations in which compulsory license may be granted, it only sets out certain conditions for the issuance of non-voluntary license. Leaving the matter to the signatory states, TRIPS Agreement imposes safeguards to avoid abuse of rights. The specific terms therefore vary from country to country. The signatory states decide each case of granting a compulsory license on case-by-case basis. It would be against the essence and spirit of Article 31 of TRIPS Agreement if a person becomes legally entitled to get a compulsory license automatically upon fulfillment of certain conditions.[112]

There is a condition that proposed user must have made reasonable commercial efforts to negotiate with the owner of the patent for permission to use the patent for a reasonable period of time.[113] However, this condition of prior negotiation with the owner of the patent may be dispensed with in the cases of national emergency, or situations of extreme urgency, or for public non-commercial use. These exceptions have been discussed before.

The TRIPS Agreement makes a provision that the owner of the patent must be provided an adequate royalty as a matter of right.[114] Remuneration is decided on the case-by-case basis depending on the economic value of the authorization. In order to determine whether or not any decision of granting a compulsory license was legally valid and to provide an opportunity to the patent owner to prevent abuse of his right, TRIPS

[110] Article 30 of the TRIPS Agreement
[111] Holmer, "Applying U.S. Antitrust's Rule of Reason", 676.
[112] Jain, Compulsory Licenses,33.
[113] Article 31(b) of the TRIPS Agreement
[114] Article 31(h) of the TRIPS Agreement

Agreement obliges the signatory states to a judicial review or other independent review.[115] The reviewing authority must be a higher one having the power to reverse, vary or annul the original decision of the license granting authority.

There is also a provision in the TRIPS Agreement which allows compulsory license in the case of dependant patents. "A dependent patent is one that can be used only after infringing an earlier existing patent."[116] Consequently, both parties cannot make effective use of the innovation; invention of the second party violates patent of the first party and first party is also barred from using the second party's improved innovation. Therefore the improved invention would not be used if the parties fail to reach a licensing agreement. As a result, the community would not be able to reap the fruits of the innovation. Compulsory licensing provisions may be invoked to force the parties to either allow use of the patent after receiving remuneration agreed upon between the parties or cross-license their patents to ensure working of the patent.[117]

It must be noted that an extended period of time was granted to the developing and least developed countries to conform to TRIPS Agreement. An extended period up to January 1, 2000 was given to developing countries during which they were not required to conform to most of the provisions of the TRIPS Agreement. The least developed countries were given an initial transition period up to January 1, 2006. In November 2005, however, the WTO member countries agreed on further extension until July 1, 2013, or to date an underprivileged state is no longer included in the category of least

[115] Article 31(i) of the TRIPS Agreement
[116] For details visit <http://www.alrc.gov.au/publications/27-compulsory-licensing/dependent-patents>, (last accessed date February 13,2012).
[117] Yosick, "Compulsory Patent Licensing", 1287.

developed countries, if that occurs before the end of the deadline.[118] A further extension in the deadline until January 1, 2016 was given to the least developed countries by the TRIPS member nations.[119]

However, for pharmaceuticals and agricultural chemicals, the TRIPS member nations that were yet to provide patent protection on January 1, 1995 were under two obligations. Firstly, these countries were under an obligation to receive patent applications from inventors from January 1, 1995; they could, however, delay their decision to grant or not to grant patent until the end of the extended period. The aforementioned obligation is under article 70, paragraph 8 of the TRIPS Agreement which is also called 'mailbox' provision because it allows states to receive and store the applications. Secondly, if a state allowed marketing of such products during the extended period, the state was under an obligation to provide exclusive marketing rights to the patent applicant for five years, or until a judgment was made on the application for the grant of patent. This obligation was, however, subject to certain conditions. This provision is found in Article 70, paragraph 9 of the TRIPS Agreement.[120]

Article 31(f) of the TRIPS Agreement puts an important limitation on the use of involuntary license. Article 31(f) of the TRIPS Agreement stipulates that "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use."[121] A narrow interpretation of this provision suggests that non-voluntary license can be used only for consumption of the product within the country. It cannot be used for export of the product manufactured under compulsory license. As a

[118] Jenkins, Compulsory Licensing, 372.
[119] Bird, "Developing Nations", 211.
[120] Jenkins, Compulsory Licensing, 373.
[121] Article 31(f) of the TRIPS Agreement

consequence, the access to essential life saving medications may remain an unattainable dream in the countries which lack pharmaceutical manufacturing capacity or ability to reverse engineer the needed pharmaceutical product.[122]

This provision has a twofold effect on developing and least developed countries. Firstly, the countries having insufficient or no manufacturing capacity cannot import drugs from countries that produce and export generic drugs, thus, denying availability of essential pharmaceuticals to their masses. Secondly, this restriction of the domestic market restricts the flexibility of developing countries which have the capacity to manufacture drugs to boost their economy by authorizing the export of compulsory licensed drugs. If a developing nation with enhanced technology such as India, Brazil, South Africa and the like has invoked compulsory licensing and is able to produce generic drugs, it still cannot supply the compulsory licensed drugs to other countries because of the domestic market limit provided in the Article 31(f).[123]

According to another interpretation of Article 31(f), the purpose of this provision may not be to prohibit the grant of compulsory licenses for the purpose of exporting the products manufactured under compulsory license, but to put a limitation on such export; it may mean that compulsory licensed goods should not be allowed to be exported in competition with the owner of the patent.[124] Article 31(f), however, remained an obstacle for underprivileged states to obtain affordable generic medicines from the developing countries which have the capacity to manufacture cheaper generics.

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[122] The manufacturing capacity here means the capacity to manufacture a specific product, and not the general capacity to manufacture pharmaceutical products.
[123] Durojaye, "Compulsory Licensing And Access To Medicines", 51.
[124] A.S. Lowenfeld, *International Economic Law*, (Oxford University Press :2002),108.

The controversy between developed and poorer countries with regards to interpretation of Article 31(f) is indicative of the fact that TRIPS provisions are not capable of exclusive interpretation.[125] This issue of limitations put by Article 31(f) was raised at Doha, Qatar in 2001.[126] However, compromise between developing and developed countries in this regard could be reached in 2003 and was adopted in WTO General Council's Decision.

Taken together, TRIPS provided relatively stringent worldwide norms of patent protection which best suited the advanced countries and research based pharmaceutical industry.[127] No doubt, TRIPS Agreement contains safeguard provisions for developing and underdeveloped countries. However, implementation in practice of these provisions has never been easy for the developing and underdeveloped countries. The developing countries managed to obtain some rights at international level; due to various factors like a threat of economic and political pressure (for instance, withdrawal of foreign aid or tariff benefits,[128] or even threat of trade sanctions from certain developed countries[129]), they have not been fully able to actually invoke and use these legal rights.

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[125] Jain, Compulsory Licenses, 48.

[126] Sreedhar Janodia, D. Ligade, V. S. Udupa, "Solution to contentious issue of Article 31(f) of TRIPS agreement",*Indian Journal of Medical Research, Vol. 128 Issue 1*, (2008), 84, last accessed date February 13,2012, doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=34&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

[127] Jerome H. Reichman, "Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options, Journal of Law", *Medicine & Ethics, Vol. 37 Issue 2*, (2009), 247, last accessed date February 13, 2012,doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=34&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

[128] Gregory Shaffer, "The Challenges of WTO Law: Strategies For Developing Country Adaptation", *World Trade Review*, (2006),193, last accessed date February 13, 2012,.doi:http://journals.cambridge.org/action/quickSearch?quickSearchType=search_combined&inputField1=The+challenges+of+WTO+law%3A+strategies+for+developing+country+adaptation&fieldStartMonth=01&fieldStartYear=1800&fieldEndMonth=12&fieldEndYear=2012&searchType=ADVANCESEARCH&searchTypeFrom=quickSearch&fieldScjrnl=All&fieldSccats=All&selectField1=%23&jnlId=&journalSearchType=all.

Ellen't Hoen, senior advisor on intellectual property for UNITAID[130], says that "while most countries' national legislation contains provisions for use of compulsory licensing, it does not mean countries use it in practice."[131] Implementation of provisions regarding compulsory licensing is fraught with challenges, heated legal battles and multiple litigations and is severely opposed and criticized not only by the developed countries but also by pharmaceutical companies.

Tedious and cumbersome procedure to obtain a compulsory license is another reason for rare use of compulsory licensing provisions. If a country wants to avail TRIPS flexibility of compulsory licensing, the judicial and administrative procedure may take nearly three years to obtain the license.[132]

It is pertinent to note that though the provisions relating to non-voluntary licensing are safeguard provisions, Article 31 of TRIPS permits all WTO member countries to issue non-voluntary licenses. Its application is not restricted to least developed or the poorest countries.[133] Practically, in most of the developed countries, general compulsory licensing provisions are rarely invoked. According to a study conducted a decade ago, Switzerland has never invoked compulsory licensing provisions;

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[129] Manthan D. Janodia, J. Venkata Rao, N. Udupa, "Differences between Begonia roxburghii A.DC and B. tessaricarpa", *Current Science, Vol. 91 Issue 8*,999, last accessed date February 13,2012, http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=28&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

[130] UNITAID is an international facility for the purchase of drugs against HIV/AIDS, Malaria and Tuberculosis. It was founded in September 2006 on the initiative of Brazil and France. The organization's principal strength is the negotiation of low prices for drugs on the basis of its strong financial means. For details visit <http://www.unitaid.eu/> (last accessed date April 16, 2012)

[131] Goldis Chami, Samuel Wasswa-Kintu, "Compulsory Licensing Of Generic Drugs Remains Mired In Quagmires", *CMAJ: Canadian Medical Association Journal, Vol. 183 Issue 11*, (2011), 705, last accessed date February 13,2012, doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=26&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

[132] Udupa, "Differences between Begonia roxburghii", 998.

[133] Outterson, "Disease-Based Limitations", 3.

Japan has invoked eight times since 1960; France invoked three times since 1953, Canada invoked general (non-pharmaceutical) compulsory licensing provisions eleven times since 1935. Compulsory licenses are granted more frequently in countries which in their national laws provide for special compulsory licensing provisions for pharmaceutical and food patents.[134] Even where compulsory licensing provisions are rarely or never used, it is reasonable to assume that the presence of such provisions has significance in the patent system. Owing to the threat of compulsory licensing, patent owners negotiate licenses that they would otherwise refuse to negotiate.

1.5.2.2 Doha Declaration on TRIPS Agreement and Public Health

'Declaration on TRIPS Agreement and Public Health' was adopted during the fourth Ministerial Conference (a meeting of the world's trade ministers) of the WTO in Doha, Qatar in November 2001 in order to deal with the issues of public health, especially the issues resulting from epidemics like tuberculosis[135], malaria and the like and the global concerns like HIV/AIDS.[136] The members agreed that TRIPS should permit WTO member countries to take measures to protect the health of their citizens.[137]

The Doha Ministerial Declaration affirmed the right of nations to use the safeguards provided under TRIPS to meet public health concerns. Moreover, it stated that public health crisis can represent a national emergency.[138] Paragraph 6 of the

[134] Gottschalk, "Vital Speeches of the Day",22.
[135] Paragraph 1 of the Doha Declaration mentions HIV/AIDS, tuberculosis, and malaria. However, it is argued that Paragraph 1 of the Doha Declaration should be interpreted broadly and generously to cover other important diseases.
[136] Jain, "Compulsory Licenses", 43.
[137] Jenkins, "Compulsory Licensing", 372.
[138] Barton, "TRIPS"149.

Declaration[139] expressly acknowledged the issue faced by the WTO member countries having no capacity to manufacture generic drugs due to the restrictions put by Article 31(f) of the TRIPS Agreement. Doha Declaration allowed member nations to take possible steps to protect public health including import of the needed drugs from other countries that had the ability and willingness to help if patent holders of pharmaceutical products had no objection.[140]

Taken together, although the purpose or intention of the Doha Ministerial Declaration was not to amend the TRIPS Agreement in any considerable manner[141], it was a victory of the developing world against the advanced world and the research-based brand-named pharmaceutical industry.

1.5.2.3 WTO General Council's Waiver Decision

Doha Declaration allowed third world countries lacking industrial capacity to manufacture drugs to import the needed drugs. But it left one important issue unsolved. If a poorer country wishes to import generic drugs produced under compulsory licensing, Article 31(f) of the TRIPS Agreement, which puts a condition of the domestic market, does not allow producers of the generic drugs to export the same.[142]

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[139]Full text of the Doha Ministerial Declaration is available online at doi:http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm, (Last accessed date April 12, 2012).

[140] Reichman, "Compulsory Licensing of Patented", 249.

[141] Carlos M. Correa, "Supplying pharmaceuticals to countries without manufacturing capacity: Examining the solution agreed upon by the WTO on 30th August", *Journal of Generic Medicines, Vol. 1 Issue 2,* (2004),117, last accessed date February 13,2012, doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=34&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

[142] Frederick M. Abbott: Rudolf V. Van Puymbroeck, "Compulsory Licensing for Public Health", *The World Bank, Washington,* (2005), 64, last accessed date February 13,2012, doi:http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2005/08/30/000012009_20050830130225/Rendered/PDF/334260rev0pub.pdf.

Due to conflicting interests of the developed and developing countries, finding an agreeable solution to this dilemma was quite difficult. On August 30, 2003, as a result of two years of negotiation, a compromise was reached and adopted as Decision of the WTO General Council.[143] This Decision[144] waives two provisions of Article 31 of the "TRIPS Agreement" viz. paragraph (f) which put 'domestic market' limitation on the generic drug exporting countries, and paragraph (h) which is regarding adequate remuneration requirement.

The waiver, however, is not absolute. It can be used to the extent necessary and subject to certain conditions. The state intending to use this waiver must be an eligible importing country i.e. either least developed[145] or a developing country with insufficient drug manufacturing capacity. Moreover, the eligible importing country must notify the Council for TRIPS along with information like name and expected quantity of the product needed and a confirmation that the country lacks manufacturing capacity and wishes to grant compulsory license under Article 31 of the TRIPS Agreement.[146] The Council will review the notification before giving approval. In cases of an outbreak of an epidemic, this condition may cause delay in the availability of the required drug. Furthermore, the quantity of drugs that can be manufactured for export under a non-voluntary license is subject to restrictions. There is a further condition on the country

[143] The General Council, which is composed of representatives of all WTO member countries, exercises the functions of the Ministerial Council when the latter is not in session, as well as other functions assigned to it under the WTO Agreement.

[144] Full text of WTO General Council's Waiver Decision is available at <http://www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf>, as Annex 1 of the document, p.33, (last accessed date April 11, 2012)

[145] List of least developed countries is available online atdoi:http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm, (Last accessed date April 13, 2012)

[146] Abbott, "Compulsory Licensing for Public Health", 10.

wishing to export compulsory licensed drugs that it would do so on a "non-commercial basis".[147]

Similarly, the exporting country shall also notify the "Council for TRIPS"[148] of the issuance of the compulsory license along with some information like the product for which compulsory license has been issued, name and address of the licensee , the quantity of the product[149], duration of the compulsory license, and the country to which the product is to be supplied.[150] In order to prevent misuse of the Waiver, the products manufactured shall be distinguished from the generics which are manufactured for domestic use. The distinction can be made through distinguishable packaging or coloring or special shape of the products.[151] This Waiver, subject to the aforementioned conditions for both the importing and the exporting countries, though tried to address the initial problem caused by Article 31(f), it seems to have created more hurdles.

1.5.2.4 Article 31bis: An Amendment to the TRIPS Agreement

The 6 December 2005 amendment in the TRIPS Agreement is based on the WTO General Council's Waiver Decision. Although the wording of the amendment is different, it contains almost the same elements as the Decision. Five paragraphs of Article 31bis[152] are compatible with the text of paragraph 2, 3, 6, 9 and 10 of the Waiver Decision.[153] The

[147] Durojaye, "Compulsory Licensing And Access To Medicines", 52.
[148] The Council for TRIPS is the body, open to all members of the WTO, that is responsible for adminstering the TRIPS Agreement, in particular monitoring the operation of the Agreement.
For details visit <http://www.wto.org/english/tratop_e/trips_e/intel6_e.htm>, (Last accessed date April 13, 2012)
[149] The objective of this condition is to discourage production and export of the product to third country markets on commercial basis.
[150] Durojaye, "Compulsory Licensing And Access To Medicines", 53.
[151] Abbott, "Compulsory Licensing for Public Health", 10.
[152] Full text of Article 31bis is available online at <http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm>, (Last accessed date April 13, 2012)
[153] Durojaye, "Compulsory Licensing And Access To Medicines", 55.

purpose of this amendment was to address the limitations and confusion surrounding Article 31(f) of the TRIPS Agreement. Article 31bis still leaves some ambiguities, for instance, it does not state formula for determining adequate remuneration.

1.6 Conclusion

Although patent encourages monopoly and overpricing, it is a necessary evil because without patent protection firms have no incentive to develop new products. Thus, patent protection is necessary to ensure innovation; the patent is therefore an imperfect but effective instrument to promote the development of new products. The pharmaceutical patent protection, however, works well only in high income countries with citizens having purchasing power to buy expensive patented pharmaceuticals. It does not work well in developing and least developed countries because of different factors, affordable access to medicines being the most important of them.

Compulsory licensing is therefore yet another necessary evil. It is a violation of the rights of the patent holder. But this violation sometimes becomes necessary in order to ensure availability of essential products at affordable prices. Compulsory licensing is an effective 'cost-cutting' and 'access-assuring' tool in the hands of developing and under developed countries which they may use to circumvent the patent laws remaining within the flexibilities provided by the WTO. Consequently, they may promote affordable availability of essential medicines for the masses who would otherwise not afford such medicines. To sum up, a compulsory license falls mid way; neither full patent protection is granted, nor is it denied altogether.

CHAPTER 2

FLEXIBILITIES UNDER TRIPS AND PRACTICAL IMPLICATIONS FOR THIRD WORLD COUNTRIES

2.1 Introduction

Fundamental human rights[154] and intellectual property rights (IPRs) are two entirely different fields of law that evolved independently. The relationship between the two entirely different fields of law became direct and obvious after the TRIPS Agreement came into effect because TRIPS provided patent protection to pharmaceuticals. Normally, intellectual property law does not give due importance to the promotion and protection of fundamental human rights. One of the reasons behind this may be the fear that taking into account of human rights would result in uncertainty of the intellectual property rights making the whole system of the IPRs protection unmanageable.

Moreover, when TRIPS Agreement was concluded, the problems faced by the third world countries, especially due to an outbreak of epidemics and pandemics, were not foreseen and public health concern was not given due importance. Consequently, states in the developing world are faced with a dilemma with pharmaceutical patent protection on one hand and access to drugs on the other hand. Higher price of drugs due to monopoly provided to the patent holders is a common concern of developing countries considering stronger IPRs protection.

[154] Human rights protect the fundamental rights of individuals and groups. Fundamental rights can be defined as entitlements that belong to all human beings by virtue of their being humans.

Instead of having mechanisms in favor of access to essential medicines in its main provisions, the TRIPS included them as exceptions. Compulsory licensing and parallel importation are two such flexibilities provided to the low-income countries. But poor countries are unable to use the legitimate flexibilities provided to them because of numerous factors, economic and political pressure being the most notable of them.

2.2 Health Care and Access to Medicines as a Human Right

Provision of public health care has been a major concern not only for the third world countries but also for developed countries.[155] Not only international treaties and conventions but also Constitutions and municipal laws of many states acknowledge the importance of a healthy life. A number of international instruments recognize the right to health as a human right.

In 1948, the United Nations Universal Declaration of Human Rights (hereinafter UDHR) asserted that "Everyone has the right to a standard of living adequate for the health and well being of himself and of his family, including food, clothing, housing, and medical care."[156] In 1966, Article 12 of the International Covenant on Economic, Social and Cultural Rights (hereinafter ICESCR) reaffirmed the right to health as a human right.[157] The right to health care has been further elaborated in the Convention on the

[155] Richard P. Rozek, "The Effects of Compulsory Licensing on Innovation and Access to Health Care",*Journal of World Intellectual Property, Vol.3, Issue 6,* 896, last accessed date February 13,2012, Doi:http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2000.tb00158.x/pdf.,

[156] Article 25(1), *Universal Declaration of Human Rights,*
For details visit <http://www.un.org/en/documents/udhr/index.shtml#a25> (last accessed date April 22, 2012).

[157] The International Covenant on Economic, Social and Cultural Rights (ICESCR) is a multilateral treaty adopted by the United Nations General Assembly on 16 December 1966, and in force from 3 January 1976. Available at, < http://www2.ohchr.org/english/law/cescr.htm>, (last accessed date April 22, 2012).

Rights of Child,[158] the Convention on Elimination of all forms of Discrimination Against Women (hereinafter CEDAW),[159] and the International Convention on the Elimination of All Forms of Racial Discrimination (hereinafter ICERD).[160]

Similarly, at national level, right to health as a human right has been recognized in the national constitutions of at least 135 states.[161] For instance, constitution of Thailand,[162] South Africa,[163] and Brazil[164] contains provisions guaranteeing a right to health care.[165] Access to essential medicines, though expressly recognized by only five countries as a prerequisite to the right to health[166], is given much importance under

[158] Article 24(1), *Convention on the Rights of Child 1989*, Available at, < http://www.unicef.org/crc/> (last accessed date April 22, 2012)

[159] Article 12(1) and Article 14(2)(b), *Convention on Elimination of all forms of Discrimination Against Women 1979*,online available at,< http://www.un.org/womenwatch/daw/cedaw/text/econvention.htm>, (last accessed date April 22, 2012).

[160] Article 5(e)(iv), *International Convention on the Elimination of All Forms of Racial Discrimination 1965*,available at doi:http://en.wikipedia.org/wiki/Convention_on_the_Elimination_of_All_Forms_of_Racial_Discrimination ,(last accessed date April 22, 2012).

[161] Dilip K. DAS, "Intellectual Property Rights and the Doha Round", *Journal Of World Intellectual Property*, (2005), 522, last accessed date February 13,2012, doi:http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2005.tb00236.x/pdf.

[162] Section 51, *Constitution of the Kingdom of Thailand*, ,last accessed date April 22, 2012,doi:http://en.wikisource.org/wiki/Constitution_of_Thailand_%282007%29/Chapter_3. It provides the right to health care.

[163] Section 27, *Constitution of South Africa*. Available at, <www.info.gov.za/documents/constitution/1996/a108-96.pdf> , (last accessed date April 22, 2012).

[164] Article 196, *Constitution of Brazil*, available online, < http://karari.org/de/node/36870> , (last accessed date April 22, 2012).

[165] Pier DeRoo, "Public Non-Commercial Use Compulsory Licensing For Pharmaceutical Drugs In Government Health Care Programs", *Michigan Journal of International Law*, (2011),364, last accessed date February 13,2012,doi:http://students.law.umich.edu/mjil/uploads/articles/v32n2-deroo.pdf.

[166] Rudolf V. Van Puymbroeck, "Basic Survival Needs and Access to Medicines – Coming to Grips with TRIPS: Conversion +Calculation", *Journal of Law, Medicine & Ethics, Vol.38, Issue3*, (2010), 522,last accessed date February 13,2012,doi: http://onlinelibrary.wiley.com/doi/10.1111/j.1748-720X.2010.00510.x/pdf.

international law as an obligation of states to protect the fundamental human right to health.[167]

States, owing to these commitments made at national and international level, are obliged to protect the health and life of their nationals.[168] States are therefore under an obligation not to interfere with the right to health care and to take all appropriate and feasible administrative and legislative measures to make sure that this is right is not violated. States should also prevent those trying to interfere with the right to health. Moreover, states, while entering into international agreements or treaties, should make sure that it would not have an adverse effect on the right to health.

Over 14 million patients of curable or preventable diseases die each year.[169] About one-third of the world's population cannot afford necessary medicines. The situation is even grimmer in the most affected regions of Asia and Africa.[170] It may be astonishing to note that about 80 percent of the world's population comprises of developing countries but they buy hardly 20 percent of world's pharmaceuticals.[171] Low

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[167] Jillian Clare Cohen-Kohler, Lisa Forman, "Addressing legal and political barriers to global pharmaceutical access: Options for remedying the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the imposition of TRIPS-plus standards, Health Economics", *Policy and Law, Vol.3,* (2008),249,last accessed date February 13,2012, doi: http://journals.cambridge.org/action/displayFulltext?type=1&pdftype=1&fid=1914284&jid=HEP&volumeId=3&issueId=03&aid=1914276.

[168] M. Rafiqul Islam, "The Generic Drug Deal of the WTO from Doha to Cancun, A Peripheral Response to a Perennial Conundrum", *Journal Of World Intellectual Property, Vol.7, Issue 5,* (2005),689, >,last accessed date February 13,2012,http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2004.tb00224.x/pdf.

[169] Third World Network, "TRIPS, Drugs and Public Health: Issues and Proposals", *Intellectual Property Rights Series, Vol.2,* (2001),4,accessed date February 13,2012, http://www.twnside.org.sg/title2/IPR/pdf/ipr02.pdf..

[170] Philippe Cullet, "Patents and medicines: the relationship between TRIPS and the human right to health", *International Affairs 79,* (2003),143,last accessed date February 13,2012, doi:http://onlinelibrary.wiley.com/doi/10.1111/1468-2346.00299/pdf.

[171] Faizel Ismail, "The Doha Declaration on TRIPSan d Public Health and the Negotiations in the WTO on Paragraph 6why P h w Needs to join the Consensus", *Journal of World Intellectual Property, Vol.6, Issue*

purchasing power of the masses in these countries may be one of the major reasons behind this. Moreover, about 90 percent people living in the developing and least developed countries (LDCs) pay for medicines from their own pocket.[172]

2.3 The Relationship between TRIPS and the Human Right to Health

Fundamental human rights and intellectual property rights are totally different from each other. While IPRs are temporary rights provided by the states to authors or inventors; such rights can be revoked or transferred by the state; whereas fundamental human rights are inalienable and timeless.[173] Though human rights law and intellectual property law have mainly evolved independently, the relationship between the two entirely different fields of law is increasingly becoming direct and obvious because of pharmaceutical patents.[174]

The fact remains though that intellectual property law does not give due importance to the promotion and protection of fundamental human rights. The term 'human rights' can hardly be seen in the intellectual property treaties and most of the advocates and scholars of intellectual property rights are alien to the fundamental human rights principles. One of the reasons behind this may be the fear that taking into account of human rights would result in uncertainty of the intellectual property rights making the whole system of the IPRs protection unmanageable.[175]

3, (2003),395,last accessed date February 23,2012, doi: http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2003.tb00221.x/pdf.

[172] Puymbroeck, "Basic Survival Needs", 539.

[173] Cullet, "Patents and medicines", 152.

[174] *Ibid* 139.

[175] Hans Morten Haugen, "Patent Rights and Human Rights: Exploring their Relationships", *Journal of World Intellectual Property Vol. 10, Issue. 2,* (2007),114, last accessed date February 23,2012,doi:http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2007.00316.x/pdf.

TRIPS Agreement –one of the most comprehensive treaties on intellectual property rights- introduced a strict legal regime for the protection of IPRs. IPRs protection is particularly more important in the pharmaceutical industry in order to enable pharmaceutical industry to recoup its investment and development cost and to provide incentive for further innovation and research. To develop new successful molecules is a costly process which involves a lot of spending on research and development[176]. Patents are therefore considered lifeblood of the pharmaceutical industry.[177]

TRIPS Agreement provided protection to patents in all fields of technology, including pharmaceuticals for a period of twenty-years.[178] Moreover, though WTO Agreements are meant to foster free trade, patent protection under TRIPS has trade restrictive implications; it not only increases the price of imported patented pharmaceuticals but also reduces the level of their trade flows.[179]

Prior to TRIPS, pharmaceuticals were excluded from patent protection in domestic laws of about fifty countries. Even many of the present world's developed countries excluded pharmaceutical products from patent protection prior to TRIPS, For instance, "Germany until 1968, Switzerland until 1977, Italy until 1978, Norway,

[176] Cullet, "Patents and medicines", 141.

[177] William W. Fisher III and Cyrill P. Rigamonti, "The South Africa AIDS Controversy A Case Study in Patent Law and Policy", *Law and Business of Patents, Harvard Law School*, (2005),5, last accessed date March 13,2012,doi: http://cyber.law.harvard.edu/people/tfisher/South%20Africa.pdf.

[178] Sandra Bartelt, "Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health", *Journal Of World Intellectual Property, Vol.6, Issue 2,* (2003), 283,last accessed date February 23,2012,doi:http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2003.tb00202.x/pdf.

[179] Islam, "The Generic Drug Deal",690.

Portugal and Spain until 1992, Finland until 1995".[180] TRIPS forced all countries to provide patent protection to pharmaceuticals.[181] However, keeping in view the problems of developing and under developed countries, they were provided extended period for compliance with the new obligations.

Nevertheless, States in the developing world are faced with a dilemma with pharmaceutical patent protection on one hand and access to drugs on the other hand. Higher price of drugs due to monopoly provided to the patent holders is a common concern of developing countries considering stronger IPRs protection.[182] When TRIPS Agreement was concluded, the problems faced by the third world countries, especially due to an outbreak of epidemics and pandemics, were not foreseen and public health concern was not given due importance.

Towards the end of 1990s, with the outbreak of HIV/AIDS pandemic,[183] especially in Africa, the relationship between access to medicines and TRIPS Agreement was discussed at World Health Organization (WHO) and World Intellectual Property Organization (WIPO) in order to address the problems faced by the developing world.[184]

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[180] F M Scherer: Jayashree Watal, "Post-Trips Options for Access to Patented Medicines in Developing Countries", *Commission on Macroeconomics and Health*, (2001), 4,last accessed date March 23,2012, doi: http://www.icrier.org/pdf/jayawatal%20.pdf.

[181] Puymbroeck, "Basic Survival Needs", 525.

[182] Richard P. Rozek, "The Effects of Compulsory Licensing on Innovation and Access to Health Care", *Journal of World Intellectual Property, Vol.3, Issue 6,* (2000),892, last accessed date March 23,2012,doi:http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2000.tb00158.x/pdf.

[183] A pandemic is an epidemic of infectious disease that spreads through human populations across a large region: for instance multiple continents, or even worldwide. For details visit <http://en.wikipedia.org/wiki/Pandemic>, (last accessed date April 23, 2012).

[184] Jacques H.J. Bourgeois, "Thaddeus J. Burns, Implementing Paragraph 6 of the Doha Declaration on TRIP Sand Public Health The waiver Solution", *Vol.5, Issue 6,*(2005), 836, last accessed date March 23,2012,doi:http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2002.tb00184.x/pdf.

Public health concern as a political priority emerged for the first time at international level.[185]

In 2001, the United Nations Sub-Commission on Human Rights[186] recognized that "there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other."[187] The World Intellectual Property Organization (WIPO) also says that "conflicts may exist" between the two.[188] Doha Declaration 2001 and WTO General Council's Waiver Decision of 2003 were the result of the efforts of the representatives of third world countries who raised their voices at 2001 WTO ministerial conference.

Thus, changes were made in the TRIPS obligations to provide more flexibility to the poorer countries and to increase the safeguards that countries could use remaining within TRIPS obligations to improve public health care. But whether the changes were substantial or cosmetic and to what extent the third world countries have been able to use these flexibilities and mechanisms is a debatable issue. The human rights impact depends on how the developing countries practically use the safeguards provided under TRIPS Agreement.[189]

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[185] Robert Bird: Daniel R. Cahoy, "The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach", *American Business Law Journal, Vol.45, Issue 2*, (2008), 286, last accessed date March 23,2012,http://onlinelibrary.wiley.com/doi/10.1111/j.1744-1714.2008.00056.x/pdf.

[186] See Resolution 2001/21, *Intellectual Property And Human Rights*, United Nations Sub-Commission on Human Rights, UN Doc. E/CN.4/Sub.2/RES/2001/21 (2001),doi: http://www.unhchr.ch/huridocda/huridoca.nsf/%28Symbol%29/E.CN.4.SUB.2.RES.2001.21.En?Opendocument, (last accessed date April 24, 2012).

[187] DeRoo," Public Non-Commercial Use", 364.

[188] Haugen, "Patent Rights and Human Rights",97.

[189] *Ibid*,101.

The private and philanthropic sectors have been actively working for increasing availability of essential medicines in the most affected regions of the third world. The Bill and Melinda Gates Foundation[190] AIDS program in Botswana is just one example. There are various instances where even the much criticized pharmaceutical companies have made non-profit investments on humanitarian grounds. The first AIDS hospital and the first AIDS laboratory constructed by Bristol Myer-Squibb Philanthropy[191] in Botswana (Africa), Pfizer's[192] initiative to build the first Infectious Disease Institute in Uganda, the Institute for Tropical Diseases (NITD) built by Novartis[193] in Singapore, and the AIDS Hospital built by Abbott Laboratories[194] in Tanzania are some of the examples.[195]

No doubt, these initiatives are providing access to health care to a limited number of people in some parts of the third world but only philanthropic work is no solution to the problem of access to essential medicines. Some substantial steps must be taken both at national and global level to overcome the barriers to access to necessary drugs.

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[190] The Bill & Melinda Gates Foundation is the largest transparently operated private foundation in the world, founded by Bill and Melinda Gates. The primary aim of the foundation is to enhance healthcare and reduce extreme poverty. For further details visit <http://www.gatesfoundation.org/press-releases/Pages/comprehensive-hiv-aids-partnership-000710.aspx>, (last accessed date April 25, 2012).

[191] Bristol-Myers Squibb Philanthropy, "An Introduction To Secure The Future", last accessed date April 25, 2012http://www.securethefuture.com/our_experience/commitment.shtml.

[192] Pfizer, "Global Health Infectious disease", *The world's largest research based Pharmaceutical company*, last accessed date April 25, 2012,doi: http://www.pfizer.com/responsibility/global_health/%20infectious_diseases_institute.jsp.

[193] Novartis Global, "Access to Health Care",doi:http://www.novartis.com/corporate-responsibility/access-to-healthcare/index.shtml, (last accessed date April 25, 2012).

[194] Abbot Laboratories, "Global Health Care & Medical Research", last accessed date April 25, 2012,doi:http://www.abbott.com/index.htm.

[195] Alec Van Gelder : Philip Stevens, "The Compulsory License Red Herring", *International Policy Network*, (2010),last accessed date March 23,2012,9, http://scholar.googleusercontent.com/scholar?q=cache:7yHHlJFIXuwJ:scholar.google.com/+Roche+v.+Natco&hl=en&as_sdt=0,5.

Although there are various barriers to access to necessary drugs in the third world (like extreme poverty owing to which people cannot buy even the generics, improper health infrastructure[196], lack of effective health care system in rural areas of the developing countries, lack of research and development in the neglected diseases, lack of political commitment, lack of fiscal resources[197] etc.), TRIPS obligations are held primarily responsible for access problems.

Representatives of the developing countries and non-governmental organizations express concern that stringent patent law will inhibit access to essential drugs.[198] On the contrary, there are those who argue that not protecting IPRs will inhibit access to health care because the monopoly provided to pharmaceutical companies through patent protection enables them to recover costs of research and development and to finance further research and development projects.[199] Not protecting IPRs adversely affects the access to essential medicines because of the reluctance of pharmaceutical firms to introduce products in the countries lacking patent protection.[200] Instead of going into details of these arguments, the focus here is on the flexibilities provided by the TRIPS –

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[196] In 2001, African governments signed up to the Abuja declaration, in which they pledged to allocate 15 per cent of their budgets to health. A 2010 study published in the Lancet found only four countries had met this commitment. Health spending in some of the countries was even below five per cent.
For further details visit <http://www.who.int/healthsystems/publications/abuja_declaration/en/index.html> (last accessed date April 25, 2012).

[197] Ismail, "The Doha Declaration on TRIP", *395.*

[198] Rozek, "The Effects of Compulsory Licensing on Innovation and Access to Health Care, 897.

[199] Jon Matthews, "Renewing Healthy Competition" And Why Abuses of The Trips Article 31Standards Are Most Damaging To The United States Healthcare Industry", *Business, Entrepreneurship, & The Law, vol. VI:I,* (2010),133, last accessed date March 13,2012,
doi:http://digitalcommons.pepperdine.edu/cgi/viewcontent.cgi?article=1056&context=jbel&sei-redir=1&referer=http%3a%2f%2fwww.google.com.pk%2furl%3fsa%3dt%26rct%3dj%26q%3dpfizer%2bcancelled%2bits%2bplan%2bto%2bconstruct%2ba%2bmodern%2bproduction%2bfacility%2bin%2begypt%26source%3dweb%26cd%3d1%26ved%3d0cb8qfjaa%26url%3dhttp%253a%252f%252fdigitalcommons.pepperdine.edu%252fcgi%252fviewcontent.cgi%253farticle%253d1056%2526context%253djbel%26ei%3dgs6at8qqmjdirqfzwo3hdg%26usg%3dafqjcng_0vaghxnxpm91rkadatzvfzocka#search=%22pfizer%20cancelled%20its%20plan%20construct%20modern%20production%20facility%20egypt%22.

[200] Rozek, "The Effects of Compulsory Licensing"899.

especially compulsory licensing- and the practical implications for the third world in the implementation of these flexibilities.

2.4 Costs of Implementing TRIPS for Third World Countries

TRIPS Agreement is criticized by many for protecting the interests of the rich countries and giant pharmaceutical companies without giving due consideration to the costs of implementing TRIPS for low and middle economy countries with weak innovation capacity and improper legal, administrative and enforcement infrastructure. Owing to weak innovation capacity of their own, majority of patent owners in the third world are foreign inventors; most of the benefits of stringent patent laws therefore flow out into foreign pockets.[201] Access to essential drugs, due to limited purchasing power of masses in the third world, is also a major concern and a much debated issue.

Keeping in view the situation of poorer countries, some flexibilities were provided, under the Doha Declaration, within TRIPS Agreement like 'compulsory licensing' and 'parallel importation'. The Doha Declaration is not self-executing and requires changes in the national laws for its implementation.[202] Most of the third world

[201] Travis j. Lybbert, "On assessing the cost of TRIPS Implementation", *World Trade Review* (2002), 310, last accessed date March 23,2012,doi: http://journals.cambridge.org/action/displayFulltext?type=1&pdftype=1&fid=142116&jid=WTR&volumeId=1&issueId=03&aid=142115.

[202] South Bulletin, "The Doha Declaration on TRIPS": *The State of Implementation*,6,last accessed date March 23,2012, doi:http://www.southcentre.org/index.php?option=com_content&view=article&id=1657%3Asb58&catid=144%3Asouth-bulletin-individual-articles&Itemid=287&lang=en.

countries have updated their intellectual property laws in order to conform with TRIPS obligations[203] and to avail the flexibilities afforded by the TRIPS Agreement.

The issue is, however, of implementation of these laws and the costs of availing these flexibilities. Firstly, the procedure for availing these flexibilities is unnecessarily complicated and burdensome. The procedure is time-consuming, involves substantial financial expense, and holds no guarantee of success.[204] Secondly, there are various practical implications for third world countries owing to which the flexibilities are, in many instances, only provided in the statute books and do not serve the desired practical purpose. Some of the implications for the developing world are briefly discussed here.

2.4.1 Foreign Direct Investment (FDI)[205]

The growth of local industry in developing countries is heavily dependent on investment that comes from outside the country.[206] Developing states may have to pay a heavy price for providing affordable access to medicines to their citizens by invoking compulsory licensing provisions. The pharmaceutical companies may mistrust the promises made by such nations to protect and enforce patent rights. If a nation is lacking security of intellectual property rights, pharmaceutical companies would think twice before making investments in that country.

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[203] Assafa Endeshaw, "Asian Perspectives on Post-TRIPS Issues in Intellectual Property", *Journal Of World Intellectual Property, Vol.8, Issue 2,* (2008),234, last accessed date February 23,2012, Doi: http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2005.tb00247.x/pdf.

[204] South Bulletin, "The Doha Declaration on TRIPS", 8

[205] Foreign direct investment, in its classic definition, is defined "as a company from one country making a physical investment into building a factory in another country. It is an investment abroad, usually where the company being invested in is controlled by the foreign corporation. It is a firm's transfer of assets from one country to another country in order to generate wealth for the owner of the assets. An example of FDI is an American company taking a majority stake in a company in China". For details visit <http://www.going-global.com/articles/understanding_foreign_direct_investment.htm> (last accessed date April 26, 2012).

[206] Abbott, "Compulsory Licensing for Public Health", 160.

Therefore, a country may lose a potential source of economic growth by issuance of compulsory licenses.[207] The patent holding pharmaceutical companies may withdraw from the states not fulfilling their commitments of patent protection; at least, they may withhold their new drugs.[208] Stringent patent protection on the other hand may lead to greater foreign direct investment. Thus, there is a straightforward relationship between foreign direct investment and intellectual property protection.[209]

For instance, Egypt, a middle-economy country with great potential for economic growth, has faced the consequences of its mishandled efforts to provide affordable access to pharmaceuticals to its citizens. In spite of its relatively high literacy rate and cheap labor force, Egypt has a suffered a continuous decline in foreign direct investment from "$948 million in 1987 to $598 million in 1995 to $428.2 million in 2001-2002"[210] because of its poor record of intellectual property protection.

In 2002, for example, Egyptian government first provided full patent protection to renowned Pfizer drug 'Viagra[211]' but only after two months, Egyptian government granted unlimited compulsory license in response to domestic pressure especially from local pharmaceutical manufacturers.[212] As a reaction to this decision, Pfizer cancelled its

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[207] Cahoy, "The Impact of Compulsory Licensing",284.
[208] Jerome H. Reichman, "Compulsory Licensing of Patented", 13.
[209] Jamie Feldman, "Compulsory Licenses: The Dangers Behind The Current Practice", 160, *doi:*http://www.hofstrajibl.org/media/blogs/a/Compulsory%20Licenses%20The%20Dangers%20behind%20the%20Current%20Practice.pdf, (last accessed date March 23,2012).
[210] Cahoy, "The Impact of Compulsory Licensing",301.
[211] Viagra is the brand name for Sildenafil citrate, and is used for treating erectile dysfunction and pulmonary arterial hypertension. Originally developed by scientists in Great Britain, it was brought onto the market by Pfizer Inc., a US pharmaceutical company.
For details visit doi:http://www.medicalnewstoday.com/articles/232912.php, (last accessed date April 27, 2012)
[212] Bird, "Developing Nations", 211.

plan to construct an additional production facility in Egypt.[213] Moreover, in the wake of the same issue, the Pharmaceutical Research and Manufacturers Association of America (hereinafter PhRMA[214]) told Egyptian representatives that pharmaceutical companies had cancelled their plans to invest $300 million in Egypt owing to weak intellectual property laws of the country.[215]

2.4.2 Unilateral Trade Sanctions

The advanced countries have the tendency to ensure implementation of TRIPS in the developing world by their own unique mechanisms. For instance, the 'Special 301[216]' mechanism of the United States is an effective tool to speed up the implementation of TRIPS Agreement in the developing world. Section 182 (also referred to as the "Special 301" provision[217]) of the Trade Act of 1974 authorizes the office of the United States Trade Representatives (hereinafter USTR[218]) to review laws and practices in foreign

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[213] Matthews, "Renewing Healthy Competition",133.

[214] Pharmaceutical Research and Manufacturers of America (PhRMA), founded in 1958, "is a trade group representing the pharmaceutical research and biopharmaceutical companies in the United States. PhRMA's stated mission is advocacy for public policies that encourage the discovery of new medicines for patients by pharmaceutical and biopharmaceutical research companies".
For details visit <http://www.phrma.org/>, (last accessed date April 27, 2012)

[215] S. Aziz, "Linking Intellectual Property Rights in Developing Countries with Research and Development, Technology Transfer, and Foreign Direct Investment Policy: A Case Study of Egypt's Pharmaceutical Industry", *ILSA Journal of International and Comparative Law Vol. 10, Issue. 1*,(2003, last accessed date April 27, 2012,doi:https://litigationessentials.lexisnexis.com/webcd/app?action=DocumentDisplay&crawlid=1&srctype=smi&srcid=3B15&doctype=cite&docid=10+ILSA+J+Int%27l+%26+Comp+L+1&key=4bdb9af0b546c12bf48dd5833eaf6ac1.

[216] The U.S, and western pharmaceutical companies have routinely used the Special 301 "mechanism for authorizing trade sanctions and lawsuits at the WTO and in domestic courts to oppose policies implemented by other countries that are unfavorable to pharmaceutical company interests". *See* Sarah Boseley, "How the U.S. Wields a Big Stick for Big Pharm", *Guardian*, (2003), doi:http://www.guardian.co.uk/world/2003/feb/18/aids.sarahboseley4, (last accessed date April 27, 2012).

[217] The full text of the section can be accessed at <http://www.ipo.org/AM/Template.cfm?Section=International_Issues&ContentID=3264&template=/CM/ContentDisplay.cfm>, (last accessed date April 27, 2012).

[218] The Office of the United States Trade Representative (USTR) is the United States government agency responsible for developing and recommending United States trade policy to the president of the United States

countries with regards to protection of intellectual property and prepare an annual Special 301 Report[219] on the basis of which sanctions can be imposed on the countries that are non-serious in TRIPS compliance and have not revised their intellectual property laws.[220] Trade pressure is exerted on developing countries under the threat of sanctions under the 'Special 301' mechanism.

For instance, this mechanism was used against South Africa when in 1997, after the outbreak of the HIV/AIDS epidemic, it attempted to authorize parallel importation of affordable medicines through amendment in its patent law[221]. The United States tried to put pressure with a threat to impose unilateral trade sanctions against South Africa if the proposed legislation was passed.[222] The United States, however, had to withdraw trade pressure in this instance due to outrage around the world from the general public, human rights groups, AIDS activists and consumer advocates[223] that caused significant damage

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For details visit <http://www.ustr.gov/>, (last accessed date April 27, 2012).

[219] It is analyzed that "the Special 301 Report is prepared annually by the Office of the United States Trade Representative (USTR) under Section 182 as amended of the Trade Act of 1974. The reports identify trade barriers to US companies and products due to the intellectual property laws in other countries. Each year the USTR must identify countries which do not provide adequate and effective protection of intellectual property rights or fair and equitable market access to United States persons that rely upon intellectual property rights".
For details visit <http://www.ustr.gov/about-us/press-office/reports-and-publications/2011/2011-special-301-report>, (last accessed date April 27, 2012).

[220] Forman, "Addressing legal and political barriers", 241.

[221] Section 15C was inserted into the South African Medicines and Related Substances Control Act (MRSCA). The primary purpose of this amendment was to enable South Africa to benefit from lower prices abroad for the same drugs. For details visit http://www.ncbi.nlm.nih.gov/pubmed/19555268, (last accessed date April 27, 2012).

[222] A. P. Valach, "TRIPS Protecting the Rights of Patent Holders and Addressing Public Health Issues in Developing Countries", *Chicago-Kent Journal of Intellectual Property Vol. 4, Issue 2* ,(2005), >, last accessed date April 27, 2012,
.doi:https://litigationessentials.lexisnexis.com/webcd/app?action=DocumentDisplay&crawlid=1&doctype=cite&docid=4+Chi.Kent+J.+Intell.+Prop.+156&srctype=smi&srcid=3B15&key=d5661df69a048447176c9a6a2dbef3c8.

[223] Forman, "Addressing legal and political barriers",241.

to the election campaign of Al Gore, the presidential candidate in the 2000 presidential elections in the US.[224]

More recently, the 'Special 301 Reports' issued in 2009 and 2010 pressed developing countries to limit compulsory licenses for essential medicines (e.g. Thailand) and to restrict their freedom to define the scope of patentability (e.g. India) .[225] Therefore, the fear of potential vulnerability to unilateral trade sanctions from the United States[226] prevents developing and least developed countries from exercising the flexibilities, exceptions and safeguards provided under TRIPS Agreement.[227]

2.4.3 Bilateral Trade Agreements

While the developing world is facing practical problems in implementing TRIPS Agreement, the European Union and the United States of America have set new intellectual property standards going even further than TRIPS Agreement.[228] Under regional and bilateral trade agreements with over 60 countries, the US has decided to implement TRIPS-plus[229] intellectual property standards. These agreements extend patent

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[224] Third World Network, "TRIPS, Drugs and Public Health",26.

[225] "Human Rights Groups to Challenge Special 301", doi:http://a2knetwork.org/human-rights-groups-challenge-special-301, (last accessed date April 27, 2012).

[226] Colleen Chien, "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?", *Berkeley Technology Law Journal, Vol. 18,* (2003),895, last accessed date April 3,2012),http://digitalcommons.law.scu.edu/cgi/viewcontent.cgi?article=1019&context=facpubs&sei-redir=1&referer=http%3A%2F%2Fscholar.google.com.pk%2Fscholar%3Fq%3Dcompulsory%2Blicensing%2Bof%2Bpatents%26hl%3Den%26btnG%3DSearch%26as_sdt%3D1%252C5%26as_sdtp%3Don#search=%22compulsory%20licensing%20patents%22.

[227] Islam, "The Generic Drug Deal", 690.

[228] Puymbroeck, "Basic Survival Needs" , 537.

[229] Many developing countries have been coming under pressure "to enact or implement even tougher or more restrictive conditions in their patent laws than are required by the TRIPS Agreement – these are known as 'TRIPS plus' provisions. Countries are by no means obliged by international law to do this, but many states have had no choice but to adopt these, as part of trade agreements with the United States or the European Union. These have a disastrous impact on access to medicines". For further details visit <http://www.msfaccess.org/content/trips-trips-plus-and-doha>, (last accessed date April 27, 2012).

life beyond twenty years limit set by the TRIPS Agreement, limit use of compulsory licensing, prohibit parallel imports, and discourage market entry of generics even after the expiration of patent protection.[230]

It might be surprising to note that many of these countries are developing countries already facing the issues of availability of necessary drugs. In return of these agreements, the third world countries get access to Western investment, low tariffs on particular goods, and foreign aid. But new commitments made under these agreements would further aggravate the public health situation in these countries. The situation may become grimmer if the generic drug suppliers like India and Thailand bow to foreign pressure and enter into TRIPS-plus agreements that prohibit the use of non-voluntary licenses for export.[231]

These bilateral and regional TRIPS-plus agreements, therefore, undermine the existing TRIPS safeguards, exceptions, and flexibilities.[232]

2.4.4 The Risk of Retaliatory Action

Political pressure exerted by developed countries prevents developing and least developed countries from exercising their rights under TRIPS Agreement.[233] Faced with the risk of retaliatory action from developed countries, their giant corporations, and industry lobbies, the third world countries do not feel free to enact policies and laws on

[230] Forman, "Addressing legal and political barriers", 241.
[231] *Ibid.*
[232] South Bulletin, "The Doha Declaration on TRIPS"r, 7.
[233] For instance, in the summer of 2007, the government of Bangladesh got letters from European Union trade commissioner Peter Mandelson and U.S. Ambassador to Thailand, Ralph Boyce, after it announced plans for a compulsory license for HIV drugs.
For details visit <http://www.worldcrunch.com/drug-companies-battle-against-indian-pharmaceutical-pirates/4890>,

parallel imports and compulsory licensing for essential life-saving drugs.[234] They have been provided rights under TRIPS but the decision to make use of these rights is plagued by political considerations.[235]

For instance, in 2006, when Thailand[236] granted compulsory license for *efavirenz*, the United States, with the threat of high tariffs for Thai exports[237], exerted pressure on Thailand to ban parallel imports and to revoke the compulsory license and negotiate with Merck.[238] The pharmaceutical industry also reacted strongly against the Thai government's efforts to provide affordable access to necessary drugs.[239] The giant pharmaceutical companies are not only well funded but also well organized; they are supported by powerful governments like the United States and the European Union[240], and are, therefore, fully capable of exerting formidable pressure on third world countries.[241] The International Federation of Pharmaceutical Manufacturers Association (IFPMA) openly condemns issuance of non-voluntary licenses.[242]

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[234] Third World Network, "TRIPS, Drugs and Public Health", 26.
[235] South Bulletin, "The Doha Declaration on TRIPS", 7.
[236] Government of Thailand issed order, "Citing the high drug prices and its obligation to provide access to essential medicines, Thailand issued government use (GU) orders for three drugs on the national essential medicines list: *efavirenz* (November 2006), *lopinavir/ritonavir* (January 2007), and *clopidogrel*, a heart disease drug marketed as Plavix by BMS (January 2007). The patent holders were entitled to a royalty of 0.5% of the total sales of the generic product. The GU authorised the Governmental Pharmaceutical Organisation (a Thai State-owned enterprise) to import or produce generic versions of these products for non commercial use in the public health sector. Initially the GU was used for importation". For details visit <http://www.keionline.org/content/view/90/1>, (last accessed date April 27, 2012).
[237] Third World Network, "TRIPS, Drugs and Public Health", 26.
[238] South Bulletin, "The Doha Declaration on TRIPS*r*, 7.
[239] "Compulsory Licensing And The Anti-Competitive Effects of Patents for Pharmaceutical Products: From A Developing Countries' Perspective", 56.
[240] Bird, "Developing Nations", 214.
[241] For instance, when Thailand issued a compulsory license for Kaletra, an AIDS medication produced by Abbot, the U.S. drug maker responded by denying Thai patients access to its other life-saving drugs. For details visit <http://www.worldcrunch.com/drug-companies-battle-against-indian-pharmaceutical-pirates/4890>, (last accessed date June 4, 2012).
[242] Muhammad Asif Awan, "Pakistani Pharmaceutical Industry in WTO regime-Issues and Prospects",, *Journal of Quality and Technology Management, 01, 9,* (2005), last accessed date June 4, 2012, doi: http://pu.edu.pk/images/publication/PPI_in_WTO_%20regime-Issues_and_Prospects.pdf.

2.4.5 Technology Transfer

Article 66, paragraph 2 of the TRIPS Agreement stipulates:

> "Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base."[243]

Moreover, paragraph 7 of the Declaration on TRIPS Agreement and Public Health (Doha Declaration adopted on 14 November 2001) "reaffirms the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2"[244] of the TRIPS Agreement.

Everyone has a right to benefit from scientific inventions and technological advancements.[245] More importantly, economic development of third world countries, especially those with adequately developed technology infrastructure and a strong base of human capital, relies heavily on transfer of technology from industrialized economies who almost enjoy a monopoly on the development of new knowledge and high-level technologies. No intellectual property rights protection poses a threat of imitation or reverse engineering[246] of high-technology imported products. Stringent patent protection, on the other hand, can cause inordinate delay in technology transfer to the developing

[243] Article 66, paragraph 2 of the TRIPS Agreement. Full text of TRIPS Agreement is available online at <http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm> (last accessed date May 5, 2012)
[244] Paragraph 7 of the Declaration on TRIPS Agreement and Public Health. Full text of Doha Declaration is available at < http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> (last accessed date May 5, 2012)
[245] Islam, "The Generic Drug Deal", 688.
[246] Reverse engineering is the process of discovering the technological principles of a device, object, or system through analysis of its structure, function, and operation and to apply the findings to produce something similar.
For details visit <http://en.wikipedia.org/wiki/Reverse_engineering> (last accessed date May 5, 2012)

world[247] because the patent holder enjoying monopoly over the new technology excludes all others rendering the invention beyond the reach of poor masses in the third world.[248] Edwin Mansfield[249], an American professor of economics, concluded that:

> The strength or weakness of a country's system of intellectual property protection seems to have a substantial effect, particularly in high-technology industries, on the kinds of technology transferred by many U.S firms to that country.[250]

TRIPS Agreement was expected to give due importance to the issue of transfer of technology from developed to underprivileged countries. But TRIPS Agreement did not create mandatory obligations for transfer of technology.[251] A corresponding obligation was created under aforementioned article 66.2 of the TRIPS Agreement, but practically advanced nations did not comply with article 66.2. This corresponding obligation was reaffirmed in 2001 in Doha Declaration, again without producing desired results. Again, the TRIPS Council, in 2003, adopted a decision on implementation of article 66.2 and devised a reporting mechanism under which developed nations were supposed to submit reports to the TRIPS Council on actions taken or planned by them to fulfill their commitments under article 66.2. Again, this mechanism could not produce desired results because most of the reports submitted failed to meet the reporting criteria.[252]

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[247] DAS, "Intellectual Property Rights and the Doha Round", 43.
[248] Islam, "The Generic Drug Deal", 688.
[249] Edwin Mansfield (1930–1997) was a professor of economics at University of Pennsylvania from 1964 and until his death. From 1985 he was also a director of the Center for Economics and Technology. Edwin Mansfield is best known for his scientific results concerning technological change / diffusion of innovations, and also for his textbooks on microeconomics, managerial economics, and econometrics. For details visit <http://en.wikipedia.org/wiki/Edwin_Mansfield> (last accessed date May 5, 2012)
[250] Rozek, "The Effects of Compulsory Licensing"901.
[251] Islam, "The Generic Drug Deal", 688.
[252] South Bulletin, "The Doha Declaration on TRIPS", 10.

In the absence of mandatory obligations for transfer of technology, the developing countries should develop their patent regime in such a manner as to strike a balance between IPRs protection and their economic development goals. Compulsory licenses can therefore be used as one of the channels to improve flows of technology to the third world remaining within the flexibilities provided under TRIPS Agreement.

However, there is another exactly opposite opinion that weak patent protection is one of the major impediments in the transfer of technology to the third world countries.[253] Foreign direct investment (FDI) is another channel for technology transfer to the poorer countries. Compulsory licensing has a significant negative impact on foreign direct investment. Use of compulsory licenses is associated with weakening of protection of intellectual property rights and, thus, condemned by industrialized economies.

2.4.6 Lack of Technical Expertise

In order to use flexibilities provided under TRIPS Agreement and Doha Declaration, member states need to review and amend their national laws. Lack of technical expertise in the field of intellectual property in the underprivileged countries has been an impediment in fully availing the flexibilities provided under TRIPS by incorporating them in the national laws.[254]

TRIPS Agreement's provisions especially those regarding compulsory licenses and parallel importation, are coupled with conditions which make them difficult to invoke effectively and speedily. The countries which do not have adequate technical expertise

[253] Rozek, "The Effects of Compulsory Licensing"109.
[254] South Bulletin, "The Doha Declaration on TRIPS", 16.

face difficulties in interpretation and implementation of the TRIPS provisions that lack legal clarity and common understanding.[255] Necessary technical assistance should therefore be provided to developing countries in relation to intellectual property in order to enable them to reform their legal and administrative systems. TRIPS Agreement provides for this technical cooperation. Article 67 of the TRIPS Agreement stipulates:

> In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favor of developing and least-developed country Members....[256]

In 1996, TRIPS Council agreed that the developed country members would provide annually information about the steps taken by them to fulfill their commitments made under article 67. In addition to individual member states, Intergovernmental organizations like World Intellectual Property Organization (WIPO) and World Trade Organization (WTO) should undertake capacity building work to ensure technical assistance to developing countries that lack the capacity to reform their domestic IPRs regimes to avail TRIPS-compatible flexibilities.[257]

2.4.7 High Litigation Costs

The cost of patent litigation is not trivial.[258] Owing to high litigation costs, third world countries are extremely reluctant to become party to patent litigation.[259] Drug and health

[255] Third World Network, "TRIPS, Drugs and Public Health", *125.*

[256] Article 67 of the TRIPS Agreement. Full text of TRIPS Agreement is available online at <http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm> (last accessed date May 5, 2012)

[257] South Bulletin, "The Doha Declaration on TRIPS", 11.

[258] In December 1998, the New York Times reported that the median cost of U.S patent litigation was $1.2 million per side, whereas costs of litigation in complex cases were much higher. The largest component of these costs is attorney's fee but it also includes expert witness fees, travel costs, and document management

patents are the most litigated patents[260] and developing and least developed countries can hardly be expected to have significant capacity and economic incentive to litigate claims against authorization of parallel importation and grant of non-voluntary licenses.

In the aforementioned case of South Africa, for instance, when in 1997, after the out break of the HIV/AIDS epidemic, South African government attempted to authorize parallel importation of affordable medicines through a controversial legislative proposal,[261] it triggered reaction of pharmaceutical companies. Thirty nine multinationals, being the stakeholders in this matter, moved the High Court of South Africa whereby they challenged the constitutionality of the proposed amendment.[262]

Luckily, in this case, the multinationals had to drop their case due to outrage around the world from the general public, human rights groups, AIDS activists and consumer advocates[263]; otherwise one can imagine the potential litigation cost in this case. Thirty-nine multinational pharmaceutical companies, including giants like Bristol-Myers Squibb[264] could easily afford the litigation cost but the governments of developing countries do not see much economic incentive in bearing such heavy costs of litigation.

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and production costs. For details visit <http://www.harborlaw.com/newsletters/november.pdf> (last accessed date May 5, 2012).

[259] Love, "Compulsory Licensing: Models for State Practices", 5.

[260] Ibid, 4.

[261] Section 15C was inserted into the South African Medicines and Related Substances Control Act (MRSCA). The primary purpose of this amendment was to enable South Africa to benefit from lower prices abroad for the same drugs. For details visit <http://www.ncbi.nlm.nih.gov/pubmed/19555268>, (last accessed date April 27, 2012).

[262] "Ofeibea Quist-Arcton, South Africa: Battle Against Pharmaceutical Giants Continues", 2001. For details visit <http://allafrica.com/stories/200104170346.html> (last accessed date May 23, 2012).

[263] Third World Network, "TRIPS, Drugs and Public Health", 25.

[264] Bristol-Myers Squibb, is a pharmaceutical company, headquartered in New York City. The company was formed in 1989, following the merger of its predecessors Bristol-Myers and the Squibb Corporation. Squibb was founded in 1858 in New York, while Bristol-Myers was founded in 1887 also in New York For further details visit <http://en.wikipedia.org/wiki/Bristol-Myers_Squibb>,(last accessed date May 23, 2012).

In addition to the legal fee, such disputes impose considerable time costs on developing countries.[265] Although challenge was withdrawn in the aforementioned case due to intense public pressure, the potential threat of similar challenges still exists.[266] Governments of third world countries may therefore be reluctant to invoke compulsory licensing provisions keeping in view the considerably high potential costs of patent litigation and time costs. This consequently restricts the use of compulsory licensing.

2.4.8 Insufficient Progress during Transition Period

The TRIPS Agreement came into effect on 1st of January in 1995. The third world countries were, however, provided extended period for compliance with TRIPS Agreement keeping in view their technical, administrative, financial, and economic constraints.[267] Developing countries were granted an extended period up to January 1, 2000. The least developed countries were given an initial extended period up to January 1, 2006. In November 2005, however, the WTO member countries granted further transition period until July 1, 2013.[268] Later, the deadline for least developed countries was further extended to January 1, 2016.[269]

During the transition period, developing and least developed countries were exempted from the obligation of patent protection and data protection with regards to

[265] Bird, "Developing Nations", 213.
[266] Third World Network, "TRIPS, Drugs and Public Health", 26.
[267] WTO and the TRIPS Agreement. Available online at <http://www.who.int/medicines/areas/policy/wto_trips/en/index.html> (last accessed date May 24, 2012).
[268] Jenkins, Compulsory Licensing, 372.
[269] Bird, "Developing Nations", 211.

pharmaceutical products.[270] The purpose behind granting this extended period was to provide time to these countries to make their national legislation and local practices compatible with the TRIPS provisions and to develop their technological base before full compliance with the TRIPS obligations. The transition period is even more significant from a public health perspective.[271] These countries were provided time to develop their local pharmaceutical manufacturing capacity to avoid various practical implications of TRIPS. But the third world especially the least developed countries failed to fully utilize of the transition period.

Financial constraints may be an obvious reason for not achieving the fundamental objectives of the transition period. The United States' annual expenditure on its patent and trademark office is about $1 billion.[272] Other developed countries also spend huge amounts of money on their patent examination mechanism. Third world countries, especially least developed countries, can hardly afford to allocate huge sums in this regard.

Moreover, third world countries were dependent on the developed world to achieve objectives of the transition period because technology transfer was an integral component of the extended period. According to Article 66, paragraph 2 of the TRIPS

[270] United Nations Industrial Development Organization, "Transition Period for Least Developed Countries", Available online at <http://www.local-pharma-production.net/index.php?id=98> , (last accessed date May 24, 2012).

[271] South Perspectives, "The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?", (2006), last accessed date March 23,2012.
http://www.southcentre.org/index.php?option=com_content&view=article&id=70%3Athe-use-of-flexibilities-in-trips-by-developing-countries-can-they-promote-access-to-medicines&catid=41%3Ainnovation-technology-and-patent-policy&Itemid=67&lang=en.

[272] James Love, "Compulsory Licensing: Models for State Practices in Developing Countries, Access to medicine and Complince with the WTO TRIPS accord", *Intellectual Property Rights Series*, (2004), 4, last accessed date March 20,2012,
doi: http://www.twnside.org.sg/title2/IPR/pdf/ipr06.pdf.

and paragraph 7 of the Doha Declaration, the technologically advanced states are obligated to provide incentives to encourage transfer of technology to the least developed countries.[273] It has been shown by the available evidence that technologically advanced states failed to comply with Article 66, paragraph 2 of the TRIPS Agreement.[274]

Thus, not only third world countries but also the developed countries are equally responsible for not achieving the fundamental objectives of the transition period because they too did not meet their commitments made under Article 66.2 of the TRIPS Agreement.

2.4.9 Risk of Counterfeit Drugs[275]

Although, so far, the focus has been on implications which restrict poor countries from availing the flexibilities provided under the TRIPS Agreement, third world countries face certain problems even if they successfully invoke the compulsory licensing provisions despite all economic and political pressure.

Risk of falsely labeled substandard counterfeit drugs with little or no therapeutic value is one such issue associated with the use of compulsory licensing in the third world countries. Purpose of granting a compulsory license by government of a poor country may be to promote access to affordable drugs for its citizens with low purchasing power,

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[273] South Bulletin, "The Doha Declaration on TRIPS", 10.

[274] UNAIDS , "Implementation of TRIPS and Access to Medicines for HIV after January 2016: Strategies and Options for Least Developed Countries", (2011), 11, last accessed date March 20,2012,doi:http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2258_techbrief_TRIPS-access-medicines-LDC_en.pdf .

[275] Counterfeit drugs are products that are presented in such a way as to look like legitimate or genuine products although they are not that product. A counterfeit drug may contain inappropriate quantities of active ingredients, may contain ingredients that are not on the label, or may be supplied with inaccurate or fake packaging and labeling. For further details visit <http://en.wikipedia.org/wiki/Counterfeit_medications> (last accessed date May 24, 2012).

but this sometimes results in prevalence of fake or counterfeit drugs. This mixing of fake and generic medicines[276] undermines access to necessary medicines for underprivileged masses in the developing world.

In 2008 and 2009, for instance, generic medicines from India (they were not patented in India) were seized by Customs authorities in Germany and Netherlands. These drugs were destined for Africa and Latin America.[277] Most of the African countries lack the capacity to manufacture drugs. They therefore import generic medicines from generic producers and are particularly concerned about falsified substandard drugs. According to a survey conducted by World Health Organization (WHO), about 30 percent of the sampled medicines for curing malaria taken from Ethiopia, Kenya, Ghana, Cameroon, Nigeria, and Tanzania did not meet international quality standards.[278]

The situation is not much different in the rest of the third world. World Health Organization (WHO) estimated that 25 percent of the total medicine consumed in the third world countries is counterfeit or substandard.[279] The buyers in the low income countries can hardly distinguish between the generic copies of the patented drugs and the counterfeit or fake drugs. They purchase the falsified drugs which may prove silent killers

[276] Generic medicines are legitimately produced medicines that are the same as original brand name products with the same active ingredients but that are manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights. Although they may not be associated with a particular company, generic drugs are subject to the regulations of the governments of countries where they are dispensed. Generic drugs are labeled with the name of the manufacturer and the adopted name (nonproprietary name) of the drug. Since generic manufacturers do not bear any research and development cost but only the manufacturing cost, the drug produced under the compulsory license will almost always be cheaper than the patented drug.
For details visit < http://en.wikipedia.org/wiki/Generic_drug> (last accessed date May 24, 2012).

[277] Supporting Strategic Leadership in Global Health Diplomacy in East, Central and Southern Africa, "Preventing substandard, spurious medicines and protecting access to generic medicines in Africa", (2011), last accessed date March 20,2012,
doi: http://www.seatini.org/publications/policybriefs/preventing_substandard_medicines.pdf,

[278] *Ibid* 2.

[279] World Health Organization, "Substandard and Counterfeit Medicines", 2003, last accessed date May 24, 2012, doi: http://www.who.int/mediacentre/factsheets/2003/fs275/en/.

because the counterfeit medicines are not only devoid of effect but may also contain toxic substances.

Consequently, anti-counterfeit laws are being proposed or enacted by many poor countries; Kenyan Anti-Counterfeit Act of 2008[280] is just one example. Efforts are being made at international level as well to curb global trade of fake products. In October 2011, for instance, developed countries including Australia, New Zealand, Japan, Canada, and the United States signed a new international treaty called the Anti-Counterfeiting Trade Agreement (ACTA).[281] In January 2012, the European Union and 22 member countries of the European Union also signed this treaty.

Practically, so far, developing world has not been able to curb the prevalence of falsified counterfeit drugs. Some critics of compulsory licensing even suggest that instead of relying on compulsory licensing to gain access to drugs, governments of developing countries should buy patented products directly from the manufacturers at negotiated prices.[282]

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[280] In 2010, the High Court of Kenya suspended implementation of the Act "in as far as it applies to generic medicines." The case was filed by three people living with HIV challenging sections 2, 32 and 34 of the Act as unconstitutional. For details visit < http://afro-ip.blogspot.com/2010/04/kenyas-anticounterfeit-law-suspended.html> (last accessed date May 24, 2012).
In August 2010, the Kenyan Anti-Counterfeit Act of 2008 was replaced by the Kenyan Anti-Counterfeit Regulations 2010. For details visit
<http://www.coulsonharney.com/LawArticles/Documents/THE%20KENYAN%20ANTI-COUNTERFEIT%20REGULATIONS%202010%20-%2026102010.pdf> (last accessed date May 24, 2012).

[281] DG EXPO Policy Department, "The Anti-Counterfeiting Trade Agreement (ACTA): An Assessment", *European Parliament*, 2011, 8, last accessed date May 20,2012, doi:http://www.europarl.europa.eu/committees/en/studiesdownload.html?languageDocument=EN&file=43731.

[282] "Fake Drug Progress in Kenya and Compulsory Licensing", 2010, Available online at <http://afro-ip.blogspot.com/2010/09/fake-drug-progess-in-kenya-and.html> , (last accessed date May 24, 2012).

2.4.10 Reducing Incentives to Innovate

Reduction in incentives to innovate is yet another drawback of non-voluntary licensing faced by third world countries. Not only use but also the predictability of compulsory licensing has a negative impact on pharmaceutical innovation. The drugs can be divided into two broad categories: First, "global drugs" like cancer drugs and HIV/AIDS vaccines that are primarily created for rich markets but are also needed by the developing world. Second, the drugs that are needed only by poorer countries like drugs to treat tuberculosis or malaria.[283] The drugs specific to third world are not priority of multinational pharmaceutical companies because of less financial gain. Threat of non-voluntary licensing in the developing world further adds to the concerns of the multinationals rendering them extremely reluctant to initiate and carry out research and development investment on pharmaceutical products specific to the poorer countries.

When the multinationals are not willing to invest in poverty-related diseases because they do not consider it a profitable investment, private research-based pharmaceutical companies of the developing countries may play a vital role. But excessive use of non-voluntary licensing by the developing countries may adversely affect the private research-based pharmaceutical industry of the country.[284] By establishing an appropriate correlation between profit and risk through careful use of compulsory licensing, developing countries may encourage their private research-based

[283] *Chien, "Cheap Drugs at What Price"892.*

[284] Reichman, "Compulsory Licensing of Patented", 7.

pharmaceutical companies to invest in the third world specific ailments in the hope of monetary gain.[285]

Appropriate laws and regulations should therefore be adopted by developing countries to make use of TRIPS flexibilities. Courts and patent offices of poor countries should act as vigilant stewards of public interest. Governments of developing countries should use TRIPS flexibilities with extreme caution keeping in view the direct and indirect consequences of their decisions.

2.5 Conclusion

Though WTO, under TRIPS, provided flexibilities to developing and under developed countries and over the period of time tried to facilitate the poorer countries to use such flexibilities, still a lot of steps need to be taken to facilitate the member countries to effectively use compulsory licensing provisions in order to improve availability of necessary drugs at affordable prices.

No doubt compulsory licensing is an effective legitimate tool in the hands of developing and least developed nations to provide essential drugs to their citizens, in order to avoid costly and needless litigation and to minimize negative effects, this tool must be used with caution after giving due consideration to compliance with municipal and international law and keeping in view the external political, social, and economic conditions.

[285] *Ibid*, 4.

Developing countries must think twice before implementing compulsory licensing provisions even in situations of national emergency. Compulsory licensing may provide a short-term solution to public health crises but, at the same time, it may generate undesirable long-term effects on the economic development of the country. The reaction of the owners of a patent may be so serious that a developing or under developed country may face economic consequences. The pharmaceutical companies may mistrust such states and decide not to engage in foreign direct investment (FDI). This loss of foreign investment may be a heavy blow for the economic growth of a poorer country. Thus, a state may have to pay quite a heavy price for improving access to needed medicines for its masses.

To sum up, there are implementation gaps between theory and practice of compulsory licensing; WTO member states have been provided flexibilities under TRIPS Agreement but third world countries are not able to avail the flexibilities due to numerous practical implications which restrict them from availing the flexibilities provided in the TRIPS Agreement. The flexibilities are, in many instances, only provided in the statute books and do not serve the desired practical purpose.

Only implications have been discussed in this chapter without suggesting detailed solutions to the problems faced by the developing and least developed countries with regards to use of compulsory licensing. Suggestions and recommendations would be made in the last chapter. Moreover, so far, rather general approach has been chosen to highlight the issues. Next chapter specifically deals with Indian and Pakistani compulsory licensing provisions in the light of Indian cases Roche v. Natco and Bayer v. Natco.

CHAPTER 3

INDIAN AND PAKISTANI COMPULSORY LICENSING REGIMES

3.1 Introduction

The compulsory licensing provisions though present in municipal laws of WTO member states are seldom used by the developing world owing to numerous practical implications which have been discussed in the second chapter. Use of compulsory licensing provisions is particularly rare in the sub-continent resulting in the dearth of case law on the issue. Towards the end of 2007, first application for the grant of Doha style compulsory license was made in the legal history of India. Though the application in this case (Roche Pharmaceuticals[286] v. Natco Pharma Limited[287]) was withdrawn before final judgment, it raised many important issues with regards to statutory and procedural laws of India relating to compulsory licensing of patents. Indian compulsory licensing provisions were tested for the first time in this case.

In July 2011, Natco Pharma Ltd. brought another compulsory licensing application, this time under Section 84 of the Indian Patent Act 1970, for manufacture and sale of Bayer Corporation's patented product Sorafenib. In March 2012, the Controller granted first Indian compulsory license to Natco. Both these cases deserve a

[286] Roche Pharmaceuticals is one of the largest pharmaceutical companies in the world by revenue. The company is based in Basel, Switzerland. For details visit <http://www.roche.com/about_roche.htm>, (last accessed date May 26, 2012).
For more details visit <http://www.wikinvest.com/stock/Roche_Pharmaceuticals_%28RHHBY%29>, (last accessed date May 26, 2012).

[287] NATCO PHARMA LIMITED was incorporated in Hyderabad in the year 1981 with an initial investment of INR 3.3 million. With a modest beginning of operations as a single unit with 20 employees, NATCO today has five manufacturing facilities spread across India. For details visit <http://www.natcopharma.co.in/>, (last accessed date May 26, 2012).

detailed analysis to understand the Indian compulsory licensing regime. An effort shall be made in this chapter to analyze key Indian compulsory licensing provisions in the light of the aforementioned Indian cases. An analysis of Pakistani compulsory licensing provisions shall also be made in the later part of this chapter.

3.2 Indian Compulsory Licensing Regime

India is a leading producer and exporter of generic drugs to third world countries. About 80% of the medicine used to treat HIV/AIDS is supplied by India.[288] Until the end of the transition period in 2005, India was not obligated to provide patent protection to drugs.[289] Consequently, India's generic pharmaceutical industry grew tremendously. India is still one of the largest generic manufacturers in the world. Not only 70% of India's domestic demand is met by its generic pharmaceutical industry but also India exports 11 billion US dollars worth of generic drugs annually.[290] There are about 20,000 generic manufacturers in India and over 70% of the generic drugs supplied worldwide are manufactured in India.[291]

Indian patent law contains liberal compulsory licensing provisions.[292] Fredrick Noble, a UK Patent Assistant, asserts that "from a worldwide perspective, Indian patents appear to be more vulnerable than many and Indian law is unsympathetic to holders of

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[288] Priya Shetty, "Drug Company Up For Rematch Against Clause Prohibiting Indefinite Extension Of Patents", *Novartis Challenges India's Patent Law*, http://www.nature.com/news/novartis-challenges-india-s-patent-law-1.10262>, (last accessed date April 20,2012).

[289] Bayer challenges 'compulsory license' ruling, for detail see, <http://health.india.com/news/bayer-challenges-compulsory-license-ruling/>, (last accessed date April 20,2012).

[290] Ranjit Devraj, *India Affirms Role as Developing World's Pharmacy*, <http://ipsnews.net/news.asp?idnews=107126>, (last accessed date April 20,2012).

[291] Drug Companies Battle Against Indian Pharmaceutical Pirates, <http://www.worldcrunch.com/drug-companies-battle-against-indian-pharmaceutical-pirates/4890>, (last accessed date April 20,2012).

[292] Holmer, "Applying U.S. Antitrust's Rule of Reason", 688.

pharmaceutical patents".[293] India's goal was to "encourage the founding of local industries to break the choke hold of foreign chemical companies".[294] According to Dr. Jens Hammer, a patent attorney, "so far all decisions in India have come down on the side of the generic manufacturers".[295]

As regards a brief history of Indian patent law, Patents Act 1970 (India) replaced Indian Patents and Designs Act 1911. Substantial amendments were made in the Patents Act in 2002 and then again in 2005 in order to make Indian patent law TRIPS compliant.[296]

Indian compulsory licensing regime provides for two types of compulsory licensing provisions. Firstly, Indian law, under Section 92(A) of the Patents Act, provides for special Doha style compulsory licensing provisions to authorize manufacture and export of generics to countries lacking pharmaceutical manufacturing capacity of their own.[297] Secondly, Indian law, under Section 84 of the Patents Act, provides for ordinary compulsory licensing provision to authorize the manufacture of generics for domestic market use. Both the provisions have been analyzed as under in the light of practical Indian cases Roche v. Natco and Bayer v. Natco respectively.

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[293] Frederick Noble , "Indian Patent Office Grants Licence For Anti-Cancer Drug", last accessed date April 20,2012,
Doi:http://www.albrightpatents.co.uk/articles/indian-patent-office-grants-licence-for-anti-cancer-drug/.
[294] Holmer, "Applying U.S. Antitrust's Rule of Reason", 688.
[295] Drug Companies Battle Against Indian Pharmaceutical Pirates, <http://www.worldcrunch.com/drug-companies-battle-against-indian-pharmaceutical-pirates/4890>, (last accessed date April 20,2012).
[296] Jain, Compulsory Licenses, 37.
[297] Natco vs Roche/Pfizer: Hearing on the Right to Hearing, 2008, http://spicyipindia.blogspot.com/2008/03/natco-vs-rochepfizer-hearing-on-right.html?dhiti=1&p, (last accessed date April 20,2012).

3.2.1. Roche Pharmaceuticals v. Natco Pharma Ltd.

3.2.1.1. Erlotinib Hydrochloride

"Erlotonib hydrochloride is a drug used to treat non-small cell lung cancer and pancreatic cancer."[298] Under the brand name or trade name Tarceva[299] it is marketed by OSI Pharmaceuticals[300], Genetech[301], and Roche Pharmaceuticals in different parts of the world. Tarceva was primarily developed by OSI Pharmaceuticals. Roche and Genentech later entered into a marketing agreement with OSI Pharmaceuticals for the global development and commercialization of Tarceva. As a result of this business partnership, now Tarceva is marketed by OSI Pharmaceuticals and Genetech only in the United States, whereas it is marketed by Roche Pharmaceuticals in the rest of the world. OSI Pharmaceuticals and Roche Pharmaceuticals successfully secured patents for Erlotinib in more than 50 countries including the United States, Europe, and Japan.[302]

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[298] Erlotinib hydrochloride (trade name Tarceva) is a drug used to treat non-small cell lung cancer, pancreatic cancer and several other types of cancer.
For details visit <http://en.wikipedia.org/wiki/Erlotinib>, (last accessed date May 26, 2012).

[299] Tarceva is a trade name for the generic drug name Erlotinib. It is specifically indicated as monotherapy to treat non-small cell lung cancer in patients who have failed to respond or has ceased responding to at least one round of chemotherapy. For details visit <http://www.medilexicon.com/drugs/tarceva.php>, (last accessed date May 26, 2012).
For more details visit <http://www.chemocare.com/bio/tarceva.asp>, (last accessed date May 26, 2012).

[300] OSI Pharmaceuticals, Inc. is an American pharmaceutical company based in Long Island, New York with facilities in Colorado, New Jersey and the United Kingdom.
For details visit <*www.osip.com/*>, (last accessed date May 26, 2012).

[301] Genentech Inc., or Genetic Engineering Technology, Inc., is a biotechnology corporation, founded in 1976 by venture capitalist Robert A. Swanson and biochemist Dr. Herbert Boyer. Genentech is among the world's leading biotech companies, with multiple products on the market and a promising development pipeline.
For details visit <http://www.gene.com/gene/about/>, (last accessed date May 26, 2012).

[302] Hafiz Aziz ur Rehman, "WTO, Compulsory Export Licences and Indian Patent Law", *Nordic Journal of Commercial Law*, (2011), 17, last accessed date May 20, 2012, doi:http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1855805.

3.2.1.2 Erlotinib (Tarceva) Patent despite Pre-Grant Opposition by Natco

On March 30, 1995, OSI Pharmaceuticals filed a patent application in India for Erlotinib. On April 10, 2007, Natco Pharma Ltd. –an Indian generic company based at Hyderabad- filed a pre-grant opposition to the drug with the objections that Erlotinib lacked novelty[303] and inventive step[304]. This pre-grant opposition was made under Section 25(1) of the Patents Act 1970 of India[305] which provides procedure and grounds for pre-grant opposition. These objections were, however, removed by the applicants.

Natco Pharma Ltd. also tried to attack claims of the applicants under Section 3(d) of the Patents Act 1970 of India which stipulates that "the mere discovery of any new property of new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant". Thus, under Article 3(d), incremental innovations may not be allowed to get a patent in India.[306] Section 3(d) aims to prevent companies from the practice called 'ever-greening'. Companies slightly modify their medicine and re-patent them to extend their monopoly and keep generic competition off the market. This is

[303] Novelty is a patentability requirement. An invention is not patentable if the claimed subject matter was disclosed before the date of filing.

[304] The inventive step and non-obviousness reflect a same general patentability requirement present in most patent laws, according to which an invention should be sufficiently inventive — i.e., non-obvious — in order to be patented.

[305] Full text of Section 25(1) of the Patents Act 1970 (India) is available online at <http://indiankanoon.org/doc/1443542/>, (last accessed date May 26, 2012).

[306] It is worth noting that a limited study by the Indian Pharmaceutical Alliance has come out with a list of 86 patents granted for pharmaceutical products by India after 2005 which inventions are not breakthrough drugs but only minor variations of existing pharmaceutical products. Thus, Section 3(d) of the Patents Act 1970 (India) is not a bar for patenting of significant incremental innovations.
For details visit <*www.nipoonline.org/Section-report.doc – India*>, (last accessed date May 26, 2012).

called 'ever-greening'.[307] In July 2007, the Patent Office decided in favour of the applicants (OSI Pharmaceuticals) who consequently managed to secure a patent for Erlotinib or Tarceva (patent no. 196774) despite all objections raised by Natco Pharma Ltd.

3.2.1.3 Compulsory License Application for Erlotinib (Tarceva)

Natco Pharma opposed grant of patent to Erlotinib, but patent was granted despite pre-grant opposition. Having failed in its attempt, Natco Pharma had an opportunity for post-grant opposition.[308] But instead of availing the opportunity for post-grant opposition, Natco Pharma applied to Delhi Patent Office for Doha style compulsory license[309] for Erlotinib- a Roche's patented cancer drug- for export of the pharmaceutical to Nepal[310]- a least developed country in South Asia that joined WTO in April 2004[311] and has no obligation to provide patent protection to pharmaceuticals until January 1, 2016.[312] This application made in 2008 under Section 92(A) of the Patent (Amendment) Act 2005 of

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[307] "Novartis Lawsuit Threatens Access to Medicines for Millions", Available online at <http://www.oxfam.org/en/node/133>, (last accessed date May 26, 2012).

[308]"Roche-Natco update: Public interest again?", 2010, last accessed date April 20,2012, doi:http://spicyipindia.blogspot.com.au/2010/05/roche-natco-update-public-interest.html?dhiti=1&p.

[309] The first and only Doha style compulsory license for public health reasons was issued by Canada under Section 21 of the Canadian Patent Act for the production of TriAvir -an HIV/AIDS drug patented by Apotex- for export to Rwanda.
See Holger P. Hestermeyer, "Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines" , doi:http://www.asil.org/insights071210.cfm, (last accessed date June 3, 2012).

[310] Nepal's share of annual health expenditure as a percentage of the national budget was 5.1% in 2001-03. Nepal's rank in terms of the UNDP Human Development Index (HDI) is 142 among 177 countries. There have been a number of estimates of cancer incidence in Nepal. Some estimates show that the incidence of cancer is approximately 120 per 100,000 head of population, and it is assumed that there are 35,000 to 40,000 cancer sufferers in the country. For details visit <http://hdr.undp.org/en/statistics/>, (last accessed date May 26, 2012).
For more details visit <http://www.who.int/countries/npl/en/>, (last accessed date May 26, 2012).

[311]World Trade Organization, "Member Information: Nepal and WTO", last accessed date May 26, 2012,doi:http://www.wto.org/english/thewto_e/countries_e/nepal_e.htm.

[312] Vikas Asawat, "Access to Affordable Medicines in the Current Patent Regime: An Indian Perspective", *India,* (2011), 7, last accessed date May 20,2012
doi:http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1808605.

India was an unprecedented move from Natco. It was India's first ever compulsory license application.[313] The application was for permission to manufacture and export 30,000 tablets of Tarceva to Nepal. A 5% royalty was, however, offered to Roche Pharmaceuticals by Natco Pharma.

3.2.1.4 Interlocutory Petition by Natco Pharma

The Delhi Patent Office identified some lacunas in the application filed by the Natco Pharma and communicated the same to the patentees. With the main issue of grant or non-grant of compulsory license still pending, Natco Pharma Ltd. filed an interlocutory petition asserting that under Section 92 A, the compulsory licensing hearing should take place between the Delhi Patent Office and Natco Pharma; the patent holders enjoyed no right to be heard in the proceedings of this case and should therefore not be allowed to participate in the hearing.[314]

It was quite natural and logical for the Patent Office to decide first the interlocutory petition and then take up the main matter. On March 19, 2008, the Delhi Patent Office held a hearing on the patentee's right to become a party and participate in the hearing. The patentees argued that they had a right to be heard on the basis of both statutory and common law grounds. They contended that the party whose interest can be harmed has an inherent right to be heard under the principles of 'natural justice' and 'due process'. They also relied on certain statutory provisions like Section 80 of the Patents Act 1970 (India) and Rule 129 of the Patents Rules 2003 (India) under which Patent Controller is required to provide an opportunity to be heard to the parties to a proceeding

[313]Divya Subramanian, "TRIPS And Compulsory Licensing: The NATCO Nuance",(2008), 5, last accessed date May 20, 2012,doi:http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1289992.
[314] Subramanian, "TRIPS And Compulsory Licensing: The NATCO Nuance", 5.

before exercising any discretionary power adversely. Furthermore, the patentees relied on Indian cases[315] in which reliance was made on *audi alteram partem*[316] to establish the right to be heard.[317]

Natco Pharma, on the other hand, relied on literal construction or language of Section 92 (A) and the reasoning or intention behind the use of such language. They argued that Section 92 (A) is different from domestic compulsory licensing provisions (Section 84 and Section 92) which clearly provide a hearing opportunity to the parties. The intention of Section 92(A) is to provide a mechanism for Doha Style compulsory license. Natco Pharma contended that by not including the patentee's right of being heard in the provision, the legislature did not make an unintentional omission. The intention of the legislature was to adopt a straightforward, relatively fast track and expeditious mechanism to deal with special situations of public health crisis in the least developed importing countries having no manufacturing capacity of their own. Section 92(A) is intentionally silent on the point of the right to be heard and therefore deliberately excludes intervention or interference of the patentee in order to expedite the procedure.[318] Natco Pharma asserted that:

> On analysis of the section 92(A) of the Indian Patent Act, it is clear that law specifically excludes any interference or intervention or even participation by the patentee. Therefore, the question of contesting the grant of license does not

[315] Maneka Gandhi v Union of India (1978) 1 SCC 248.
[316] *Audi alteram partem* is a Latin phrase that literally means hear the alternative party too. It is most often used to refer to the principle that no person should be judged without a fair hearing in which each party is given the opportunity to respond to the evidence against them.
In Nuclear Tests case, the principle of audi alteram partem was referred to by even the International Court of Justice (ICJ). *Nuclear Tests* [1974] 265(ICJ).
For details visit <http://en.wikipedia.org/wiki/Audi_alteram_partem>, (last accessed date May 26, 2012).
[317] Rehman, *WTO, Compulsory Export Licences 28.*
[318] *Ibid.*

> arise. The entire mechanism is a departure from the usual procedure of grant of compulsory license and is aimed at giving effect to and fulfilling the objectives of said Doha Declaration which emphasizes on the rapid response to the urgent needs of the least developed countries or developing countries for immediate access to patented medicines.[319]

On July 4, 2008, the matter of right to be heard was resolved by the Delhi Patent Office. The interlocutory petition filed by the Natco Pharma was dismissed by the Assistant Controller of Patents and Design Hrdev Karar and patentees were allowed to participate in the proceedings for the grant of compulsory license.[320] One of the reasons stated by the Assistant Controller of Patents and Design for providing right to be heard to the patentees was to ensure that Section 92(A) -the key provision of Indian Patent Act- was not abused. Moreover, the importance of submissions of patentees could not be denied in deciding remuneration and terms and conditions of the grant of involuntary license.[321] The Assistant Controller said:

> It may be observed that the requirements as mentioned in section 92(A) and the rules made thereunder impliedly demand the presence of the patentee...The principle *audi alteram partem* would be more beneficial for proper administration of justice. Therefore, the patentee is required to be invited to the hearing in respect of proceedings of section 92(A).[322]

The *mens rea* behind the decision of the Assistant Controller seems to be to impart justice and fair play by affording the patentees an opportunity to present their case. The Assistant

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[319] *Ibid.*

[320] Swarup kumar, "Compulsory Licensing Provision Under Trips: A Study Of Roche Vs Natco Case In India Vis-À-Vis The Applicability Of The Principle Of Audi Alteram Partem", *Scripted*, (2010), 142, last accessed date May 25, 2012, doi:http://www.law.ed.ac.uk/ahrc/script-ed/vol7-1/kumar.pdf.

[321] *Ibid.*

[322] Rehman, "WTO, Compulsory Export Licences", 29.

Controller, in his decision, followed the principle that "justice should not only be done, but it should appear to have been done.[323]

The decision was, however, criticized by many who argue that by affording the right to be heard to the patent holders, the Assistant Controller unnecessarily burdened the already cumbersome procedure for the grant of compulsory license. They contend that the purpose of Doha style compulsory licensing provisions is to dispense with formalities in cases of health emergency. They further argue that unnecessary delay may be caused by potentially protracted hearings and right of appeal against the decision of the Patent Office; such an inordinate delay may defeat the very purpose of Doha style compulsory licensing provisions. Mr. Swarup Kumar - a senior IPR Associate/Attorney with the IP law firm Groser & Groser in India-, for instance, says that "providing for an opportunity of being heard to a patentee, towards achieving the ultimate aim of securing access to medicines for the least developed countries might make the already burdensome procedure a little more cumbersome".[324]

3.2.1.5 Notification to the Council for TRIPS

Though the decision of the Assistant Controller of Patents and Design was mainly concerning the patentee's right to be heard or to participate in the proceedings, it also discussed certain other points regarding maintainability of the Natco Pharma's application for the grant of involuntary license. For instance, Natco Pharma did not provide any substantial proof to establish their claim that Nepal was facing a public health crisis

[323] Swarup Kumar, "Compulsory Licensing Provision Under Trips: A Study Of Roche Vs Natco Case In India vis-à-vis The Applicability Of The Principle Of Audi Alteram Partem", 142, last accessed date April 20,2012, doi:.http://www.law.ed.ac.uk/ahrc/script-ed/vol7-1/kumar.pdf.
[324] Kumar, "Compulsory Licensing Provision Under Trips", 148.

owing to unavailability of Erlotinib (or Tarceva) and intented to utilize the Doha style compulsory license or 30 August WTO Waiver Decision mechanism to import the needed pharmaceutical produced under a non-voluntary license.[325]

Para 2(a)(i) of the 2003 WTO Waiver Decision provides that: "the eligible importing Member has made a notification to the Council for TRIPS specifying the names and expected quantities of the product(s) needed".[326] Moreover, the importing country is also obliged to establish that it has no or limited capacity to manufacture the drug that it intends to import under compulsory license. Para 2(a)(ii) of the 2003 WTO Waiver Decision provides that:

> The eligible importing Member(s) has made a notification to the Council for TRIPS, that confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision[327]

Nepal, being a least developed country, is exempted from the obligation of establishing its insufficient manufacturing capacity. Para 2(a)(iii) imposes yet another obligation on the importing country that "where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Article 31 of the TRIPS".[328] Nepal is exempted from this obligation as well owing to the same reason. Being a least developed country, it is not bound to have a product patent

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[325] Natco vs Roche/Pfizer: Hearing on the Right to Hearing, 2008, http://spicyipindia.blogspot.com/2008/03/natco-vs-rochepfizer-hearing-on-right.html?dhiti=1&p, (last accessed date April 20,2012).

[326] Full text of WTO's General Council's Waiver Decision of August 30, 2003 is available online at <http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm>, (last accessed date May 26, 2012).

[327] *Ibid*

[328] *Ibid*

regime for pharmaceuticals until the end of the transition period. Grant of compulsory licensing is therefore irrelevant in this instance.

As regards the first obligation i.e. the requirement of notification, Counsels for patentees argued that no formal notification was made by Nepal to demonstrate its intent to use the Doha style mechanism. They contended that Natco was relying upon a notice issued by the government of Nepal that could not be equated with the formal notification. It was just a letter that approved import of Tarceva from India during the period 2006-2007. The letter was not more than drug regulatory clearance and therefore could not be used as a conclusive evidence of either prevalence of a public health emergency in Nepal or Nepal's intent to use the special compulsory licensing mechanism designed for such cases.[329]

3.2.1.6 Withdrawal of Application by Natco Pharma Ltd.

After dismissal of interlocutory petition by the Assistant Controller of Patents and Design on July 4, 2008, it was expected that normal proceedings about the actual question of grant of compulsory license would resume, and the Patent Office would decide on merits of the case after hearing both parties. However, in September 2008, in an unexpected move, Natco Pharma Ltd. requested the Controller of Patents to withdraw its application.[330]

[329] Rehman, "WTO, Compulsory Export Licenses"..
[330] *Ibid*, 30.

3.2.1.7 Comments on Roche v. Natco

Though Natco's unexpected decision to withdraw the application for the grant of compulsory license was disappointing, the significance of this case cannot be denied. Section 92(A), a provision of Indian patent law with an indeterminate clause came up for interpretation before a competent adjudicating authority. For the first time in India, application of export oriented compulsory licensing provisions in the Indian patent law were tested. Though proceedings on the actual question of grant of compulsory licensing were yet to be initiated, the interlocutory petition raised various procedural issues which can cause inordinate delay in the grant of compulsory license if not resolved once for all.

No doubt, settled principles of law do not emerge from a single instance, the importance of Assistant Controller's decision cannot be denied in resolving the issue of 'right to be heard of the patentee' to some extent. Patent office's decision would help to avoid lengthy debates on the issue in future applications under Section 92(A). With more cases on compulsory licensing, more loopholes in the Indian compulsory licensing provisions would emerge and changes in the law may be made in the light of judgments in such cases. It will take much less time in deciding compulsory licensing cases if, instead of lengthy proceedings on procedural disputes, focus of the Patent Office remains on the substantive merits of the cases.

As regards possible reason behind unexpected withdrawal of application by Natco Pharma, firstly, Natco Pharma rushed into litigation without compliance with procedural requirements under national and international compulsory licensing regime. This may be because of negligence on their part or lack of technical expertise which is a serious issue

in the developing world. Secondly, the issue of the notification requirement created serious doubts about maintainability of Natco's compulsory licensing application. Natco might have withdrawn application to save huge cost of apparently fruitless litigation.

Moreover, it is pertinent to note that Nepal remained silent on this issue and never tried to establish the prevalence of a pressing public health problem in Nepal despite the fact that the compulsory license was sought by Natco to export the drug to Nepal. One can guess the possibility of political and economic pressure exerted on the poor country to keep it indifferent to the whole controversy.

3.2.1.8 Analysis of the Relevant Provision

Least developed countries like Nepal lack manufacturing capacity of their own. They import necessary drugs from generic producers like India, Thailand, Brazil, and South Africa. Such import is in accordance with the spirit of the Waiver Decision 2003 subject to fulfillment of certain conditions. Section 92(A) of the Patents (Amendment) Act 2005 (India) incorporates this spirit of the Waiver Decision 2003 and provides for compulsory licensing for export of pharmaceuticals to countries having little or no capacity to manufacture pharmaceuticals. Section 92(A) stipulates that:

> Compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India. The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory license solely for manufacture and export of the concerned pharmaceutical product to

such country under such terms and conditions as may be specified and published by him.[331]

Section 92 A therefore provides avenue for grant of involuntary license only for export the drugs to underprivileged third world states having no manufacturing capacity of their own. This very first application filed by Natco Pharma for grant of compulsory licensing under Section 92 A was a test case for this important provision of the Patents (Amendment) Act 2005 (India). Latha Jishnu of Business Standard in New Delhi soon after filing of this application reported that "The first application for a compulsory license filed in India, has put a key provision of the Indian Patents (Amendment) Act 2005 under the scanner".[332]

A close reading of Section 92(A) shows that:

- the importing country (normally an underprivileged country in the third world) must prove that it has insufficient or no manufacturing capacity;
- a party seeking compulsory license for a patented pharmaceutical product[333] under Section 92(A) is required to secure compulsory license in the country to which it intends to export the pharmaceutical product;
- Section 92 A mechanism can be used to secure compulsory license if the pharmaceutical product is needed to address the public health problems in the

[331] Section 92A (1) and (2) of the *Patents Act 1970 (India)*. Available online at <http://www.indiaip.com/india/patents/acts/patent_act_2005/patents_act_2005.htm>, (last accessed date May 26, 2012).
[332] Latha Jishnu, *Cancer drug puts licence, patent rules to test*, Business Standard, 2008, Available online at <http://in.rediff.com/money/2008/jan/16drug.htm>, (last accessed date May 26, 2012).
[333] The diagnostic kits required for the use of the patented product are also covered under the purview of Section 92 A.

importing country and government of the importing country has permitted such party for importation of the patented pharmaceutical products from India;

- the provision is completely silent about the requirement that the applicant for the compulsory license shall first attempt to obtain a voluntary license from the patent holder;
- the provision does not make any clear reference to the procedural requirement of notification from the importing country;
- the provision is completely silent about the royalty payment[334] and no formula has been devised or referred to for calculation of a royalty payment leaving the matter to the sole discretion of the Controller of Patents;
- the provision is completely silent on the question of a patentee's right to be heard or to participate in the proceedings;

As regards the question of manufacturing capacity and securing compulsory licensing of the patent in the importing country, in the above case, Nepal being a least developed country is exempted from both these requirements. Similarly, the procedural requirement of prior negotiation with the patentee may also be dispensed with in serious health crisis.

As regards, notification requirement, the patentees, in the Roche v. Natco, raised this issue contending that the letter produced by the Natco pharma was not conclusive evidence of prevalence of public health crisis in Nepal. However, the last two observations regarding royalty and the right to be heard are more significant because of

[334] Clause 3 of the 2003WTO Waiver Decision states that adequate remuneration (pursuant to Art 31 (h) of TRIPS) has to be paid to the patentee.

their relationship and interdependence. Omission of right to be heard of the patentee in the provision triggered heated debate even before initiation of proceedings on the main question of grant of compulsory licensing.

Para 3 of the WTO General Council's Waiver Decision provides that in circumstances of each case "adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value"[335] of the authorization. In the absence of any predetermined formula for calculating the specific royalty rate, the Patent Office has no option but to determine adequate remuneration only after gathering all relevant evidence from the patentees that can help to judge economic value of the patented product. Patentees are a necessary party to the proceedings because without having access to vital information in the sole possession of the patentees, the Controller of Patents cannot have an exact idea of the nature of the invention and possible costs incurred on the invention. The patentee therefore should be given a right to be heard not only to determine reasonable or adequate royalty but also to decide terms and conditions of the compulsory license.

Moreover, the omission of the right to be heard in the provision may not necessarily mean denying of the right to the patentees because there is no mention of royalty or remuneration in the provision but still there is no difference of opinion that royalty must be paid to the patentee.

[335] Full text of WTO's General Council's Waiver Decision of August 30, 2003 is available online at <http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm>, (last accessed date May 26, 2012).

To sum up, in order to avoid procedural disputes and potential abuse of the provision, Section 92(A) must have clearer procedural guidelines with regards to fixing of royalty, patentee's right to be heard, and notification requirement.

3.2.2 Bayer Corporation[336] v. Natco Pharma Limited

3.2.2.1 Sorafenib Tosylate

Sorafenib, originally patented in the United States in 1999[337], is a kidney and liver cancer patented drug of Bayer Corporation which is sold under the brand name 'Nexavar'. Sorafenib is not a life-saving drug, but a life extending or life prolonging drug.[338] The life of a patient can be extended by 4-5 years and 6-8 months in the case of kidney cancer and liver cancer respectively. It is pertinent to mention that the patient needs to use the pharmaceutical throughout their lifetime.[339] It is also worthy noting that in India, one month dose of Sorafenib costs Rs.2,80,428/- (Rs.33,65,136/- per annum).[340]

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[336] Bayer AG is chemical and pharmaceutical company founded in Germany in 1863. It is well known for its original brand of Aspirin. For over a quarter of a century, Aspirin became synonymous with Bayer but the company lost its naming right during World War 1, due to its German origin. Bayer started its marketing in America soon after its inception in Germany. Bayer Corporation, a party in the case Bayer v. Natco, is American arm of Bayer. Bayer Corporation is an internationally renowned manufacturer of innovative drugs. In the 1990s, it invented 'sorafenib', a liver and kidney cancer drug which is subject of controversy in the Bayer v. Natco case.
For details visit <http://en.wikipedia.org/wiki/Bayer_USA>, (last accessed date June 8, 2012).

[337] Raja Murthy, "India patent bypass delivers life-saving blow against cancer", last accessed date April 20, 2012, doi:http://www.atimes.com/atimes/South_Asia/NC21Df01.html.

[338] Betsy Vinolia Rajasingh, "India's first compulsory licence over Bayer's patent", (2012), .last accessed date April 20,2012, *doi:http://jiplp.blogspot.com/2012/05/indias-first-compulsory-licence-over.html*

[339] Frederick Noble, "Indian Patent Office Grants Licence For Anti-Cancer Drug", doi:http://www.albrightpatents.co.uk/articles/indian-patent-office-grants-licence-for-anti-cancer-drug/, (last accessed date April 20,2012).

[340] NATCO Pharma Limited v. Bayer corporation, CLA, no 1, 2011. Available online at <http://ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf>, (last accessed date June 8, 2012).

On January 12, 2001, Bayer applied for Sorafenib product patent in India. The patent was granted on March 3, 2008 under patent number 215758.[341] The drug was, however, launched in India in 2009 after receiving regulatory approval for importation.[342]

3.2.2.2 The Compulsory Licensing Application by Natco

Natco Pharma Ltd. developed the process for manufacturing of Sorafenib and in April 2011, received a license from the Drug Controller General of India for bulk manufacturing and marketing of Sorafenib in India. Natco Pharma approached Bayer Corporation for a voluntary license to manufacture and sell a generic version of their patented pharmaceutical product in India. The voluntary license was, however, denied by the Bayer Corporation.

Under Indian patent law, an application for compulsory licensing is allowed only after a lapse of three years after the grant of patent. Since the patent was granted in 2008, on July 29, 2011, Natco filed an application before the Controller General of Patents, Designs and Trademarks (CGPDTM) for the compulsory license in respect of Sorafenib under Section 84(1)(a)(b)(c) of the Indian Patent Act 1970.[343] Natco alleged that the patented invention does not satisfy the reasonable requirements of the public; the patented invention is not available to the public at a reasonably affordable price; and the

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[341] Joseph Alexander, "Planning Commission Calls For Grant Of More Compulsory Licences To Ensure Drug Security",*doi:http://pharmabiz.com/NewsDetails.aspx?aid=68849&sid=1, (last accessed date April 20,2012).*

[342] Patricia Van Arnum, "Pharmaceutical Industry Faces Compulsory Licensing in India", <http://www.pharmtech.com/pharmtech/Pharmaceutical-Industry-Faces-Compulsory-Licensing/ArticleStandard/Article/detail/766949?ref=25>, (last accessed date April 20,2012).

[343] Patralekha Chatterjee, "India's Generics-Big Pharma Battle Drops Drug Prices, Raises Legal Debate", doi:http://www.ip-watch.org/2012/05/20/india%E2%80%99s-generics-big-pharma-battle-drops-drug-prices-raises-legal-debate/, (last accessed date April 20,2012)

patented invention is not worked in the territory of India. Moreover, Natco Pharma proposed to sell the drug at a price of Rs.8800 for a month's therapy.[344]

3.2.2.3 Preliminary Issues Raised by the Patentee

On October 7, 2011, Bayer Corporation filed an interlocutory petition seeking a stay on the ground that Natco Pharma had infringed their patent on Sorafenib and an infringement suit against Natco was pending in the Delhi High Court. On October 27, 2011, the Patent Office refused the patentee's request for a stay in the matter. The parties were heard on January 13, 2012 and the patentee raised several preliminary issues during the course of the hearing. For instance, the patentee raised an issue that the application should be rejected on the ground that the applicant had suppressed a material fact that Cipla, another generic manufacturer in India, had been selling Sorafenib at the cost of Rs.30,000/- for a month's therapy since April 2010.

Natco Pharma in reply submitted that they were aware of the pending infringement suit filed by the patentee against Cipla but it was not suppression of a material fact because the pending suit had no relevance to the compulsory licensing application. It was the duty of the patentee and not of any third party to meet the demand of the patented drug in the Indian market. Moreover, an infringement suit was pending against Cipla. Cipla could be injuncted by the High Court at anytime and supply of Sorafenib by Cipla could stop totally. The objection raised by the patentee was therefore overruled.

[344] Arnum, "Pharmaceutical Industry Faces Compulsory Licensing in India".

3.2.2.4 The Main Issue/Controversy

As the application for the grant of compulsory license was made under Section 84(1)(a)(b)(c) of the Indian Patent Act 1970, the main issues to be decided in the case were as under:

- Whether the reasonable requirements of the public with respect to the patented invention had not been satisfied.
- Whether the patented invention was not avail able to the public at a reasonably affordable price.
- Whether the patented invention was not worked in the territory of India.[345]

Under Indian patent laws, compulsory license could be granted if anyone of these three grounds was established.[346] The submissions of the Applicant and the Patentee on these issues are as under:

- **Reasonable Requirements of the Public**

The Applicant relied on statistics published in GLOBOCAN 2008[347] to support their contention that Bayer's patented invention had failed to fulfill the reasonable requirements of the public. According to the publication, there were approximately 20000 liver cancer patients in India while the number of kidney cancer patients was about 8900. Whereas no bottles of Sorafenib were imported in 2008 and only 200 bottles of the

[345] "Compulsory licensing: Road ahead" , doi;http://viamediagroup.in/paradox.html>, (last accessed date June 4, 2012)

[346] Khomba Singh, "Bayer demands withdrawal of Natco Pharma's compulsory licence", doi:http://articles.economictimes.indiatimes.com/2012-05-19/news/31778153_1_compulsory-licence-natco-pharma-compulsory-licensing, (last accessed date June 4, 2012).

[347] GLOBOCAN 2008 is a publication by GLOBOCAN project of the World Health Organization. The aim of the project is to provide contemporary estimates of the incidence of, mortality and prevalence from major type of cancers, at national level, for 184 countries of the world.
For details visit < http://globocan.iarc.fr/>, (last accessed date June 8, 2012).

patented drug were imported in 2009. There was a huge difference between supply and demand of the drug. Consequently, the product in question was out of stock or not available in common pharmacies even in metro cities of India. The patentee thus failed to meet the demand of even 1% patients in India, the Applicant contended.

In reply, the patentee also relied on GLOBOCAN 2008 contending that Sorafenib was needed by the liver and kidney cancer patients who were in advanced stage.[348] Thus approximately 4838 (out of 20000) liver cancer patients and about 4004 (out of 8900) kidney cancer patients were entitled for treatment with Sorafenib. Moreover, the patentee argued that supply of the drug was not necessary in villages as the treatment with the drug should be supervised by doctors.[349] Furthermore, the patentee argued that supply of the drug was considerably enhanced due to sale of Sorafenib by Cipla.[350]

- **Reasonably Affordable Price**

The Applicant contended that price of the drug was too high for a common man in India and the patentee had failed to meet the demand for the drug on reasonable terms. Rs.2,80,428 –price fixed by Bayer Corporation for a month's therapy- was more than total income of three and half years of a government worker in India.[351] About 30% Indians were already below the poverty line[352]; the exorbitant price of the drug would

[348] Rahul Dhote & Mita Sheikh, Krishna & Saurastri Associates, "Natco win: Deterrent for FDI?", doi:http://www.moneycontrol.com/news/the-firm/natco-win-deterrent-for-fdi_682903.html,(last accessed date June 4, 2012).

[349] NATCO Pharma Limited v. Bayer corporation, CLA, no 1, 2011. Available online at <http://ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf>, (last accessed date June 8, 2012).

[350], Krishna & Saurastri "Natco win: Deterrent for FDI?".

[351] Murthy, "India patent bypass delivers life-saving blow against cancer".

[352]The poverty line set in India is already below international standards. In March 2012, Planning Commission further reduced poverty line to Rs 28.65 per capita daily consumption in cities and Rs 22.42 in rural areas.For details visit <http://ibnlive.in.com/news/indias-poverty-line-now-lowered-to-rs-28-per-day/240737-3.html>, (last accessed date June 8, 2012).

push more Indian population below the poverty line.[353] Setting of such a high cost of the drug was unfair, anti-competitive and misuse of the monopolistic rights, contended the Applicant.

The patentee, in reply, justified the high price on the ground that innovation was not possible without huge costs spent on research and development. Manufacturing of innovative products was different from that of generics which are mere copies of the patented products. Almost 75% of the total research and development cost was incurred on failed projects. That cost too was recouped by setting a high price of successful formulas. Moreover, the patentee submitted that the term 'reasonable' means reasonable not only to public but also to patentee. Therefore there must be a balance between public interest and interest of the innovator taking into account the cost incurred on research and development.[354]

- **Patented Invention not Worked in the Territory of India**

The Applicant contended that the patented invention was not worked in the territory of India because it was being imported into India and not being manufactured in India. The patentee had failed to exploit the patent in India without ascribing any reason for such neglect. The patentee already having manufacturing facilities in India had no excuse for not working the patent in India.[355]

[353] Murthy, "India patent bypass delivers life-saving blow against cancer".
[354] NATCO Pharma Limited v. Bayer corporation, CLA, no 1, 2011, Available online at <http://ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf>, (last accessed date June 8, 2012).
[355] Jose Madan, Adheesh Nargolkar and Fiona Desouza of Khaitan & Co, *A Rare Win for Natco!*, <http://www.moneycontrol.com/news/features/a-rare-win-for-natco_682506.html>, (last accessed date June 4, 2012)

In reply, the patentee argued that 'worked in India' did not mean 'manufactured in India'. Domestically worked meant 'commercial working' or 'supplied to the Indian markets'.[356] Bayer argued that the words 'manufacture in India' were deleted from Section 84(7)(a)(ii) while amending the patent law in 2002.[357] Moreover, the patentee contended that manufacturing of the product required huge investments on infrastructure and logistics which could further increase the manufacturing cost of Sorafenib -a product of small global demand. The quantity of the product required in India therefore did not justify spending of huge amounts on infrastructure and logistics.[358] Furthermore, under Article 27 of the TRIPS Agreement, the patentee's right should not be affected only because of importation of the patented product.[359]

3.2.2.5 The Order of Grant of Compulsory License

After 18 hours of hearings in three days, on March 9, 2012, minutes before leaving his office on the last day of his stint at the Indian Patent Office, P.H Kurian, Controller General of Patents, issued the order of grant of first Indian compulsory license[360] to Natco Pharma allowing it to manufacture and sell Bayer's patented product Sorafenib.[361]

As regards the question of meeting reasonable requirements of the public, the Controller concluded that even if Bayer's estimate of cancer patients in India is accepted, the negligible quantity of the drug imported into India by Bayer could hardly suffice for 2

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[356] Krishna & Saurastri "Natco win: Deterrent for FDI?",2012

[357] Rajasingh, "India's first compulsory licence over Bayer's patent", 2012,

[358] NATCO Pharma Limited v. Bayer corporation, CLA, no 1, 2011, Available online at <http://ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf>, (last accessed date June 8, 2012).

[359] Krishna & Saurastri , "Natco win: Deterrent for FDI?",(2012)

[360] The compulsory licence is valid till the patent for Nexavar expires in 2021. <http://www.business-standard.com/india/news/us-to-keep-an-eyeindias-compulsory-drug-licensing-move/473520/>, (last accessed date June 9, 2012).

[361] Breaking News: "India's First Compulsory License Granted", (2012), doihttp://ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf>, (last accessed date June 4, 2012)

percent cancer patients.[362] This nominal quantity of the drug was available only at certain premier hospitals and that too was excessively high-priced rendering it unaffordable for potential users. The Controller therefore concluded that the patentee had not adequately met the demand of the patented invention on reasonable terms.[363]

As regards the question of reasonably affordable price, the Controller rejected Bayer's interpretation of the term and concluded that the term 'reasonable' used in the provision referred predominantly to the purchasing power of the public.[364]

With regards to question of 'working of the patented invention in the territory of India', the Controller referred to Article 5(A)(2) of the Paris Convention according to which patentee's failure to work the invention may be used as a ground for grant of compulsory license. Moreover, the Controller referred to Article 2(1) of the TRIPS Agreement under which member countries are required to comply with provisions of the Paris Convention. Furthermore, the Controller referred to Section 83(b) of the Patents Act 1970 (India) which stipulates that: "they (patents) are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article."[365] Applying the rationale of Section 83(b), the Controller concluded that working of the invention in India meant manufacturing of the patented product in India and not mere its importation

[362] Nandan S. Nelivigi, James R.M. Killick, Carolyn B. Lamm, Gregory J. Spak, Dimitrios T. Drivas, Bijal V. Vakil, "Indian Patent Office Grants Compulsory License for Bayer's Nexavar: Implications for Multinational Drug Companies", doi:http://www.whitecase.com/alerts-04022012/, (last accessed date June 4, 2012)

[363] Betsy Vinolia Rajasingh, "India's first compulsory licence over Bayer's patent", (2012), *doi:http://jiplp.blogspot.com/2012/05/indias-first-compulsory-licence-over.html, (last accessed date April 20,2012).*

[364] Bijal V. Vakil, "Indian Patent Office Grants Compulsory License for Bayer's Nexavar: Implications for Multinational Drug Companies", (2012).

[365] Full text of Section 83(b) of the Patents Act 1970 (India) is available online at <http://indiankanoon.org/doc/471445/>, (last accessed date June 9, 2012).

in India. Bayer had therefore failed to comply with Section 84(1)(c) of the Indian Patent Act 1970.[366]

The grant of compulsory license was, however, subject to certain conditions. Firstly, Natco was required to pay a 6% royalty to Bayer on net sales of Sorafenib manufactured under the compulsory license. Secondly, Natco was not allowed to charge more than Rs.8800 for a month's therapy.[367] Thirdly, Natco was required to manufacture the drug at its own manufacturing facility. Fourthly, the generic version of the drug could only be sold within territory of India and Natco was not allowed to export the drug.[368] Fifthly, the generic version must have a distinct physical appearance, trade name, and packaging.[369] Moreover, Natco Pharma committed to donate the drug free of cost to six hundred needy patients every year. The Controller also recorded this commitment in the order for the grant of compulsory license.[370]

3.2.2.6 Implications of the Controller's Decision

The Controller's decision, which brought down the costs Sorafenib by 97 percent, was appreciated by many, especially cancer patients, human rights activists and advocates of cheaper drugs, who believe that it would bring relief, hope and cheer for helpless cancer patients[371] in India who –in the absence of any form of health insurance- were unable to

[366] Vakil, "Indian Patent Office Grants Compulsory License", (2012).
[367] Patralekha Chatterjee, "India's Generics-Big Pharma Battle Drops Drug Prices, Raises Legal Debate", doi:http://www.ip-watch.org/2012/05/20/india%E2%80%99s-generics-big-pharma-battle-drops-drug-prices-raises-legal-debate/, (last accessed date June 4, 2012).
[368] Arnum, "Pharmaceutical Industry Faces Compulsory Licensing in India",(2012).
[369] Fiona Desouza of Khaitan & Co, "A Rare Win for Natco", (2012)
[370] Breaking News: "India's First Compulsory License Granted", (2012), http://ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf, (last accessed date June 4, 2012).
[371] Government surveys have shown that 65 percent of the 1.1 billion population of India falls into debt as result of 'out-of-pocket' healthcare spending.
Doi:http://ipsnews.net/news.asp?idnews=107126, (last accessed date June 4, 2012)

afford the excessively expensive therapy otherwise.[372] The price set by the patentee could be afforded only by richest patients in India and importation of a very negligible quantity of the drug was testimony to this fact.[373]

Supporters of the ruling believed that this bold decision would check abuse of patent rights and put pressure on other brand name pharmaceutical companies to rethink and revise prices of their products. Soon after this judgment, Roche Holding, a Swiss drug maker, announced that it will cut price on two of its cancer drugs, Herceptin and Mabthera[374], and partnered with an Indian pharmaceutical company Emcure Pharmaceuticals to repackage and sell the same under different brand names only in the Indian markets.[375]

But at the same time, the ruling by the Patent Office was criticized by many, especially brand name pharmaceutical producers, who assert that the research carried out by pharmaceutical companies is not only costly but also fraught with risks.[376] A successful molecule that reaches the market in the form of a drug is prepared only after thousands of failed experiments and companies set a high price to recoup the cost spent

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[372] Rajasingh, "India's first compulsory licence over Bayer's patent", (2012), *doi:*http://jiplp.blogspot.com/2012/05/indias-first-compulsory-licence-over.html, (last accessed date April 20,2012).

[373] Brook Baker ,"Bayer Appeals Indian Compulsory License for Nexar", (2012), doi: http://infojustice.org/archives/20207,, (last accessed date June 4, 2012).

[374] Marie Daghlian, "US Protests India's Compulsory License for Nexavar", doi:http://www.burrillreport.com/articleus_protests_india%E2%80%99s_compulsory_license_for_nexavar.html, (last accessed date June 4, 2012).

[375] Bayer challenges 'compulsory license' ruling, for detail see, <http://health.india.com/news/bayer-challenges-compulsory-license-ruling/>, (last accessed date April 20,2012

[376] Pharmaceutical companies assert that only five out of 5,000 experimental compounds in development will reach clinical trials stage: and then out of the five, only one will reach the drug stage. Thus each successful molecule that makes it as a drug needs to pay for the thousands of those molecules that fail. And all this comes with a heavy price tag ranging from $ 4-12 billion for each approved drug that will reach the marketplace.
<http://viamediagroup.in/paradox.html>, (last accessed date June 4, 2012)

on R&D.[377] Such arbitrary use of compulsory license will embolden other Indian generic manufacturers[378] to bring more such applications which will consequently not only undermine innovation[379] but also impact key drugs in the pipeline.

This grant of compulsory license was unique because the license was issued neither in a situation of 'extreme urgency' or 'national emergency' nor for 'governmental use'. Such practice could provide generic manufacturers an opportunity to compete with multinational pharmaceutical companies without making any investments in research and development.[380] The ruling will make the international investors think twice before considering India for investment and is likely to have an adverse effect on foreign direct investment (FDI) especially in the pharma sector.[381]

As expected, India had to face political backlash and opposition from governmental pressure groups in the US and Europe. In its latest report, United States Trade Representative (USTR) placed India on the Priority Watch List. Its 2012 Special 301 Report says: "The US would closely monitor developments concerning compulsory licensing of patents in India, following the broad interpretation of the law in a recent

[377] Europe invests more that 27 billion in pharmaceutical Research & Development (R&D) every year, according to a report conducted by the European Federation of Pharmaceutical Industries and Associations, while the US invests an estimated $67 billion annually in biopharmaceutical research. <http://articles.economictimes.indiatimes.com/2012-03-27/news/31245102_1_compulsory-licence-patent-owner-indian-patent-office>, (last accessed date June 4, 2012)

[378] Generic manufacturer Natco has also asked for a compulsory license for Selzentry, and AIDS medication made by the U.S. drug company Pfizer. Natco competitor Cipla, in the meantime, has asked for a license for Merck's AIDS medication Isentress. <http://www.worldcrunch.com/drug-companies-battle-against-indian-pharmaceutical-pirates/4890>

[379] Joseph Alexander, "Planning Commission Calls For Grant Of More Compulsory Licences To Ensure Drug Security",(2012), *doi:*http://pharmabiz.com/NewsDetails.aspx?aid=68849&sid=1, (last accessed date May 20,2012).

[380] "Compulsory licensing: Road ahead". (2012) , doi:http://viamediagroup.in/paradox.html, (last accessed date June 4, 2012)

[381] Dr Ajit Dangi , "Government's actions in the last few months sends a clear signal to an international investor that he is not welcome", (2012), doi: http://www.expresspharmaonline.com/20120415/management01.shtml, (last accessed date June 4, 2012).

decision by the Controller General of Patents".[382] Mr. John Castellani, President and CEO of the Pharmaceutical Research and Manufacturers of America (PhRMA) too condemned the decision saying that "it was not an appropriate tool even if granting compulsory licenses might be a legal option. The responsibility to promote the development of new drugs lies with all countries, not solely those in the developed world".[383]

Similarly, Mr. John Bryson, United States Commerce Secretary, in a meeting with India's Commerce and Industry Minister, said that the decision "would discourage new investments and dilute the international patent regime".[384] Similarly, Ranjit Shahani, Chief Executive Officer, Novartis India and President, Organization of Pharmaceutical Producers of India, said that "the move will work to the detriment of patients through the negative impact they (CLs) will have on future investment in innovative pharmaceuticals".[385]

This legal battle is far from over. Bayer Corporation, on May 4, 2012, appealed against the decision in the Intellectual Property Appellate Board (IPAB) Chennai demanding withdrawal of the compulsory license.[386] A party losing the case before IPAB

[382] Joe C Mathew, "Puts India on priority watch list, which means US trade body doubts India over intellectual property rights",(2012),http://www.business-standard.com/india/news/us-to-keep-an-eyeindias-compulsory-drug-licensing-move/473520/, (last accessed date June 4, 2012).

[383] "PhRMA speaks out against compulsory licensing in India",(2012), doi:http://www.gabionline.net/layout/set/print/content/view/full/1820, (last accessed date June 4, 2012).

[384] Marie Daghlian, "US Protests India's Compulsory License for Nexavar", (2012), http://www.burrillreport.com/articleus_protests_india%E2%80%99s_compulsory_license_for_nexavar.html, (last accessed date June 4, 2012).

[385] Ranjit Devraj, "India Affirms Role as Developing World's Pharmacy",(2012), http://ipsnews.net/news.asp?idnews=107126, (last accessed date April 20,2012).

[386] Patralekha Chatterjee, "India's Generics-Big Pharma Battle Drops Drug Prices, Raises Legal Debate",(2012), doi:http://www.ip-watch.org/2012/05/20/india%E2%80%99s-generics-big-pharma-battle-drops-drug-prices-raises-legal-debate/, (last accessed date June 4, 2012).

may appeal to the courts.[387] Keeping in view past experiences and money and legal firepower multinational companies have, one can easily expect prolonged inevitable litigation on the issue right up to the Supreme Court in India and even at WTO.[388]

3.2.2.7 Comments on Bayer v. Natco

As regards the concern for humanity and issue of affordability of drugs, the decision should be lauded as a brave move by India. Price of Sorafenib would decrease by 97% as a result of this ruling which would bring hope and relief for many.

As regards the question of access to the drug, nothing can be said with certainty even after this ruling. Firstly, price of the drug is not the only hurdle in access; there are many bigger problems like lack of diagnosis, weak health care infrastructure, lack of trained health care staff, inadequate distribution of the drug etc. which adversely affect access to even affordable medicines. Moreover, in a country where a person earning less than Rs.30 per day is considered above the poverty line, it is really difficult to decide the affordable price. According to World Health Organization[389], even the drugs that are off patent in India are affordable to only 20% of the Indian population.

In the absence of any long-term commitments from the Indian government to alleviate poverty and improve health infrastructure, and in the presence of a huge

[387] Jose Madan, Adheesh Nargolkar and Fiona Desouza of Khaitan & Co, "A Rare Win for Natco!,",(2012), *doi:*http://www.moneycontrol.com/news/features/a-rare-win-for-natco_682506.html, (last accessed date June 4, 2012)

[388] Shakti Chakraborty , "There is no sweeping right or wrong simply because there are many factors that are to be considered", (2012), *doi:* http://www.expresspharmaonline.com/20120415/management01.shtml, (last accessed date June 4, 2012).

[389] Ranjit Shahani , "Compulsory licensing Patients vs Patents?",(2012), *doi:* http://www.expresspharmaonline.com/20120415/management01.shtml, (last accessed date June 4, 2012).

profitable generic pharmaceutical industry in India, the decision keeps one skeptical about actual motives behind the decision.

Compulsory licensing option must be used with caution only after exhausting all other efforts and only in certain exceptional circumstances. But this decision is unique because compulsory license has been granted not in exceptional circumstances or public health emergency, and not for government use. If more such licenses are granted in India as a rule and not as an exception, and other poor countries also follow suit, hardly any pharmaceutical patent shall remain protected in the third world. This will deprive the innovators of their right to benefit financially from their intellectual property which will consequently undermine innovation in the pharma sector because the meager amount paid as royalty can't provide incentive for further research.

To be very realistic, we cannot expect from multinationals to spend billions of dollars on research and development on humanitarian grounds and let the generic manufacturers replicate their drugs and reap the fruits of their labors after paying a nominal amount as royalty. At the same time, the exorbitant prices fixed by the multinationals owing to lack of competition cannot be justified. Third world countries must use compulsory license as a bargaining tool to negotiate with multinationals on discounted prices of drugs. An ideal solution would be to reach a middle-ground in order to strike a perfect balance between public interest and corporate profits by devising a mechanism under which multinationals are adequately compensated as a result of such decisions.

3.3 Pakistani Compulsory Licensing Regime

Pakistan[390] is a member of WTO, WIPO, and Berne Convention on Copyrights. Prior to WTO, IPR regime in Pakistan consisted of Merchandise Marks Act 1889, Patents and Designs Act 1911 (which provided for compulsory licensing under Section 22, 23, and 23A)[391], Patents and Designs Rules 1933, Secret Patents Rules 1933, Trademarks Act 1940, Copyright Ordinance 1962, Trademarks Rules 1963, Customs Act 1969, and Pakistan Penal Code.

Though eligible for the transition period till 2005[392], Pakistan, in an effort to fulfill its TRIPS obligations, promulgated the Patent Ordinance 2000, Copyright Amendment Ordinance 2000, Industrial Designs Ordinance 2000, and Trademarks Ordinance 2001, as presidential ordinances.[393] The remedy of compulsory licensing is available under Section 59 of the Patents Ordinance 2000 which stipulates:

> On request, made in the prescribed manner to the Controller after the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last, the Controller may issue a non-voluntary license to prevent the abuses

[390] Pakistan has been on USTR's Special 301 Watch List since 1989 because of widespread piracy especially of copyrighted materials. According to USTR report, in 2003, Pakistan was the fourth largest source of counterfeit and pirated goods seized by the U.S. Customs Service.
For details visit
<http://worldtradereview.com/news.asp?pType=N&iType=A&iID=157&siD=9&nID=33489>, (last accessed date June 4, 2012).

[391] Karimullah Adeni, "Compulsory Licensing Of Life-Saving Medicines" ,(2012). Doi:http://www.aliassociates.com.pk/article4.html, (last accessed date June 4, 2012).

[392] World Health Organization, "Pharmaceutical Country Profile". *Country Report Pakistan*,(2010),9, last accessed date June 4, 2012, doi:http://www.who.int/medicines/areas/coordination/pakistan.pdf.

[393] Awan, "Pakistani. Pharmaceutical Industry in WTO regime-Issues and Prospects", 8.

which might result from the exercise of the rights conferred by the patent, for example, failure to work.[394]

A careful reading of the provision reminds of Article 5(A)(2) of the Paris Convention 1883 which provides for compulsory licensing in order to prevent abuse of exclusive patent rights.[395] Compulsory license may also be granted under Section 58(1)(iii) of the Patents Ordinance 2000 in instances where patent holder refuses to grant voluntary license to a third party on reasonable commercial terms and conditions. Moreover, the compulsory license may be granted under Section 58(1)(iv) of the Ordinance in instances where the patent has not been exploited in a manner which contribute to the promotion of technological innovation and to the transfer and dissemination of technology.

The provisions, therefore, do not take into account the developments with regards to compulsory licensing from 1883 to date; there is no mention of government use in public health crisis, reasonable requirements of the public, reasonable affordable price etc. Moreover, the Ordinance does not provide for special Doha style compulsory licensing.

If we compare Pakistani compulsory licensing provision with Indian compulsory licensing provisions, we find Indian provisions more elaborative and more purposeful, and tailored to suit their national objectives. Pakistani provision seems less effective even as a negotiating tool and there is hardly any instance where Pakistan tried to put

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[394] Full text of the Patent Ordinance 2000 is available online at <http://www.ipo.gov.pk/patent/Downloads/PatentsOrdinance2000_Amendmentsfinal.pdf>, (last accessed date June 4, 2012).

[395] "Is Article 31BIS Enough? The Need To Promote Economies Of Scale In The International Compulsory Licensing System", *Temple Int'l & Comp. L.J.* , (2008), 166, Last accessed date April 1, 2012, doi: http://www.temple.edu/law/ticlj/ticlj22-1Gumbel.pdf.

compulsory license pressure on pharmaceutical companies to drop prices of their products.

It seems that while enacting the provision, Pakistan completely forgot its commitments made in Article 38(d) of the Constitution of the Islamic Republic of Pakistan which stipulates:

> The state shall provide basic necessities of life, such as food, clothing, housing, education, and medical relief, for all such citizens, irrespective of sex, caste, creed, or race, as are permanently or temporarily unable to earn their livelihood on account of infirmity, sickness, or unemployment.[396]

Pakistan needs not only to update its patent law but also to improve its health and pharmaceutical infrastructure, if it is serious in fulfilling its commitments made in the Constitution. There are 478 licensed pharmaceutical manufacturers in Pakistan[397] most of which are operating with outdated machinery without assurance of quality standards because of inconsistent government policy.[398] Moreover, Pakistan needs to be clear about what are its national objectives and must enact its laws accordingly instead of copy pasting treaty obligations in its municipal laws.[399]

3.4 Conclusion

An analysis of the Indian compulsory licensing provisions, in the light of practical cases, shows that Indian provisions are wide and liberal. Presence of broad based public interest

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[396] Full text of the Constitution of the Islamic Republic of Pakistan is available online at <http://www.mofa.gov.pk/Publications/constitution.pdf>, (last accessed date June 4, 2012).
[397] World Health Organization, "Pharmaceutical Country Profile", *Country Report Pakistan*, (2010), 10, doi:http://www.who.int/medicines/areas/coordination/pakistan.pdf, (last accessed date June 4, 2012).
[398] Awan, "Pakistani Pharmaceutical Industry in WTO regime-Issues and Prospects",6.
[399] Articles 27, 28, 34 and 50 of the TRIPS Agreement have been reproduced as Sections 7, 30, and 61 of the Patent Ordinance 2000.

based compulsory licensing provisions in the patent law is a cause of concern for multinationals. Such compulsory licensing provisions have practical significance only for such countries which have a well established generic manufacturing industry. Indian generic manufacturing industry is fully capable of exploiting such broad compulsory licensing provisions.

Natco Pharma failed in its first attempt to get a special Doha style compulsory license under Section 92(A) because it had a weak case on technical grounds. It applied for license without fulfilling procedural requirements. Still the case had significance because it highlighted many key issues that needed clarity in the Indian patent law. In the second case, Natco Pharma applied for ordinary compulsory license under Section 84 and first Indian compulsory license was granted in this instance.

India, being an emerging economy, is different from other third world countries and could therefore withstand economic and political pressure exerted by multinationals and technologically advanced countries. Grant of first Indian compulsory license in the absence of any exceptional circumstances of public health crisis and in the presence of a huge generic pharmaceutical industry has been looked at with apprehensions and serious skepticism. If more such licenses are granted in India and in the rest of the third world as a rule and not as an exception reserved for certain special circumstances, it would undermine patent protection and consequently innovation.

CHAPTER 4

CONCLUSION AND RECOMMENDATIONS

4.1 Conclusion

An examination of the literature reveals that patents provide monopoly rights to patent owners to manufacture, sell, and import the product resulting in overpricing of the patented products. Without patents, the inventors and innovators can neither be adequately compensated for their costs of research nor be encouraged or motivated for further research to develop new and improved products. Patent protection is therefore accepted as a necessary evil despite its conflict with the competitions laws.

As regards patent protection for pharmaceuticals, prior to TRIPS, pharmaceutical products were excluded from patent protection in the third world and even in some advanced countries. TRIPS made patent protection of all products mandatory without any exception. Access to drugs was not a concern for advanced countries where per capita income is high and citizens prefer to buy patented drugs. But it was a serious concern for third world countries where purchasing power in general is low and access to drugs is a problem especially in public health crisis.

The monopoly right of the patentee, however, carries a corresponding duty towards public at large. The patentee is entitled to enjoy the right as long as he discharges his duties. There must be checks and balances to make sure that the monopoly right is not abused. TRIPS included flexibilities or safeguards like compulsory licensing and parallel importation to address the public health concerns of the third world countries and to avoid misuse of the exclusive rights by the patent owner. As the license

authorizes a third party to use the patent without consent of the patent holder, it is in conflict with patent protection. But it is accepted as yet another necessary evil in order to improve access to essential medicines in situations like public health crisis. Compulsory license therefore falls mid way; neither absolute protection is granted, nor is it denied altogether.

TRIPS provided this flexibility and most of the member states incorporated the same into their municipal laws but the safeguard remained practically ineffective because of multiple factors which do not allow the underprivileged countries to use the legitimate flexibilities. Concerns like costly and needless litigation, the fear of economic consequences e.g. loss of Foreign Direct Investment, threat of political pressure, risk of retaliatory action by giant multinational pharmaceutical companies bar politically weak and economically fragile third world countries from invoking compulsory licensing provisions.

It is pertinent to note that even if a third world country invokes compulsory licensing despite all odds, it backfires because the compulsory licensing mechanism is poorly regulated and confusing in the third world countries. There is a sheer of lack technical expertise to understand the practical implications and legal ramifications of compulsory licensing resulting in mishandled situations which pose a serious threat to already economy of such countries.

Following main conclusions may be drawn from previous analysis:

- Patent protection is in conflict with both competition laws and human rights law; Patents are necessary for innovation but there must be safeguards to prevent

misuse of monopoly rights and to cope with certain special circumstances like public health crisis.

- Compulsory licenses can be justified as a legitimate flexibility or safeguard and should be considered as an essential part of patent law especially after adoption of TRIPS which provided mandatory patent protection to pharmaceuticals.
- There are loopholes and ambiguities in the existing compulsory licensing provisions of 'TRIPS Agreement' and 'Doha Declaration on TRIPS and Public Health' resulting in controversies and costly litigation. For instance, language of TRIPS is vague concerning the meaning of the word 'reasonable'. Moreover, it allows the individual nation to decide what constitutes a national emergency without involving any third party fact-finder in the determination of national emergency.
- There are various practical implications for the third world countries owing to which they normally do not even consider the option of compulsory licensing, resulting in very few practical instances of grant of compulsory licenses in the developing world.
- Amendments should be made in the existing compulsory licensing regime to make the compulsory licensing provisions more objective and less ambiguous to avoid controversies and to prevent any potential abuse of the provisions.

To sum up, there are implementation gaps between theory and practice of compulsory licensing. WTO member states have been provided flexibilities under TRIPS Agreement but third world countries are not able to avail the flexibilities due to multiple practical problems which restrict them from availing the flexibilities. The flexibilities are, in many

instances, only provided in the statute books and do not serve the desired practical purpose.

4.2 Recommendations/Suggestions

The above conclusion suggests that the compulsory licensing arrangement provided to the low-income countries to ensure affordable access to essential medicines to their citizens could not serve the desired purpose due to numerous reasons. Some recommendations in this regard are as under. The following recommendations may be helpful both for the World Trade Organization (WTO) and the member states of WTO to make best use of the existing system and to introduce reforms and amendments in the already existing system.

4.2.1 Balance between Patent Holder's Interests and Public Interest

No doubt, the inventor or innovator must be provided adequate reward for his effort in order to enable him not only to recover his costs of research but also to have an incentive for further research. But there must be a balance between patent holder's interests and public interest. The price of patented products, especially pharmaceutical products, must be set in such a rationale way that pharmaceutical companies are adequately compensated for their research and innovation and at the same time the product (drug) remains affordable for the poor people.

4.2.2 Improvement in Judicial and Patent Infrastructure

There is a need for a better equipped patent and judicial infrastructure in developing countries to deal with increasing number of intellectual property issues. Developing

countries should institute at least one specialist IP court in the country for an efficient patent litigation. If this is not possible, at least the existing courts of big cities should have IP specific benches. Judges of these IP specific benches must be adequately qualified and must fulfill appropriate eligibility criteria. Moreover, these judges must be provided extensive IP training to enable them to discharge their duties efficiently in the desired manner. Furthermore, the patent system of a country must be neither too expensive nor too cumbersome to administer. Every effort must be made to remove loopholes in the patent system which can be exploited by either party.

4.2.3 Improvement in Physical Infrastructure

Patent protection is not the only hurdle in access to drugs; there are multiple factors other than patents which adversely affect the availability of needed drugs. For instance, weak physical infrastructure is one such factor. Developing countries cannot effectively cope with the public health crisis unless they improve their medical and transport infrastructure and establish their industrial sector. A very minute percentage of their national budget is spent on health resulting in sheer lack of properly trained healthcare staff and poor health infrastructure. Such a fragile infrastructure in the poorer countries is unable to provide adequate health facilities even in normal conditions not to talk of public health crisis. With such a deteriorating healthcare infrastructure, the poor countries cannot meet the challenges of health crisis even if they invoke compulsory licensing provisions.

In public health crisis there is a need to produce the needed drug on a significant scale, and deliver the same quickly to those in need of it. Countries lacking scientific infrastructure and industrial base to reverse engineer the patented

pharmaceutical product cannot manufacture the needed drug in significant amounts. Similarly the countries lacking efficient network of roads, railways, seaports, and airports cannot transport or deliver the needed drug in the regions where it is urgently needed. Thus, compulsory licensing is no solution if the state granting compulsory lacks the ability to exploit it properly. An improved physical infrastructure, on the other hand, not only improves access to drugs by fully exploiting the compulsory license but also brings other local benefits like jobs and investments

4.2.4 Awareness and Prevention Programs

Following the principle "prevention is better than cure", the developing countries must be willing to spend some money on awareness and prevention programs to undercut the crisis created by epidemics and pandemics. Such programs are particularly useful in case of diseases to which a stigma is attached because of religious or cultural reasons. HIV/AIDS, for instance, is considered a shameful disease because it is transmitted through possible immoral conduct. Instead of receiving treatment at the right time to save themselves and others from the pandemic, the infected individuals refuse to even acknowledge their infection owing to the stigma attached with the disease. Thus, it is the duty of the states to take timely action to spread awareness among masses through media campaigns, mobilizing the NGOs, and awareness programs.

4.2.5 Strategies to Counter Costly Patent Litigation Pressure

The giant multinational pharmaceutical companies have money and legal firepower to put a pressure on third world countries. In order to avoid spending huge amounts on costly patent litigation, the poor countries must do their homework and comply with national

and international law on the issue before invoking compulsory licensing provisions. They must try their best to know and perform their obligations before resorting to compulsory licensing. They must enhance their technical expertise in the field of intellectual property laws to know the nitty gritty of the compulsory licensing mechanism and the legal ramifications involved in its use.

4.2.6 Strategies to Counter Extra-Legal Pressure

Developing countries normally cannot withstand the political and economic pressure exerted by powerful states and giant pharmaceutical companies. This is because of the fact that developing countries lack the strength, sustenance, and vision to compose themselves into a homogeneous group in the WTO to raise a common voice for their concerns. Developing countries must show unity for their common concerns irrespective of their geographical variation and difference in level of development. Moreover, they may form alliances with developed states and even with international health organizations and non-governmental organization (NGOs) to constrain extra legal pressure. Through unity, coordinated behavior, and adoption of collaborative position, developing countries may extract more fair prices from patent holders through collective bargaining.

Further, effective use of media and mobilization of Non-Governmental Organizations and human rights activists can be very useful in instances where global powers and giant multinational pharmaceutical companies try to place corporate interests above the grave medical concerns during a health crisis. Media and human rights activists

may present the issue of access to drugs as an issue of *ordre public*[400] or morality in order to shape public opinion in favor of poor countries. Multi-national corporations (MNCs) are normally very much concerned about public opinion and their reputation or perception among consumers because any negative impression about these companies has an adverse effect on sale of their products. They can afford to bear high costs of patent litigation but they can afford to bear huge financial losses when the matter of access to drugs comes to the court of public opinion.

Furthermore, developing countries may use the forum of WTO's Dispute Settlement Body (DSB[401]) to resolve disputes relating to compulsory licensing of patents. Developed states, owing to the risk of a binding negative decision, are normally reluctant to use the DSB forum; they rather rely on political and economic pressure to achieve their desired results in such disputes.

4.2.7 Strategies to Counter Risk of Counterfeit Drugs

Counterfeit drugs may be even toxic with unavoidable side effects resulting in loss of consumer's confidence in health care providers and medicines. A consumer is less likely to buy a fake drug if he is familiar with his medicine and knows about side effects of the bogus drug. Thus, risk of illness or death from the use of falsely labeled substandard

[400] The public policy doctrine or ordre public concerns the body of principles that underpin the operation of legal systems in each state. This addresses the social, moral and economic values that tie a society together. laws are most likely to be effective when they are consistent with the most generally accepted societal norms and reflect the collective morality of the society. Ordre public encompasses the protection of public security and the physical integrity of individuals as part of society.
For details visit < http://www.iprsonline.org/unctadictsd/docs/RB2.5_Patents_2.5.3_update.pdf> (last accessed date June 2, 2012)

[401] The Dispute Settlement Body (DSB) of the World Trade Organization (WTO) makes decisions on trade disputes between governments that are adjudicated by the Organization. The DSB is, in effect, a session of the General Council of the WTO: that is, all of the representatives of the WTO member governments, usually at ambassadorial level, meeting together. It decides the outcome of a trade dispute on the recommendation of a Dispute Panel.
For details visit <http://en.wikipedia.org/wiki/Dispute_Settlement_Body> (last accessed date June 2, 2012)

counterfeit drugs with little or no therapeutic value can be reduced to some extent through consumer education about identification and hazards of counterfeit drugs. Moreover, governments of developing countries should acquire and use modern technologies to identify the counterfeit drugs from genuine drugs because both may look exactly the same to the naked eye. Further, manufacturers of branded drugs may use distinguishable features –like unique stickers which cannot be imitated easily- on packaging to help the consumer distinguish between fake and genuine drugs. Furthermore, the law enforcement agencies must take action against laboratories manufacturing counterfeit drugs and pharmacies selling these fake drugs.

4.2.8 Narrowly Tailored Compulsory Licensing Provisions

Compulsory licensing provisions must not be too broad to allow unnecessary use of the flexibilities. The part of patent law relating to compulsory licensing must be made more objective and less ambiguous. The subjective approach adopted in compulsory licensing provisions can be easily manipulated. Moreover, the affected patent holders must be taken on board while making legislation on compulsory licensing. Their participation may be helpful in avoiding many potential problems which can arise when the provisions are actually tested during litigation.

4.2.9 Adoption of Royalty Guidelines

In order to reduce uncertainty, to expedite litigation, and to ensure transparency, the system of setting royalty or remuneration for the patent holder should be relatively predictable and easy to administer. An ideal approach in this regard would be to adopt royalty guidelines.

4.2.10 Avoid Over Reliance on Compulsory Licensing

No doubt developing countries can invoke compulsory licensing provisions to maximize access to essential life saving medicines, but this is a short term and emergency solution to public health crisis. Developing countries should use it carefully to avoid undesirable potential consequences. Developing countries must avoid over reliance on compulsory licensing. Moreover, they must make sure that compulsory licenses are not derailed into trade protection measures for local interests. They must never use these flexibilities as opportunities to expand their domestic industry into new fields e.g. generic pharmaceutical industry. Advanced states even apprehend that the developing countries have a tendency to manufacture cheap versions of the patented drugs and export the same back to the developed countries.[402]

To keep a check on potential abuse of compulsory licensing provisions because of loopholes and vagueness of TRIPS provisions, grounds for the grant of compulsory licensing must be clearly defined. Moreover, instead of giving complete authority to member states to determine the existence of national emergency and grant a compulsory license, WTO should retain its role in deciding as to whether there is a legitimate need for grant of non-voluntary license. WTO Commission consisting of capable, reliable, experienced, and unbiased members should decide on merit on the basis of reports submitted by the member state intending to use compulsory license and ground realities or actual situation in that state. The already existing 'Council for TRIPS' may be delegated the authority to consider and decide on non-voluntary licensing applications.

[402] Re-exportation of the products is a serious concern for pharma companies, as illustrated in the Glaxo vs Dowelhurst case where low cost AIDS drugs meant for Africa allegedly found their way back to the UK.For details visit <http://www.ipsofactoj.com/international/2005/Part12/int2005(12)-009.htm>, (last accessed date June 3, 2012).

4.2.11 Use of Other Available Options

Developing countries must use all other available options to promote greater access before resorting to compulsory licensing only in grave situations of public health crisis. Some of the alternative means to improve access to necessary medicines may be as under:

- Tariff barriers have effect on the prices of products imported into the country. Normally, developing countries levy high import tariffs even on pharmaceutical drugs in order to raise their revenue. Some developing states intentionally raise import tariff particularly on pharmaceutical products in order to protect and develop their local generic manufacturing industry. High import tariff and other trade barriers raise the price of drugs and consequently have a disastrous effect on access to drugs. States faced with the public health crisis should lower tariffs on necessary medicines to reduce prices of such medicines.

- Governments of developing countries should negotiate with the patented pharmaceutical manufacturers and request them to lower the prices on humanitarian grounds in situations of public health crisis. If the pharmaceutical companies are willing to help, governments of developing countries should buy patented products directly from the manufacturers at negotiated prices.

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