International Islamic University Islamabad

Patent's compulsory licensing regulations in Pakistan

Supervised BY

Aurangzeb Mehmood

Submitted By

Ali Said

Registration No. 18-FSL/LL.M (ITL)/F-04

Faculty of Shariah and Law

International Islamic University Islamabad,

PAKISTAN

(2007)

International Islamic University Islamabad

Patent's compulsory licensing regulations in Pakistan

Supervised BY

Aurangzeb Mehmood

(Expert in corporate and legal affairs)

Submitted By

Ali Said

In partial fulfillment of the requirement for the

Award of the degree

Of

Master of laws

In

(International Trade Law)

Faculty of Shariah and Law

International Islamic University Islamabad,

PAKISTAN

(2007)

Ali Said khan Mashwani (Advocate)

INTERNATIONAL ISLAMIC UNIVERSITY

ISLAMABAD, PAKISTAN

Student's Name and Registration Number

Advocate: Ali Said Khan Mashwani

Registration No.18-FSL/LL.M (ITL)/F-04

INTERNATIONAL ISLAMIC UNIVERSITY ISLAMABAD, PAKISTAN

REPORT ON THESIS PRESENTATION

EXAMINATION COMMITTEE

MEMBERS OF THE THESIS APPROVING COMMITTEE

1. **(Supervisor)** _____

2. **(Internal Examiner)** _____

3. **(External Examiner)** _____

LIST OF ABBREVIATIONS

1) **AIDS:** Acquire Immune Deficiency Syndrome.
2) **DSB:** Dispute Settlement Body.
3) **E.G:** For Example.
4) **GATT:** General Agreement on Tariff and Trade.
5) **GSP:** General system of preference.
6) **HIV:** Humane Immunodeficiency Virus.
7) **HTTP:** Hyper Text Transfer Protocol.
8) **HIV/AIDS:** Humane Immunodeficiency Virus/ Acquire Immune Deficiency Syndrome
9) **I.E:** That is.
10) **IMFPEIPRS:** International Monetary Fund for Protection and Enforcement of Intellectual Property Rights.
11) **IPA:** Intellectual Property Authority.
12) **IIPA:** International Intellectual Property Authority.
13) **IPL:** Intellectual Property Laws.
14) **IPO:** Intellectual Property Organization – Pakistan.
15) **IPR:** Intellectual property rights.
16) **ITL:** International trade law.
17) **JPUNASID:** The joint program of the united nations on Acquire Immune Deficiency Syndrome.
18) **MNC:** Multi-national Corporations.
19) **NGOs:** Non-governmental organizations.
20) **TRIPS:** Agreement on Trade-Related Aspects of Intellectual Property Rights.
21) **UK:** United Kingdom.
22) **UN:** United Nations.
23) **UNAIDS:** United Nation Agency for International Development and Services.
24) **UNMDGP:** United Nations millennium development goals project
25) **USA:** United States of America.
26) **US:** United States.
27) **USSR:** Union of Soviet Socialist Republics.
28) **WHO:** World Health Organization
29) **WIPO:** World Intellectual Property Rights Organization.
30) **WTO:** World Trade Organization.
31) **www:** World Wide Web.
32) **£:** Pound Sterling. It is a sign, uses for British currency.

DEDICATION

For my Parents

"Who are my ideals and have always been a fortune of love, courage and inspiration for me".

And

Beloved son

Muhammad Salman Mashwani

Though he is a little one

But

I wish that he may be a great scholar.

ACKNOWLEDGEMENT

First and the foremost, I wish to express my humble thanks in the honour of Almighty Allah who awarded me with this life and bestowed on me His countless blessings. All of good qualities I have are what He has granted me and what I have earned is the long list of deficiencies. May Almighty Allah enable me to develop myself into a better and caring human being and a competent Consultancy/ advocacy Professional, to assist the helpless people for acquiring their rights from the encroachers, Aamin.

I am obliged and grateful to Prof. Aurangzeb Mehmood, my internal supervisor, who is not only an authority on the Intellectual property laws in Pakistan but unquestionably a visionary legal personality. This is he, who has always been source of inspiration to me. His undoubted patience, extremely pleasant personality, always acting as a lighthouse, mega courage and stamina has been a wonderful gift for all and especially for me.

I have learnt to walk as a professional because of his unmatchable guidance, which has taught me modesty, confidence, patience, dynamism, fairness, and a better and courageous human being.

I am extremely grateful to my affectionate and respectable teacher Professor Muhammad Munir (Assistant Professor, Faculty of Shariah and Law) for his kindness and supportive attitude to facilitate the students in general and me in special.

I am grateful to Mr. Hafiz Aziz-ur-Rahman (Assistant Professor in Law, IIUI), Mr. Col. ® Muhammad Youns (Lecturer in Law, IIUI), Mr. Ahmad Mukhtar, Section Officer,

Ministry of Commerce, Government of Pakistan, Islamabad) and Mr. Muhammad Anwar Khan (Legal expert in WTO affairs, Intellectual Property Organization "IPO" Government of Pakistan Islamabad) for their technical and moral support, valuable guidance and continuous cooperation, generouses help and inspiration in the completion of this research paper.

I am grateful to my parents and my uncles Mr. Rahman Said Mashwani and late Jehan Badshah Mashwani, for their unending support, efforts and difficulties they faced during the course of time, while bringing me up to the present state of my life.

I am deeply indebted to my younger brothers, sisters particularly to Mr. Shah-mo-Rad Khan Mashwani and Mr. Inayat-uallh Mashwani and other family members for their prayers, financial and moral supports. I am also grateful to my teacher and colleague Mr. Dilawar Jan (LL.B (H) Shariah & Law, IIUI). This is he, whose advices played an important role in my life and he is always a source of courage and character for me.

All my friends and colleagues who were there during the coursework have been very caring and I am thankful to all of them.

I especially extend my hearty feelings and thanks to Mr. Tariq Jamal, LL.M (Shariah & Law, IIUI), Mr. Sher Ahmad Khan, LL.M (International Commercial Law, UK), Mr. Muhammad Jan, LL.M (International Law, IIUI), Mr. Muhammad Fayyad Khan Yousafzi, LL.M (International Law, IIUI), Mr. Muhammad Saeedullah, LL.M (International Law, IIUI), Mr. Shafqat Hakim, M.CS (GIK, SITT), Mr. Muhammad Ziarat Shah (LL.B (H) Shariah & Law, IIUI), Mr. Hamidullah, LL.B (H) Shariah & Law, IIUI), Mr. Nasurallh Khan, (Senior Mobilizing Officer, PIMAN), Mr. Zahid Iqbal (PST), Mr. Atta-u-llah Khan, (PST), and Ihsanullah Khan Advocate (High Court, Peshawar) for giving moral and technical support in the hour of need.

It will be injustice that if I do not indebt my thanks to Mr. Aziz-ul_Hakim, M.S Architecture Engineering, University of Peshawar), Mr. Muhammad Imran Khan Maidan, B.A (H) (Ussulddin, IIUI), Mr. Amjad Ali khan Martung, M.B.A (Telecommunications, IIU I), Mr. Jehan Gir Khan, M.S (Computer Science IIUI), Mr. Husain Ahmad Khan Shangla, LL.M (Corporate Law, IIUI), Mr. Muhammad Israr Khan, LL.B (H) Shariah & Law, IIUI) and Mr. Asif Raza Khan, LL.B (H) Shariah & Law, IIUI), for their kind etiquettes and encouraging response whenever I acquire their skills and assistance in the time of need.

Advocate: Ali Said Khan Mashwani

TABLE OF CONTENTS

INTRODUCTION

When man appeared on Earth planet, since that time his major weapon for survival is the ability to fixed innovative solutions to the problems he encounters. The development of civilization over the centuries has been marked by countless inventions and innovations, facilitating the life of mankind more comfortable and easier.

Indeed we cannot imagine today's world over having evolved without all the inventions and innovations. Over the past two hundred years with the acceleration of technological progress the life of mankind has changed in a radical way and innovations has become an important part of our everyday realities.

In patents acceleration compulsory licensing is an instrument which encourage competition, supply market and reduce prices. Therefore it should be employed, to balance the interest of inventors and customers of their works, through granting the permission by owners and inventors to manipulate their creations.

To understand the concept of compulsory licensing, one has to first understand what a patent is.? A patent is an exclusive right granted by government to the first inventor of a new manufacture or invention, that he or his licensee shall have the sole right to make and sell such manufacture or invention for a limited period of time.

While compulsory licensing is an authorization granted by government to a party other than the holder of patent on an invention to use that invention without the consent of the patent holder. The compulsory licensing acts to restrain the exercise of those private rights which are vested in the patent holder for public interest.

The issue of patent protection has received increasing attention internationally since the establishment of WTO in 1995. In deciding to become a member of WTO, a country must agree to follow its rules. A certain number of treaties are therefore binding on all WTO members. One such treaty is the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights), which sets out minimum standards in relation to intellectual property. All WTO member countries have to comply with these standards by changing their national regulations (where necessary) to follow the provisions of the agreement.

With respect to drugs, the major difference between TRIPS and previous multilateral agreements is that, the TRIPS require countries to grant patent protection to pharmaceutical products for a minimum period of 20 years, while in pervious it was for sixteen years.

The TRIPS Agreement does leave the WTO member countries with a certain amount of freedom. The member countries are allowed, under certain conditions, to issue compulsory licenses against the will of the patent holder. The conditions are; that the products manufactured under a compulsory license must be for domestic market, and there will be some reasonable remuneration to the inventor.

However, many developing countries lack the manufacturing capability in pharmaceutical products. Therefore the WTO decision of 30 August 2003 by the name of Doha Declaration on the TRIPS Agreement, seeks to overcome this difficulty by allowing WTO Members to grant compulsory licenses for the production and sale of patented pharmaceutical products to third countries with insufficient or no manufacturing capacity in the pharmaceutical sector.

For example, a country with high HIV prevalence the government could decide that it is in the public interest to ensure that appropriate drugs are manufactured locally and made available at a cheaper price. Such action should be legal under the TRIPS Agreement.

Compulsory license is also using as a tool for resolving antitrust disputes by counteracting the monopolistic use of patents. In some countries, health care is so heavily subsidized that a significant portion of a government's budget is spent on medication. The threat of compulsory licensing helps negotiate a lower price for patented drugs. But in policy responses to health threats posed by serious infectious disease, compulsory licensing can become a highly charged political issue among the governments.

This is why, when pharmaceutical companies in the Western world develop and manufacture drugs effective against malaria, HIV and AIDS, tuberculosis, and other common ailments in developing nations, poor countries and activist non-governmental organizations often target their intellectual property for seizure.

For example, Mozambique, Zambia, and Zimbabwe all issued compulsory licenses for antiretroviral drugs in 2004, allowing generic manufacturers in India and Africa to produce AIDS drugs without buying the patent rights to do so[1]. The patent holder typically gets royalties in order to keep the final price as low as possible.

International disputes sometimes break out between the patent holder and licensee's government, each trying to protect its own biotech industry. However, many countries are under strong pressure, particularly from the United States and the multinational pharmaceutical industry to adopt legislation that provides a higher level of patent protection than is required by TRIPS and ITL (international trade law).

In designing defences against pandemics and bioterrorism, planners sometimes seek huge supplies of antibiotics. Here, the issue is not so much the cost per dosage as the number of dosages on the market. Many modern drugs have long production cycles, sometimes as long as a year, so the drug companies must always estimate future demand for their patented drugs and vaccines.

[1] htpp://www.cptech.org.com, last visited: 05/07/2006.

The number of victims in a flu pandemic or anthrax attack could exceed any reasonable prediction, and for the original maker to increase production could itself be a lengthy process. Disaster response plans often call for compulsory licenses to drastically increase the supply, with the patent holder's royalties usually. To design a compulsory licensing system, which may fits national needs and objectives. Some developing countries intended to protect their right to price mechanism control under TRIPS, which would help to ensure affordable access to the medicines.

Compulsory licensing is a mechanism for the increase of competition among the pharmaceutical companies, for supply of goods to the markets and reduction in prices .But however, some pharmaceutical companies afraid from that mechanism of compulsory licensing which lower the prices for pharmaceuticals and would lead to the deterioration of product quality and loss of control over regulatory standards.

The TARIPS agreement has given more power to the multinational companies against the state's national in developing countries. In this respect, it is worth mentioning that the US pharmaceutical industry filed a case against the South African government's legislation that adversely affected its exports when African government allowed domestic medicine manufacturing under compulsory licensing to combat HIV/AIDS in 1998[2].

Pakistan Obligations and IPR-Related Measures

As a member of the WTO, Pakistan is committed to fulfil its TRIPS obligations. Pakistan is also a member of the Paris Convention on patents/ compulsory licensing and the World Intellectual Property Rights Organization (WIPO) for protection of intellectual property in general and patents in special.

---

[2] http://www.iipa.com, last visited: 18/06/2006.

Pakistan promulgated the Patent Ordinance on December 2, 2000, to amend and consolidate the law relating to the patent. Under section No.4 of this Ordinance, a Patent Authority will be established for the grant of patents and administration of granted patents[3]. Earlier, patents were registered under the Patent and Design Act, 1911.

At that time protection for patents was for processes only, and the duration of protection normally was 16 years. But now under this Ordinance protection is granted to both product and process patents[4] and the term of protection is twenty years[5].

Article 27 of the TRIPS Agreement provides that WTO member states, shall provide patents for any invention, either a product or a process for creating a product, provided that the new product/process, involve an inventive step, and are capable of industrial application[6].

Being a member of WTO, Pakistan has changed its own laws for compulsory licensing according to the multinational regime, but what are these laws and their mutual comparison is an unsolved issue?

WTO leaves member countries with a certain amount of freedom which are allowed under certain conditions, to issue compulsory licenses against the will of the patent holder to over come a emergency. For example, for a country with high HIV prevalence, the government could decide that it is in the public interest to ensure that appropriate drugs are manufactured locally and made available at a cheaper price. Such action should be legal under the TRIPS Agreement.

[3] Patent Ordinance-2000, section. 4.
[4] *Ibid*, section. 30(2), a & b.
[5] *Ibid*, section. 31.
[6] Article. 27(1) of the TRIPS Agreement-1995.

The purpose of this paper is to provide concrete examples on how compulsory licenses have been provided for in national and International laws and their mutual comparison. I have endeavoured to do some research on this extremely important topic, "Patent's compulsory licensing regulations in Pakistan". In Pakistan on this topic as yet, such research is not available. So this will be very fruitful for students and International commercial practicing lawyers in Pakistan.

Though the application of compulsory licensing of intellectual property covers a number of different areas, but this paper focuses mainly on its application in the field of patents. The paper first gives a list of abbreviations, acknowledgement and than in its first chapter it introduces the patent, its scope and kinds as well as compulsory licensing and its accessories.

This is followed by an analysis of the concept of compulsory licenses and of its regulation under multinational regimes i.e. of the TRIPS Agreement, Paris convention, and Doha Declaration.

The third chapter discuss compulsory license under Pakistani Laws and its comparison with multinational regime. The fourth and the last chapter elaborates compulsory licensing and pharmaceutical patents in Pakistan, leading questions regarding compulsory licensing, recommendations and conclusion. At the end a list of glossary is attached to the research paper, which is followed by a detailed bibliography.

CHAPTER-I

PATENT'S COMPULSORY LICENSIG

This chapter is divided into two parts, the first one is about Patent's definition, scope and kinds, while the second one is about the Compulsory Licensing and it's accessorises.

1.1: Patent

1.1.1: Definition of Patent

The patent has been defined by various experts differently, the main theme of which, is in the following lines; Patent statutes define the term 'patent' in terms of invention and then specify the criteria of patentability.

i. Blacks' law dictionary has defined the patent as, "An official document giving the holder the sole right to make, use or sell an invention and preventing other from copying it"[1].

ii. While the Jowitis dictionary of English law defines the patent, that " patent is permission granted by the government to the inventor for a stated period of time, conferring upon him a monopoly of the exclusive right to make, use and vend the invention or discovery"[2].

iii. Paul defines that the "patent is an official document given by a national government to an inventor 'or business or corporation, who wishes to have sole

[1] Blaks law dictionary, 5th edition p. 848, (William Wordsworth Press London-1979).
[2] Jowitis dictionary of English law p. 1223, (Sweet and Maxwell, *Ltd.* 1980).

rights over a product for a limited amount of time. Once the patent is granted, no one else has the right to make, sell, market, or profit from the invention"[3].

iv. Collins dictionary of law defines that the, "patent is an exclusive right granted by Government to the inventor assuring him for selling and using his invention for a limited period of time[4].

v. The Concise dictionary of Law defines that the, "patent is an official paper conferring an exclusive right, privilege on one, issued by government to an inventor and his legal heirs over an invention for a given length of time, usually for twenty years.

The person to whom the patent has granted is called patentee. The person who grants the patent is called patentor. The place which issued the patent is called Patent Office and the invention which is obvious/ clear and open is called patentable invention[5].

1.2: Scope of Patent

The object of granting a patent is to encourage and develop new technology and industry. An inventor may disclose the new invention only if he is rewarded, otherwise he may work secretly. In consideration of the grant of monopoly for a limited period of time, the inventor discloses the details of the new invention and the method of working it, so that after the expiry of monopoly period others can use the invention or improve upon it.

Thus the theory upon which the patent system is based is that the opportunity of acquiring exclusive rights in invention stimulates technical progress in four ways:

---

3 http://www.uspto.gov.com. last visited: 12/07/2006.

4 Patrick Hanks, Collins dictionary of law p. 1074, (William Collin Sons-1981).

5 L.B. Curzon, the concise dictionary of law p.321 and Chambers 20th century dictionary by A.M Macdonald p. 972, (Pitman Publishing London-1990).

1) That it encourages research and invention.
2) That it induces an inventor to disclose his discoveries instead of keeping them as a trade secret,
3) That it offers a reward for the expenses of developing inventions to the stage at which they are commercially practicable,
4) That it provides an inducement to invest capital in new lines of production[6].

The life of the patent is usually 20 years almost in every country of the world e.g. United States of America, European Union, United Kingdom, India[7] and Pakistan etc.[8]. An inventor may sell all his rights to the patent, or may opt to sell only a certain part of it. When the patent holder licenses his or her product to a manufacturer, for example, he or she receives royalties based on the sale of the product or invention.

In case of infringement the patent holder can file a claim to sue the accused. Pakistan has its own law for patents protection. In Pakistan, patents are registered under the Patents ordinance 2000. The duration of protection normally is 20 years[9].

The Patents Ordinance confers on the patentee exclusive privilege for making, selling and using his invention throughout Pakistan and of authorizing others so to do. The primary purpose of the Patent Ordinance is to protect new invention and to encourage the growth of innovations in the country.

Patents give an inventor or business corporation the legal right and protection to own their invention. This means the patent holder now has a legal monopoly and can do with it, what he/she desires for the life of the patent within the specified period accordingly. Patent protection means that the invention cannot be commercially made, used, distributed or sold without the patent owner's consent.

---

[6] P. Narayanan, intellectual property law 3rd edition. p.12, (Eastern Law house Culcutta-1998).
[7] *Ibid*, p. 13.
[8] W. R. Cornish, Intellectual property (patent, copyright, trade marks and Allied rights) p. 99, (Sweet &Maxwell ltd London-1981).
[9] Patent Ordinance-2000, sec. 31.

These patent rights are usually enforced in a court, which, in most systems, holds the authority to stop patent infringement, in Pakistan the High Court[10]. Conversely, a court can also declare a patent invalid upon a successful challenge by a third party[11]. A patent owner has the right to decide who may or may not use the patented invention for the period in which the invention is protected i.e. twenty years. The patent owner may give permission/ license to other parties for using that invention on mutually agreed terms.

The owner may also sell the right of the invention to someone else, who will then become the new owner of the patent. Once a patent expires, the protection ends, and an invention enters the public domain. Patents provide incentives to individuals by offering them recognition for their creativity and material reward for their marketable inventions.

These incentives encourage innovation, which assures that the quality of human life is continuously enhanced. All patent owners are obliged, in return for patent protection, to publicly disclose information on their invention in order to enrich the total body of technical knowledge in the world.

Such an ever-increasing body of public knowledge promotes further creativity and innovation in others. In this way, patents provide not only protection for the owner but valuable information and inspiration for future generations of researchers and inventors. The first step in securing a patent is the filing of a patent application.

The patent application generally contains the title of the invention, as well as an indication of its technical field; it must include the background and a description of the invention, in clear language and enough detail that an individual with an average understanding of the field could use or reproduce the invention[12]. An invention must in general, fulfil the following conditions to be protected by patentability:

[10] Patent Ordinance-2000, sec. 67.
[11] *Ibid*, sec. 24.
[12] *Ibid*, sec. 13, 14 &15.

1) **Novelty:** No system grants valid patents for inventions that are already known. It must show an element of novelty[13], that is, some new characteristic which is not known in the body of existing knowledge in its technical field.

2) **Inventive step:** This means that the invention must be clear and not be obvious to a person skilled in it[14].

3) **The invention must be capable of industrial application:** Invention shall be considered to be capable of industrial application if it can make or used in any kind of industry. The industry shall be understood in its broad sense. It shall cover in particular agriculture, handicraft, fishery and services[15].

A patent is granted by a national patent office or by a regional patent office, which do work in a number of countries, including Pakistan, which has its own patent office established under the patent ordinance[16]. According to these systems, an applicant cans requests for the protection of the invention in one or more countries, and each country decides whether to grant patent protection within its borders or not?

The WIPO administered Patent Cooperation Treaty (PCT) provides for the filing of a single international patent application which has the same effect as national applications filed in the designated countries of the PCT. An applicant seeking protection may file one application and request protection in as many signatory states as needed.

Under PCT system, in order to obtain patent protection in the designated states, a patent shall be granted by each designated state to the claimed invention contained in the international application[17].

---

[13] W.R Cornish, Intellectual property Patents, copy right, Trade marks and allied rights) p. 137 & 138, (Sweet& Maxwell *Ltd.* London-1981).
[14] Robert Broadgat & Fidelmla White, Commercial law p.370, (Blackstone press-1987).
[15] Patent Ordinance-2000, sec. 10 (1).
[16] *Ibid,* sec. 4 (1).
[17] Patent Law Treaty -1978, Art. 3.

It is important to file a patent application before publicly disclosing the details of the invention. In general, any invention which is made public, before an application is filed would be considered prior art[18].

1.3: Kinds of Patent

There are three different kinds of patent, these are discussed in the following lines:

a) **Utility Patents:** These are granted to anyone who invents or discovers any new and useful process, machine, Chemical, Mechanical, or Electrical inventions manufacture, or compositions of matter, or any new and useful improvement thereof. Process' means a process or method; new industrial or technical processes may be patented. 'Manufacture' refers to articles which are made. Composition of matter relates to chemical compositions and may include mixtures of ingredients as well as new chemical compounds. Animal patents fall within this category. It is protected for twenty years.

b) **Plant Patents:** Plant Patens are granted to any person who has invented or discovered and asexually reproduced any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings. After a patent expires, anyone may use the invention without the inventor's permission.

c) **Design patents:** These are granted on any new, original, and ornamental design for an article of manufacture[19]. Each type of patent confers "the right to exclude others from making, using, offering for sale, or selling" the invention or importing the invention. It is important to note, however, that patents do not protect ideas, but rather protect inventions and methods that exhibit patentable subject matter.

---

[18] T.A. Blance White, Patents for inventions p. 30 &113, (Steven Sons *Ltd.* London-1983).
[19] http://www.google/search/kinds of patents.com, last visited: 12/07/2006.

A patent empowers the owner of invention to take legal action against others to prevent the unlicensed manufacture, use, importation or sale of the patented invention. This right can be used to give the proprietor breathing space, to develop a business based on the invention, or another person or company may be allowed to exploit the invention and pay royalties under a licensing agreement.

The invention must be "unobvious" to "a person having ordinary skill in the art to which said subject matter pertains". In other words, someone in the field of technical expertise must view the invention as something surprising and unexpected. This requirement is the one, on which many patentability disputes hinge. This requirement prevents patent protection from being granted to meaningless improvements on prior inventions and basically limited patentability to inventions that truly enhance social utility.

1.2: Compulsory Licensing

1.2.1: Definition of Compulsory Licensing:

Compulsory Licensing is comprised of two words i.e. "**Compulsory**" and "**Licensing**". Various Legal philosophers and language experts defined both the words differently as such in the following lines.

i. Compulsory; means "must done"[20].

ii. Licensing; means "an official document showing that the permission has been given to do, own, or use"[21].

i. Compulsory; means "by force, involuntary"[22].

ii. License; means "The permission by competent authority to do an act which without such permission would be illegal. This permission may be granted by an authority in written from an other person empowering him to make or use the patented article for a limited period or in a limited territory[23].

---

[20] Oxford advanced learners dictionary p. 235, (Oxford University Printing Press-1996).
[21] *Ibid*, p. 679.
[22] Blacks law dictionary 5th edition p. 260, (William Wordsworth Press-1979).
[23] *Ibid*, p. 829.

i. **Compulsory**; means "coercion"[24].

ii. **License**; means "formal permission or leave to do or not to do some thing"[25].

License; means "a power given by the competent authority to do some act which without such authority could not lawfully be done"[26].

The person who has the license is called licensee and all this bargain is to be conducted under the special legislation in this regards.

So compulsory Licensing is an authorization granted by a government to a party other than the holder of a patent on an invention to use that invention without the consent of the patent holder. The patent granted by government in a favour of a particular person, gives that person certain rights.

Compulsory license acts to restrain the exercise of those private rights in the public interest. This is a mechanism through which government limit the private power that resides in the grant of patents. It acknowledges that the public interest will prevail private interests. A general requirement under article 31 of the TRIPS on the proposed user to first seek the authorization from the patent holder can be waived in the case of national emergency, other circumstance of extreme urgency, and in cases of public non-commercial use[27].

The term public refers to the use for public benefits. Thus non-commercial use may be defined either in relation to the nature of the transaction or in relation to the purpose of the use. So the conclusion is, that "the compulsory licenses are licenses that are granted by a government to a person or an agency, other than the patent holder to use patented product or process without the consent of the patent owner". It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property right, the

[24] The new hamlyn encyclopedic world dictionary p. 338, (Gorgen Press London-1971).
[25] *Ibid*, p. 960.
[26] E.R Hardy Invamy, Mozley and whitely Law dictionary p. 270, (Butter woods London-1988).
[27] G.M Chaudhry, Intellectual property laws in Pakistan-TRIPS agreement, Art. 31. b, (Federal Law house Rawalpandi-2005).

TRIPS Article No.31[28]. Compulsory license is an essential governmental instrument to intervene in the market, limit patent and other intellectual property rights in order to correct anti-competitive practices.

1.2.2: Scope of Compulsory Licensing

Compulsory licensing of intellectual property is remedy for anticompetitive practices. It involves using of a legal intervention to restrict the monopoly rights of existing patent holders and make generic drugs more available in the market for poor people on lower prices. Compulsory licensing is most commonly used by the sovereign as a means to correct anticompetitive practices, for reasons of national defence, to promote the public interest, public health, in cases of emergency, and in the absence of "working" i.e., when the holder is not "exploiting" its patent.

The use of compulsory licensing will be particularly important in areas of biotechnology, where companies are staking out very broad patent claims. Compulsory licensing has recently received a considerable attention as pharmaceutical companies and activist groups seek to advance their respective political agendas over the right to drug access for life threatening diseases.

Compulsory licensing enables a government to issue a license to a company, government agency or other party the right to use a patent without the title holder's consent. Compulsory licenses play an important role in the health of patent sensitivity. Such license constitutes an important tool to promote competition and increase the affordability of drugs, while ensuring that the patent owner obtains compensation for the use of the invention.

In current public discussion, this is usually associated with pharmaceuticals, but it could also apply to patents in any field, of technology, drugs research and development. The

[28] Art. 31of TRIPS agreement-1995.

term "compulsory licensing" does not appear in the TRIPS Agreement. Instead, the phrase "other use without authorization of the right holder" appears in the title of Article (31)[29]. Compulsory licensing is only a part of this sense of "other use".

According to the World Health Organization, more than one third of the world's population lacked regular access to essential drugs. Every year, millions of children and adults in developing countries around the world still died from diseases that could be easily treated by drug therapies, and more economically treated with generic drugs[30]. To cope this situation the WHO has recommended the use of compulsory licenses where there is "public interest or a national emergency" in order to ensure that drug prices are consistent with local purchasing power.

UNAIDS has also recommended the use of such licenses, as provided under the TRIPS Agreement such as, in countries where HIV/AIDS constitutes a national emergency. The TRIPS Agreement specifically allows member states to grant compulsory licenses on grounds to be determined by each member country (Article 31). The TRIPS Agreement specifies some conditions for the granting of compulsory licenses, which are the following:

a) That a license be voluntarily requested before being granted on compulsory terms, non-exclusivity, and no encourages response come from the patent holder within a reasonable period of time, i.e.150 days from the request[31].

b) According to article (31.h) of the TRIPS an adequate remuneration will be pay within a "reasonable period of time to the patent holder. The remuneration for a

---

[29] G.M. Chaudary, Intellectual property laws in Pakistan and International treaties p. 1403, (Federal Law house Rawalpandi -2005).

30 Jonathon D. Quick Dr. Director of essential drugs and other medicines, world health organization, The worldwide role of generic pharmaceuticals, (International generic pharmaceuticals Association -1999).

31 http://www..southcentre.org/publication/publichealth-12htm.com. last visited: 22/10/2006.

compulsory license shall be determined as a percentage of net sales, taking into account the value of the license in the relevant domestic market and the average royalty rates usually paid in the sector or branch to which the invention belongs. The remuneration can be reduced or excluded when the license is granted to remedy anticompetitive practices[32].

c) According to article (31.b) of the TRIPS this attempt at negotiation (Voluntarily requested) with the patent holder is not required if the drug is to be used for "public non-commercial use" if there is a "national emergency such as natural catastrophe, war or epidemics" or other situation of "extreme urgency," or if a judicial or administrative process has determined that the patent owner has engaged in "anti competitive" practices.

d) The patentee shall have the right to request from a competent higher authority (court) the review of any decision relating to the legal validity of a compulsory license or to the remuneration determined by the national authority. An application for review shall not suspend the effects of a granted license.

Furthermore, the TRIPS Agreement stipulates that a compulsory license must be "predominantly" for the supply of the domestic market (Article 31.f), in the country issuing the license. But the limitation of this Article (31.f) however, may not apply when a compulsory license is granted to remedy anticompetitive conduct (Article 31.k)[33]. The Article (31.f) of TRIPS is likely a barrier to more affordable drugs, while many developing countries lack the ability to produce their own generic drugs, which means that use of compulsory license as a method for obtaining generic versions of patented products is hindered, as they will need another country to manufacture the pharmaceutical product and export it to them.

---

[32] G.M.Chaudary, Intellectual property laws in Pakistan and International treaties on IPRS, p.1404, (Federal Law house Rawalpandi-2005).

[33] *Ibid.*

It means that the WTO agreement, TRIPS provides for compulsory licenses of patents in Article 31, saying "other uses" with a number of restrictions on the use of compulsory licenses. While the Paris Convention for the Protection of Industrial Property plainly states in article No. (5.2) that "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"[34].

The Doha Ministerial Declaration in 2001 on the TRIPS Agreement and Public Health stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health, by promoting both access to existing medicines and the creation of new medicines for all[35].

The WTO members decided in their meeting at Doha, that the members should have to grant compulsory licenses for the production and sale of patented pharmaceutical products intended for export to third countries with insufficient or no manufacturing capacity in the pharmaceutical sector[36].

In practice there are two reasons for compulsory licensing. The first relates to the technology itself and is most obviously seen in the compulsory licensing of pharmaceutical products. Recent examples are licensing of anti-HIV/AIDS drugs in South Africa and the anthrax antibiotic ciprofloxacin in USA and Canada.

These cases were the strong motivation behind compulsory licensing in these countries which were against the use of the compulsory licensing in vast perspective e.g. USA, Canada and Japan. The pharmaceutical industry research based countries opposed compulsory licensing on the grounds that they discourage investment, research and

[34] The Paris Convention -1967, Art. 5(2).
[35] http:// www.wto/min(01)dec/2.com. last visited: 12/10/2006.
[36] http:// www.The Doha declaration on TRIPS and public health.com. laat visited: 16/03/2006.

development[37]. But now –a-days they are in favour of compulsory licenses after the USA was threatened by anthrax weaponization in 2001. The US administration forced the maker of Cipro, for an affordable price to protect Americans from biological warfare. The authorities determine the reasonable compensation for use of a patent in a public health emergency, to protect it and maintain incentive for new drug development. They modified the so-called "Doha Declaration on 30 August 2003" which promotes the ability of developing[38], nations to secure lower priced medicines to combat public health crises and add in this definition the infectious diseases and bioterrorist attacks which are serious threats to public health and tranquillity.

The second reason for compulsory licensing is to remedy an anti-competitive behaviour, and to increase competition. So compulsory licenses are generally available for lack or insufficiency of working to remedy anti-competitive practices, for cases of emergency, governmental use, and for other public interest grounds.

Now the developed countries also provide for use of compulsory licenses. Many developing countries that have recently revised their patent laws have also defined a more or less comprehensive list of reasons for the granting of such licenses. Pakistan being a member of the international community also brought its laws according to the international regulation for patent's compulsory licensing.

1.2.3: Why do Governments Issue Compulsory Licenses

Governments have traditionally had the right to issue compulsory licenses to intellectual property/ patent, computer and software area, to develop interoperable products mainframe markets, because it is an available remedy, when the patent owner is abusing market power[39]. Governments issue compulsory licenses to broaden access to technologies and information in order to achieve a number of public purposes. The

[37] http:// www.google.com/compulsory licensing.com, lst visited: 16/03/2006.
[38] http://www.cptech.org.com. last visited: 18/05/2006.
[39] http://www.cptech.org/ip/health/cl.com. last visited: 18/05/2006. "The Ergas Committee Report (Commonwealth of Australia,- 2000)".

Government issue compulsory licenses as remedies for problems of monopoly and anticompetitive practices. Many countries have provisions in their laws for compulsory licensing if the patent owner refused to make the invention available for public interest reasons, such as to correct cases where pharmaceuticals are "available to the public in insufficient quantity or at abnormally high prices". Compulsory license of patent is an instrument, ultimately for the sake of community welfare[40].

The governments should have to issue compulsory license for the prevention of smuggling. In smuggling one party purchase drugs a third party in another country on lower prices where the drugs prices are lower and than sale it in the first country on rational lower prices, rather the manufacturer of the first country charged high prices. The smuggling strongly hit the local manufacturing medicine products. If the government does not issue compulsory licences, than the local pharmaceutical industry and market will destroy due to the increasing of smuggling.

In the absence of compulsory licensing the governments may use the option of parallel importing which can low the drugs price but can affect the local manufacturers. For instance, in Britain, where parallel importing is common, the list price for Glaxo Welcome's Retrovir is £125, but consumers can purchase the same proprietary drug imported from other European countries for as little as £54[41].

If the government does not issue compulsory licensing than the use of parallel importing will be the best option with many countries particularly in poor countries, to improve access to essential drugs because of limited local capacity to produce raw materials and undertake drug manufacturing. The government issue compulsory licensing to protect counterfeiting, grey marketing, hoarding and keep control on inflation, because it is a tool for the development of competition and reduction of prices in the markets.

---

[40] http://www. wipo.TRIPs.pharma-policy.com. last vivited:12/06/2006.

[41] http:// www.google.com/compulsory licensing and parallel importing.com. last visited:13/06/2006.

When governments issue compulsory licenses, the result is sharp decrease in prices of the products. For this reason, many developing nations argue for the right to issue compulsory licenses for pharmaceuticals that are normally very expensive for their citizens. During the negotiations for the TRIPS agreement, however, most developed nations argued for harsh restrictions on compulsory licenses to safeguard their domestic industries, and America was one of them.

Thus, an ostensible tension among developing and developed nations is mounting over the use of compulsory licenses, for example the dispute between South Africa and United States of America in 1998. When South Africa introduced legislation to allow the health minister to issue compulsory licenses for pharmaceuticals, because a large number of its citizen affecting from AIDS[42]. Even more troubling is the lack of advanced medicines available to those affectees.

But the United States interpreted those actions to be in violation of intellectual property standards in TRIPS, and threatened trade sanctions. These two governments finally did settle the matter quietly, without the involvement of the WTO's DSB. Many countries in the world have permitted in their national laws issuance of compulsory licences, e.g. in Australia, "exploitation by the Crown" of a patent, including use "by a person authorized in writing by the commonwealth or a state is not an infringement" of a patent.

In Germany, "a patent shall have no effect where the federal government orders that the invention be exploited in the interest of public welfare." The Malaysian patent law has special provisions for "rights of government" which authorizes the government to "make use and exercise any invention" subject to the payment of reasonable compensation. In Singapore, the patent law has a provision for "use of patented inventions for services of government" which permits a government department to "make, use and exercise exploration of inventions".

[42] http://www.who.org.com, last visited: 15/06/2006.about who See AIDS drugs policy, Africa policy information center, supra note & see also Peter Hawthorne, A Blighted generation Southern Africa ,has been most severely hit by
AIDS.

The patented invention for any purpose which appears to the government necessary for several purposes, including "public non-commercial use". The New Zealand patent law has a provision for "use of patented inventions for services of the Crown" authorized in writing by the government. In the Philippines, the relevant provision is "use of invention by government" which says, a government agency or third person authorized by the government may exploit the invention even without agreement of the patent owner.

The Irish patent law has provisions for "use of inventions for the service of the state" which authorizes a government minister to use the invention for any purpose which appears to such minister to be necessary for the maintenance of supplies and services essential to the life of the community. The UK law provides for "use of patented inventions for services of the Crown" and the government's powers are quite broad, setting compensation[43].

The patent law of Pakistan is also allowed the state's competent authorities to issue compulsory licensing, whenever they think fit for public interest[44]. When the government issues compulsory licensing, against her, or the third person who is authorized by the government to use that very patent for any purposes .e.g. for public use, the patent owner does not have the right to obtain an injunctive relief. This use or authorization by the government is not to be considered infringement of the patent rights.

The patent holder does, however, have a right of compensation, and the decisions regarding compensation, including appeals. The general rule is in Article No. 31 (h), the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization[45]. It is clear that countries (controllers) have considerable discretion in setting compensation.

[43] http:// www.google.com/compulsory licensing in different countries.com. last visited: 16/06/2006.
[44] Patent Ordinance-2000, sec. 58.
[45] TRIPS Agreement-1995, Article. 31 (h).

Article 1 of the TRIPS says that the "member shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice"[46]. The governments of the developing countries, like Pakistan has a limited access to new pharmaceutical products, are more likely than other countries to implement legislation permitting compulsory licensing under a broad range of circumstances for compulsory licensing.

As compulsory licensing is an authorization granted by a government to a party other than the patent holder of a patent on an invention to use that invention without the consent of the patent holder. So it may be concluded such as:

(i) It means that it is granted by the government in favour of particular person that gives that person certain rights.

(ii) The compulsory licensing acts to restrain exercises of private rights in the public interest.

(iii) This is a mechanism through which the governments limit the private power that resides in the grant of patents.

(iv) It is a mechanism which is used by the developing countries for access to medicine successfully. The developing countries should have to prove their good faith in granting of compulsory licensing for access to medicine.

(v) It is also used by the governments as a remedy for anti-competitive practices[47].

---

[46] *Ibid*, Art.1

[47] Islamabad Law Review p..466, third edition -2003.

1.2.4: Compulsory Licensing and its impact on innovation

The use of compulsory licensing will be particularly important in areas of biotechnology, where companies are staking out very broad patent claims. Compulsory licensing of patents is sometimes used to increase the consumption of new beneficial technology. Some countries will force an inventor to sell the rights to his work at a government specified price if he fails to work/exploit his patent in the given time.

When someone develops new technology, government may allow him to hold the patent, but also has the right to force a license to its own choice of manufacturer for public interests. Governments often appropriate the patent rights to technologies they intend to incorporate into infrastructure, civil engineering, new weapons, or government-funded science projects.

These licenses are also used as a tool for resolving antitrust disputes by counteracting the monopolistic use of patents. In some countries, health care is so heavily subsidized that a significant portion of a government's budget is spent on medication. The threat of compulsory licensing helps negotiate a lower price for patented drugs. But in policy responses to health threats posed by serious infectious disease, compulsory licensing can become a highly charged political issue.

The pharmaceutical companies of the developed countries manufacture anti-epidemic drugs e.g. malaria, AIDS, tuberculosis, and other diseases, while the developing countries and the poor countries often violating it for piracy/counterfeiting. In a situation like this compulsory licensing is bridge for taking the car across, means creates balance between the consumers and manufacturers, in which the patent holders will get reasonable royalties, otherwise they will suffer without any remuneration and the product will be consumed on lower price with sufficient supply market[48]. Compulsory licensing is beneficial for 80% of the world's population because the consumers of it are the middle-

[48] http://www.wikipedia.org/Compulsory_license.com, last visited:18/06/2006.

income countries, where piracy and patentability could be hardly prevented due to local influential and poverty, e.g. in 1998, 39 pharmaceutical companies of the USA filed a lawsuit against South Africa /Nelson Mandela the African president.

They hoped to stop the government from producing the generic drugs that would have made treatment affordable for the country's AIDS victims under compulsory licensing. Even Al Gore the than time vice president of US, supported the lawsuit, travelling to South Africa to threaten the government with trade sanctions if they did not revoke the law. A public outcry ensued, and critics accused pharmaceutical companies of valuing profit over human life. These companies pressurized the African government.

But the African government did what any responsible government would do. They passed a law that would give them the power to bring drug prices down, allowing compulsory licensing. Similarly TRIPS Agreement allows governments to override patents and allow generic production, through a strategy known as compulsory licensing.

During the anthrax crisis in the year of 2001, Congress threatened to use compulsory licensing to obtain the antibiotic Cipro more cheaply and quickly from generic manufacturers. The United States had signed the TRIPS agreements in 1994, recognizing that developing country have the ability to do just what the U.S. would later do with Cipro. It means that the issuance of compulsory licensing is legal step to cope with the national emergency and public epidemic, without the consent of the patent holder.

The example of Cipro now in hand, developing countries successfully secured affirmation at the WTO Ministerial meeting in Doha on 30 August, 2003, that they have the right to parallel import and issue compulsory licenses, and that the TRIPS Agreement should be interpreted and implemented in a manner supportive of WTO Members right to protect public health in particular, and to promote access to medicines for all in general[49].

[49] http:// www. Doha ministerial declaration.com. last visited: 18/06/2006.

1.2.5: Effect of Compulsory Licensing on Public Health

In general, poorer countries do not have their own pharmaceutical industries and the drugs needed to treat diseases are too expensive. Pharmaceutical manufacturers are cautious about supplying drugs at lower prices to the poor countries, which may adversely affect their higher price markets elsewhere.

This issue was discussed in the WTO ministerial meeting in connection with TRIPS, on 30 August 2003. In the light of that discussion, the WTO members have the to granted compulsory licences for production if certain conditions are fulfilled; e.g. first request for voluntary license, payment of reasonable remuneration, for the public interests[50].

The member States with generic pharmaceutical manufacturers would be able to grant compulsory licences, allowing those manufacturers to make medicines for export to any least-developed country, member of the WTO. Countries in need would notify to the WTO, the medicines they need and it would be up to the generic companies to decide to apply for licences to manufacture them.

Evidence of a specific request to the applicant must be provided from the authorized representatives of the importing countries. This should help ensure the effective control of the amount of product supplied under compulsory licences. Licences must be non-exclusive and non-assignable and limited to acts needed to manufacture and export the specified quantities of the named products and would be exported only to the mentioned countries.

The pharmaceutical patent holder will no doubt still be concerned with the royalties they will receive the reasonable amount. The effects of compulsory licensing are to increase competition, to supply the market, and possibly to reduce prices. So the Doha ministerial declaration allows generic pharmaceutical companies to produce patented medicines for export to poor countries that do not have the resources to produce them.

[50] The TRIPS Agreement-1995, Art. 31. (b & h).

TRIPS permits member-countries to exclude entirely from the scope of patentable subject matter a range of inventions, including certain living organisms, surgical and therapeutic methods and inventions to protect animal or plant life or to avoid prejudice to the environment[51]. The innovator pharmaceutical companies were not enthusiastic supporters of these provisions[52].One of the problems that the implementation of patents that will pose challenges to the developing countries would be the increase in the cost of drugs with consequences for public health.

This has become a general problem for all developing countries, which lack the necessary research and development infrastructure, and if production of generic pharmaceuticals is stopped, access to extremely expensive life saving drugs will not be possible for patients in developing countries.

The solution for this problem is the issuance of compulsory licensing, because in it both the patent holder and the consumer benefited by royalty and lower price supply respectively, as the TRIPS agreement says that members may adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development[53].

The very first Article of TRIPS agreement defends the compulsory licensing, by saying, "Members of the WTO may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement . Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own system and practice"[54].

---

[51] *Ibid,* Art. 27 (a) & (b).
[52] http:// www.google.com/doha declaration.com. last visited: 19/06/2006.
[53] Art. 8 (1) of TRIPS Agreement-1995.
[54] *Ibid,* Art.1 (1).

So here the words, "members shall not be obliged to implement in their laws more extensive protection than is required by this agreement" it is impliedly indicate on the permission, granting of compulsory licensing, because this Agreement itself negate the very strict protective law which is not required and never oblige the member states.

On the other hand this Agreement adopts measures for the protection of public health and promotion of public interest, and usually the governments' issues compulsory licenses in the time of national emergency and public epidemics. As this agreement (TRIPS) has specifically mentioned in one of its Article No. 31, for granting of compulsory licensing in the sense of words, "other use without authorization"[55], that the "compulsory license would be allowed for generic product" to cope the shortage of medicine and maintain the prices lower.

The use of compulsory licensing by developing countries will contribute to raising the degree of competition, which will certainly cause a reduction in the price of medicine, quality and quantity in the market. Compulsory licensing for global drugs, in the developing countries, does not have a negative effect on investments in research in developed countries, because the developed countries itself need for compulsory licensing as it was realized in the case of USA anthrax 2001.

So it may be acknowledged that compulsory licensing is an exceptional resource which should be used by governments in exceptional circumstances, established by law. The rational use of compulsory licensing may favour the transfer of technology to produce medicines for countries in areas of vital interest for the health of the population[56]. Compulsory licensing attempts to strike a balance for promoting access to the existing drugs.

[55] *Ibid;* Art. 3.
[56] Barbara Rosenberg, patentee de medicaments e-Commerce international; a parameter to trips and compulsory licenses, page. 178, (University of Sao Paulo- 2004).

1.2.6: Violation of compulsory Licensing

Almost all the international regimes on WTO agreements have admitted the importance of the compulsory licensing. Therefore it is required from the member states to bring their national laws according to the WTO regime. Thus almost all the member states have adopted in their domestic laws provisions for compulsory licensing. It is very difficult for the member states to violate compulsory licensing. The violation of compulsory licensing means the assignment of absolute right to the patent holder on his patentability even during the entire state of national emergency and catastrophic, which is against the public interest.

However some members of the WTO were against compulsory licensing in the early time of the WTO establishment, majority of them were the developed states, e.g. USA, Canada and Japan. They are, arguing that the compulsory licensing is anti-quality and anti-development. But later on they return from this contention when they threatened by anthrax scare in 2001.

During this time there was a strong pressure from the manufacturers of Cipro, which is the best known treatment for the potentially deadly bacteria, while millions of people were in dire need for that medicine. Eventually they accepted the importance of compulsory licensing and issued the same for medicine (Cipro) manufacturing about a million tablets from other pharmaceutical companies.

So now almost every member state of the WTO is against of the violation of compulsory licensing, it means that, they do not favour the assignment of absolute right to the patent holder on his patentability. His right of patentability my exploit and explore with certain conditions during the entire course of national emergency and public epidemics.

1.2.7: The role of compulsory licensing in the protection of patents

It is clear that the inventor, who has no exclusive right of control over his invention, cannot exclude rivals from manufacturing or using it[57]. It is also asserted that only with the establishment of a firm legal monopoly on invention will give a feel of confidence to the inventor to bring his new product to the market[58].

But it renders largely unnecessary, destructive litigations so for, in the developing countries, because there is no strong protection of patents, where one party sues the other for patent infringement and the other counter-claims that the patent is invalid. If the patent monopolist wins, he drives the infringer from the market; if he loses, then his invention is destroyed.

Compulsory licensing is a solution for problems such like that, by litigations would be less vicious since it would not be determinative of the sole right to operate within a market. It means that the competent authority may allow the third party to use that very invention and grant the patent holder royalties[59].

So the patent holder can only sue that party for the payment of a reasonable licenses royalty and nothing else, because the use of an invention under governmental permission is no infringement. Moreover the compulsory licensing encourages the manufacture and use of inventions by competition among the competing firms.

Thus compulsory licensing is a way of access to the patent, reduction of litigations and prices, because compulsory licensing allows each and every competitor to explore and exploit the invention in open market.

---

[57] Jeremy Phillips, Introduction to Intellectual Property Law, p. 24, (Butterwort & co.London-1986).
[58] Irving Mandell, The Economic Impact of the Patent System, p. 32, (1983).
[59] Jeremy Phillips, Introduction to Intellectual Property Law, p. 27, (Butterwort & co.London-1986).

The compulsory Licensing of Patent is playing a very important role in day to day human life. It felicitates their lives by reduction of prices, supply market and increases competition among the manufacturers.

Even it provides protection to patent also, because if we allow the patentable invention to be manufactured then there would be less chances of its piracy, otherwise the piraters would exploit it without any permission and remuneration to the patent holder ruthlessly.

Patent rights can be more powerful, and generally harder to obtain and more expensive to enforce, but the compulsory licensing is the strong instrument for the protection and rationalization of these rights. It helps the country to acquire some new technology from other countries.

CHAPTER-II

COMPULSORY LICENSING UNDER MULTINATIONAL REGIMES

Keeping in view the importance of the compulsory licensing, various significant international treaties are governing patent's compulsory licensing. The most universal of these is the WTO TRIPS Agreement, to which almost all countries of the world are parties. This has led to significant harmonization of patent law worldwide, particularly in the last decade of the 20th century and continuing into the present century.

As the TRIPS agreement is the very significant agreement in regards of granting of compulsory licensing, therefore it incorporates portions of the Paris Convention, the Doha Declaration, and others, are notably new in this regards. Without terming it such, TRIPS allows for compulsory licensing admits several provisions in Article 31 of the TRIPS Agreement[1].

TRIPS grants a monopoly on a patented product to the holder of the intellectual property rights for 20 years as a reward of investment in research and development in that product and as an incentive for further investment[2]. In practice, this leads to monopoly pricing and higher costs of pharmaceuticals.

But the way to deal and cope with monopoly pricing, is the 'compulsory licensing' which TRIPS incorporated as one of its very famous provision i.e. article No.31 (a) of the TRIPS agreement[3]. Moreover, it will be difficult, if not impossible, for smaller

[1] G.M Chaudhry, International treaties on IPRS p.1404 &1405, (Federal Law house Rawalpandi -2005).
[2] Art. 33 of the TRIPS Agreement-1995.
[3] *Ibid*, Article No. 31(a).

economies to benefit from compulsory licensing unless they are allowed to import or export patented pharmaceuticals on the basis of compulsory licensing. From a health perspective, compulsory licensing plays an important role in supply of medicine for various diseases. Access to medicine in the developing and least developed countries is a very debatable issue; the example is the South Africa's AIDS crisis.

These countries lack many resources and usually do not have access to most pharmaceuticals, including essential drugs. But these countries tend to be less able to benefit from new more sophisticated treatments that are the ones protected under TRIPS, for instance, treatments for HIV/AIDS. For HIV/AIDS treatments, the major beneficiaries of compulsory licensing would be middle income countries. While it is clear that some HIV/AIDS medications can be effectively used also in very poor countries.

The most sustainable and meaningful way to achieve access to pharmaceuticals in developing countries is through the using compulsory licensing. It is assumed, that through the TRIPS Agreement permission for the granting of compulsory licensing, the patentable inventions will be eventually become publicly available, and investments in this area are to be made useful.

But the current balance of investment in pharmaceutical research and development clearly points out the problem with this approach. Recent emphasis on pharmaceutical research and development as a global public good and the consequent necessity for the developed world to pay higher prices in order to ensure access to pharmaceuticals in the developing world, but by issuance of compulsory licensing, the developing countries can solve this problem.

Rights to use compulsory licensing should not be narrowed to a specific disease, country, and the scope of economy or depend on the gravity of public health problems. Imports and exports under compulsory licensing should be ensured in order to take into account differences in capacities between larger and smaller economies.

Compulsory Licensing is a mechanism to enhance developing country's access to the current knowledge and information at low costs in order to ensure free access to educational research and scientific purposes, public health and medicines for epidemics. TRIPS Agreement is the significant international treaty which has focused on compulsory licensing in its various provisions.

2.1 TRIPS – 1995

TRIPS, to-date, is the most comprehensive multilateral agreement on intellectual property Rights including patent. Patents Contain to the protection of new varieties of plants; the layout-designs of integrated circuits; and undisclosed information including trade secrets and test data. TRIPS allow compulsory licensing for patents in some of its provisions.

2.1.1: Analysis of the relevant provisions

The key provision in the TRIPS regarding compulsory licensing of patents is Article 31, "Other Use without Authorization of the Right Holder". However, many other Articles are also highly relevant. Particularly, at least Article 1, 7, 8, and 27.2, 30, 31 and Article No. 44 [4]. Article No.1, provides impliedly for compulsory licensing by saying, "members may, but shall not be obliged to implement in their law more extensive protection than is required"[5] in this text there is place for compulsory licensing i.e. the non-implementation of extensive protection to patent, because if there is extensive protection, than its violation would be very difficult, but here the text is flexible and indicating on compulsory licensing.

While Article No. 7 says, "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantages of producers and users of technological knowledge and a manner conducive to social and economic welfare and to a balance of rights and obligations"[6].

---

[4] *Ibid*, Art. 31 (a), 1, 7, 8, 27.1, 30 and 44.
[5] *Ibid*, Art. 1 (1).
[6] *Ibid*, Art. 7.

It is very clear from this section that the sole purpose of the protection and enforcement of intellectual property right, is the promotion of invention, technological development and the establishment of a balance between the rights and obligations and same is the purpose of compulsory licensing, as it establish a balance between price and supply in market.

Article No 8, says, "members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, to promote the public interest in sectors of vital importance to their economic and technological development"[7], as the main theme of this article is the protection and promotion of public health and public interest of vital importance and same is, of the compulsory licensing.

So this article provides some flexibility for government to enact legislation for the granting of compulsory licensing. Article 27.2 also provides for compulsory licensing to protect ordare public or morality, protect human, animal or plant life or health to avoid serious prejudice to the environment etc.

Original text of the article is, "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordare public or morality, including protecting human, animal or plant life or health to avoid serious prejudice to the environment"[8].

Article no 30 provides limited exceptions to the exclusive rights conferred by a patent. This exception is the granting of compulsory licensing, which is totally against the exclusive right of patentability. It protects the public interest and breaks monopoly. Text of the article is, "members may provide limited exception to the exclusive rights conferred by a patent".[9]

Article No.31 is a mega provision on the issuance of compulsory licensing. It specified the terms and conditions and other accessories with full detail from sub-article "a" to (iii) of "k". It is very clear and most comprehensive document in this regards.

---

[7] *Ibid,* Art. 8 (1).
[8] *Ibid,* Art. 27 (2).
[9] *Ibid,* Art. 30.

Article No.44 (2) also provides for compulsory licensing, which a government grant to a third person other than the patent right holder to cope the arisen situation. Text of the article says "use by government or by third party authorized by government, without the authorization of the right holder".[10]

Article 31 of the TRIPS sets outs the framework for national laws on use without authorization of the patent owner. It says: "other use without Authorization of the Right Holder"[11]. Where the law of a member state allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected.

(a) Authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a member in the case of 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 or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive,

---

[10] *Ibid,* Art. 44 (2).
[11] *Ibid,* Art. 31.

(d) Such use shall be non-exclusive;

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

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

(g) Authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

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

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

(j) Any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.

The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) Where such use is authorized to permit the exploitation of a patent "the second patent" which cannot be exploited without infringing another patent "the first patent", the following additional conditions shall apply:

(i) The invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) The owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and

(iii) The use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent[12].

It is concluded that the following conditions are required to be fulfilled before granting compulsory licensing by the competent authority;

(i) Prior request from the right holder/ patentee for the use of the patent,

(ii) That request must be on reasonable commercial terms,

(iii) The owner of the patent does not give response to such request in reasonable period of time,

(iv) The scope and duration of such use shall be limited to the purpose for which it was authorized,

(v) Such use shall be non-exclusive; it means that any time it can be revoked, as well as the patent-holder can continue to produce.

(vi) Such use shall be non- assignable, it means that, that very third party cannot confer the right of use to any other person on its own behalf.

(vii) Such use shall be predominantly for the supply of the domestic market, it means that not be for commercial purposes,

(viii) Such authorization shall be liable to adequate protection of the legitimate interests of the person so authorized,

---

[12] G. M. Chaudhry, Intellectual property laws in Pakistan and International treaties p.1403, 1404-1405, (Federal Law house Rawalpandi -2005).

(ix) The right holder shall be paid reasonable remuneration/royalties, taking into account the economic/market value of the authorization,

(x) The right holder can sue the granting authority in the court of law for remuneration if refused,

These conditions and requirements may be waived by a member state in the following cases;

(i) In the case of national emergency,

(ii) Other circumstances of extreme urgency,

(iii) Public interest,

(iv) Public epidemics.

These conditions should be read together with the related provisions of Article no.27.1, which require that the patent rights shall be enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced[13]. Article 31 of the TRIPS agreement gives countries broad discretion on government use of compulsory licensing. For example, there is no limitation on the grounds upon which a government can authorize use of a patent by third parties, such as the instrument of public welfare and interest, which allows the government to grant the license at any time to any one.

The Agreement re-affirms the well-established principle of national treatment; in its Article No.3[14], which means that the nationals of any country member of the Agreement are to be treated in the same way as nationals of the country where protection to patents or compulsory licensing are granted.

It also extends to IPRS the most-favoured-nation clause; in its Article No.4[15], which means that all member states of the agreement shall be consider accordingly equal members of the treaty and would not be any discrimination over there even in protection

[13] TRIPS Agreement-1995, Art. 27.1.
[14] *Ibid*, Art. 3.
[15] *Ibid*, Art. 4.

or licensing granting. It also facilitates legislating limitations to exclusive rights, as well as the enactment of legislative provisions concerning the compulsory licensing. In particular, the grounds mentioned in Article 8.1 are relevant for the granting of compulsory licensing, for example the pharmaceutical field in order to keep prices at a reasonable level or to ensure access to particular medicines by the population.

Nothing in the TRIPS Agreement prevents, in effect, the granting of compulsory licences for reasons such as public interest, public health or environmental protection, subject to the conditions set out in the Agreement. The Agreement further allows national legislation to determine the rights that can be exercised by the licensee, including production. Lastly, the minimum patent lifetime stipulated in the agreement is 20 years, counted from the filing date.

A compulsory license issued by a member may be given effect by another member. Such other member may authorize a supplier within its territory to make and export the product covered by the licence predominantly for the supply of the domestic market of the member granting the licence. It means that inside the territorial jurisdiction of the granted licensing country. It is explained by Article 31(f) of the TRIPS Agreement which says products made under compulsory licensing must be "predominantly for the supply of the domestic market of the member authorizing such use[16]".

This applies to countries that can manufacture drugs. It limits the amount they can export when the drug is made under compulsory licence. And it has an impact on countries unable to make medicines and therefore wanting to import generics. They would find it difficult to find countries that can supply them with drugs made under compulsory licensing.

This problem was resolved on 30 August 2003 when WTO members agreed on legal changes to make it easier for countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines for themselves. The decision of the August 30th 2003, waives exporting countries' obligations under

[16] *Ibid,* Art. 31 (f).

Article 31(f) i.e. "supply of the domestic market" and now any member country can export generic pharmaceutical products made under compulsory licences to meet the needs of importing countries. Carefully negotiated, these conditions aim to ensure the beneficiary countries can import the generics without undermining patent systems, particularly in rich countries and all WTO member countries are eligible to import under this decision. Production and export under these conditions do not infringe the rights of the patent holder. Nothing in the TRIPS Agreement shall prevent members from establishing or maintaining marketing approval procedures for generic medicines and other healthcare products.

Nothing in the TRIPS Agreement shall prevent members from disclosing or using information held by its authorities or the patent holder where it is so required for reasons of public interest, including where such disclosure or use is necessary to implement effectively any compulsory licences. The TRIPS agreement allows compulsory licensing as part of the agreement's overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs, under the sense of words "other use without authorization of the right holder" appears in the title of Article 31[17].

2.1.2: TRIPS and Public Health

Health is Wealth, to be protected at any possible cost. This issue was discussed with some detail in regards of access to medicines, the impact of patent protection on pharmaceuticals and successful pursuit of public health in developing courtiers like Pakistan, which is a critical issue of public health importance among the member countries of the TRIPS agreement. The possible impact of the implementation of TRIPS agreement on access to medicine and public heath facilities is one of the hot debated issues. It is assumed that a strict implementation of TRIPS provisions, related to public health will lead to substantial increase in drug prices, particularly in developing countries including Pakistan.

[17] *Ibid*, Art. 31 (a).

Due to this the delivery of public health services and medicines will suffer in these countries, and the spread of diseases, will added to their worries, such as Malaria, HIV/AIDS, Tuberculosis and other epidemics. Realizing the importance of public health and its dilapidated conditions in developing and least developed countries especially at the time of public epidemics the members agreed to de-escalate the problem and make them accessible to medicines for all, by giving them the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted, each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency.

2.1.3: The TRIPS Agreement and the "patentability" of medicines

The TRIPS agreement, made in 1994 during the Uruguay Round, determined that all the signatories agree to establish a minimum standard of protection of intellectual property. Various themes were regulated by TRIPS, such as authors' rights, brands, patents, confidential information and industrial designs.

The application of these rules was ensured by the system of solution of controversies of the WTO, which improved the mechanism of resolving disputes which existed in GATT. TRIPS allowed for the patenting of products and processes which represent innovation and are suitable for industrial use. In this sense, protection of innovation was the main objective. Thus, the link between intellectual properties was strengthened in such a way that repression of piracy should foster economic flows among the members of the WTO.

Patents create incentives for innovation and publication of inventions, remunerating the inventor for the investments he makes. It must be pointed out, however, that the patent system contains a cost represented by the possible abuse of power of the monopoly of the title holder.

The patent may also be used to block the inventive activity of third parties, which would obviously harm society. Various reasons are usually put forward to justify the need to concede patents of pharmaceutical products:

1) Firstly, the discovery of new medication requires a long period of time and considerable investments.

2) Secondly, pharmaceutical products can be copied and introduced on the market irregularly. For many years patents were not granted to pharmaceutical products. In developed countries, it was only in 1976 that Japan passed legislation for the sector, while Switzerland adopted a similar measure in 1977. Spain, Portugal, Greece and Norway created patent systems for pharmaceutical products in 1992.

Until to the end of eighties about 40 developing countries, including the most densely populated did not have patent systems for medicines in general. This was based on the social importance of medication and on the belief that patents would lead to abuse the monopoly power[18]. The "patentability" of pharmaceutical products, agreed upon during the Uruguay Conference.

TRIPS Article 7 states that the regime of intellectual property rights should contribute to the promotion of innovation, and the transference and spread of technologies, able to lead financial and social welfare. Article 8 states that States can adopt the necessary measures to protect public health and nutrition as well as to promote public interest in sectors which are vital for social, economic and technological development. The measures

[18] http://www.google./digital libreries.com, last visited: 20/07/2006. Library/food and drug law journal/ Adi Gillat, compulsory licensing, effects on the conflict between innovation and access in the pharmaceutical industry, page 6, (2003).

adopted should, however, be compatible with the TRIPS agreement[19]. Some exceptions were made by TRIPS to the general obligation to concede patents. Article 27 (2) authorizes members to restrict the concession of patents if the inventions may endanger human life or health. Despite the efforts made during the Uruguay Round Conference, it was not possible to reach to a definition of the expression "limited exceptions" in Article 30 of the TRIPS agreement.

However, there is a close link between article 7 and article 30, which, when read together leads to the conclusion that, states should make compatible the protection of the rights of the patent holder and the need to consider the legitimate interests of third parties. Article 30, in its turn, allows States to restrict the exclusive privileges granted by the patents. For this to happen, some prerequisites must be present[20].

The exceptions are to be limited to the rights of monopoly, and cannot prevent the exploitation of the patent or cause unreasonable harm to the legitimate interests of the patent holder. Argued that in the case of illnesses like AIDS, developing countries can establish restrictions on the rights of patent holders in order to reduce the cost of pharmaceutical products and enable the poorer part of the population to have greater access to them. Countries have the right to regulate the exercise of the rights granted by the patent in order to fulfil the public good.

In this context, compulsory licensing appears as an important instrument to increase the supply of medicines at lower prices. The agreements of the TRIPS assigned compulsory licensing the task of solving problems created by the patent system. It authorizes a third party to manufacture, use or sell a patented invention without the authorization of the title-holder, under clearly stated circumstances[21]. Article 31 allows for the concession of compulsory license in cases of monopoly power abuses granted by the patent, or when

---

[19] Philippe Cullet, Patents and health in developing countries in law and development; facing complexity in the 21st century, p. 82 & 83 (Cavendish publishing, London, -2003).
[20] *Ibid*, p. 83.
[21] Carlos M. Correa, Public health and Patent legislation in developing countries, p. 17, (Tulane printing press-2001).

public interest demands it. Such flexibility is essential for the adoption of public policies geared to protecting health. The increase in medication costs caused by the "patentability" of pharmaceutical products can be off set by regulatory measures that will enable social groups with a lower income to have access to medications [22]. It is interesting to observe that developing nations have seldom made use of the flexibility of the TRIPS agreement.

The Doha declaration about TRIPS and public health in 2001 maintained the flexibility of the Agreement negotiated during the Uruguay Round Conference, which allowed the implementation of public policies that facilitate access to medications. The decision that nothing in the agreement would be interpreted in such a way as to prevent countries from adopting their own public health policies was of the utmost importance[23].

It establishes a sense that the title-holder has the right to prevent the medication from being launched on other markets. The fact that some countries are unable to benefit from the flexibility offered by TRIPS is particularly serious. Once it is granted, compulsory licensing may not produce the expected results due to the lack of technical ability of local industry.

The member countries of the WTO will be able to import medicines through compulsory licensing if domestic industry proves unable to supply the needs of the domestic market. The decision of the General Council established a number of safeguards to prevent medications produced through compulsory licensing for developing countries from supplying the market of developed countries.

Such safeguards include, among other requirements, the form, colour, and type of packaging of the products sold. The decision, which will be interpreted and implemented

[22] Jose Marcos Nogueira, Intellectual property rights, the world trade organization and public health, journal of international law, p. 3, (Law printing press- 2003).
[23] Carlos M. Correa, public health and patent legislation in developing countries in Tulane journal of technology & intellectual property, p. 17, (Tulane printing press-2001).

in good faith, will deal with public health issues and will not aim at achieving goals of commercial or industrial policies. The developing countries should use compulsory licensing to promote access to medications in the following situations[24]:

(i) A declared state of national emergency, as in cases of natural catastrophes, wars or epidemics;

(ii) When there is a public health crisis, to ensure the population's access to essential medications, or situations of public interest, including those of national security;

(iii) Identification of anti-competitive behaviour;

(iv) Governmental use, to foster access to medicines on non-commercial grounds;

(v) When lack or insufficiency in exploiting the patent hinders access to health or prevents the development of a vital sector of the country's economy;

(vi) Public interest[25].

2: Compulsory licensing & WTO demand

WTO is an organization of the almost all countries of the world, for the development, facilitation and enhancement of trade among the member states. WTO strongly protected and enforced Intellectual Property Rights. The members of the WTO agreed on the demand for compulsory licenses. The delegations of the member states recognized the gravity of the public health problems afflicting many developing and least-developed countries, especially those affected by public epidemics.

---

[24] Compulsory patent licensing in view of the WTO ministerial conference, declaration on the TRIPS agreement and public health in Journal, Patent and Trademark office society, 3, page 3, February- 2002.

[25] Carlos M. Corea, integrating public health concerns into patent legislation in developing countries, p.143-(Tulane printing press-2001).

The members observed the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address the problem of new medicine protection and maintaining their prices. Therefore they agreed on the granting of compulsory licensing by the member states and freedom to determine the ground upon which such licenses are granted and even to determine the circumstances, what constitutes national emergency.

They encourage the member countries to takes measures for the protection of public health. They allowed those members, with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.

2.2: The Doha declaration -2001

The Doha Declaration-2001 on TRIPS and public health contains both a promise and an obligation to interpret and implement the TRIPS Agreement in a manner supportive of a WTO member's right to protect public health and promote access to medicines for all. The declaration was a victory for developing countries.

The Doha ministerial declaration is the very important document in regards of access to pharmaceutical products and public health, because in it for the first time the developed countries agreed on the granting of compulsory licensing to medicines necessary for public health.

So many other conferences were also held from time to time e.g. in Singapore Dec.1996, Geneva May. 1998, Seattle Nov.1999, Cancun Sep.2003 and Hong Kong Dec.2005, etc. Than the same has been agreed in the Doha declaration of Sep. 2003, among the ministers, that, "while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include; that each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are to be granted.

That each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. The effect of the provisions in the TRIPS Agreement that are relevant to intellectual property rights is to leave each member free to establish its own regime for IPRS.

The TRIPS agreement permit the countries to export medicines and other inventions to address health needs, e.g. "members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties"[26].

2.2.1: Importance of the Doha Declaration

The very strict patent protection which extended to pharmaceuticals has always been and continues to be an issue of the public debate and discussion. Developing countries and NGOS (non-governmental organizations) argue that strict enforcement of pharmaceutical patent holders' rights has resulted in high prices, which render unaffordable to poor countries drugs for the treatment of epidemics. The fact is that, the patent holders' exclude others from selling or making their exact or substantially similar patented products for the term of the patent.

This period of exclusivity provides the patent holder with the power to control the selling price of the patented product. The strict patentability example may be considered in the case of South Africa. The tragedy was that, of the nearly 25 million people infected but only about 25000 people, of them, have access to life-prolonging medicines.

---

[26] G.M Chaudhry, the Intellectual property laws in Pakistan and International treaties on IPRS p.1403, (Federal Law house Rawalpandi-2005).

Consequently, in a continent where the death count from AIDS threatens the lives at large scale, the government has sought to provide access to pharmaceuticals by enacting legislation based on a legal theory known as compulsory licensing to address the AIDS pandemic[27]. The Pharmaceutical companies of the developed countries, particularly the US, filed a suit against the South African government. After the South African case and the Cipro/ anthrax weaponization incident occurrence, the fourth WTO Ministerial Conference took place, in November 2001 in Doha, Qatar, to provide guidance and reduce any ambiguities relating to the compulsory licensing provisions of TRIPS. The draft of the ministerial declaration was submitted by the developed countries for compulsory licenses.

The ministerial text intended to discuss two major issues; the scope of the term "public health" and the ability of members without adequate manufacturing capacities to seek the benefits of compulsory licensing. The result of the meeting in Doha was a, "Declaration on the TRIPS Agreement and Public Health" which was unanimously adopted by the member countries[28]. The United States was in a difficult position to object to the demands of developing countries.

Finally official agreed on declaration and set relatively broad conditions under which a country could grant a compulsory license for pharmaceuticals. The Declaration goes beyond a broad reference to TRIPS flexibilities for compulsory licensing, which plays an integral role in quelling of epidemics that afflict the populations of developing and least developed member countries.

The justifications for issuing compulsory licenses was that, it reduces the issuing country's dependence on imports, increasing the number of competitors in the marketplace, and protecting and developing local industry usually the pharmaceutical industry. They agreed in the conference that, the WTO should not place barriers on members lacking adequate domestic manufacturing capacities to issue compulsory licenses to foreign pharmaceutical manufactures and the trade ministers of the Doha

[27] http://www.wto.org/july 11, 2002.com, last visited: 09/08/2006.
[28] http://www.annualreport by the director general of the wto/dec.10 2001, last visited: 10/09/2006.

declaration should consider a system in which members lacking manufacturing capacities issue compulsory licenses for importation of needed pharmaceuticals, and exporting members concurrently issue compulsory licenses for export[29]. The Declaration also states that each country" has the right to determine what constitutes a national emergency or other circumstances of extreme urgency", and indicates that "public health crises, including those relating to HIV/AIDS, tuberculosis, malaria or other epidemics" can represent such a situation. Doha declaration provides to safeguard against unaffordable prices for much needed medicines.

The Doha declaration affirms the right of WTO members to employ other measures to facilitate the protection of public health and promote access to medicines. But the implementation of these measures in developing countries is far from completion; therefore countries should take urgent measures to cope the situation by adopting their national patent laws.

2.2.2: Problems remain with TRIPS after the Doha Declaration

Although the Doha declaration tried to resolve the arisen problems to the every possible extent, but still a major problem remains, the problem is a restriction in TRIPS specifically in Article 31(f) on" compulsory licensing", namely the requirement that the license must be used" predominantly"[30] for supplying the domestic market of the country issuing it.

This means countries with private generic drug companies or state-owned manufacturing capacity are prevented from issuing compulsory licenses allowing the manufacture of generic versions of patent-protected drugs primarily for export to other countries.

This restricts possible sources of supply for the majority of developing countries that cannot afford high prices of patented medicines but lack domestic capacity to

[29] http://www.wto.org/ July 11, 2002.com. last visited: 18/09/2006.
[30] Art. 31 (f) of TRIPS Agreement-1995.

manufacture their own generic versions. In the Doha Declaration, WTO member countries recognized this problem and pledged to solve it within a year. However, over a year and several million deaths later, WTO members had failed to reach an agreement on a solution that would overcome this TRIPS obstacle and enable countries lacking manufacturing capacity to make effective use of compulsory licensing. Very importantly, these wealthy countries of the union sought to restrict any "solution" to apply only to a handful of diseases, claiming that the Doha Declaration was only intended to apply to HIV/AIDS, tuberculosis, malaria and similar "infectious epidemics. Member countries of the TRIPS Council have proposed to restrict use of compulsory licensing for developing countries to "national emergencies or other circumstances of extreme urgency".

2.2.3: Restrictions on the use of compulsory licenses

Compulsory licensing is an exception to the general rules of commercial transitions therefore, there may be some restrictions on its uses. Compulsory licenses for pharmaceuticals are one of the most important tools for ensuring generic competition. In other fields of technology they are commonly used by industrialized countries. They are especially important now that all WTO countries with pharmaceutical manufacturing capacity, except for least developed countries, may provide patents for pharmaceutical products and processes.

Generic production of new medicines will increasingly become dependant upon compulsory licensing, meaning that flexible conditions for granting compulsory licenses must be in place in order to ensure the continued supply of affordable generic medicines. As compulsory license is a public authorization to others than the patent holder to produce, sell and export a particular product.

However, it is of no use if the drug regulatory authority cannot register any generic drug during the life of the patent. It leads to restrict the use of compulsory licenses in future regional and bilateral free trade agreements, in order to preserve the full use of this important safeguard for low and middle income countries. The TRIPS Agreement obligates WTO members to provide patent protection on medicines for 20 years which is

more than enough. One hundred and forty two countries have attended this fourth session of Doha, 9-14 November 2001, negotiated and adopted the Doha Declaration, firmly placing public health needs above commercial interests and offering much needed clarifications about key flexibilities in the TRIPS Agreement related to public health[31]. All of them agreed upon the granting of compulsory licensing, when the specific conditions arises, otherwise compulsory licensing may not be granted by any member state.

2.2.4: Compulsory Licensing and Doha Declaration on Public Health

The Doha Public Health Declaration, although primarily aimed at pharmaceutical patents, could very well be the first step in a broader challenge to the overall value of Intellectual property protection for economic development. The principal of non-discrimination, among technological sectors, with respect to the availability of patents and the enjoyment of patent rights, runs at the very heart of the TRIPS Agreement.

The agenda for the Doha Ministerial Declaration on Public Health of November 14, 2001, to sets two specific task; (i). The TRIPS Council has to find a solution to the problems countries may face in making use of compulsory licensing if they have too little or no pharmaceutical manufacturing capacity. (ii) and extends the deadline for least-developed countries exemptions on pharmaceutical patent protection until 1 January 2016. In this Declaration the WTO member stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health by promoting both access to existing medicines and the creation of new medicines.

They agreed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. They underscored countries' ability to use the flexibilities that are there in the TRIPS Agreement, including compulsory licensing. They agreed that the countries which are unable to produce pharmaceuticals domestically can obtain supplies of copies of patented drugs from other countries. One cannot limit or

[31] http://www.cptech.org.com, last visited: 25/09/2006.

restrict with certainty the scope of the Doha Public Health Declaration to those pharmaceutical patents providing access to medicines, and the fundamental grounds of the export compulsory licensing. So now under compulsory licensing those countries which are insufficient or no manufacturing capacity in the pharmaceutical sector, are allowed to obtain such capacity indirectly[32]. The Doha Public Health Declaration upsets the balance between the TRIPS Agreement and public policy measures.

Normally the person or company applying for a license has to have tried to negotiate a voluntary license with the patent holder on reasonable commercial terms. Only if that fails than a compulsory license may be issued, and even when a compulsory license has been issued, the patent owner has to receive payment. The ministers agreed on the following points:

1) We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2) We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3) We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

[32] http://www.google/search/wt/min01/dec.com, last visited: 28/09/2006.

4) We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

5) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

6) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

7) We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement[33].

8) We affirm that the least-developed countries will not be obliged, to apply provisions on pharmaceutical patents until 1 January 2016.

9) We stress to the importance, implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines.

---

[33] http:// www.google/search/wt/min/01/s 14 November 2001.com, last visited:10/10/2006.

2.3: Paris Convention-1967

Basically this was priority Convention for the protection of industrial property, which was held in March 20, 1883, as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967, and as amended on September 28, 1979)[34].

The Paris Convention for the protection of industrial property is an international intellectual property treaty, adhered by, about 168, member countries, which help those who wish to obtain patent protection in more than one country.

At the beginning Pakistan was not a member to it, but later on, due to its importance Pakistan enters to it on July 22, 2004[35]. The Paris Convention, as it is usually called, provides that each country guarantees to the citizens of the other countries the same rights in patent matters that it gives to its own citizens. The substantive provisions of the Convention fall into three main categories; national treatment, right of priority, common rules for all.

Under the provisions on national treatment, the Convention provides that, as regards the protection of industrial property, each contracting state must grant the same protection to nationals of the other contracting states as it grants to its own nationals. Nationals of non-contracting states are also entitled to national treatment under the Convention if they are domiciled or have a real and effective industrial or commercial establishment in a contracting state.

The Convention provides for the right of priority in the case of patents. This right means that, on the basis of a regular first application filed in one of the contracting states, the applicant may, within a certain period of time i.e.12 months for patents and utility models, 6 months for industrial designs and marks, apply for protection in any of the other contracting States; these later applications will then be regarded as if they had been filed on the same day as the first application.

---

[34] http://www.google/paris convention.com, last visited: 12/10/2006.

[35] G. M. Chaudhry, Intellectual Property Laws in Pakistan p. 1463, (Federal Law house Rawalpandi.2005).

In other words, these later applications will have priority, hence the expression "right of priority"[36], over applications which may have been filed during the said period of time by other persons for the same invention. Moreover, these later applications, being based on the first application, will not be affected by any event that may have taken place in the interval, such as any publication of the invention or sale of articles bearing the mark or incorporating the industrial design.

The Convention lays down a few common rules which all the contracting states must follow. The more important are the following:

- Patents granted in different contracting states for the same invention are independent of each other; the granting of a patent in one contracting state does not oblige the other contracting states to grant a patent; a patent cannot be refused, annulled or terminated in any contracting state on the ground that it has been refused or annulled or has terminated in any other contracting state. The inventor has the right to name as such in the patent. The grant of a patent may not be refused, and a patent may not be invalidated, on the ground that the sale of the patented product, or of a product obtained by means of the patented process, is subject to restrictions or limitations resulting from the domestic law.

- Each contracting state that takes legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exclusive rights conferred by a patent may do so only with certain limitations[37]. Thus, a compulsory license based on failure to work the patented invention may only be granted pursuant to a request filed after three or four years of failure to work or insufficient working of the patented invention and it must be refused if the patentee gives legitimate reasons to justify his inaction.

[36] Paris Convention-1967, Art. 4 (1&2).
[37] *Ibid*, Art. 5 (2).

- Furthermore, forfeiture of a patent may not be provided for, except in cases where the grant of a compulsory license would not have been sufficient to prevent the abuse. In the latter case, proceedings for forfeiture of a patent may be instituted, but only after the expiration of two years from the grant of the first compulsory license[38].

If there was no Paris Convention, then for the obtaining of patent in both countries, the inventor would have to file an application in both the countries simultaneously or nearly simultaneously because the publication of the patent in one country would bar filing a patent application in other country.

But because of this Convention, however, the inventor need only to file in one of the two countries, and may postpone filing in the other country for almost a year. When the filing is done in one country the applicant merely "claims priority" from the filing in the first country, and the patent office in the second country will treat the application as if it had been filed on the date in which the first country was filed[39].Compliance with all of the substantive provisions of the Paris Convention is mandatory even for countries which are not yet party to that convention, if they are the member of the WTO (World Trade Organization).

Such compliance is mandatory as from the date of general application in each country bound to apply the provisions of the Agreement on Trade Related Aspect of Intellectual Property Rights, TRIPS Agreement.

In its Article No. 2, the TRIPS Agreement obliges members to comply with articles 1 to 12 and article No. 19 of the Paris Convention, e.g. "members shall comply with article 1

[38] *Ibid,* Art. 5 (3).
[39] *Ibid,* Art. 4bis (2), Art. 6 (1).

through 12 and article 19 of the Paris convention"[40]. These articles says respectively about the establishment of a union for the protection of patent, establishment of special services for the communication to the public of patents and for making special agreement among the member countries for the protection of patents[41]. The Paris Convention thus, is very helpful to inventors, for several reasons, such as:

1) Filing in many countries costs a lot of money. The Paris Convention allows the inventor to defer that cost. What's more, if events during the year lead to a decision to abandon the attempt to get patents, then the Paris Convention allows the inventor to save all the money that would have been spent in the countries other than the first country.

2) Filing in many countries is often time consuming and involved. Often the text of the patent application has to be translated into several languages. It is necessary to engage in correspondence with patent agents or attorneys in each of the countries involved.

In the absence of the Paris Convention, an inventor would have to do these things in a hurry, in many countries at once, necessitating large courier bills, a lots of faxes, and a lots of rush translations. The Paris Convention allows the translating and international correspondence to be undertaken over the course of a year rather than all at once.

3) The Paris Convention also provides for the right of priority in the case of patents. These rights means that, on the basis of a regular first application filed in one of the member countries, the applicant may, within a certain period of time, apply for protection in all the other member countries.

These later applications will then be treated as if they had been filed on the same day as the first application. Thus, these later applicants will have priority over applications for

[40] G. M. Chaudhry, International Treaties on IPRS p. 1393, (Federal Law house Rawalpandi- 2005).
[41] Art. 1, 12 & 19 of The Paris convention -1967.

the same invention which may have been filed during the same period of time by other persons. However, this concept of priority right applies only to the countries which are members of the Paris Convention. Almost all the industrialized countries are members of this treaty/Paris convention.

Under the Paris Convention, the term "patent" is interpreted broadly to encompass all forms of patent laws created within its member nations[42]. The Paris Convention sought to eliminate unequal treatment by any nation's domestic laws toward foreign patent holders through the "National Treatment" provision in Article no. 2[43]. For example, the Convention promulgated that it be necessary to treat foreign patent holders equally for patent fees, patent terms, and the time period within which the patent holder must work the patent to avoid the granting of compulsory licenses.

Under the Paris Convention, compulsory licenses are permitted to solve the problem of under utilized patents. The Paris Convention clearly addresses for the granting compulsory licensing of patents in Article 5(A). According to this article each country may take legislative measures providing for the grant of compulsory licences to prevent the abuses which might result from the exclusive rights conferred by a patent for invention, for example failure to work or insufficient working[44].

Under Article No.5A-(4) of the Paris Convention, compulsory licenses for failure to work or insufficient working of the invention may not be requested before four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever expires last. A compulsory license shall be non- exclusive and shall not be transferable, even in the form of the grant of a sub-license[45].

The minimum time limit for non-exploitation is three or four years. The patent owner must be given a longer time limit, if he can give legitimate reasons for his inaction, for example, that legal, economic or technical obstacles prevent working, or working more intensively, the invention in the country. If that is proven, the request for a compulsory

[42] *Ibid*, Art. 1 (4).
[43] *Ibid*, Art. 2 (4).
[44] *Ibid*, Art. 5 (2).
[45] *Ibid*, Art. 5 (4).

license must be rejected, at least for a certain period of time. The time limit of three or four years is a minimum also in the sense that national law can provide for a longer time limit. The compulsory licenses for non-working or insufficient work in must be a non-exclusive license and can only be transferred together with the part of the enterprise benefiting from the compulsory license. The patent owner must retain the right to grant other non-exclusive licenses and to work the invention himself.

Moreover, as the compulsory license has been granted to a particular enterprise on the basis of its known capacities, it is bound to that enterprise and cannot be transferred separately from that enterprise. These limitations are intended to prevent a compulsory licensee from obtaining a stronger position on the market than is warranted by the compulsory license, namely to be ensure sufficient working of the invention in the country. The provision of Article No. 5A (4) is only applicable to compulsory licenses for non-working or insufficient working. It is not applicable to the other types of compulsory licenses for which the national law is free to provide.

Such other types may be granted to prevent other abuses, for example excessive prices or unreasonable terms for contractual license or other restrictive measures which hamper industrial development. Compulsory licenses may also be granted, on the grounds of public interest, in cases where there is no alleged abuses by the patent owner of his rights.

These are, in particular cases where a patent for invention affects a vital public interest, for example in the fields of defence or public health. All these types of compulsory licenses can be grouped together under the general heading of compulsory licenses in the public interest.

National laws are not prevented by the Paris Convention from providing for such compulsory licenses, and they are not subjected to the restrictions provided for in Article 5A. The expiration of the time limits provided for compulsory licenses, which relates to failure to work or insufficient working. The original text of article no.5A of the Paris Convention, regarding compulsory licensing is in the following lines:

a) Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the union shall not entail forfeiture of the patent[46].

b) 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[47].

c) Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license[48].

d) A compulsory license may not be applied on the ground of failure to work or insufficient working before 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; it shall be refused if the patentee justifies his inaction by legitimate reasons.

Such a compulsory license shall be non–exclusive and shall not be transferable, even in the form of the grant of a sub–license, except with that part of the enterprise or goodwill which exploits such license[49]. So compulsory license of patent is also permitted by the Paris Convention in its substantive provisions to eliminate monopoly and balanced the market for consumers.

---

[46] *Ibid*, Art. 5.A (1).
[47] *Ibid*, Art. 5.A (2).
[48] *Ibid*, Art. 5.A (3).
[49] Ibid, Article No. 5.A (4).

CHAPTER-III

COMPULSORY LICENSING UNDER PAKISTANI LAWS AND ITS COMPARISON WITH MULTILATERAL REGIME

Pakistan's failure to adequately protect intellectual property Rights, constitutes one of its most severe barriers to trade and investment. The U.S. government has placed Pakistan on the Watch List every year since 1985 due to widespread piracy, especially of Patent materials. In 2002, Pakistan was the fourth largest source of counterfeit and pirated goods seized by the U.S. Customs Service.

The vast majority of these counterfeited goods were optical media piracy, (ten optical disc factories in Pakistan currently produce an estimated 230 million unlicensed discs annually, the majority of which are exported); unauthorized reproduction of U.S. printed works; and textile design piracy [1]. The software piracy ratio in Pakistan is 86%.

In May 2004, the United States Government downgraded Pakistan from Watch List to Priority Watch List in its Special 301 review. Also, in June 2004, the United States Government agreed to consider a GSP petition filed against Pakistan by entertainment industry representatives due to extensive production and export of illegal optical disks in Pakistan.

[1] http:// www.google/ipa.com. last visited:21/10/2006. And Role of IPO Pakistan in IPR promotion and enforcement by Yasin Tahir, Director General IPO-Pakistan- 2007.

In July 22, 2004, Pakistan acceded to the Paris Convention for the protection of industrial property. In 2000 and 2001, being a signatory to Trade Related Intellectual property Rights, Agreement TRIPS under WTO, Pakistan required up gradation of its intellectual property infrastructure in tandem with global trends. Accordingly the existing legislation on Intellectual Property i.e. Copyrights, Patents and Trademarks has been upgraded and the revised laws have been promulgated as follows:

1. The Patents ordinance -2000 (amended in-2002),
2. The Registered Designs Ordinance -2000,
3. The Registered Layout designs of Integrated Circuits Ordinance- 2000,
4. The Trade Marks Ordinance-20001,
5. The Copy Rights (amendment) Ordinance-2000
6. The Patent Rules-2003

Having brought its substantive legislation on IPRS in compliance with WTO obligations, Pakistan has strengthen its IP protection and enforcement mechanisms by consolidating and integrating the existing Intellectual Property Offices which were functioning under three different Ministries as patents under Ministry of Industries, Copyrights Ministry of Education and Trade Marks Ministry of Commerce.

In order therefore, to streamline and reinforce the functioning of IP system in Pakistan and to develop an effective enforcement mechanism, an integrated Intellectual Property Organization (IPO- Pakistan) has been established vide Ordinance No. V of 2005 dated 8th April 2005 (promulgated on 10th August 2005 Annex-I).amended under Ordinance No. VII of 2006.

This Organization will function as an autonomous organization with financial and functional autonomy. It is no more under any ministry. It is working under the supervision of cabinet division. It is envisaged that apart from providing an integrated administrative and enforcement support to the existing IP laws, IPO-Pakistan would also work for the enactment and enforcement of new laws in the areas like Traditional Knowledge and Geographical Indications etc.

A high powered Policy Board has been established to oversee, guide and control the IPO-Pakistan to enable it to achieve its organizational objectives. It consists on a Chairman of the Policy Board and Head of the Organization, who is an expert professional from the private sector, Deputy Chairman, Planning Commission is the Vice Chairman of this Policy Board. Director General of IPO- Pakistan is a Federal Secretary (BPS- 22) with Rapid capacity building and enhancement of the new organization. The major functions of the organization are the following:

1) In the immediate period, the new Organization needs to focus on effective implementation and enforcement of existing IP laws as our major trading partners are insisting on effective enforcement of IPRS as a pre-requisite for greater investment flows and even professional and business market access. Such focus would essentially include assurance that existing IP laws conforms all relevant international conventions to which the Government of Pakistan is committed.

2) Conceptually, IP must be viewed as instrument to promote exports, such as through trademarks, brands, geographical indications, create a framework for domestic innovation and technology acquisition patent, licensing.

3) There can also be negative effects of IPRS, such as the impact on prices of certain goods, by virtue of the temporary monopolies of the IPR holders and the concept of compulsory licensing.

4) IPO-Pakistan is mandated to embark on a well formulated programme to reach out to user groups and key stakeholders so that they greatly benefit from IP development and enforcement. The scientific community, business groups especially ,the

Information Technology Sector software designers and creators of cultural services authors, musicians should especially be encouraged to obtain IP protection of their creations and business assets.

5) IP Organization has to strengthen the culture of compliance, protect and reinforce IP rights and curb its violations. Pakistan ensures a most effective system of protection of all rights in the fields of intellectual property particularly the patent.

To equip the country with a mechanism recognising, protecting and enforcing intellectual property rights in all fields of industrial and economic activity, Pakistan has complied with almost all its obligations under the TRIPS Agreement, mostly by promulgation of entirely new laws to replace the old laws, and, in the case of Patents, by incorporation of necessary amendments to the existing law, as a result the Patent ordinance-2000, came into existence.

3.1: Patent Ordinance -2000

Pakistan as a member of WTO and signatory to the Agreement on Trade Related Aspects of Intellectual Property Rights "TRIPS" undertook to amend its patent law to conform to TRIPS obligations. It is worthy to be mentioned that on December 2, 2000 the President of Pakistan promulgated the Patents Ordinance, 2000 which complies with TRIPS' requirements, as well as, replaced the Patents and Designs Act 1911; it corresponds to the regime of new patent laws promulgated around the globe.

For the first time under this Ordinance protection has granted to product and process patents both[2], while in previous there was protection only to product patents. The life of the patent has been extended to 20 years, from 16 years; the new law is a remarkable departure from nearly century old legislation. These are the salient features of the new

[2] Patent Ordinance-2000, sec. 30 (a & b).

law. This ordinance bears the concept of compulsory licensing in its Chapter-XVI as such, "compulsory licenses, licenses of right, exploiting of patents and revocation"[3].

3.1.1: Analysis of the relevant provisions

The key provisions in the Patents Ordinance, 2000 regarding compulsory licensing of patents are sections 58 and 59. Section 58 explains the patent's exploitation by a Government agency or third person, while section 59 is about the powers of controller in granting compulsory licenses. The original text of section 58, "Subject to sub-section (2), where:-

(i) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or
(ii) The Federal Government has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti competitive, and the Federal Government is satisfied that the exploitation of the invention in accordance with this sub-section would remedy such practices; or
(iii) The patent holder refuses to grant a license to a third party on reasonable commercial terms and conditions; or
(iv) Where patent has not been exploited in a manner which contributes to the promotion of technological innovation and to the transfer and dissemination of technology, the Federal Government may, even without the consent of the owner of the patent, decide that a Government agency or a third person designated by the Federal Government may exploit a patented invention.

(2) The Federal Government shall, before taking any decision under sub-section (2), give the owner of the patent and any interested person an opportunity of being heard if he wishes to be heard.

[3] *Ibid*, chapter. XVI.

(3) The exploitation of the patented invention shall be limited to the purpose for which it was authorized and shall be subject to the payment to the said owner of an adequate remuneration therefore, taking into account the economic value of the Federal Government authorization, as determined in the said decision, and where a decision has been taken under sub-section (1), the need to correct anti-competitive practices.

(4) A request for the Federal Government authorization shall be accompanied by evidence that the owner of the patent has received, from the person seeking the authorization, a request for a contractual license, but that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time:

Provided that this sub-section shall not apply in cases of:–

(i) national emergency or other circumstantial urgency provided that in such cases the owner of the patent shall be informed of the decision of the Federal Government as soon as reasonably practicable;

(ii) public non-commercial use; and

(iii) Anti-competitive practices determined as such by a judicial or administrative body in accordance with clause (ii) of sub-section (1).

(5) The exploitation of a patented invention in the field of semi-conductor technology shall only by authorized either for public non commercial use or where a judicial or administrative body has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is anti-competitive and if the Federal Government is satisfied that the issuance of the non voluntary license would remedy such practices.

(6) The authorization shall be considered on its individual merits and shall not prohibit:-

(i) The conclusion of license contracts by the owner of the patent;

(ii) The continued exercise, by the owner of the patent, of his rights under section 30; or

(iii) The issuance of a non-voluntary license under section 59.

(7) Where a third person has been designated by the Federal Government, the authorization may only be transferred with the enterprise or business of the person or with the part of the enterprise or business within which the patented invention is being exploited.

(8) Where the exploitation of the invention by the Government agency or third person designated by the Federal Government is authorized under clause (i) of sub-section (1), it shall be predominantly for the supply of the market in Pakistan.

(9) Upon request of the owner of the patent, or of the Government agency or of the third person authorized to exploit the patented invention, the Federal Government may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(10) Upon the request of the owner of the patent, the Federal Government shall, subject to adequate protection of the legitimate interest of the persons so authorized, terminate an authorization if it is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to the decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by it has failed to comply with the terms of the decision.

(11) Notwithstanding the provisions of sub-section (10), the Federal Government shall not terminate an authorization if it is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by it justified the maintenance of the decision.

(12) an appeal shall lie to the High Court against the decisions of the Federal Government under sub-sections (1) to (9)"[4].

While the text of the section 59 is, "(1) 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 if he is satisfied that the patented invention is not exploited or is insufficiently exploited by working the invention locally or by importing in Pakistan.

(2) Notwithstanding the provisions of sub-section (1), a non-voluntary license shall not be issued if the owner of the patent satisfies the Controller that circumstances exist which justifies the non exploitation or insufficient exploitation of the patented invention in Pakistan.

(3) The decision issuing the non-voluntary license shall fix:-

(i) the scope and function of the license;
(ii) the time limit within which the licensee must begin to exploit the patented invention; and
(iii) The amount of the adequate remuneration to be paid to the owner of the patent and the conditions of payment.

(4) The beneficiary of the non-voluntary license shall have the right to exploit the patented invention in Pakistan according to the terms set out in the decision issuing the license, shall commence the exploitation of the patented invention within the time limit fixed in the said decision and, thereafter, shall exploit the patented invention sufficiently.

(5) If the invention claimed in a patent, hereinafter referred to as "later patent", cannot be exploited in Pakistan without infringing a patent granted on the basis of an application

[4] *Ibid*, sec. 58.

benefiting from an earlier filing or, where appropriate, priority date, hereinafter referred to as "earlier patent", and provided that the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent, the Controller, upon the request of the owner of the later patent, may issue a non-voluntary license to the extent necessary to avoid infringement of the earlier patent.

(6) Where a non-voluntary license is issued under sub-section (5), the Controller upon the request of the owner of the earlier patent shall issue a non-voluntary license in respect of the later patent.

(7) In the case of a request for the issuance of a non-voluntary license under sub-sections (5) and (6), sub-section (3) and (4) shall apply in mutatis mutandis with the provision that no time limit needs to be fixed.

(8) In the case of a non-voluntary license issued under sub-section (5), the transfer may made only with the later patent, or, in the case of a non-voluntary license issued under sub-section (6), only with the earlier patent.

(9) The request for the issuance of a non-voluntary license shall be subject to payment of the prescribed fee.

(10) The provisions of sub-sections (2) to (10) of section 58 shall apply mutatis mutandis for issuance of a non-voluntary license under this section"[5].

Two new circumstances have been included in section 58(1) of the Patents Ordinances in which the Federal Government may grant a compulsory license to a government or agency or a third party. These two new circumstances reflect the provisions of Article 31(b) and Article 7 of TRIPS. Which read as follows?

(i) When the patent holder refuses to grant a license to a third party on reasonable commercial terms and conditions; or

[5] *Ibid*, sec. 59.

(ii) Where patent has not been exploited in a manner which contributes to the promotion of technological innovation, transfer and dissemination of technology.

However, the provision of section 58 fail to prescribe the period after the filing of an application for the grant of a patent or after the patent has been granted there is no specific period has been mentioned. In such case the powers of compulsory licenses granting under section 58 may be exercised by the government.

This period is prescribed in Article 5A(4) of the Paris Convention and is also reflect in section 59 of the Patents Ordinance 2000 with respect to voluntary licenses but does not extend to compulsory licenses under section 58. Further, the amendments made in sub-section (1) of section 59 of the Patents Ordinance 2000 are likely to result in confusion. This sub-section has been reworded as follows:

Section 59(1): "On request, made 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 which might result from the exercise of the rights conferred by the patent, for example, failure to work."

3.1.2: Patentable Inventions

In Pakistan an order to qualify grant of patent, the law requires an invention to be new, involving an inventive step, and be capable of industrial application. Section 8 of the law provides that an invention shall be considered novel if it does not form part of the state of art. State of art is defined to include[6].

[6] *Ibid*, sec. 8.

a) Everything disclosed to the public anywhere in the world, by publication in tangible form or by oral disclosure, by use or in any other way, prior to the filing date of application.

For the purpose of patent's novelty it is no more concerned in Pakistan, that what is publicly known or used in the territories of Pakistan prior to the date of the patent application. The public use or knowledge of an invention any where in the world before the date of the application would prejudice the novelty of the invention.

Applicants for patents should therefore, take particular care to see that their inventions are not publicly used any where in the world, prior to the date of their patent applications. Inventive step is defined with its traditional meaning of non-obviousness to a person skilled in the art. Industrial application is defined to include capability of the invention to be used in any kind of industry.

The law emphasizes that the industry shall be understood in its broadest sense. It shall cover in particular agriculture, handicraft, fishery and services[7]. The invention qualifying for patentability in Pakistan must be refused, if, in the opinion of the Controller, its use would be contrary to law or morality. Thus, an apparatus for gambling, or an application for burgling houses or a method of adulterating food would be regarded as an invention contrary to law or morality, and would not be a proper subject-matter for a patent.

The new law provides priority arrangements for all WTO member countries if in Pakistan application is filed within 12 months of the priority country filing. Priority documents are required to be filed either along with the application, or within 3 months, or within such further period as the Controller may on good cause allow. This is a concept which exists in the member countries of the Paris Convention-1967.

[7] *Ibid*, sec. 9(1).

3.2: Patent rules-2003

To explain some sections of Patent Ordinance -2000, the government of Pakistan issued some rules in 2003, by the name of "Patent Rules-2003".

In these rules, rule no. 44 is concerned to compulsory licensing. Rule 44 (1) explains clause (iii) of sub-section (3) of section 59. Clause (iii) of sub-section (3) of section 59 is regarding the adequate remuneration to be paid to the owner of the patent. So rule 44 (1) specified this amount of remuneration, that the patentee shall be entitled to a payment up to three percent (3%) remuneration by the licensee, on the basis of total sales of that chemical product taking into consideration its trade price[8].

Sub-rule (2) of rule 44 clarifies sub- section (1) of section 59. Sub- section (1) of section 59 is about the controller's power for issuance a non-voluntary license/ compulsory license on request to a third person, in the case of his satisfaction that the patented invention is not exploited/ non-working or insufficiently exploited/ working by the patentee within the given time.

In this concern sub-rule (2) of rule 44 says, that in the given situation a compulsory licensing may be granted to the applicant subject to the condition, that if that very patent is chemical product, that may be use agriculture sector or medicines with the health care requirements of government of Pakistan as well as breaks the monopoly in the market for public interest.

It further says, that being a patent holder, liable for remuneration as mentioned above, it is required from the owner of the patent, to meet the requirements of the licensee in regards of patent, otherwise the licensee shall be at liberty to make available such requirements from anywhere. The conclusion is that, if the patent is not worked so as to satisfy the reasonable requirements of the public at a reasonable price the Controller may grant a compulsory license to any applicant to work the patent, to prevent the patentees to

[8] Rule. 44 of Patent Rules- 2003.

use their patent rights as in instrument of monopoly wider in scope or longer in duration which is not affordable for the public.

The original text of the rule 44 is given in the following paragraphs;

"Compulsory licenses:- (1) For the purpose of this Ordinance the patentee shall be entitled to a payment up to three percent remuneration by the licensee, on the basis of total sales of that chemical product taking into consideration its trade price, under clause (iii) of sub-section (3) of section 59.

(2) Subject to the sub-section (1) of section 59, none or insufficient exploitation of a patent in case of a chemical product intended for use in agriculture or medicines shall be determined on the basis of health care requirements of Pakistan and monopolization of the market against the public interest.

Provided, that the patent holder does not make available the subject patented product, in sufficient quantities, so as to meet the requirement of the licensee(s). The licensee(s) shall be at liberty to import or procure the said chemical product form anywhere"[9].

3.2: Comparison of both the laws

It is rather a humble attempt which is moved and forwarded by me to explain patent's compulsory licensing under Pakistani laws and to compare Pakistani situation with multilateral regimes. So the comparison of both the laws has taken into consideration in the following memorandum such as;

i. The TRIPS agreement, does not mention in it text the term of, "compulsory licenses" in any of its provision, except the sense of the words, "other use of without authorization of the right holder". While the Doha Ministerial Declaration 2001 clearly mention the term of compulsory licenses for first time, "says that each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted". The Doha

[9] G.M. Chaudhry, Intellectual Property Code, p. 771, (Federal Law house Rawalpandi -2004).

Declaration-2001 on TRIPS interprets and implements the TRIPS Agreement in a manner supportive of a WTO member's right to protect public health and promote access to medicines for all. On the other hand the Paris convention clearly addresses the term of compulsory licenses of patents in Article 5(A). As far Pakistani law is concerned, it has also mentioned the term of compulsory licenses in CHAPTER-XVI of the Patent ordinance-2000[10].

ii. According to TRIPS agreement authorization/ such use shall be non-exclusive, it means that any time it can be revoked, as well as the patent-holder can continue to produce it, and usually it must be granted mainly to supply the domestic market. The Paris convention also identifies that compulsory licenses shall be non-exclusive. While the Doha declaration says that the strong patentability is in the favour of those countries, which can manufacture drugs.

It has negative impact on those countries which are unable to make medicines and therefore wanting to import generics. The declaration of August 2003 solved this problem by allowing the countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines for themselves.

So the Doha Declaration gives broader sense rather than TRIPS' limitation to the domestic market. The same provision is here in Pakistani law, that, "such exploitation (exploitation under compulsory licenses) by government agency or third person, shall be pre-dominantly for the supply of the market in Pakistan[11].

iii. According to TRIPS compulsory licensing must be non-assignable by the licensee to any other person without the prior permission of the competent authority. Same is there in Paris convention, that compulsory licensing shall not be transferable to any one.

[10] Patent Ordinance -2000, Chapter -XVI.
[11] *Ibid*, sec. 58(8).

The Pakistani Patent ordinance is also preponderate this concept, that, any third person authorized for patent's exploitation by Federal Government, shall remains only to that authorized business [12].

iv. According to TRIPS there will be a prior request by the granting authority from the right holder/ patentee for the use of the patent. The patent law of Pakistan also takes this theme that, "a request shall be made from the patent owner before granting compulsory licensing for contractual license and this shall be accompanied by evidence[13]. Here Pakistani law only exceeds the evidence association.

v. That request must be on reasonable commercial terms. Under Pakistani law also the request must be on reasonable commercial terms[14].

vi. The owner of the patent does not give response to such request in reasonable period of time. In Pakistan we have also the same that, "the patent holder refuses to grant a contractual license to the third party on reasonable commercial conditions within reasonable period of time"[15].

vii. The scope and duration of such use shall be limited to the purpose for which it was authorized. Also law in Pakistan limited such exploitation/compulsory licenses to the purpose for which it was authorized[16].

---

2 *Ibid*, sec. 58(7).
[13] *Ibid*, sec. 58 (2) (iii) & (4).
[14] *Ibid*, sec. 58 (2) & (4).
[15] *Ibid*, sect. 58 (2) (iii).
[16] *Ibid*, sec. 58 (3).

viii. Such authorization shall be liable to adequate protection of the legitimate interests of the person so authorized. The same is in Pakistani laws also. It means that if the third party failed to comply with the terms and conditions, or if the situations which led to such authorization have ceased to exist and are unlikely to recur, the government may on the request of the original owner terminate such authorization[17].

ix. The right holder shall be paid reasonable remuneration, taking into account the economic value of the authorization. Pakistani law also addresses the same, by the name of "reasonable commercial terms" "adequate remuneration" to be paid to the owner of the patent, taking into account the economic value of the patent[18]. The patent Rules-2003, further clarifies the adequate remuneration or reasonable commercial terms, that the patentee shall be entitled to payment up to three percent remuneration by the licensee, on the basis of total sale of that product[19]. The amount of reasonable/ adequate remuneration/royalty shall be paid to the original owner of the patent.

x. Under multinational regime the right holder can sue the granting authority in the court of law for remuneration if refused.

Here in Pakistan also this right has been granted to the right holder that, "he can file an appeal against the decision of the Federal Government or of the controller in the High court, on any of the given situation[20].

---

[17] *Ibid*, sec. 58(10).
[18] *Ibid*, sec. 58 (2) (iii) & (3) and sec. 59 (3) (iii).
[19] Rule. 44(1) of Patent Rules-2003.
[20] Patent Ordinance-2000, Sec. 58 (12).

xi The competent authority has the power of termination/ refusal when those conditions recur under which such authorization has been granted. The same is in Pakistani laws also. The member states have the right to waive the above mentioned condition for non-voluntarily/ exploitation/use without authorization/ compulsory licenses whenever the following situations exist;

In the case of national emergency, but the TRIPS does not determine the limit of national emergency, same is the concept of the Doha declaration. It empowers the members to determines, what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

The patent ordinance 2000, undertakes the same provision that, "in the case of national emergency or other circumstantial urgency the above mentioned conditions not to be fulfilled. In such case the patent owner shall be informed of the decision of the Federal Government as soon as possible.[21]

(i) Public interest,
(ii) Public epidemics.
(iii) Public non- commercial use.
(iv) Other circumstances of extreme urgency,
(v) Where such use (use without authorization of the right holder) is permitted to remedy anti-competitive practices. Pakistani laws also mentioning the same as such; public non-commercial use and anti-competitive practices the sub-sections of sec.58 shall not apply.

xii TRIPS agreement gives governments' broad discretion in respect of compulsory licenses granting. For example, there is no limitation on the grounds upon which a government can authorize use of a patent by third parties, such as the instrument of public welfare and interest, which allows the government to grant the license at

[21] *Ibid*, sec. 58 (4) (i).

any time to any one. The same instrument is here in Pakistan, "the government may grant compulsory licensing to third person to exploit a patent for the public interest, national security nutrition, public health etc[22].

xiii According to Doha declaration each member is free to establish its own regime for Intellectual Property Rights. The same has entertained by the Paris convention also, "each contracting state takes legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exclusive rights conferred by a patent and Pakistan being a member of these agreements has fulfilled the pledge of amending its intellectual property laws especially the patent law to bring them into the conformity of the new regime of globe trends.

xiv The Paris convention authorizes the member countries to make laws for the prevention of abuses i.e. market monopoly, which might be result from the exercise of exclusive patent rights. If such abuse arose, the member countries shall grant compulsory license to indemnify it, but if the compulsory license could not prevent such abuses, the competent authority can revoke or forfeiture the said license, but to the Paris Convention this license shall not be forfeiture or revoke before the completion of tow years from the grant of that compulsory license.

xv According Paris Convention compulsory licensing may not be granted before the expiration of four years of the patent filing date in case of failure to work. With the compliance of this convention after three years from patentability a compulsory licensing may be granted to a third person in the case of insufficient working.

Same is under Pakistan Patent Ordinance-2000, "no request shall be made by third person to the controller for compulsory licenses before the expiration of four

[22] *Ibid*, sec. 58(2) (i).

years from filing date on patent in the hands of the owner or before the passing of three years from the date when the patent has granted and during this mentioned time he, she (the patent owner) could not sufficiently exploit it[23].

xvi According to Paris Convention the compulsory licenses shall not be granted in the case of insufficient working within the prescribed period of time if the patentee justifies his inaction with sound reasons. Same realized by Pakistani laws, that if the owner of the patent satisfies the Controller/ government with sound grounds, which justify his case for non-exploitation or insufficient working of the patented invention, in such case compulsory shall not be issued subject to the conditions that he will specify;

a. the scope and function of the license
b. Time limit in which he must began the exploitation of the patented invention.
c. Adequate remuneration shall be paid to the owner of the patent according to the terms and conditions[24].

Nothing in the TRIPS Agreement shall prevent members from establishing or maintaining marketing approval procedures for generic medicines and other healthcare products. Nothing in the TRIPS Agreement shall prevent members from disclosing or using information held by its authorities or the patent holder where it is so required for reasons of public interest, including where such disclosure or use is necessary to implement effectively any compulsory licensing.

After this comparison of both the laws, it is precious to be mentioned that being a signatory to multinational regime-(Trade Related Intellectual property Rights, Agreement, Paris Convention and Doha Declaration on Public health, Pakistan has up graded its intellectual property infrastructure in tandem of globe requirements, by having

[23] *Ibid*, sec. 59 (1).
[24] *Ibid*, sec. 59 (3) (i, ii, iii).

brought substantive legislation on IPRS e.g. Patent ordinance-2000, etc, in compliance with WTO obligations, and has strengthen its IP protection and enforcement mechanisms by establishment of IPO (Intellectual Property Organization-Pakistan), legitimized and backed by, "Intellectual Property Organization of Pakistan Ordinance-2005 amended in 2006).

This Organization is functioning as an autonomous organization with financial and functional autonomy under the auspicious of Director General of IPO- Pakistan. It will correspond to the new regime of patent laws promulgated around the globe. It is worthy to be mentioned that Pakistan has ensured a most effective system of protection of all rights in the fields of intellectual property particularly the patent's compulsory licensing, as law has been changed, upgraded and brought to the conformity of the multilateral regime word by word. There is no need to afraid that Pakistani law does not conform to international regimes in regards of patent's compulsory licenses because Pakistan has an integrated management and active chain of intellectual property enforcement.

The existing IP laws especially patents law regarding compulsory licensing is conform to all relevant international conventions which Government of Pakistan has signed. But reforms in both the laws may not be out of consideration, because some areas are still reformable to avoid the lacunas. These lacunas have point out in chapter-IV of this paper in recommendations.

CHAPTER-IV

LEADING QUESTIONS REGARDING COMPULSORY LICENSING AND RECOMMENDATIONS

Writing of research paper is very tough and time taken job. It swelled out human body from feet to forehead, but every research has some specific goal and objective, which the researcher highlights in his concluding chapter to be submitted to the competent authority for more reforms and up gradation for more and more human facilitation. Following these rules, I pointed out the following issues and lacunas, which may be considered for reformation as a model for good state practices:

4.1: Compulsory licensing and pharmaceutical patents in Pakistan

From health perspective it is important to see what kind of drugs are being produced, imported and supplied by pharmaceutical companies working in Pakistan. It is to be observed that either the supplied medicines are essential or not required from health perspective? Whether the prices of the drugs are reasonable or high, out the purchasing power of the buyer? Majority of the national and even multinational pharmaceutical companies manufactures unessential and expensive drugs for which equally effective but cheaper alternatives are available.

Pakistan is a developing country has membership of the major multinational regimes. In July 22, 2004 Pakistan singed Paris convention for the protection of intellectual property

rights. Pakistan upgrades her laws and permitted granting of patent's compulsory licensing under section 58 and 59 of the patent ordinance 2000. But in Pakistan not yet any compulsory license has granted to any one, for two reasons:

a) The people do not request to the controller for granting patent's compulsory licensing for the exploitation of any patented invention, either by local influence, political pressure or poverty.

b) During the public epidemics the national and International donors supplies medicines for communicable and non-communicable diseases as we seen during the Earthquake of 8th October 2005, in which six hundred crore rupees promised to be donated to Pakistan by donor agencies, e.g. IBRD, Islamic Bank and others.

The WHO, consumed 25% of the drugs for AIDS in developing countries including Pakistan annually. According to Dr. Salaim, Deputy Chief Provincial AIDS Control Programme, to the Government of NWFP, there are nine million people affected from aids all over the world and three million deaths have been occurred due to aids in the last seven years, while, 3000, HIV/AIDS cases have been registered in Pakistan[1].

According to recent estimate by the World Heath Organization (WHO), one third of the world's population lacks access to essential drugs. In such phenomena it is very difficult for a country like Pakistan to over come on the situation. So the poor suffer the most and unnecessarily remain sick as poverty and diseases are alternate with each other as cause and effect.

Sub-standard expired and counterfeit drugs are increasingly found in national and local markets; as a result many people may be died as Voren tablets for pain, frequently founded in the local market smuggled from India. Unfortunately in Pakistan the top twenty big multinational pharmaceutical companies have monopolistic behaviour and refuse to manufacture the required medicines on low cost, to the public on cheaper price,

[1] The News, January 10, 2007, p. 10.

e.g. Abbot, Novartis etc. This trend of big pharmaceutical companies develops monopoly in the market. On the other hand the country itself has lack research to necessary pharmaceutical production particularly to extreme life saving drugs, 95% of raw material are imported by the pharmaceutical companies. The main policy challenge from a health perspective is to ensure the medicine security in Pakistan and the price of available medicine for the whole population is not compromised as required.

Monopoly pricing and higher cost of pharmaceuticals is a very serious problem in Pakistan, because the TRIPS as well Pakistan Patent Ordinance-2000, grants a monopoly on a patented product to the patent holder for 20 years. As a result, the price of medicines has tended to increase, affecting people in developing countries like Pakistan.

The adoption of a patent system in these countries has harmed poorer people who cannot afford to buy medicine. Pakistan is already in Product patent reeling under monopolistic prices charged by Multi-national Corporations (MNC). The drugs prices in Pakistan are very high comparatively to the other countries of the region. For example the price of Cipro Flexocine 10 tablets costing Rs.50 in India, and costs Rs. 400 in Pakistan. Anti Ulcer Medicine Ranitidine costing Rs.25 per packet in India cost Rs. 142 in Pakistan.

In Pakistan there is burden of disease and non-availability of necessary medicines is the head stricken problem.

Presently there are three kinds of problems:

1) Non-existence of drugs for existing health problems.
2) Need for new drugs to replace the drugs which are increasingly becoming ineffective.
3) Need to develop drugs for newly emerging diseases.

In Correspond to (WHO) for the eradication of the problems the government of Pakistan for first time prepared a list of essential drugs in 1994 with the consultation of relevant experts reviewed in 1995, 2000 and 2004, containing on 452 different drugs[2], but the prices of these drugs are also beyond the purchasing power of the common man. According to the data compiled by the UN Millennium Development Goals Project, 40 million people are infected by the AIDS virus in developing countries, with 26.6 million on the African continent. About 93% of those infected with the AIDS virus cannot afford to buy the anti-retroviral medicines which they need.

The Joint Program of the United Nations on AIDS believed that unequal access to treatment at acceptable prices is one of the main reasons for the low levels of survival in poor nations. In developing countries the poor are victims of a large number of infectious diseases such as tuberculosis, malaria, respiratory infections, diarrhea, cholera etc, for which there is little or no access to medication. The treatment of other illnesses such as diabetes, asthma, heart disease and mental illness is insufficient, as the medication available is beyond the purchasing power of a large part of population in Pakistan.

In 2003-04 the number of Pakistan in tuberculosis, a communicable disease was eight. It was estimated that there were around 1.5 million patients in Pakistan while more than two laces new person found this disease every year, but now Pakistan is on sixth number and three laces person found this disease every year. About 60 thousand people die due to tuberculosis in Pakistan annually[3]. Pakistan is suffering much from this disease rather than the regional countries.

The pharmaceutical industry in Pakistan is the second largest in the country and about 450 licensed pharmaceutical companies working in Pakistan including the 30 multinational but in the list of the first twenty largest companies there is no domestic manufacturer. The drugs companies usually manufacture the unessential and expensive drugs which are not actually required due to its alternative availabity, while costing the

[2] Essential drugs list of Pakistan, MOH,Islamabad, p.7- 2004.
[3] The daily Gung Rawalpandi p.3, dated February 24th 2007.

poor people for high prices. According to an independent estimate about 48% of the people in the population of 149 million live below the line of poverty[4], means earning less than a dollar per day, 83% of the population has no sanitation and 65% of the population has no purified or clean water for drinking. Two corer children do labour due to poverty and one crore and eighty laces are unemployed. The number of children in Pakistan under 18, years is six crore and 67 lace.

Every year, 51 laces and 63 thousand children born and seventh lace and fifty five thousand dies due to improper health facilities. In Pakistan literacy rate is 51.6 out of the 149 million of population. The State Bank has cleared in one of its report for the year of 2005-06 that the educational budget of Pakistan is comparatively less rather than the other eight countries of the sub-continent[5]. The life expectancy in Pakistan is 63 years. It is less comparatively to the regional countries e.g. India 66, Srilanka 72, and ect[6].

Therefore that part of the population is unable to purchase medicine for a normal infection and disease. As Pakistan has adopted all her law according to the conformity of International regime granted to the owner of patent protection for 20 years as a monopoly right, for globalization and liberalization, may lead to economic growth but is not necessarily good for health. Because patentability for 20 years develops monopoly, decrease competition, increase prices and scarce supply market, as the example of American pharmaceutical companies versus Government of South Africa in 1998 as well as the A.G Boyer Corporation in 2001.

In a situation like that compulsory licensing is an incentive for the conducive environment where business expansion may be flourishes and access to medicine may clearly be indicated. The possible implementation of compulsory licensing will lead to substantial decreases in drugs prices, which enable the country to overcome on the communicable disease such as HIV/AIDS, malaria, tuberculosis, Dingy various, cancer, and all types of Hepatitis, child's infectious diseases e.g. polio, leprosy and cholera.

---

[4] Islamabad Law Review, p. 486, third edition-2003.
[5] Dr. Shahid Hassan Saddiqi, the Daily Newspaper Gung Rawalpandi, Feb.10 2007.
[6] Doger test guide for tehsiladar, p.no.121, by Muhammad naeem Kahn-2006.

My thesis does not ignore the important role that patents play in fostering of invention and technological progress. My purpose is only to point out that compulsory licensing promotes social well-being to the extent that it obviates/ preventing the drawbacks of a patent system. The government should have to show good faith in granting compulsory licensing when requested by third party to exploit the patent.

Compulsory licenses may be granted to remedying the anti-competitive practices to facilitate public health and promote access to medicines as an urgent measure to reduce prices and make full use of the flexibilities in the TRIPS agreement as affirmed by Doha declaration. It will enable the country to structure as a better public heath and access to affordable medicines.

4.2: Leading questions

The following are some key issues regarding compulsory licensing in addition to recommendations which are included:

1) It is stated that granting of compulsory licensing is high political issue of conflict among the developed and developing countries, because of pharmaceutically developed states do not favour so much compulsory licensing, while the beneficiaries are middle class economy countries. If these states issues compulsory licensing for pharmaceutical product, the developed states will oppose them, and if Pakistan would grant patent's compulsory licensing the same resentment will be the fate of Pakistan. Arguing the example of USA pharmaceutical companies versus South African Government in 1998 during HIV/AIDS crisis in South Africa.

   The USA challenged the African government for violation of patentability, as the African Government lower prices of medicines under legal philosophy of compulsory licensing. It may be argued them that now after the anthrax crisis in 2001; the developed countries allowed compulsory licensing particularly for

pharmaceutical, as United States of America (USA) did for the supply market and reduction of prices of the Cipro Flexocine against AG. Boyer Corporation, as well as have been used extensively in Japan, and Europe for a variety of purposes, including computers, software, biotechnology and other modern technologies.

The state representative of USA stressed on the granting of compulsory licensing for pharmaceutical in Doha Ministerial conference-2001. It is convinced to them that compulsory licensing should be granted to strike a balance between competition, supply market and reduction prices of drugs. It does not have a negative effect on investments and research in Pakistan.

2) Unfortunately the big pharmaceutical companies in developing countries including Pakistan have monopolistic behaviour, manufactures expensive medicines not essential and required for which alternate but equally effective available. It was commented in WTO Ministerial declaration of August 30th, 2003 that Countries in need for pharmaceuticals would notify to the WTO, the medicines they need and it would be up to the generic companies to decide to apply for licences to manufacture them. To break this monopoly the only remedy is the compulsory licensing with the developing countries like Pakistan.

3) A question to be answered is frequently being heard, that compulsory licensing slows the availability of new medications into the market, because, with the threat of being subject to compulsory license, pharmaceutical companies chooses not to introduce their medicines in those countries where compulsory licensing is practicable at a large scale.

For example, when Canada implemented legislation in the 1970s that broadly permitted compulsory licensing with little compensation for patent holders, the pharmaceutical sector went into decline and fewer new products introduction in the Canadian markets[7]. They may be answered that compulsory licensing an emergency, authorized instrument

[7] http:// www.google./compulsory licensing.com. last visited: 08/01/2007.

exception to the general rules, for a product of public non-commercial use and in the time of national emergency. The Canadian markets problem was in seventies, at that time there was no such international forum like WTO, while now a days almost all countries of the world are members of the WTO, have been agreed on the granting of compulsory licenses on adequate remunerations and medicine exporting to those countries, do not have sufficient manufacturing capacities.

If pharmaceutical companies do not introduce their products in the market of the developing countries the local hacker pirates their products and will smuggle, which affect their economy badly. This is why in the year of 2001, when there was the anthrax crisis, Congress threatened to use compulsory licensing to obtain the antibiotic Cipro more cheaply and quickly from generic manufacturers. Bayer Corporation, who holds the patent on Cipro, immediately offered to dramatically lower its prices and increase production. So this is the compulsory licensing, which supply market and reduce prices.

The second is, that now Canada is also, has the most extensive experience with the use of compulsory licenses for pharmaceutical drugs. Canada routinely granted compulsory licenses on pharmaceuticals, with compensation based upon royalties, typically set at 4% of the competitor's sales price.

4.3: Recommendations

The following recommendation may be forwarded to the legislature for improvement of the situation:

1) The national and international regimes gave absolute discretion to the governments for granting compulsory licensing during national emergency and public epidemics. It is recommended that a standard may be determines of public epidemic and emergency to role out the misuse of this discretion. The agenda for the next WTO ministerial meeting may be this issue to adopt an agreed definition among the members for emergency and public epidemic to avoid the possible abasement.

2) Article 58 of patent ordinance-2000 and article 31(h) of TRIPS agreement provides that on the granting of compulsory licensing, adequate remuneration shall be paid to the patent owner but there is no specific time period for payment of that remuneration. Therefore I recommend adoption of remuneration/ royalty guidelines and specific time period for the payment of remuneration at international and national level to reduce uncertainty. It is suggested that the next agenda of WTO ministerial conference would be the solution of this issue.

3) It is recommended that for the protection of plagiarism and enforcement intellectual property rights there should a special force, well trained and aware of IPRS at national and international level, like Interpol, because police corruption and unawareness is a big problem as they do delaying tactics in the implementation of law in almost all the developing countries including Pakistan.

4) Almost all the developing countries have the lack of legal resources and an overburdened and ineffective court system that prevents the conclusion of even the simplest criminal case, which run on endlessly. This delay encourages smuggling and piracy and monopoly. If the police arrest any one found in abuses the courts could not entertains the case in months even takes years for decision due to overburden and ineffective court system. It is recommended that special courts may establish at international level has sub-braches in the member countries to adjudicate IPRS disputes quickly even regarding compulsory licenses.

5) It would be injustice if we totally blame the enforcement mechanisms. The main responsible element is the involvement of, lack financial cost in terms of administering the IPRS in developing countries, like Pakistan. The citizen of the developing countries could not afford the expensive medicines for their diseases due to poverty.

To undertake the issue an international fund may be establish financing by member countries on proportionality basis, means the country where more registered patents will contributes more. This fund may use for the development and enforcement intellectual property, named, International Monetary Fund for Protection and Enforcement of Intellectual Property Rights (IMFPEIPRS).

6) An other issue which may be tackle by developing countries including Pakistan is the high price monopoly in pharmaceutical patents, as the TRIPS and Pakistan Patent Ordinance-2000, both grants monopoly on a patented product to the owner for 20 years as a reward for intervention in research and development in that product and as an incentive for further investment. If we decrease the term of protection affect the investment.

The adoption of a patent system in these countries has harmed poor people who cannot afford to buy medicine. In South Africa in 1998 approximately one in five adults are living with HIV/AIDS, but in South Africa, no one except the exceedingly rich could afford the drugs. In South Africa, making treatment universally available at such prices would have bankrupted the government.

The drugs were expensive due to only one source of medicines and strong patentability. It is the compulsory licensing which can over comes the problems of non-existence of drugs for existing health problems, need for new drugs to replace the drugs which are increasingly becoming ineffective and need to develop drugs for newly emerging diseases by pharmaceutical companies otherwise the pharmaceutical companies would manufactures the medicines of their own choice and will sell on very high prices beyond the purchasing power of the poor people.

As a result the poor are victims in a large number of infectious diseases such as tuberculosis, malaria, respiratory infections, diarrhea, etc, for which there is little or no access to medication.

7) An other problem in all the development countries like Pakistan is the medicine piracy, which is a challenge to their economies and pharmaceutical products. This evil increases in the prices of quality drugs for public health and affect the national economy. A more significant case is of voren a tablet smuggles from India. This issue continuously effects on the research-based pharmaceutical industry. If the government grant compulsory licensing, under which these drugs may manufactures with quality, frequent availability and low prices, the evil may be removed.

8) The time period for granting compulsory licensing in case of non- exploitation of insufficient working under national and multinational laws is three and four years respectively, is too much. In so long time the public may suffer very much from epidemics and catastrophes. This period may reduce to one and two years respectively, or so.

9) There is nothing in the law for the proper arrangement of medicine supply to the market. Some time some unnecessary drugs are frequently available in the market, but some very necessary disappear. The law should clear in "letter and spirit" for every thing and should be no lacunae there in the law. The government should have to collect data of, national essential drugs, and do proper arrangement for its supply in the market on reasonable prices.

10) Moreover, the general experience of many multinational pharmaceutical companies in Pakistan is that the time required for the registration process often is two years and sometimes longer.

For the benefit of patients in Pakistan, and in view of increasing costs of pharmaceutical research and development and limited patent life of drugs, it is vital to keep the procedure of registration as brief as possible. It is suggested that the Government of Pakistan has to complete a registration process within a maximum period of twelve months.

11) The patent Ordinance-2000 does not grant patents for "animals and plants. Nothing in the law clearly mentioned in this regards, therefore a provision may insert for plants and animals patentability.

12) There should be more openly provision to authorize the competent authority for granting compulsory licensing for the use of patents to address public health emergencies; e.g. HIV/AIDS, tuberculosis, malaria or other illnesses, a government could give general authorization for the competitive sector to supply particular types of drugs to the maximum level, by paying a modest royalty to the patent owner, saving time and lowering barriers to entry, and probably increasing the number of generic competitors. In my opinion, it should be done right now our national laws for all HIV/AIDS related medicines to cope the arising situations.

13) In addition, the penalties for infringement should be more severe, this could result in the formation of an effective deterrent to patential infringers.

14) The Doha Declaration, may be modified, which promotes the ability of developing nations to secure lower priced medicines to combat public health crises.

15) There should be legislation especially address the licensee to maintain better quality and quantity of the products, to eliminate further counterfeiting, piracy and to protect consumer interest by market expansion for genuine business.

CONCLUSION

In my concluding remarks, I would like to record my sincere appreciation to Aurangzeb Mehmood, my supervisor, for the opportunity provided me, to comprehend my research paper, in this regards I visited IPO, which is newly established organization for the protection of Intellectual Property in Pakistan.

I sincerely hope that IPO will endeavour its efforts for the protection of patent rights in Pakistan and will introduce compulsory licensing for more and more generic products, to supply market and reduction of prices which leads positive competition and standard quality of the products. I hope that they will constitute a separate tribunal for handling over IPRS disputes.

My research paper has examined the incentive arguments that explain existing compulsory licensing provisions in Patent laws comparatively in Pakistan and the multinational regimes. Compulsory licensing is explained as a method of providing the correct incentives, access, balance, by encouraging production in the absence of patent protection or by encouraging utilization in the presence of individual or collective market power for supply, prices reduction and regularization.

In these cases, the policy can be justified since owners' rewards are more closely, if imperfectly, related to the value of works. It has also been shown that compulsory licensing corrects imbalances between the suppliers and the consumers.

It can safely be said that Pakistan provides a strong and sophisticated framework of intellectual property laws to protect the valuable rights of owners in various fields associated with economic and cultural activities, but as perfection is Divine attribution and Divinely law, therefore some suggestions have been recommended to the concerned authorities for the enhancement of the present situation to role out the points of impeachment.

In this paper I have outlined a policy for lowering the price of pharmaceuticals in a country like Pakistan for important diseases while at the same time maintaining the research and development incentives of research firms.

In nutshell, it is worth to be mentioned that if there is no compulsory licensing than the consumers would face either the domestic monopoly price or higher prices in the world market. Our own patent system should be based on excellent use of our scientific research to give a big welfare boost to poor countries while supporting the full implementation of TRIPS in the developing world which is also used in our own self-interest, e.g. the granting of patent's compulsory licensing increases competition among the manufacturers for better quality of product on low price and supply in the market accessible for every one.

GLOSSARY

Anthrax: Infection with the bacterium Bacillus anthracis, which in animals (sheep and cattle), takes the form of a fatal acute septicemia, and in humans. Affects the skin, causing development of a pustule, or the lungs, causing wool sorters' disease, a form of pneumonia.

Assignment: A transfer of rights in intellectual property. An assignment of a patent, for example, is a transfer of sufficient rights so that the recipient has title to that very patent.

Catastrophe: A sudden and widespread or noteworthy disaster; an extreme misfortune. Calamity, disaster, tragedy, trouble, misfortune and misadventure.

Compulsory License: Authorization for/by a government or company to make and sell a product, for example drug without the permission of the patent holder. Compulsory licenses are generally issued on the basis of public interest e.g. public health, national emergency, public epidemic or defence.

Design Patent: A government grant of exclusive rights in a novel, no obvious, and ornamental industrial design. A design patent confers the right to exclude others from making, using, or selling designs that closely resemble the patented design. A design patent covers ornamental aspects of a design;

Duration: The term or length of time that a patent right lasts. As a result of the Uruguay Round conference (TRIPS), the duration of the patent protection is 20 years from the date on which the patent application was filed.

Essential Drugs: Those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage form.

First to file: For patents, a rule under which patent priority, and thus entitlement to a patent, is determined by which inventor was the first to file a patent application, rather than who was first to actually invent. This is the rule followed by almost every nation in the world except the United States.

First to invent: A rule under which patent priority is determined by which inventor was the first to actually invent, rather than who was the first to file a patent application. First to invent is the rule followed in the United States.

Generic: generic as a product- particularly a drug- that are not produced under patent.

Generic Drug: A pharmaceutical product usually manufactured without a license after the expiry of patent or other exclusivity rights. For example, Aspirin is a widely available generic drug.

Infringement: Infringement of a utility patent involves the making, using, selling, offering to sell, or importing of a patented product or process without permission. Infringement of a design patent involves fabrication of a design that, to the ordinary person, is substantially the same as an existing design, where the resemblance is intended to induce an individual to purchase one thing supposing it to be another.

Invent: The human creation of a new technical idea and the physical means to accomplish or embody the idea.

IPO: (Intellectual Property Organization). It is an organization for the promotion and protection of intellectual property rights in Pakistan, established in 2004.

Integrated circuits: A line that encloses an area component of various elements harmoniously. It is a particular method of enclosing the component of various elements.

Joint Inventors: Two or more inventors of a single invention who collaborate in the inventive process.

Layout-designs: A drawing showing the design of a proposed piece of printing, sometimes with specifications for production; the preparation of such drawings; the design details of the manufacture, or to arrange or set out something in a particular way; the tools or apparatus pertaining to some occupation etc.

License: A permission to use a patent right, under defined conditions as to time, context, market line, or territory. It has two kinds: "exclusive licenses" and "nonexclusive licenses. It is a license in which the licensor promises that he or she will not grant other licenses of the same rights within the same scope or field covered by the exclusive license. In a nonexclusive license, title remains with the licensor. A patent license is a transfer of rights that does not amount to an assignment of the patent.

Manufacture: Refers to articles which are made.

Novelty: It is one of the three conditions that an invention must meet in order to be patentable. Novelty is present if every element of the claimed invention is not disclosed in a single piece of prior art.

Obviousness: A condition of non-patentability in which an invention cannot receive a valid patent because a person with ordinary skill in that technology can readily deduce it from publicly available information.

Ordinary Skill in the Art: That level of technical knowledge, experience, and expertise possessed by an ordinary engineer, scientist, or designer in the technology that is relevant to the invention, or an ordinary level of proficiency in the particular technology in which an invention is made.

Paris Convention: Means the Paris Convention for the protection of industrial property, signed at Paris on March 20, 1883, as revised an amended in 1967.

Patent: A title granted by the public authorities conferring a temporary monopoly (up to 20 years) for the production and sale of an invention or discovery. By this granted right the inventor can excludes others from making, using, or selling the invention.

Patent for invention: Inventions protected by patent rights.

Pharmaceutical: Pertaining to the preparation, use, or sale of medicinal drugs.

Pharmaceutical product: Means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health.

Piracy: Unauthorized reproduction or use of something, as a book, recording, computer program, or patent violation or violence committed without lawful authority,

Plant patent: on a new variety of living plant. Patents do not protect "ideas," only structures and methods that apply technological concepts.

Proprietary drug: A pharmaceutical product made and sold under a brand name.

TRIPS: Means Agreement on Trade-Related Aspects of Intellectual Property Rights covers a new field in multinational trade law. The agreement describes minimum standards that member countries of the World Trade Organization (WTO) must adopt in order to ensure that new products, including drugs, are protected by patents.

Therapy: The medical treatment of illness; a system of treatments, activities, etc.

Utility: The usefulness of a patented invention. To be patentable, an invention must operate and be capable of use, and it must perform some "useful" function for society.

Utility Patent: Its cover the functional aspects of patent (product and process). A design patent and a utility patent can cover different aspects of the same article, such as an automobile or a table lamp.

WIPO: (World Intellectual Property Organization). One of the 16 "specialized agencies" of the United Nations system. WIPO, head office located in Geneva, Switzerland, was created in 1967 and is responsible for promotion and protection of intellectual property throughout the world.

WTO: (World Trade Organization). WTO is the only global international organization dealing with the rules of trade between nations. Located in Geneva, Switzerland, it was created at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) negotiations in 1994 to oversee the operation of GATT.

The WTO entered into force with respect to the United States on January 1, 1995. One hundred forty-nine nations are members of the WTO (as of June 2005), accounting for over 97 percent of world trade.

BIBLIOGRAPHY

1. AT, Hudson and JK, Macleod, Mercantile law, Butterworth London (1980).
2. A.G. Sarre, Clivem Schmittoff & David, Mercantile Law, Steven & sons London, (1984).
3. Carlos M. Correa, Public Health and Patent Legislation in Developing Countries in Tulane Journal of Technology & Intellectual Property, page 17, spring, (2001).
4. G.M Chaudhry & Chaudhry M. Zarar Iqbal, The Intellectual Property, Intellectual Property Laws in Pakistan and International treaties on Intellectual Property Rights, Federal Law house Rawalpandi, (2005).
5. G.M. Chaudhry, The Intellectual Property code by Federal law house Rawalpandi (2004).
6. Jeremy Phillips Introduction to Intellectual Property Law Butterworth & Co. London. (1986).
7. Jowitts dictionary of law, Sweet and Maxwell Ltd. (1980).
8. Jose Marcos Nogueira Intellectual Property Rights, the World Trade Organization and Public Health: Journal of International Law Page 3, (Tulane printing press-2003).
9. Karkara, DR. Lal, s commentaries on L aw of Copyright, Patents and Neighbour right. Delhi. (1986).
10. L.B Curzon, Dictionary of law, Pitman Publishing London (1990).
11. Muhammad Iqbal Khan Mokal: Law terms & phrases, Law publishing company Lahore. (1978).

12. Philippe Cullet, Patents and Health in Developing Countries in Law and development, Facing Complexity in the 21st Century, Cavendish Publishing, London, page 82, 83. (2003).
13. P. Naraiyanan: Patent Law, Eastern law house Calcutta (1998).
14. P. Narayanan, Intellectual Property Law, Estrean law house kolkata (19 98).
15. Robert Broadgat & Fidelmla White, Commercial Law, Blackstone presses (1987).
16. Richard Wincor & Irving Mandell: The Protection of Intellectual Property (1983).
17. Rai Muhammad Zafar Bhatti and Mr. Zahid Aslam Malik, Manual of intellectual property laws, Sahara Printing Press Lahore (2005).
18. A desk Reference to Intellectual Property Law, New York. (1980).
19. Ralphl. Holsinger, Media Law, Random New York (1993).
20. Rodney D Ryder, Intellectual Property and the Internet, Butterworth (2002).
21. Robret A Choate & William. Cases and Materials on Patent Laws, Published Minnesota west (1987).
22. Stephen. M. Stwart, International copyright, Patents and neighbours rights Butterworth London. (1983).
23. Styawrat Ponkshe, the Management of Intellectual Property Blackstone printing presses London (1988).
24. Shiva Sahavi Singh, The law of intellectual property rights, Deep &deep publication Ltd. New Delhi (2004).
25. T.A. Blance White, Patent for innovations, Steven & sons Ltd. London (1983).
26. Tanzeel-ur-Rahman ® Justice, Dictionary of law, Makataba khiaban Adab Lahore (1983).
27. Wincor Richard & Irving Mandell, Patent laws and legislation of United States, New York (1980).
28. W.R. Cornish, Intellectual Property, Patents, Copyright, Trade Marks and Allied rights, Sweet & Maxwell Ltd. New Fetter lane London (1981).
29. The Patent Ordinance-2000.
30. The patent rules-2003.
31. Collins English Law dictionary, P. William Collin sons. (1981).
32. Cambridge international dictionary: Cambridge university press. (1999).

33. <http://www.Google> Search.com frequently used.
34. All relevant Electronic research.
35. Islamabad law review (Third Edition) (2003).
36. Oxford advanced learners dictionary Oxford University printing press. (1996).
37. Blacks law dictionary 5th edition, William wordswort press London) 1979).
38. The new hamlyn encyclopaedic world dictionary, Gorgen London (1971).
39. Mozley and whiteley Law dictionary, E.R Hardy Ivamy. Butterwoods London (1988).
40. http:// www.phrma.org.com, last visited: 12/04/2006.
41. http:// www.ipa.com, last visited:18/06/2006.
42. http://www.us.gov.ipr.com, last visited:20/06/2006.
43. http://www.wipo.org.com, lasted visited: 12/06/2006.
44. http:// www.ipo.gov.pk, last visited: 25/06/2006.
45. http://www.google/buysafedrugs.info.com, last visited:02/07/2006.
46. http://www.who.org, last visited: 04/07/2006.
47. http://www.wto.org, last visited: 05/07/2006.
48. http://www.southcentre.org/publication/publichealth, last visited 22/10/2006