"Pharmaceutical Patents in Pakistan; Trends and Prospects"

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SUPERVISED BY

Mr. Atta-ul-Allah Mehmood

SUBMITTED BY

M. Danyal Khan

(Reg # 221-FSL/LLMCL/F09)

Faculty of Shariah & Law

INTERNATIONAL ISLAMIC UNIVERSITY ISLAMABAD

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Dissertation Committee

Internal Examiner:

External Examiner:

Supervisor:

Faculty of Shariah and Law
INTERNATIONAL ISLAMIC UNIVERSITY ISLAMABAD

"This work is dedicated to the numerous souls in the universe who yearn to explore and help"

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PREFACE

This work is the result of inspiration which I got from the plight of people suffering from fatal diseases. Humanity first should be the order of the day. With the beginning of intellectual property laws in the area of pharmaceutical products, monopolies are made in the favor of few to control the lives of others. A debate is undergoing in the world about the global intellectual property regime under the forum of World Trade Organization (WTO) in the wake of cost of essential life saving drugs. The world is divided in two parts of haves and haves not. The impacts of globalization of intellectual property laws on developing countries are dire. On one part, the developing countries are facing challenge of providence of essential medicine to their masses and on other front they are fighting to ensure global criteria of intellectual property laws in the field of pharmaceuticals. Following research will aim to enable the reader to aware oneself about the patents, its regulatory system and the impacts of its application in the field of pharmaceutical in Pakistan.

Chapter one of the topics gives a brief description of patent laws in Pakistan and the issue of public health. In the first part, it gives the complete law according to the Patent Ordinance 2000 including introduction of patent, application process, rights under patent and pharmaceutical industry of Pakistan. Second part of this chapter puts light on the pharmaceutical industry and providence of medicine. Chapter two gives the introduction to compulsory licensing, a tool available to the countries against the arbitrary use of monopolies created under patent laws. Chapter gives the description of compulsory licensing under TRIPS Agreement and laws on the topic of compulsory licensing in Pakistan. The chapter also gives the justification for the use of compulsory licensing. Chapter three deals with the comparative study on patentability under different laws with a special focus on Indian patent regime. Chapter four deals with enforcement issues regarding pharmaceutical patents in Pakistan and injunctive relief is illustrated with the help of different case laws of Pakistan. The second part of chapter four gives a view of pharmaceutical industry, patent regime and providence of health in Pakistan. In this part of the issue of public health in Pakistan is discussed under the policy matter of Pakistan which is enunciated under the Constitution of Pakistan 1973. It also gives a brief about international standards of patents and local needs of Pakistan.

In Pakistan, the issue of compatibility with global intellectual property laws and providence of essential life saving drugs can be met by the smart use of concessions being provided by the TRIPS, Doha Ministerial Declaration and other international commitments as world knows the right to life is the vital of all human rights.

This work will give a picture of pharmaceutical patents in Pakistan, challenges and various ways to meet these challenges.

ABBREVIATIONS

World Trade Organization	(WTO)
Intellectual property	(IP)
Intellectual Property Rights	(IPRs)
Trade Related Aspects of Intellectual Property Rights	(TRIPS)
World Trade Organization	(WTO)
World Intellectual Property Organization	(WIPO)
General Agreement on Tariffs and Trade	(GATT)
The North American Free Trade Agreement	(NAFTA)
European Patent Convention	(EPC)
Teaching, Suggestion, or Motivation	(TSM)
Dispute Settlement Body	(DSB)
United State's Patent and Trade Mark Office	(USPTO)
Civil Procedure Code	(CPC)
Gross Domestic Production	(GDP)
Gross National Production	(GNP)
ZEFIX, OSTAD, ZEFFIX, MELFEX	(Name of various drugs)

Chapter: 01: "INTRODUCTION TO PATENTS IN PAKISTAN AND MODERN DEVELOPMENTS"

1.1. INTRODUCTION

The idea of property was limited to the tangible goods in the ancient times and then it came to the intangible things also on the basis of their economic value. With the advent of technology and expansion of global population, it was needed that a person who strives for a new idea or good should have the right to exploit and benefit it. It was on the same that if a person by his work and struggle earns money and buys some commodity should have exclusive ownership rights of his or her owned thing or etc. The concept of ownership was to create an exclusive right of owner of the thing over his or her ownership and to exclude others from any intervention.

The concept of intellectual property has gone though different phases. It was once used by English monarchs to get the monopoly over certain goods in order to control the trade and economy of their country. Later, it was given to general masses to enjoy the exclusive right of their inventions for which they sacrificed their time and money. Intellectual property rights were given a new meaning of paying back the inventor for his services.

With the expansion of modern industrial ways and techniques, a number of fields were introduced on different patterns and inventions were also separated from one another. This was the time when different kinds of intellectual property were introduced as trade marks, copy rights, patents, geographical indications, circuits and etc. Now, this was the time when the humanity started paying back its benefactors.

Development of intellectual property rights led towards formation of laws dealing intellectual property laws by different nations. Last two centuries saw a new change in the shape of globalization of world and laws dealing various fields of life and intellectual property rights were among them.

Formation of *World Trade Organization* and signing of *TRIPS* agreement led towards globalization of intellectual property (IP) laws dealing various innovations. The new era of globalization of intellectual property laws have given rise to a number of constructive changes by providing a monopoly to the inventor and he or she have exclusive control of his or her

inventions and no one can intrude into right of inventor anywhere on the globe. By signing a number of international treaties, the member countries are bound to protect the invention in their territories. This productivity of global intellectual regime has given rise to counter-production by disturbing a number of inherent rights of humanity and the field of essential medicine is important of all.

Patents are granted to the novel inventions which are having their industrial applications. Field of medicine is also dealt by the laws of patent protection. Every new invention in the field of medicine can be protected by the way of patents. Patent also provide monopoly on a specific invention like all other intellectual property rights do.

With the advent of globalization and wide spread increase in population on the Earth, diseases and the essential medicine to treat them is also on boost. Now, the time demands protection of innovation trough intellectual property rights and on the same time the challenge of providence of essential medicine is also crucial. Humanity needs co-operation in order to build a global harmonious society.

In order to streamline the protection of intellectual property rights and protection of right of every human to access the essential medicine globally, a number of moves have been done in the shape of *TRIPS* and *Doha Declaration*. Countries through their global commitments are bound to ensure the implementation of intellectual property rights and innovation around the world and on other front they are given a power to control the providence of essential medicine to their masses through different ways for example compulsory licensing.

1.2. GLOBALIZATION OF IP LAWS AND ACCESS TO MEDICINE

Developing countries are not having adequate infrastructure in the field of medicine because of insecurity, lower level of income and fragile infrastructure. Access to medicine is the main issue in the Asian countries and Pakistan being one of the South Asian countries faces the same issue.[1] According to World Health Organization 31 percent of the population around the world do not have access to essential medicine and about 74% of *AIDS* drugs are under the control of companies and 77% of African still do not have access to *AIDS* treatment.[2] The value of Pharmaceutical Industry in Pakistan is around US $1.18 billion with a number of 439 registered pharmaceutical companies of which 53.3% is the contribution of multi-national companies and

[1] "Generic Medicines as A Way to Improve Access and Affordability: A Proposed Framework for Pakistan" JAMSHED, <www.jcdr.net/article_abstract.asp?issn=0973...3, (29th June, 2010)

[2] WHO Medicines Strategy Countries at the Core 2004-2007,< http://whqlibdoc.who.int/hq/2004/WHO>

_EDM_2004.2.pdf, (29th June, 2010)

the rest 46.7% are national.[3] Trade Related Intellectual Property agreement was adopted by Pakistan in 1995 and Pakistan was declared as developing country and was given task to maintain the Intellectual Property Rights (IPRs) through domestic laws. Pakistan in compliance of this international treaty introduced the *Patent Ordinance 2000.*

Initially, after the advent of *Trade Related Intellectual Property Rights Agreement (TRIPS Agreement, 1994*) some concessions were given to the developing countries, Pakistan under the laws benefited from some of them and a number of concessions were ignored while on the same time India utilized majority of them by introducing an amendment in its Patent Law in the shape of section 3(d) in which a concept that a mere new use of know substance will not entitle the person for patent right but it the new substance should also show that how much the efficacy is increased due to new use. On the basis of this legislation Indian Courts protected the local pharmaceutical industry as well as the population by providing them access to the essential life saving drugs. In fact, the *TRIPS* agreement obliges almost all *World Trade Organization* member countries to accord patents medicines, but still there is softness in agreement. As per the *TRIPS* agreement, each member country reserves the right to have its own specific format on patents. In fact, the *Doha Declaration* on *TRIPS* and Public Health clearly jotted down that the *TRIPS* agreement can and should be represented and enforced according to the *WTO* Member's right to safeguard public health and specifically to promote easy access to all Pakistan is a part of the *TRIPS* agreement, and since 2000, the Intellectual Property Legislation is duly positioned.[4] So, the need of the time is that Pakistan being the developing country should use softness of *Trade Related Intellectual Property Rights Agreement* in proper way and it will result in the welfare of both Pakistan's pharmaceutical industry which is rising with the pace of 20% annually and the masses at large.

Advent of *Trade Related Intellectual Property Rights Agreement* which was concluded in 1994 has changed the world scenario and especially the developing countries are facing new challenges to implement new standards of Intellectual Property. Pakistan being the family member of developing countries in the world faces the same and especially in the field of Patent Law, the situation is complex as working with the new international agreement along with saving its pharmaceutical industry and providing essential life saving medicines to the masses is the issue need to be tackled with great care.

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[3]Drug Control Organization, Ministry of Health, Government of Pakistan (2005),http://www.dcomoh.gov.pk/, (29th June 2010)

[4]*Doha Declaration* on *TRIPS* and Public Health, signed at *WTO* Ministerial meeting in Doha, Qatar on 14 November 2001

1.3. HISTORY OF PATENTS

Venetian Statute (1474) is the manuscript which is deemed as the first in the history of patent and patent laws which was being legislated in Italy and was issued by the Venice Republic. To issue the decree by whom anew and inventive devices, one time they had been put into practice, had to be made to the Republic for the obtaining of legal cover against probable infringers. The age of patent protection was decided as 10 years.[5]

However, the concept of Patents existed before the Venetian Statute of 1474. Inventors in England were awarded with the letter of patents by the sovereign who applied for the shield of patent protection and example of this is grant of patent in 1331 to Jhon Jempe and his company by the royal grant made with the affirmed purpose of teaching the English in a new industry. [6] First patent is assumed to be decided by the Florence Republic in 1421 and there is apparent witness of that the same type of patents were being approved by the authorities in Greek states.[7]Greek city of Sybaris bears proof that the people who discovered any new thing of luxury or profit arising commodity were being encouraged by the state authorities. [8]

Crown, in England was empowered to issue letters patent giving right to any person with domination to produce particular goods or render particular services. Another example of the patent grant beyond the patent monopoly of Jhone Kempe is the Utyman, a Flemish man, which was being awarded by Henry IV in 1449 for a period of 20 years for his invention.

These are some of the examples of early tradition of patent grant in England by which people were being paid back for their invention and work for the humanity.[9]

Initially patents were being used to collect money for the crown and were abused by the grant of patent in ordinary goods and the example of patent of salt later the court of England started interfering in it and limited the circumstances in which the right of patent was being granted. After the protest of public, it was James I, who limited the scope of patent monopolies and made the use of patent to encourage innovation. A Statute of Monopolies was being enacted by the parliament of England by which the power of Crown to issue the letter of patent was limited. Statute of Monopolies made the inventor beneficiary for the use of his or her invention for a certain span of time in years.[10]

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[5] "Terrell on Patents", 8th edition edited by J R Jones, London (Sweet & Maxwell) 1934

[6] E Wyndham Hulme, *The History of the Patent System under the Prerogative and at Common Law*, Law Quarterly Review, vol.46 (1896), pp.141-154

[7] Terence Kealey, *The Economic Laws of Scientific Research*, St. Martin's Press, 1996

[8] Gregory A Stobbs, Software Patents, Aspen Publishers, 2000, ISBN 0-7355-1499-2, page 3

[9] <http://www.ipo.gov.uk/p-history.htm>, (6th April, 2011)

[10] <http://www.ipo.gov.uk/types/patent/p-about/p-whatis/p-history/p-history-tudor.htm>, (6th April, 2011)

It was the reign of Queen Anne (1702–1714) when the lawyers made the tradition of written submission of description of invention as compulsory. The development of English patent law is deemed as the pioneer and the guiding for the patent laws of United States, New Zealand and other courtiers who gained independence for the colonial powers.[11]

In 1977, the Patent Act harmonized the patent laws of UK with the laws of the European Patent Convention. Now, as result of this move, Patent laws in United Kingdom are not based on the Statutes of Monopolies and are the mixture of United Kingdom and European Union traditions. Patent right in United Kingdom can be enjoyed for 20 years from its origin and this can be traced back to the declaration of Henry VI on the patent grant for stained glass.[12]

1.4. PATENT LAWS IN PAKISTAN

Pakistan is one of the members of the *World Trade Organization* (*WTO*) and is signatory to the Trade Related Aspects of Intellectual Property Rights (*TRIPS*) and by the way of this agreement Pakistan promised to amend its laws in confirmation with *TRIPS* obligations. The changing scenario of global development in industrial development also press the authorities in Pakistan to amend the classical Patent and Design Act 1911 as a number of latest developments are seen after 1911.

Keeping in mind the requirements posed by the Trade Related Aspects of Intellectual Property as well the basic requirement and challenges posed by the industrial changes in Pakistan, President of Pakistan promulgated *Patent Ordinance 2000* of Pakistan on 2nd December, 2000. The new patent laws allow the patent of product and process and the second new change is the life of patent which is extended as 20 years. These two developments are the clear change from the century old traditional patent laws.

Following are some of the conditions for the grant of patentability and those are as fallowing:

According to section 2(c) of the *Patent Ordinance 2000*, invention will include,

"any new and useful product, including chemical products, art, process, method or manner of manufacture, machine, apparatus or other article; substance or article or product produced by manufacture and includes any new and useful improvement of any of them and an alleged invention"

[11] <http://www.ipo.gov.uk/types/patent/p-about/p-whatis/p-history/p-history-19century.htm>, (6th April, 2011)
[12] M. Frumkin, "The Origin of Patents", Journal of the Patent Office Society, March 1945, Vol. XXVII, No. 3, pp 143 et Seq.

Process means:

"any art, process or method of new manufacture of a product and includes a new use of a known process or a product". Similarly, product is defined to include "any substance, article, apparatus, machine or a chemical product".[13]

1.4.1. Patentable Inventions

According to law, the patent will be granted to a thing which will be novel and the product or process should include inventive steps and the patent or process for which the patent is applied should have some industrial application. According to section 8 of the *Patent Ordinance 2000* an invention shall be deemed as novel if it does not form part of the state of art. State of art includes:

(i) *"thing which is disclosed to public anywhere in the world, by the way of publication in tangible form or by oral disclosure, by the way of use or in any other way, prior to the filing... and"*

(ii) *"contents of whole specification and priority documents published under the law. Inventive step is defined with its conventional meaning of non-obviousness to a person skilled in the art. Industrial application is defined to comprise 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. The law clarifies that a product consisting of a substance or composition shall not be prevented from being treated as capable of industrial application merely because it was invented for use in such a method."*

Under the *Patent Ordinance 2000*, patents are not to be approved for *"animals or plants other than micro-organisms and essentially biological process for the production of animals or plants"*. On the other hand, the new law makes clear that this probation shall not apply to "micro-biological processes or products of such processes".[14]

1.4.2. Application for Grant of Patent

Patent Ordinance 2000 demands

"every application for the grant of patent should be on the prescribed form and to include a declaration produce that the applicant is in ownership of an invention of which he, or in the case of joint application, at least one of the applicants, claims to be the actual and the first inventor. The law requires every application to be in respect of one invention only or to be in respect of a group of inventions so linked as to form a one inventive concept. Every

[13] Section 2(C), *Patent Ordinance 2000.*
[14] Sec 7(4b), *Patent Ordinance 2000.*

application should include complete or provisional specification. It is compulsory for every complete specification":

(i) to describe the application and to make cleared the inventive steps involved in the invention;
(ii) invention should be disclosed; and
(iii) the application should have a claim or claims explaining the scope of the invention for which protection is claimed.

The claim/claims of a complete specification are necessary to describe to a single invention, to be apparent and concise and to be moderately based on the matter made in the specification. Conclusion of whole application should also be furnished.

Patent Ordinance makes it compulsory on patent authorities to accept or refuse the patent application in eighteen months and it can extend to 21 months in case of extension from the date of the application of patent. If the application is acknowledged once and after the publication of it is open for opposition for four months from the date of publication in Gazette.

Following are additional information and documents relating to foreign applications:

According to section 20 of *Patent Ordinance 2000*, the Controller is empowered to call for foreign applicants of patent to mention the date and number of application for the same patent being filed by the foreign applicant abroad of the same patent of similar to it which is being filed in Pakistan. The applicant, if is required by the Controller, is bound to furnish following documents relating to foreign application. The applicant, when required by the Controller, is required to furnish with the following documents relating to foreign applications,

(i) the applicant will provide a duplicate of any document received by the applicant regarding the result of any investigation or examination made in respect of the foreign applications;
(ii) the applicant will provide a duplicate of the patent granted on ground of the foreign application; and
(iii)The applicant will provide a duplicate of any concluding decision rejecting the foreign application.[15]

[15] Chapter VI, *Patent Ordinance 2000*

1.4.3. Term of a Patent

Trade Related Aspects of Intellectual Property Rights set the time for the patent right enjoyment as 20 years from the date of application and the term for the patent right was 16 year according to the contemporary law of that time i.e. Patent and Design Act 1911.Section 106(4) of the *Patent Ordinance 2000* bears bewilderment since it provides that if at the beginning of *Patent Ordinance 2000*, a legal proceeding for infringement of a patent, or any legal proceedings for revocation of a patent is pending in any Court, the said suit or legal proceedings may be constant and disposed of under the 1911 Act, as if the new law had not come into force, provided that term of the patent shall be 20 years.[16]

1.4.4. Rights Conferred by Patent:

Patent Ordinance 2000 sets a principle that if a person other than the patent holder wants to exploit the patented invention of someone than he or she will need the permission or can exploit by the way of agreement with the patent holder. *Patent Ordinance 2000* says about the different ways of exploitation of patent and they are as under:

a) instances where the patent is about product:
   (i) using, selling, offering for sale, making and importing of the product
   (ii) to stock such product for the invention of offering for sale, selling or using
b) instances where the patent is about process:
   (i) to use the process
   (ii) To do anything or acting in on any way elaborated in (a) to obtain a product by the way of process.

According to the Patent Ordinance, if the rights of patent of its holder is violated other than in compulsory licensing and mail box provision, he or she will have the right to ensure their right through the proceeding in the court against some person for the violation of his or her right of exploiting it without agreement. Here, we will have a glance on some of the remedies being provided to patent holder.

[16] Section 106 (4), *Patent Ordinance 2000*

1.4.5. Reliefs in Suit for Infringement

According to section 61, *Patent Ordinance 2000* following are some of the reliefs being provided to the patent holder in a suit to remedy his infringement:

(i) court can order to cease from infringement,
(ii) court can stop the entry of imported commodities to enter into the market of commerce of imported goods which can cause infringement straight away after custom clearance of such goods;
(iii)court can order the guilty to pay the compensation to the right holder according to the damages suffered by the patent holder,
(iv)court can also order the cost of the case for the patent holder with the damages,
(v) in some cases, the recovery of profit and damages can be compensated even in the case where the infringer was not aware of the right or did not intentionally did the infringement of patent holder's right.[17]

1.5. GLOBAL CONCEPT OF INTELLECTUAL PROPERTY

Pakistan is among the signatory of Berne Convention, the Universal Copyright Convention and the *World Intellectual Property Organization (WIPO)*, but on the other hand, the country did not took the membership of the Paris Convention for the defense of Intellectual Property. As a member *World Trade Organization*, Pakistan is answerable to the conditions of the *Trade-Related Aspects of Intellectual Property Rights* (*TRIPS*). The United States has made a variety of steps to make convinced that Pakistan obeys its *TRIPS* promises, primarily with respect to satisfying its duty to institute a mailbox in the field of chemical, agricultural, and pharmaceutical manufactured goods patent applications.

In accordance with *TRIPS* obligations, it was binding on Pakistan to bring its patent law in conformity with *World Trade Organization*'s requirements till the conclusion of 2005, but execution remains patchy. The government is criticized for being unenthusiastic to implement the rules fully, due to the reliance of Pakistani population on despicable copy drugs. In addition to the costs involved in additional align local processes with international ought are not allowed to the government because the reorganization will take place on a massive scale. The abolition of the major trade in fake drugs presents a major task. Patent protection is a new concept in Pakistan, with laws introduced only as lately as in December 2000 in the Patent Ordinance which was amended in October 2002. The amendments restricted filings of patent to single chemical entities, limited patent guard sought for derivates, salts and biotechnology based inventions.

[17]Section 61, *Patent Ordinance 2000 of Pakistan*

Even though a patent office has freshly been recognized, motion is still at a very small scale. Intellectual property (IP) sustains as a root of difference between the government and the industry. Detailed concerns on the amendment of 2002 are also included the equivalent importation of the molecules drugs which are patented by inventor companies.

On the other hand, in latest period, pharmaceutical industry of Pakistan has again rehabilitated their disapproval of the Patents Amendment Ordinance 2002, alleging that the act does not maintain the efficiency of provisions of terms for patent protection in Pakistan. From the birth time of Pakistan, it has issues five patent legislation and of which is famous *Patent Ordinance 2000*. The laws of patent in Pakistan have divided the industry in two main groups; of which first is local which want more relaxation in patent laws and they welcomed the amendment of 2002. On the other hand is the group of multinational companies who want strict patent criteria to support their products at their own prices.

1.6. IP LAWS IN PAKISTAN AND REGULATORY SYSTEM

Ministry of Health is the fundamental regulatory body for the medicines in Pakistan. Each and every product in Pakistan which can be sold in market must be authorized by the Ministry of Health. The foundation for marketplace law is the Drugs Act of 1976, which promises for the stem pharmaceutical pricing scheme. Furthermore, registration of product is allowed merely if local manufacturing requirements are fulfilled, and Ministry of Health is also implementation of strict criteria for it. This system, in many cases results in rejection of new chemical applications.

In June 2008, a modern drug authority was founded to take the responsibility of Drug Registration Board. In the beginning, the body with the budget of 3.4 billion rupees will be responsible for the issuance of product licenses and it will also monitor the quality of medicine in Pakistan. This regulatory will work on both fronts of smoothening of registration as well as it will ensure the quality of pharmaceutical medicines. The move has been accelerated following a recent high-profile case in the Supreme Court concerning counterfeit drugs.

Authority which is established recently will have more benefit and funding in near future. It will also deal with the import and export of pharmaceutical products; mainly it will deal with the concept of rationale use of medicine. To build the structure and make reforms will also be the subject of Drug Authority.

Presently, the Drug Registration Board of the Federal Ministry of Health registered more than 40,000 product names, containing more than 1,400 molecules. All of those drugs are not available on the market, for a range of reasons, including promotional illegalities. The second are at present being investigated by a particular commission whose goal is to construct industry wide suggestions and strategy on principled drug advertising. Launch of patented medicines are vulnerable by the fact that registration period can be as long as two years. On the other hand, a

new progress has seen drugs registered in two main advanced markets specifically, the US, the UK, EU, Japan and Switzerland, are carried through a speedy system in Pakistan, which skips the expert evaluation and thus improves registration period.

Keeping in view, the above mentioned fact that in the beginning of the Drugs Act, Pakistan has tried to start GMP and recently is making focusing on the implementation of Good Laboratory Practices The events are premeditated to build up exports of Pakistan in foreign country markets, which currently number more than 70, and is improving competitive tone in export tenders against countries such as India and China. Resultantly, the regulatory situation in Pakistan can be stated as complicated, with diffident in the way of a consistent infrastructure. Conditions for foreign companies are hard, with firm government pricing controls being a key blockade to market entry. Illegal copies of branded medicines and other copied products have a major market in Pakistan, acting as a more strength. Following are the issues of apprehensions raised by the *Pharmaceutical Research and Manufacturers of America (PhRMA)*

- Non- implementation of data shield as mandatory under *TRIPS* Article 39.3
- The *Ministry of Health (MoH)* keeps on disregarding process patents on the time of registration and preponderance of mailbox applications are not been granted or finally worked upon.
- The *Ministry of Health* makes a domestic manufacturing condition as a prerequisite for product registration.
- The *Ministry of Health* placed restrictions on charge manufacturing.

The pricing system of recent government is not clear, and government prices of inventive products are made at enormously low and un-informed levels. The government has not revised prices since 2001 despite the rapid increase in the inflation rate.[18]

1.7. DOMESTIC PHARMACEUTICAL INDUSTRY

Domestic manufacturers are capable to fight to a huge extent with the strappingly positioned multinational sector and due to their ability to market copies of branded and patent protected medicine. In spite of the grounds of much dissatisfaction for the multinational sector and the situation is likely to carry on for some period of time as the government aims to guard the home industry. Regardless of being on the goals for the previous few years, the modernization of the regulatory system of Pakistan and mostly patent legislation remnants slow. Being based on the reform programmes of emerging markets, patent legislation is possible to be one of the previous areas to be reformed.

[18] Pharmaceutical Health Care Report 2010

Additions to troubles continue about the standards of some manufacturing units and their devotion to legislation. An example is, in December 2008, a report open to the elements that only a $1/5^{th}$ of drug-manufacturers in Lahore were discarding their waste such as expired drugs and poisonous raw materials in water courses, thus violating the Hospital Waste Management Rules. On the other hand, the government has made the pharmaceuticals sector as a vital enlargement opportunity in the competition of new patent laws of India and other regional modernization initiatives. Harsh government pricing controls have ended up in many un-economic medicines being easy to get to only on the black market at magnified prices, or vanishing completely.

Pharmaceutical sector India is rather consistently divided between locally made generic medicines and imported prescription pharmaceuticals. According to the figures PPMA's, the local industry is responsible for an estimated 70 to 80 percent of the whole market in terms of volume and some 55 percent in provisos of value, even though the figures in 2006 have since transferred additional in favor of local manufacture. More than one hundred domestic companies are represented by the shelter of Pakistan Pharmaceutical Manufacturers Association (PPMA), with multinationals organized by the Pharma Bureau of Pakistan.

The domestic industry vestiges susceptible to imports, due to its comparatively rundown technical capacity, the lack of fiscal resources and the trust on raw materials sourced from foreign. Multinationals and foreign companies are in charge of the market in terms of value, but experience irregular and tricky market infiltration. This is due to the limited use of counterfeit in the public sector, low patient purchasing power and preventive pricing and intellectual property mechanism.

1.8. RECENT PHARMACEUTICAL SECTOR DEVELOPMENTS

In the era of current political and economic problems, in October 2008, the last President of *Pakistan Chambers of Commerce and Industry (FPCCI)* asked the government to forbid imports of goods which are not being needed for endurance, which would make the balance of payment. In July 2008, the government sterile the proposal to buy around 400 drugs from India and local drug manufacturers agitated against the offer by the commerce ministry. According to them over 1 million jobs would be troubled by the plan and over 120 million dollars value of annual exports endangered. Currently, Federal Health Ministry of Pakistan cancelled the registration of 4 thousand imported medicines, for the same reason.

In July 2008, development follows the recent criticism of wholesalers of the country and distributors by the Pakistani retailers, which condemned the so-called jamming of imports of not expensive drugs from India. This favored their claim with the fact that no fresh import licenses for Indian sourced pharmaceuticals were decided in 2005. Bulk dealers had contradicted the

argument by commenting that the numerous Indian medicines get to Pakistan through third countries, even though the tendency has had modest descending blow on prices. In the intervening time, Indian drugs are deteriorating to break in Pakistan through legal ways regardless of the introduction of zero tariffs on such imports in June 2005 enforced as a response to distributor's denial to trim down margins.

The present government intends to put up on earlier reforms aiming greater than before foreign investment and has tried to hold up investors of its purpose to maintain a steady pro-investment plan. Contrary to this, a sequence of investment sponsorship agencies, most newly the Pakistan Investment Board and its descendant, the *Board of Investment (BOI)* has missed the required authority and connection of leadership. Moreover, risks to foreign direct investment (FDI) subsist, most major being the weak intellectual property and escalating inflationary trends without resultant increases in the prices of drugs.

In September 2009, aim of Pakistan to become a momentous exporter of pharmaceuticals came under danger, after a Ugandan drug manufacturer sued a Pakistani pharmaceutical manufacturer for providing inferior goods. Mavid Pharmaceuticals had made a lawsuit against Royal Group against breach of contract after the purchase of underdone materials for therapeutic ointment named Samodex. On the other hand, after testing by the National Drug Authority (NDA), these goods revealed to be fake. Mavid Pharmaceuticals at first wanted to get back its 68,000 US dollars expenditure, but Royal Group ignored to do this. In late 2009, director of Mavid in his statement said that the company was ready to work out a deal out of the court with Royal Group for the sub-standardd goods. [19]

[19]The information is taken from the "Pharmaceutical Health Care Report 2010", it is published by Business Monitor International in May 2010.

CHAPTER: 02: COMPULSORY LICENSING; A TOOL FOR DEVELOPING COUNTRIES AGAINST THE COSTLY PATENT MEDICINES

2.1. PROLEGOMENON

Industrial revolution of eighteenth century has on one side made the life easy but counterproductively, it has divided the world at large between haves and haves not. Countries enriched with research in science and technology has better ways to meet their needs as compare to the developing or under developed countries. Now, we can divide industrial productions in two types, first category is of industrial productions without which life is possible like electronic products and etc, second category is comprised of industrial products without which life is impossible and those are life saving drugs and etc. Monopoly of developed countries over industrial productions ensured by intellectual property rights under patent regime is a new way to facilitate research and innovation.

Industrial regime is in the evolutionary process and needs a continuous back up of innovation and innovation can only be ensured if the person working on research and technology is paid back his time and investment for his innovation. A person or entity evolving in research do invests some money and time in getting an industrial application invented. This is basic instinct of humankind that he or she works for some incentive and if the reward is not paid back to him or her, the innovation will be stopped. So, the industrial regime is being protected by the intellectual property laws.

Patents are being provided for the industrial used innovations. Industrial innovations are of different kinds and most important of them are patents being awarded in the field of pharmaceuticals. Providing medicine or treatment to the diseased to save life is moral, ethical duty of humanity at large. Advent of fatal diseases in the shape of AIDS, Cancer and etc pose a new challenge to the world. Now this is duty of all of us to fight under united front against the common enemy in the shape of diseases.

Innovations were protected in earlier times also. In near past to protect innovation was the national subject but globalization of world led to the globalization of intellectual property laws also. Intellectual property laws were also globalized as the sphere of business in innovation widened to the global level. Currently, patents are granted to the industrial inventions and the time limit to exploit them is 20 years. The new invented thing should be a new idea, involving inventive steps and most important of them is its industrial application. Patent holder is given monopoly over the product and the person having patent for innovation can acquire the benefit from the product.

A great number of patents are currently being awarded in the field of pharmaceuticals for newly invented drugs. Drugs can be further divided into ordinary drugs and life saving drugs. Life-

saving drugs are those which are necessary for a patient to save his or her life against a disease. Grant of patent for the life-saving drugs like AIDS, Cancer and etc lead towards monopoly of patent holder in the area of life saving. This opens a wide area of discretion of the patent holder to increase the price of medicine and acquire undue benefit. To overcome this threat, the rule of compulsory licensing is enunciated in all laws dealing intellectual property and especially patents. Grant of compulsory license against a monopoly in product is the tool by which a government can protect its masses against high price of product. To save public health, a government can give any person other than patent holder to produce the patented innovation on low price and to the patent holder a reasonable amount as compensation.

2.2 COMPULSORY LICENSING

Compulsory licenses are generally defined as authorizations permitting a third party to make, use, or sell a patented invention without the patent owner's consent. Because they bound the power conferred by patents, compulsory licenses have long been contentious. This part in brief reviews the beginning of compulsory licenses, the point of view for and against them in both the United States and developing countries and the record of their implementation in the United States.

The current dispute over compulsory licensing is not new. For example, in the United States Senate in 1790,and in Germany in 1853, in the House of Lords in Britain in 1851 and policy makers debated over compulsory licensing considering it a way to preserve the benefits of the patent system and minimizing its troubles. On the one hand, patents fashioned positive incentives for innovation and the revelation of inventions, granted just rewards to inventors, demonstrated recognition of society for the natural property rights of inventors and generally dealt with the public goods harms linked with formation of knowledge. On the other hand, these profits came at a cost which includes the probable abuse of control power by patentees, the make use of patents to wedge inventive activity by third parties, the diversion of creative activity disproportionately towards patentable activity, and the considerable administrative costs of working a patent system. Along with these benefits and costs in mind, patent critics and advocates accepted compulsory licensing as a strategic compromise in 1873 on the Patent Congress in Vienna. In order to safeguard the enticements for innovation while increasing access to innovations themselves, the Congress adopted a condition that licensees pay patent holders reasonable compensation for their licenses. With the succeeding adoption of compulsory licensing by the Paris Convention 1983, the foremost international patent agreement of world, compulsory licensing became a match in almost all patent systems. While detailed provisions vary, compulsory licenses are generally certified in the event of un-desirable behavior by the patentee, such as anticompetitive, non-working, or blocking behavior; in the event of public need, such as government breach or national emergency or in the context of food and drugs. Licensees are commonly compulsory to pay adequate compensation to a patentee in exchange for use of a

patent. The necessary amount is generally more than a reasonable royalty and the floor for breach compensation in the United States, another basis for shrewd infringement damages. The total of compensation varies among countries commentators have observed that the UK has provided the most openhanded compensation in its drug patent licensing decisions; the United States the least generous compensation in key antitrust decisions.

2.2.1. History of Compulsory Licensing

The Intellectual Property protection had been carried out in various countries in different levels of protection. There needed to bring into line this old law to help international trade and the free stream of technology. This was indispensable in order to obtain sufficient protection in other countries of the world in view of the gap in laws.

This was felt for the first time in the year 1873 when many countries denied to display their inventions in an exhibition organized for this purpose held in Vienna. It followed deliberation, conference and finally *Paris Convention* for protection of Industrial Property, 1883 came into existence. Thereafter, Berne Convention for the protection of Literary and Artistic Works, 1886 and *Rome Convention for Artists and Performers Rights, 1961* came into existence to protect IPRs at International Level.

Later on, one International Organization particularly *World Intellectual Property Organization* (*WIPO*) also came into continuation in Stockholm in the year 1967 when last revision of Paris Convention took place. This Organization has the responsibility to manage and promote IPR on an international level.[20] However, *Uruguay Round of Negotiations* culminating into *World Trade Organization* came out with Agreement on Trade Relate Intellectual Property Rights as *TRIPS* in the year 1994 which strived to merge Intellectual Property Rights with International Trade.[21]

2.2.2. Compulsory Licensing; in Legal Perspective

General Agreement on Tariffs and Trade (*GATT*) 1995 was document regulating intellectual property issue prior to the promulgation of *WTO* laws. A number of aspects of intellectual property laws were affected by a number of treaties and examples are in the shape of Berne Convention on copyright, and patents were being regulated by the national laws of respective countries. Developing countries are poor in the field of education and modern scientific growth moreover is the lack of capacity to work for innovation through incentive. This plight of developing countries makes them dependant on developed world in the field of modern techniques to produce goods for their population. As a result, patent protection in developing countries has been negligent historically by comparison to the developed world. This "East-West" divide has given rise to many disputes where the developed world is accusing the

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[20] T.V.Malvika, INTELLECTUAL PROPERTY RIGHTS, Magazine, <http://www.tutorial.web4all.in/archives/fsug-bangalre/2006-Arjl/000754.html>, (12th November, 2009)

[21] D. H Kim.; Research Guide on *TRIPS* and Compulsory Licensing: Access to Innovative Pharmaceuticals for Least Developed Countries, <www.nyulawglobal.org/globalex/*TRIPS*_Compulsory_Licensing.htm>, (July, 2010)

developing for using drugs being given patent and monopoly by law and on other hand is the stance of developing world regarding tyrannical use of monopolies in the shape of patent which are detrimental to the existence of mankind. The product of this divide was the divide in the world regarding the protection of patents. USA being the top most propagator of intellectual property rights declared that any violation of her patent right will amount to 'unfair trade practice' under law and it will be punished with economic sanctions by America. America has taken a number of steps in this wake against developing countries.

The North American Free Trade Agreement (NAFTA) 1992 began an inclination toward the assimilation of intellectual property laws into trade agreements. *NAFTA* successfully replaced the U.S.-Canada Free Trade Agreement, which had tiny to say about intellectual property rights. But when the arrangement was extended to cover Mexico with the creation of *NAFTA*, Mexico was required to commit itself to provide intellectual property rights comparable to those in place to its North. *NAFTA* Chapter thus sets out elaborate provisions on what each Member State must do to guard intellectual property, including rations for patent defense in Article 1709. The Uruguay Round of negotiations under the auspices of *GATT* (which ultimately led to the creation of the *WTO*) was already in progress when *NAFTA* was signed. The developed members of *GATT* built on the *NAFTA* model and worked to ensure that intellectual property protection would be incorporated in the results of Uruguay Round. Resistance from developing countries was intense, but ultimately they acceded to the inclusion of what is now known as the *WTO*

Trade Related Intellectual Property Rights Agreement (*TRIPS*) contain a portion of it regarding patent protection of industrial inventions whether product or process in Articles 27-34. It is further elaborated in these articles that patent will last till 20 years. 18, 19, and 20 Process patent have wide implication on pharmaceutical industry in Pakistan and world at large Article 28 says that the patent holder must be given the exclusive right to make, use, offer for sale, or sell the patented product or the product made from the patented process. In broad-spectrum, developing nations were allowed to delay the application of most provisions of the *TRIPS* agreement for five years after its entry into force (until January 1, 2000). Least developed countries have until January 1, 2006 to comply with most *TRIPS* obligations.

2.2.3. Trips Agreement and Compulsory Licensing

Even despite the fact that Article 31 does not particularly hold the term compulsory license, it is generally referred to as the compulsory licensing provision. Fundamentally, Article 30 permits under definite circumstances, the use of the patent without prior permission from the right owner. To put off any misuse of this exception to patent rights, a definite number of conditions must be met previous to any issuance of a compulsory license. Article 31 requires an endeavor to negotiate a license with the patent owner over a reasonable period of time on reasonable commercial terms[22] before a compulsory licensing. This abovementioned prior negotiation condition is waived in the event of national emergency or other circumstances of extreme urgency. The degree to which a given circumstances could be considered a national emergency or extreme urgency has raised a vast deal of disagreement. However, the *Doha Declaration* has tempered the different interpretations by granting each member state the right to define what constitute a national emergency or other circumstances of extreme urgency.[23]

Moreover the right to be consulted preceding the issuance of a compulsory license, the right holder shall be paid sufficient remuneration in the circumstances of each case, taking into account the economic value of the authorization.[24] Nevertheless, if the compulsory license is issued in order to correct an anticompetitive practice, the prior negotiation or the patent holder information is waived.[25] This provision is especially vital in a price analysis. As mentioned, it can be used to remedy and anti-competitive practice connected to a price fixing or constraint of output. This could be a positive threat for the leverage of the pricing for the pharmaceuticals, especially in developing countries.

Most prominently, with regard to access to medicines, Article 30 (f) provides a national use obligation of the compulsory license. Since most of the developing countries that could take advantage of the Article 31 exception to tackle the public health crisis are short of adequate manufacturing capacities, the compulsory license exception was thorny to use in reality. However, in the transitional period a country, such as India, was able to supply most of the developing countries with cheap drugs. But this possibility ended with the expiration of the transitional period.[26]

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[22]Article 31 (b) *TRIPS*
[23]Doha declaration, point 5 (c)
[24]Article 31 (h) *TRIPS*
[25]Article 31 (k)
[26]BakhoumMor, "*TRIPS*, PATENT RIGHTS AND RIGHT TO HEALTH: "PRICE" OR "PRIZE" FOR BETTER ACCESS TO MEDICINE?", available on www.ssrn.com.

2.2.4. Compulsory Licensing in the United States

In consistent with a focus on innovation, the government of U.S.A has used compulsory licenses to control anticompetitive behavior. By 1977, the Federal Trade Commission had issued about 125 decrees over thousands of patents and a variety of technology. In recent times, such decrees have been planned in the context of price-fixing, mergers, and the abuse of control or market power. Compulsory licensing has also been projected as a solution to the problem of patent grants, wherein broad or manifold patents over technology areas put off follow-on research. Intentional or compulsory patent pools, in which the rights to use manifold patents are exchanged among patentees have been wished-for as a way to beat the refusal of patentees to license an invention and the administrative burden associated with licensing.

However, compulsory licensing has been used to additional public interests, mainly by enabling the government of U.S.A to use patented inventions without authorization. Even though courts have categorically resisted issuing compulsory licenses just because a patentee chooses not to utilize her invention, the government of U.S. Routinely relies on 28 U.S.C. § 1498 to inoculate its use of inventions without the permission of patentee. The statute confines a remedy of patentee for infringement by the government or a government contractor to sensible and entire compensation. By not allowing for injunctive relief, the statute efficiently *TRIPS* patentees of the right to prevent others from using their inventions.

Although the statute was in the beginning conceived with wartime urgency in mind, the government has utilized it in a large range of situations. Since 1948, the year of the enactment of statute in its current form, the Court of Federal Claims and its predecessors have resolute almost three hundred cases, connecting a large variety of technologies, under § 1498. Even though this figure is astonishingly large, it arguably understates the use of compulsory licenses by the government because it excludes cases resolved without litigation and infringement that goes unnoticed by the patentee.

In some infringement suits in opposition to the government that have been decided on the merit, plaintiff patentees have won just over 1/3rd of the time, as compared to a 58% winning rate of patentees against accused infringers in general. Other than the context of § 1498, compulsory licenses have been endorsed for public policy reasons, but on a more narrow scale.

2.2.5. American Opposition to the Concept of Compulsory Licensing

Within the broad framework of compulsory licensing, however, here has been modest consensus on the finest way to implement compulsory licensing. In current times, nowhere has the discrepancy in views been more pronounced than in the context of the compulsory licensing provisions of *TRIPS*. This was principally evident during the discussions behind these provisions. While the United States considered these provisions with distrust and doubt, developing countries made the claim about them to be an essential part of a workable patent system. Commentators have noted that the consequential provisions, discussed under, were left intentionally unclear, reflecting the inability of parties to come to an accord. The disparity in views on patents between the United States and developing countries is motivated in part by differences in economic standings. In developing countries, foreigners apply for most of the patents. As a result of that, the patent system favors the transfer of control rents to foreigners outside the country, even though it is also accurate that companies may prefer not to register inventions in markets they observe as too small to be significant. In addition to this, the sky-scraping price of products sheltered by patents can put needed technology out of the reach of developing country consumers, who are generally required to pay for drugs out of pocket due to the be deficient in of healthcare infrastructure. To reimburse for these patent system costs, nonjudgmental compulsory licenses are used to widen division of and increase access to patented technologies. The situation is different in the United States since inventors of U.S.A capture a large share of patents both locally and abroad. Patent profits from both local and foreign markets return and support research performed in the vicinity of inventors of U.S.A. Another fundamental reason for the difference in perspectives derives from the rationales behind each country's system of patent grant. Normally, countries with relatively few patents consider the patent system as a way to promote the shift of technology from other countries. Compulsory licensing provides a significant defense to ensure that technology shift happens in the event of non-working or sky-scraping prices. Contrary to this, countries such as the United States assert a relatively huge share of the patents of the world and look to the patent system first and foremost as an inducement to innovate and a way to stimulate technology creation. This innovation based focus makes us to the choosy application of compulsory licensing to cases where patents obstruct rather than advance innovation.

2.2.6. Compulsory Licensing in Pakistan

Patents can be exploited by the state, in order to protect the right of public health and public order, of its citizen. This contention is enacted in *TRIPS* Agreement[27] and is further endorsed in *Doha Declaration* afterward. Compulsory licensing is a good tool against the evil monopoly of the patent holders. State can produce or allow producing someone on its behalf something which is patented by anyone in the time of necessity to protect the rights of its citizen.

State in order to award a compulsory licensing of patent awards a reasonable amount in royalty to patent holder and allows production of that patented item. In Pakistan, *Patent Ordinance 2000* deals with the patent related matters. The problem is dare because of backwardness in science and technology and the situation is more worse in the field of medicine where each year millions of Pakistani face death because of un-availability of drugs because of high prices and patent monopoly of multi-national companies.

Patent Ordinance 2000 enunciates the idea of compulsory licensing in its section 58 and 59. Section 59 talks generally about the causes and nature of compulsory licensing where section 59 talks about the procedure being adopted by the federal government in order to award compulsory license of some drug or other patented industrial product or application. Following are the provisions dealing compulsory licensing in Pakistan under *Patent Ordinance 2000*. It enunciates the fallowing methods for compulsory licensing of a drug or other patent.

Section 58: Compulsory Licenses, Licenses of Right, Exploiting of Patents and Revocation under Patent Ordinance 2000

"Exploitation by a Government agency or third person, - (1) 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

[27] Section 31, *TRIPS* Agreement 1994

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"

Aforementioned section makes the award of compulsory license conditional to interest of public of Pakistan and in particular, national security, nutrition, health and to any other important issue of public economy. It give authority to federal government in Pakistan to decide if some patent is going to make any kind of anti-competitive activity or if the patent holder refuses to the use of its patent. According to patent laws in Pakistan the patent should be exploited and used in a manner which contributes in promotion of innovation in technology and it helps in transfer and dissemination of technology. If the patent holders do not comply with the condition of promotion of technology and etc, than the federal government can exploit the patented product or patent without the consent of its owner or can appoint third person to exploit the patent in a manner which is beneficial for public interest particularly in national security in nutrition and health.

The famous maxim of no one is condemned un-heard' is rightly enunciated in *Patent Ordinance 2000 of Pakistan's* which says that the federal government in taking any decision regarding grant of compulsory licensing will give the party affecting form its decision an opportunity of being heard.[28] The exploitation of patent in the mode of compulsory licensing will be limited to its purpose and cannot be used against the patent holder against the authorization of federal government. The Federal Government will be subject to pay the payment to the patent owner and it should be adequate. In deciding the adequacy of payment, the Federal Government will keep in mind the economic value of its authorization.

The Federal Government of Pakistan, on receipt of an application to award the compulsory license of some patented product or application will check the necessary evidence that the patent owner was being requested to grant the access to its patent and the clear evidence of his refusal should be provided with application.[29] Some of the exceptions are created for the aforementioned rule and they are as under:

(i) National emergency or urgency of circumstances and it says that the owner of the patent shall be informed about the decision of the Federal Government as soon as possible.

(ii) for non-commercial use

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[28]Section 58(2), *Patent Ordinance 2000.*

[29]Secion 58(4), "(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"

In the field of semi-conductor technology, the exploitation of a patented product or process shall only by endorsed either for public non-commercial use or where a judicial or administrative body has determined that the way of exploitation of the patented invention, by the holder of the patent or his licensee, is anti-competitive and if the Federal Government is content that the issuance of the non-voluntary license would remedy such practices.

The Federal Government is authorized to end the compulsory license on a patented drug on the end of emergency or on application of patent holder by due process if it deems fit.

The concept of compulsory licensing is not novel and its history dates back to the Statute of Monopolies in 1623 in England where it was evolved as means to work locally a patented product. It was also included in the Patent Act of 1883 in England which provided for grant of the patent in case where it was not being used in public interest.[30]

Currently, Pakistan is having its patent laws in the shape of *Patent Ordinance 2000*. Chapter 16 enunciates the idea of compulsory licensing in section 58 and 59. But the effective use of these provisions to protect masses from the price hike in medicine is still a challenge.

2.3. COST OF MEDICINE AND ITS IMPACT ON PUBLIC HEALTH

Prices of Pharmaceutical in the developing countries have been the new problem being faced on the globe. The most important issue is to the epidemic disease in the shape of HIV-AIDS which attacks many of the developing worlds. The plight of access to essential medicines in those developing countries is deplorable and a very few fraction can access the life saving drugs because of their sky rocketing prices. This brutal treatment of humanity is leading towards death of humans in a big part of globe. South Africa is one of the examples where one among eight people is thought to be affected. The average cost of treatment annually in South Africa is about US $12,000 and this amount is too much expensive to get an infected person treated against an un-seen enemy. The situation is same in Thailand where approximately one million of its population is HIV positive; only 5% of them all have access to essential life saving drugs.[31]4 The main and foremost issue is monopoly of pharmaceutical companies and high priced patent drugs. The patent regime having its greater impacts in medicine and life saving drugs is one of the core issues of the day.

Earth is divided in two parts, one is the group of producing and the countries who are at the height of research and technology and the other group is the consuming and developing countries According to a UN report of HIV AIDS drugs, a 150Mg drug of HIV AIDS fluconzole is of $55 in Indian market where there is no patent protection being given to the drug but the same is of

[30]W.R.Cornish, Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights, p. 291, 4th Edn., Sweet & Maxwell, London, (1999)

[31]UNAID, Fact sheet, AIDS epidemic in sub-Saharan Africa, www.unaids.org.

$697 in Philippines, $703 in Indonesian market where the drug is given patent protection. Same is the case of AZT which is the AIDS treatment and it costs 600 percent in America more than it costs in India per month.[32]

On one hand the developing nation are striving to reduce the cost of life saving drugs and on the other hand is the influence of developed countries and multi-national producers of drugs. The stance of developed world is that the decrease in the prices of patented drugs affects their rights. Some of the initiatives to reduce the prices of life saving drugs are made but those have giving rise to controversy and legal actions against the developing countries and the example is of South Africa and many other countries where the legislations to reduce the prices of drugs are under legal debate.

United States also gone against Brazil's laws of compulsory licensing. Finally, developing nations got their hands together in order to protect their population against the increase in the life saving drugs prices and under the umbrella of *WTO*; they succeeded in their aim in the shape of Trade Related Intellectual Property Rights (*TRIPS*).

In result of *TRIPS* and its consequences, some of the developed countries such as USA and etc propagated their own interpretation of intellectual property laws. In the result of this campaign *Doha Declaration* on the *TRIPS* agreement and Public health occurred in Doha, Qatar and it gave a new interpretation of the already existing *TRIPS* agreement.

Impacts of *Doha Declaration* are still in the process and the developing nations are trying their level best to invoke the various concessions being provided by the ministerial interpretation of the *TRIPS* agreement. Developing countries are trying to devise more affective policies to get the maximum relief for their population against the costly life saving drugs and especially regarding fatal diseases like HIV AIDS, Cancer and etc. Such measures and policies include compulsory licensing also. Compulsory licensing is one of the mode against the absolute ownership of patent right. If a person having patent for his invention makes his or her invention away from the public access through any mode, he or she will be made to give his achievement to public access through compulsory licensing.

Now it is the need of the time that the developing countries should have a common agenda of saving their population against the costly medicine and they should try their best to draw the attention of the developed countries towards the common fight against the enemy in the shape of diseases.

[32]UNAID, Fact sheet, Access to HIV Treatment and Cure, www.unaids.org.

2.7. CONCLUSION

Pakistan being the developing country faces a number of issues and most important of them is economy. Fragile economy of Pakistan is a great hurdle in our way of becoming a welfare state. It is the duty of state to ensure public health by the providence of essential medicine to its masses. Globalization of intellectual property laws poses a great challenge to the patent regime in Pakistan. *TRIPS* compliance makes the essential life saving drugs out of the reach of ordinary public. This issue can be tackled through the true exploitation of provision of compulsory licensing. Although, Pakistan enunciated the provisions regarding compulsory licensing but the true implementation and use of it is still pending.

TRIPS enact smart guidelines for the globalization of intellectual property laws and also insure the rights of ordinary masses to save the public health through essential medicine. So, the actual compliance of *TRIPS* in the shadow of Doha Ministerial Declarations should be ensured. Health care, being the top priority of almost all states on the face of globe cannot be ignored and compulsory licensing can be used as a positive tool against the arbitrary use of monopoly by the patent holder.

State, having sovereign authority may insure the compliance of compulsory licensing along with the assurance of health to its masses. The right to essential medicine can be ensured by the intelligent use of provision of compulsory licensing by the state and all states are free to adopt mechanism for it.

CHAPTER 3: COMPARATIVE STUDY OF CONCEPT OF PATENTABILITY WITH SPECIAL FOCUS ON PATENTABILITY IN INDIA

3.1. PATENTABILITY CRITERIA; GENERAL PERSPECTIVE

With the advent of the concept of globalization, the idea of patent has also gone through harmonization at global level and a number of international treaties and agreements have been drafted among the nations. Trade related intellectual property agreement (*TRIPS*) is one of the fundamental documents among the nations and it gives the nation a free hand to decide on their intellectual property laws according to their requirements but in harmony with international standards agreed upon. This general condition makes the nations free to draft there rules. Patent legislation, being the part of intellectual property law is also different among countries. Here we will have an idea of patentability in United States and other approaches regarding patentability. Conditions for patentability are different from nation to nation but some of the universal conditions are herein under:

1. Novelty
2. Inventive steps (non-obviousness)
3. Industrial application

3.1.1 NOVELTY

Novelty is a basic requirement in any examination as to substance being capable of patent grant and is an undisputed condition of patentability. It must be emphasized, however, that novelty is not something which can be proved or established; only its absence can be proved.[33] Only inventions are the subject matters of patentability and a number of product and process are excluded for the grant of patent according to the needs of the country having patent legislation. Criteria of novelty are also drawn in different manners in different countries. In Windsurfing International Inc. v Tabur Marine (Great Britain), a 12 year old boy had made and used a sailboard in an inlet of Hayling Island. The result of this was to annul the plaintiff's priceless patent. Anticipation and infringement involved similar questions. A product which preceded the patent would infringe if it came later. Only public information is taken into account, but no matter where it is situated and in what language it is written, if it discloses the invention, it will destroy patentability. Thus it was the fact that the boy used his surfboard in public which invalidated the Windsurfer patent.[34]

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[33] *WIPO* hand book,<www.*WIPO*.int>(13th July, 2010)

[34] [1995] RPC 59

3.1.2. INVENTIVE STEPS (NON-OBVIOUSNESS)

Not only an invention should be novel but also involve inventive steps. Inventive steps stands for feature that makes the invention not obvious to a person skilled in the art and a person with ordinary brain and skill in the art should not be able to derive the claims of the invention.[35] The rationale of novelty and inventive step show two separate goals within the patent system. Rewarding creativeness and the disclosure to the public of what was not previously known justifies the condition of novelty, in that what is not new to the public cannot be said to be disclosed to it. On the other hand the rewarding and support of the enviable art of inventing is promoted by insisting on the requirement of the inventive step, since what has not been obtained by intellectual effort and activity is not regarded as suitable for prize. The inventive step requirement also provides, at least in theory, valuable protection for the competitors of the applicant for the patent for, of something is obvious, it is already part of the totality of man's intellectual resources which should remain open and available to all. The grant of monopoly to a product or process which is not new but merely obvious will inhibit competition in any field of industrial or technical activity in which a new product or process is used.

3.1.3. INDUSTRIAL APPLICATION

The product or process that is the subject matter of patent award should have its application in industry as the patent is to industrial use. Industrial use also includes agriculture and etc that differs according to the legislation of different countries.[36] Bainbridge comments:

> *"Industrial application can be equated with technical effect, and if there is some technical effect, that is if the use or working of the invention produces some tangible and physical consequences or if the invention is itself a physical entity as opposed to information, then the requirement should be met"*[37]

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[35] Mishra, Umankant, Patentabilitycriteria in different countries, <www.trizsite.com>, (13th July, 2010)

[36] *WIPO* hand book , *Industrial applicability* (3.2.2)

[37] Bainbridge, David, Intellectual Property Law, Pearson Longman 2009, p 361

3.2. AMERICAN APPROACH TOWARDS PATENTABILITY

Patent system in United States of America has its roots in its supreme legislation which says in Article 1, Section 8, and clause 8:

"The congress shall have power... To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries..."[38]

Regarding patentability, United State's patent law (Patent act, 35 U.S.C. 1 et seq)[39] which was enacted by the congress under its constitutional authority. Patentability requirements in United States are a bit different than the requirements around the world and are as under:

1. Patentable subject matter and utility (defined under section 101 of *US patent act*)
2. Novelty
3. Non- *Obviousness*

3.2.1. PATENTABLE SUBJECT MATTER AND UTILITY

It gives guidelines for the things which are patentable under US patent act 35 U.S.C. In section 101, it says:

> *"Whoever invents or discovers any new and useful process, machine, manufacture or composition of, matter, or any new or useful improvement thereof, may obtain a patent thereof, subject to conditions and requirements of this title".*[40]

Here in this section both subject matter and utility are defined and the subject matter is left open and it is more widened by the decision of US supreme court in Dimond V. Chakrabarty (1980), where the question of "whether the living organism are subject matter of paten?" was under consideration the US Supreme Court decided that "anything under the sun that is made by man is patentable". Patent laws in the world are distinct in defining the subject matter of patent as the special care is given to the domestic needs.

Regarding utility the term "industrial application" is being used as the condition for patentability. This condition delimits the boundaries of patentability as only the inventions capable of industrial applications will be applied for patent grant. Article 57 of European patent convention (EPC) says that the invention subject to the grant of patent must have industrial application in order to be patented.[41] In Pakistan section 8 of patent ordinance talks

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[38] Chaudhry G.M., The intellectual property laws in Pakistan, p 361

[39] www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf

[40] 35 U.S.C. section 103(a)

[41] Article 57, European Patent Convention, <http://www.epo.org/patents/law/legal-texts/epc.html>(17th July, 2010.)

about the industrial application generally and makes the subject matter of patent grant conditional to its application in industry which excludes a number of fields from patent grant.

3.2.2. NOVELTY UNDER AMERICAN PATENT REGIME

According to American patent law the second test for an invention which is subject matter of patent grant is novelty and it means that the thing should not be known already to anyone before the inventor.[42] Section 102 of American patent act defines the term novelty and says that thing will be novel if it is not known or used by others in this country or patetented or described in a printed publication in this or another country prior to the invention by the patent application. Novelty in USA is strict to its boundaries but in Europe all member countries to EPC have regard to the novelty of others.

3.2.3. NON-OBVIOUSNESS

The criterion of non-obviousness is the same as it is in the shape of inventive steps enunciated in all other countries. Conditions of non-obviousness was added to US patent law by the way of patent Act 1962. Non-obviousness means that whether the subject matter for patent and prior art is such that the subject matter as a whole would have been obvious to the person of ordinary skill in the art at the time, the invention was made. While applying the criteria for non-obviousness the US supreme court in Graham V. Jon Deeree Co. held that the determination of non-obviousness can be done through factual inquiries into the scope and content of prior art, the differences between the prior art and recent claim, and the level of skill possessed by a practitioner of relevant art.[43]

It was felt that it is hard to examine the non-obviousness as the condition for the patent grant so in this regard American court of appeal for federal circuit court gave a unique criterion which is called Teaching, Suggestion, or Motivation (TSM) test, under this test the subject matter of patent is deemed obvious if the prior art, the nature of problem, or the knowledge of those skilled in art, reveals some motivation or suggestion to combine the prior art teaching.

In the aforesaid case the Us supreme court decided that TSM test which is applied by the district courts or patent examiners is against the section 103 of patent act, the condition of non-obviousness is discussed in these words in this section that the claim for the grant of patent will not be maintainable if "the difference between subject matter sought to be patented and prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skills in the art to which said subject matter pertains". In plain words it says that the subject matter should 'non-obvious' at the time of its creation. American patent regime was not having a specific criterion till the

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[42] Pope Appliance Corp V. Spanish River and Pulp Mills Ltd., AIR 1929 PC 38
[43] Graham V. Jon Deeree Co, 383 U.S.1 (1966)

passing of land mark case Graham V. Jhon Deere Co. of Kanas city, in which Supreme Court defined a parameter to judge the condition of non-obviousness which is known as TSM test. TSM can be summarized in these points:

- Reference themselves
- Knowledge of those skilled in the art
- Nature of a problem to be solved, leading inventors to look to references relating to possible solutions to the problem.

In KSR V. Teleflex the subject matter was Adjustable Pedal System (APS) used in automobiles having electronic control engines. Initially Teleflex Inc held an exclusive patent for the production of APS. On the same time KSR international was the supplier of APS for automobiles with engines use cable actuated throttle controls. During 2000, KRS started production of electronic pedal position sensor in order for it to work with electronic control engines. On this Teleflex filed a suit for patent infringement on the basis of claim that design is the copy of its patent. District court in its decision agreed with KSR on its view the patent possessed by Teleflex inc. lacks condition of non- obviousness and thus the patent is invalid. In the result of appeal to Federal Circuit court by Teleflex, the court held that the district court erred in applying TSM test.

3.3. INDIAN APPROACH TOWARDS PATENTABILITY

Patent laws of India do not list the patentable inventions affirmatively. The Patent act of India gives a list of those inventions which should not be given the patent rights. The law in India regarding patents provides a mechanism for the grant of patent rights for the inventions which do not violate the provisions of law. An invention will be granted patent right if it meets the basic criteria of patentability i.e. it is new, have inventive steps and it can be applied in industrial use. The word invention is defined as the thing or process which cannot be found some one else. It is not compulsory that the invention should be complex but the necessary thing is that the inventor should be first to adopt it. The earlier interpretations of word inventions are not reliable as the the recent changes in the interpretation of term invention.

Definition of word invention according to Section 2 (j) of the Patents Act of 1970 is as follows:

"invention means any new and useful-

(i) art, process, method or manner of manufacture;
(ii) machine, apparatus or other article;
(iii)substance produced by manufacture, and includes any new and useful improvement of any of them, and an alleged invention;"

Indian patent law as it is discussed above gives the list of some of the inventions which are not patentable according to chapter two of patent act 1970 as under:

(i) *"an invention which is frivolous or which claims anything obvious contrary to well established natural laws;*
(ii) *an invention the primary or intended use of which would be contrary to law or morality or injurious to public health;*
(iii) *the mere discovery of a scientific principle or the formulation of an abstract theory;*
(iv) *the mere discovery of any new property of new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;*
(v) *a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;*
(vi) *the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;*
(vii) *a method or process of testing applicable during the process of manufacture for rendering the machine, apparatus or other equipment more efficient or for the improvement or restoration of the existing machine, apparatus or other equipment or for the improvement or control of manufacture;*
(viii) *a method of agriculture or horticulture;*
(ix) *any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products."*

To deal the question of medicine, the patent act gives a separate section 5 as under:

With respect to medicines, the Patents Act 1970 introduced an independent section 5, which stated:

"Inventions where only methods or processes of manufacture patentable

In the case of inventions-

(i) *claiming substances intended for use, or capable of being used, as food or as medicine85 or drug, or*
(ii) *relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds), no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable."*

3.3.1. NOVELTY: INDIAN APPROACH

The definition of 'new invention' according to the Amendment Act of 2005 explain any invention or technology as novel which has not been anticipated anywhere in the world. This definition endorses absolute novelty as the criteria for patentability.

This condition for absolute novelty is limited by section 25 and section 64 of the Act which gives that an opposition or revocation can be continued only if the 'invention is publicly known or publicly used in India. The courts in India have observed that whether the supposed invention involves novelty and inventive step is a mixed question of law and fact that depends on the circumstances of the case. In Neiveli Ceramics & Refractories Ltd. v. Hindustan Sanitaryware & Industries Ltd. it was held that even the disclosure to one person of the features claimed an invention earlier than the so called invention date would be enough to defeat a claim of novelty.[44]

3.3.2. INVENTIVE STEP/NON OBVIOUSNESS: INDIAN APPROACH

Indian patent Act which was amended in 2005 elaborates inventive step as a characteristic of the invention which include a technical move forward as compared to current knowledge of that thing or is having some economic importance or both that makes the inventions non obvious for a person skilled in art. Patent office of India in accordance with the draft Manual on Patent Practice and Procedure considers the following factors to determine the inventive steps:

a. Contents and the scope of patent
b. Estimating that what can be achieved in the form of technical results and economic value
c. The change in prior art and the new invention
d. At the last, the determination of non-obviousness and etc

The Patent Amendment Act 2005 makes an immense significance for the economic value aspect and it alone can win the case of inventive steps.

The courts in India have at number of times held that the inventive step or obviousness has to be judged from the prism of a person skilled in the art.[45]An ordinary person skilled in art is the one who is aware of common knowledge in pertinent art at that time. In order to deny an invention from patent grant on the ground of prior disclosure, it must be shown clearly that the invention was published before the application for the grant of patent.[46]

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[44] ManojPillai and others, "patent procurement in india" Partner, LEX ORBIS IP Practice, <www.ssrn.com>(12 August, 2010)

[45] Kishore Mahadeo Pole, G.M. Walchnad Nagar Industries Ltd v. Thermax Pvt. Ltd 1988 PTC 213

[46] BomayAgarwal Co., Alolav. RamchandDiwanchand, AIR 1953 Nag.154

3.3.3. INDUSTRIAL APPLICABILITY/UTILITY: INDIAN APPROACH

The following conditions must be satisfied for the invention to be considered industrially applicable. The invention:

a. Can be made
b. Can be used at least in one field of activity
c. Can be reproduced with the same characteristics as many times as necessary.

To be patentable, an invention must be useful, but simple usefulness is not enough to hold the patentability of a patent application. Utility is not determined by the factor of commercial or financial success and has to be determined with reference to the state of things at the filing date of the patent application.

Section 3 of Indian patent act enumerates the subjects which cannot be patentable. Section 3(d) of Indian patent act also expels one of situation from patent grant and says:

> *"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use of a known substance or of the mere use of a known process, machine or apparatus unless such process results in a new product or employs at least one new reactant".*

In nut sell this section focuses to stop evergreening of patent and limits patentability of the invention to the inventions which give the enhanced efficacy. This section was aimed to differentiate between evergreening and incremental invention[47] and protects the public health needs. It is clear under this section that a mere new form of already know substance will not be subject to patentability. In explanation of the same section, the derivatives of known substance such a esters and salts are excluded from patentability if the substance do not shows distinction in its properties regarding efficacy.[48] This provision is aimed to encourage the invention by the patent. But this section does not give any specific criterion for the grant of patent and *TRIPS* negotiation also do not put any condition on member countries to implement a uniform standard of inventions.[49]

The term efficacy is not defined in both Indian and international al standards. The high court in India explained the efficacy in these words 'the ability of drug to produce a desired therapeutic effect'. Efficacy is not defined in American patent law as well in European patent system. However, the European regulation 2309/93 which deals marketing authorization of medical product says in its article 11 that "a marketing authorization shall be refused if it appears that the quality, the safety of efficacy of medical product have not been adequately or

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[47] Shamnad, Prashant, "Ducking *TRIPS* in india: A Saga involving Novartis and the legality of section 3(d)"
[48] Raju.Kd, " The debacle of Novartis patent case in India" <http//ssrn.com/abstract=1030963> (30th August, 2010)
[49] Bridge weekly, http://www.iprsonleine.org/ictd/news/bridge11-1-pg15-16.pdf (30th August, 2010)

sufficiently demonstrated by applicant".[50] In Unite d States, it is mandatory for a pharmaceutical product to submit the clinical trial of its effectiveness. Same is in India that to obtain a patent on a pharmaceutical drug, it is compulsory to submit therapeutic efficacy, bio-availability and bio equalance data with the application for market approval.[51]

The story of glivec started in 1960 when it was invented in school of medicine at university of Pennsylvania. This miraculous drug was to treat patients of chronic myelogenous leukemia, a form of cancer. Initially it was called imatinib and after improvement, its salt was named 'imatinib mesylate'. Novarits gained its patent and after improving it further the most stable version was formed which s particular polymorphic form, the beta crystalline form. Novartis formed it and named it glivec.[52] In beginning Novartis gained patent of this drug in 40 countries and in India claimed it drug h mailbox application system. After 2005, the product patent was introduced in India through amendment.[53] On the basis of new criterion introduce by new amended law the application of Novartis was rejected on three grounds[54]:

a. Lack of novelty
b. Lack of enhanced efficacy
c. Obviousness
d. Wrongful priority

After rejection of its application, Novartis and its subsidiary company in India filed two separate petitions for the reversal of the decision of patent office and the declaration of section 3(d) of Indian patent act as unconstitutional as it was the violation of Indian commitment through *TRIPS*. In the matter before the Chennai high court, the case was in process of arguments regarding the constitutionality and *TRIPS* compliance of Indian patent laws.

Novartis in its two petitions 24754 and 24759 of 2006, challenged section 3(d) of Indian patent act against the *TRIPS* and Article 14 of Indian constitution. Court took the matter of jurisdiction and decided that it is not the court to decide the matter between two nations and referred to forum given by *TRIPS* agreement itself to resolve the matter. High court on the point of jurisdiction said:

> *"Any international agreement possesses the basic respect the choice of jurisdiction fixed under such ordinary contract, we see no compelling reason to deviate from such judicial approach when we consider the choice of forum arrived at in international*

[50] European patent convention 1973, Article 11
[51] Raju.Kd(n-15)
[52] Raju.Kd(n-15)
[53] The patent amendment act, 2005, published in India, April 5,2005
[54] Shamnad, Prashant(n-14

treaties, since we have held that this court has no jurisdiction to decide the validity of amended section, being in violation of article 27 of TRIPS..."[55]

The second question raised by the petitioner was about the discretionary powers of patent examiner as it was alleged that those powers are arbitrary and can be misused and it is violation of article14 of constitution of India. The high court decided that the provision cannot be invalidated only on the basis that it can be misused.

We here will discuss some of the issues opinion of the honorable court upon them regarding compliance of the *TRIPS* agreement by India as the constitution of India guarantees the compliance of international agreements, court was of the opinion that it does not have jurisdiction to decide the matter as the true forum to settle all issues arising under

Unfortunately, the court took the matter of jurisdiction wrong and international contract was interpreted in the shape of ordinary contract. Rather it was great to have the notion of indirect effect of international treaty. So, Madras high court was wrong in its stance that it lacks jurisdiction as nothing in *TRIPS* agreement stoops it to do so. *TRIPS* makes it clear that the matter international will solved by DSU but domestic courts are free to entertain the domestic issues.[56]

3.3.4. EFFECTS OF *TRIPS* IN INDIA

In international law states are divided in two groups on the basis of implementation of international treaties: dualist states and monist states. Only monist states are those in which an agreement or treaty have direct effect but in dualist state, any of international treaty should go under the process of recognition from the state's legislature which means a dual process that event the treaty is signed between two states, it would go to another process of assent of state's legislature. India also represents herself as dualist state and article 253 of constitution of India empowers the parliament to implement any treaty, agreement or convention with any other country. So nobody can make the law invalid except the parliament.[57] Another example is of Gramophone Co. V Birendery Pandey case of indirect effect of international agreement where some pirated cassettes were on the way of transit under the transit agreement but were seized by the Indian customs. Court deciding this case faced the question of international agreement and national law of copy rights. In its decision court held that only innocent trade was allowed through and if international law is against national law than national law will prevail as the court truly incorporated the doctrine of English court which says that:

"rules of international law are incorporated into national law unless they are in conflict with the act of parliament."

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[55] (n- 15)

[56] Shamnad, Prashant(n-14)

[57] Andraperdesh V. Mcdowell& Com, AIR 1996, SC 1627

So based on this, the court held that:

"municipal law must prevail in case of conflict. National courts cannot say 'yes', if parliament has said no to a principle of law".[58]

So it is clear that the section 3(d) which talks about the efficacy of already known substance cannot be turned down on the bases only that it is against the international agreement by the domestic courts as it was created by the parliament and both English tradition and law in India shows that in conflict of international law against national, later will prevail.

In Novartis case, the court did not decide the *TRIPS* issue but disposed it off on the grounds of jurisdiction. Event the international forum if decides will decide in favor of India as article 27 of *TRIPS* agreement says that patents shall be available for any invention... provided that they are new, involve an inventive step and are not defend and this makes the state to define the patentability criteria keeping in mind the national interest of state.[59]

If we see the patentability criteria around the world, we will know that every state have defined it in its own interest and keeping in mind its needs. United state's patent and trade mark office (USPTO) revised its utility guidelines in 2001 to cater specifically to biotechnology inventions.[60]

In the same way section 3(d) of Indian patent act 1970 is meant to stop the evergreening of patent and in this way it saves the interest of public as large. In nut shell, the criteria of enhances efficacy enunciated by article 3(d) is in accordance with the *TRIPS* agreement and do not violate any of its provision.

Indian Supreme Court has set a rule for the striking down of any provision being against constitution in AndraPardesh V. Mcdowell on two grounds: lack of legislative competence and other is violation of fundamental rights being guaranteed by the constitution of India. The stance of Novarits in the case was that section 3(d) violates the fundamental rights of equality enunciated by article 14 of constitution of India. It was advocated that lack of specific criteria of efficacy led to the arbitrariness and in this way fundamental rights of equality was curbs. The concept of arbitrariness was discussed in Roypa V. Tamil Nadu case in the discussion that administrative action leads to arbitrariness and it is against section 14 of constitution of India, Justise Bhagwati held:

"Equality is a dynamic aspect with many aspects and dimensions and it cannot be "cribbed, combined and defined" within traditional and doctrinaire limits. From a positive point of view, equality is antithetic to arbitrariness. In fact equality and

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[58] Gramophone Co. AIR 1984, SC 667

[59] Shamnad, Prashant(n-14)

[60] www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf

arbitrariness are sworn enemies; one belong to the rule of law in a republic while other to the whim and caprice of a absolute monarch".

T.R.Andhyrujina in his famous work, the evolution of due process of law by the Supreme Court says that every inequality leads to an arbitrary action; the converse is not necessary true. So, a stature cannot be struck down mere on aground that it leads to arbitrariness. Madrass High court in Novarits case says that parliament is competent to delegate some functions to administrative body.

3.4. INTRODUCTION TO PATENTABILITY IN PAKISTAN

Patent is an exclusive right granted for an invention, which is a product or process that provided a new way of doing something or offers a new technical solution to a problem.[61]

A process or product patent will ensure the three qualifications of novelty, inventive steps and its industrial application in the countries like Pakistan and India[62]. We will now briefly discuss these three criteria in detail.

3.4.1. NOVELTY

Novelty is the term that connotes that the product or the process which is the subject matter of patent process should be new and this condition is enunciated to save the innovation and *Patent Ordinance 2000* explains the idea of novelty in Section 8, it says

"Novelty. - (1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall comprise-

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 or, where appropriate, the priority date, of the application claiming the invention; or

Contents of the complete specification and priority documents published under section21 of an application filed in Pakistan;

Traditionally developed or existing knowledge available or in possession of a local or indigenous community

Notwithstanding the provisions of sub-section (2), disclosure of a patentable invention in respect of goods shall not constitute 'state of the art' if an article is exhibited at an

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[61] *WIPO* hand book (n-1)

[62] *WIPO* hand book, <www.*WIPO*.int/edocs/mdocs/govbody/en/pct_a.../pct_a_36_10.doc>, (17th July, 2010)

official or officially recognized international exhibition within twelve months preceding the date of filing of an application The Patent Office Patents Ordinance 2000 for grant of patent. If later on, the right of priority is invoked, then the period shall start from the date of introduction of the article into the exhibition. The Controller may require proof, with such documentary evidence as considered necessary, of the identity of the article exhibited and the date of its introduction into the exhibition.

In this section references to the inventor include references to any proprietor of the invention for the time being"[63]

The aforementioned section defines novelty in negative and says that inventions lack novelty if they lack the state of art and the state of art are defined as the thing which is already disclosed to public by any way will not be patentable. In the Molins Case the patent application was of a way of distributing tobacco evenly in the generation of cigarettes on a higher speed machine. The method engaged pushing the tobacco in the same direction as the paper in which it would be wrapped. There was an earlier patent in respect of a slow speed machine. The subsequent application was held to have been anticipated by the earlier patent even though the movement in the older machine was not intended to cure the problem of uneven tobacco distribution.[64]

3.4.2. INVENTIVE STEPS

Inventive steps are the second condition for patentability of a thing and it is described in section 9 of *Patent Ordinance 2000* as under:

"Inventive step.- An invention shall be considered as involving an inventive step if it has not been obvious to a person, prior to the date of application for a patent, skilled in the art having regard to any matter which forms part of the state of art by virtue of section 8."[65]

These steps shows the various process to form the state of art defined in section 8 of the *Patent Ordinance 2000* and it says that those inventive steps should not be obvious to a person before the application for a patent grant is made. The requirements of novelty and inventive step mirror two separate objectives within the patent system. Gratifying creativity and the revelation to the public of what was not previously known justifies the condition of novelty, in that what is not new to the public cannot be said to be disclosed to it. On the other hand the rewarding and encouragement of the desirable art of inventing is promoted by insisting on the requirement of the inventive step, since what has not been obtained by

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[63] Patent Ordinance 2000 of Pakistan

[64] *Molins v Industrial Machinery Co Ltd.* [1938] 55 RPC 31

[65] *Patent Ordinance 2000* (n-3)

intellectual effort and activity is not regarded as appropriate for reward. The inventive step requirement also provides, at least in theory, valuable protection for the competitors of the applicant for the patent for, of something is obvious, it is already part of the totality of man's intellectual resources which should remain open and available to all.

The grant of monopoly to a product or process which is not new but merely obvious will inhibit competition in any field of industrial or technical activity in which a new product or process is used. In the recent case of Sindh high court in Merc & Co versus Hilton Parma (pvt) Ltd, the defendant did not disclosed the manufacture process was the cause for the grant of injunction to the plaintiff.[66]

3.4.3. INDUSTRIAL APPLICATION

Product or the process that is to be patented should have some industrial applications is the third condition of patentability in Pakistani law as the section 10 of *Patent Ordinance 2000* says:

> *"Industrial application.- (I) An invention shall be considered to be capable of industrial application if it is capable of being manufactured or otherwise industrially used."*

Bainbridge comments:

> *"Industrial application can be equated with technical effect, and if there is some technical effect, that is if the use or working of the invention produces some tangible and physical consequences or if the invention is itself a physical entity as opposed to information, then the requirement should be met".*[67]

Industrial application is the last and one of the important conditions for patent grant. It is same as the patent laws of United States and India.

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[66] 2003 CLD 407[Karachi]
[67] Bainbridge (n-5)

CHAPTER 4: ENFORCEMENT ISSUES OF PATENTS IN PAKISTAN AND PATENT VS. PUBLIC HEALTH DEBATE

4.1. ENFORCEMENT ISSUES OF PATENTS IN PAKISTAN

Pakistan, even after the expiry of time in 2005 for its global commitment under *TRIPS* agreement to harmonize its intellectual property to international standards, lacks the true system of enforcement of intellectual property rights especially patent protection. In spite of establishment of Intellectual Property Organization from its establishment under *Patent Ordinance 2000* and other steps being taken by it, the country needs to do more for the awareness and enforcement of intellectual property rights.[68] A number of problems are being faced in the wake of enforcement of intellectual property rights, especially patents.

4.1.1. Lack of Awareness regarding IP rights

The basic dilemma in Pakistan is lack of awareness regarding intellectual property rights. It is not possible for a person to respect the rights of other if he does not have a proper awareness of the after effects of it to himself. So, proper awareness regarding intellectual property rights is needed and people should be told that the infringement of intellectual property rights can cause the same blow to the fabric of society as the other property rights infringement can do.

Example is the patents in industry if they are violated, it will create an environment of non-competition and the process of innovation will stop and this will be fatal to the society and every one of us are the member of same society. If the infringement of intellectual property affects a person it will affect the society and the effects will return to everyone who is member of the society.

4.1.2. Lack of Legal Education in IPRs

In the legal educational institutions throughout Pakistan, a negligible number of institutions are imparting awareness regarding intellectual property rights to its graduates. The result is in the shape of scarce number of resource persons around Pakistan on intellectual property rights. The field of intellectual property rights is emerging and bears equal importance as of

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[68] http://www.ipo.gov.pk/trademark/TrademarkJournal.aspx (22nd July, 2010)

other fields of law. So, the awareness regarding intellectual property rights should be made through the teaching of it as essential subject to the law graduates.

4.1.3. Under-developed Intellectual Property Regime

Pakistan being the developing countries has still done a little to enhance its intellectual property regime. Establishment of Intellectual Property Organization and advent of modern intellectual property laws still need a clear and workable enforcement plan which should comply with the international standards as well as it should contain enough steps to ensure the providence of essential medicines to the poor masses of this country.

4.1.4. Enforcement agencies and Political environment

The political system of Pakistan is not only rotten internally but it also effects other institutions by its involvement. Enforcement of laws is barred by the influential politicians to save their own ulterior motives. One of the example of involvement is the intervention in patent grant by the then Minister of Health, Ijaz Khan Jakhrani in President Musharraf era which was criticized by the global community.[69] Need of the time is to make the enforcement of patents as well as other intellectual property laws free from any kind of political involvement.

4.2. INJUNCTIVE RELIEF IN PHARMACEUTICAL PATENT CASES

In Pakistan a number of cases have been registered against the patent infringement and the most common remedy prayed and granted is in the shape of grant of injunction to the plaintiff along with the monetary compensation. Patent infringement falls under the scope of *Patent Ordinance 2000* which was in past Patents and Design Act 1911. Being the civil matter, the award of injunctive relief is done under the Civil Procedure Code 1908 of Pakistan.

4.2.1. Injunction and Criteria for its grant

Injunction means to stop someone from infringing the right of other by making the party at fault to do something or restraining the party at fault from doing any thing. It is an equitable remedy by the help of injunctive relief the rights of party are guarded by freezing the things to the status that it should not harm any further against the victim party. Court also makes the arrangements of temporary injunction in some cases to get the time for determining the actual status of the contention between the parties and in this time both parties are restrained from doing anything which can change the actual position or status of the subject matter.[70]

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[69] Pakistan Pharmaceuticals & Healthcare Report Q3 2010

[70] Injunction, definition, <www.law.cornell.edu/topics/injunctions.html>, *(21st May, 2011)*

In pharmaceutical patent cases mainly if some infringement occurs, it is the first priority of the patent holder to stop the party infringing its right from further infringement and to save its exclusive right for his or her innovation. So, the prayer mostly contains the injunctive relief and in most of the cases, courts in Pakistan feel no hesitation from granting the injunctive relief to the party bearing the fault. Secondly, compensation is prayed and that is the matter of evidence and is granted after the proper enquiry into the matter.

Here are some of the basic conditions for the grant of injunctive relief in pharmaceutical patent infringement cases:

- Plaintiff should have balance of convenience and it should also exist in favor of plaintiff.
- The plaintiff would have suffered irreparable loss in case of not providence of injunctive relief.
- The third condition for injunctive relief is absence of adequate remedy as the compensation can be made in monetary form.

Application for injunctive relief is made under Order XXXIX, rules 1 and 2 and they should be read with section 151 of Civil Procedure Code 1908 of Pakistan to seek the temporary injunction against the defendant.[71]

4.3. CASES REGARDING INJUNCTIVE RELIEF IN PAKISTAN

Here, we will discuss some of the important pharmaceutical patent infringement cases of different nature but main is the remedy in the shape of injunctive relief.

4.3.1. MERC & CO. versus HILTON PHARMA (PVT.) Ltd

In this case the application was moved by the plaintiff under Order XXXIX, rules 1 and 2 and they should be read with section 151 seeking interim injunction against the defendant restraining them from further infringing the right of patent of plaintiff no. 134571 and other. The plaintiff prayed court to stop the defendants from importing, manufacturing, formulating and launching the Alendorate Sodium or any product relating to it. Alendorate was a new chemical being invented by the plaintiff who helps in treating the disease of Osteoporosis, a disease which makes the bones weakening and thinning. Plaintiff were dealing in this product with the name of FOSAMAX and the defendant using the same chemical by importing it from Supriya Chemical of India made the copy of plaintiff patent drug and made their own product with the name of OSTAD which was registered with the Ministry of Health and defendant was ready to market it in near future. For the above mentioned cause of action, the plaintiff moved to the court and prayed for the injunctive relief against the defendant restraining the defendant from making the drug available in the market.

[71] MERC & CO. Versus HILTON PHARMA (PVT.) Ltd, 2003 CLD 407

The court in this case made very wise decision on the basis of rationale and law regulating patents. As the process and the product of defendant was revealed as same to the product of plaintiff. On the same time defendant took the plea that the plaintiff is importing raw material for the drug at high cost but court after looking into matter decided that the end product in the shape of medicine did not have much difference in prices as the FOSMAX was of Rs. 65.80 and OSTAD of defendant was of Rs. 59.20. On the objection of defendant on the novelty of patent of plaintiff, the court decided that the matter should be dealt by the separate proceedings challenging the novelty of drug patent of plaintiff.

In the end court allowed the prayer of plaintiff by the award of injunctive relief as the application of plaintiff carried all conditions for the grant of injunctive relief.

4.3.2. GLAXO GROP LIMITED versus EVRON (PRIVATE) LIMITED

In this case the brief facts are that the appellant prayed the court for the permanent injunction with compensation of 30 million rupees and directions to deliver all stocks of copied drug. According to the appellant, the company was the inventor of ranitidine which was discovered and developed by Glaxo and is marked as hydrochloride salt called Zantac. Zantac was the largest selling drug who makes more than 1,000 million pounds sterling annually against its prescription. According to the appellant, the defendant is importing a drug named Melfax containing the same hydrochloride salt from Canada that is the violation of intellectual property laws of Pakistan.

Court of first instance in this case rejected the plea for the grant of permanent injunction on these grounds:

- The importer in this case is the mere importer and it does not amount towards infringement of intellectual property laws.
- The basic infringement if any is taking place out of Pakistan.
- The validity of patent is questioned by the defendant.
- The plaintiff was selling its product contrary to public interest.
- The delay in approaching the court to seek the right also bars plaintiff from his right.

But the court of appeal did not agree with the stance of the court of first instance and according the court of appeal section 2 (ii) of Patent and Design Act makes the plaintiff as the only privileged of making and selling the patent invention and section 12 of the same act also makes the plaintiff to use its invention exclusively. Regarding the question of infringement by the import of drug from a country the court made it clear that the process of Melfax is same as the process of plaintiff drug which is being protected by the patent of

Pakistan under patent no. 126632. So, it is clear that import of same drug has the same affects on the rights of appellant as it is manufactured in Pakistan.[72]

In this suit the appellant was granted the interim injunction on the aforementioned grounds till the decision of the court.

4.3.3. ENGLISH PHARMACEUTICAL INDUSTRIES versus SHIRE BIOCHEM INC

The plaintiff in this case alleged that they are the manufactures of pharmaceutical products in Pakistan. It was further submitted that they invented a compound LAMIVUDINE and registered their compound under patent no. 132128, 13268 and other which were gained by the controller of patent. It was further alleged that the plaintiffs had invested millions of dollars for the invention of the aforementioned compound. The same compound is being marketed by them in Pakistan under name of ZEFIX.

According to the defendants in first instance court, the patent of defendant expired in 2006 as it was registered under Patent and Design Act 1911 as the patent was registered in 1990. The trail court made the petitioner to supply product to the Government of Pakistan according to its contract and stopped the supply drugs to the market.

In this case the trail court favored the plaintiff by making the defendants to make the records available to the plaintiff and also ordered the defendants to give a bank guarantee to the plaintiffs. In appeal the court decided that if the patent of plaintiff expired than there is no need of bank guarantee and attributed it as cumbersome beside this appellate court did not interfere in the case and dismissed the petition.[73]

[72] GLAXO versus ENRON, 1992 CLC 2382
[73] English pharmaceutical Industries versus Sire Biocem, 2007 CLD 1570

4.4. PHARMACEUTICAL PATENTS

It is the perception of legal scholars that with the advent of patent laws in the field of medicine, the price of life saving drugs will rocket towards sky and it will be very difficult for the patients of developing countries to treat them against their common fatal diseases. It is true that if the enforcement of patents is done globally without any discrimination of developing and developed countries and moreover without the discrimination of life saving and ordinary drugs, it will create havoc for the poor population of the globe and the mortality rate will go high. Main concern is regarding the life saving drugs against the fatal diseases which are common in the world. If these are treated equal to other diseases than the drugs treated these diseases will go to high price and the monopolists will control the market. It will be easy for a few to control the market and gain undue profit from there inventions by getting patents against them.

TRIPS is an agreement that is basic document being recognized by international society of states and it gives a comprehensive system to deal with intellectual property laws in modern global arena. After the advent of *TRIPS* agreement the world faced the problem of providence of essential medicine and health care against the global patent regime. To discuss these issues, 4th Ministerial Conference was held at Doha in 2001. By the efforts of global community, *Doha Declaration* was made and the aim of this declaration was to find a prompt solution for the problem of developing and under developed countries those are not having enough capacity to manufacture pharmaceutical goods.

4.5.1. Plight of Public Health and Providence of Medicines in Pakistan

Pakistan being the developing country is slow in its progress of providence of basic health care facilities to its population. Having scarce resources, the government even goes to the lowest level in the world in the wake of facilitating its population. Only 20 percent of the population in Pakistan is being provided the basic health care facilities and the rest 80 percent don't even have access to basic health care. Pakistan is the country where the situation of nutrition, infectious diseases and high fertility is at its worse condition.[74] Some of the basic issues regarding health care in Pakistan are negligent governmental behavior towards health and the other is absence of any system to facilitate its population in the field of health.

In last 20 years, it has seen a rapid change and some of the positive steps are being made by the government to provide its population a good health care system but still Pakistan need to

[74] Aziz urRehman, Hafiz, "*TRIPS* and Public Health: Implications for Pakistan", Islamabad Law Review,P457, Vol 1:3&4

go far in the field of providence of basic health care facilities at the door step of its population.

Pakistan, in the field of health care, is having two parallel systems, one is regulated by the government in the field of hospitals established by the government and are working under the Ministry of Health and other is private set up of hospitals around the Pakistan. Now, the government needs to focus on two fronts of which one is to maintain its own hospitals and other is to create a system of check and balance regarding private hospitals.

In spite of growth in last two decades, the plight of health care is not of international standards and the mortality rate is very high than the neighboring countries and Pakistan needs to go long way to make its public health sector side by side with international standards.

Currently, the budget allocated to the health in Pakistan is seriously affected by the flood and war against terrorism. Now after the flood the after effects are appearing and a number of diseases are spread in the flood hit area such as tuberculosis, malaria, pneumonia and etc. Government seems helpless in meeting the commitment of providence of essential life saving drugs to treat these diseases and if the proper steps are not taken it will be fatal to the population suffering from diseases in flood hit areas.

4.5.2. Pharmaceutical Industry versus Patent Protection

Before the advent of *TRIPS* and Pakistan became the signatory to it, Pakistan did not have any strong patent protection regime and the law regulating patents in Pakistan was known as Patent and Design Act of 1911. This act, although, was a good legislation working since the era of British. But the globalization of intellectual property laws and advent of *World Trade Organization* made the old legislation as useless. Multi-national companies criticized the old act as it did not provide the robust criteria to save their innovation and monopoly. So, the efforts were made by different channels and pressure was built upon Pakistan to make its patent laws in accordance with international standards and to comply with the *TRIPS* requirement.

As the result of this complain, a revised legislation regarding patent was presented in National Assembly in 1989 but the move was not successful as it was rejected on the apprehension that the modern patent regime under modern law will enhance the price of medicine in a country where 140 million of its population earn less than 1 dollar per day. The pressure went on for the legislation regarding patent protection and monopoly over invention. Pharmaceutical Research and manufacturer Association said that the violation of product patent in Pakistan is resulting in the shape of loss of 15-20 million US dollars.[75]

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[75] Aziz urRehman, Hafiz, <www.pharma.org>

Pakistan after all these demands promulgated its law regarding patents in the shape of *Patent Ordinance 2000.* This newly promulgated ordinance has been working for 10 years and it complies with *TRIPS* requirements. Government has introduced several amendments in it and the most important in the amendment of 2002.

Current legislation is aimed at providing essential medicine to the public to support its health as well as the global demands under *WTO* and *TRIPS* agreement. On one side this legislation will harmonize the patent laws of Pakistan with the laws of international society of states and on other side it aims to protect the public of Pakistan from arbitrary enjoyment of monopoly of patents by delimiting it to a sphere.

Pharmaceutical industry in Pakistan is divided into two main groups and of which one is local which demands a soft patent protection and takes the refuge of low cost of medicine against the strong patent protection. On the other hand are the demand of companies and majority of them are multi-national about the strict observance of their patent invention and monopoly. This issue can be solved easily by taking all concessions being providing by international agreements regarding patents to protect the public health by the way of strong price control of pharmaceutical drugs regardless of national or multi-national companies.

4.5.3. Public Health, a Public Policy Matter

Constitution of Pakistan 1973 makes the issue of public health under Article 38 (4). Public health in Pakistan is not dealt under the heading of fundamental rights and by the way of this it us dealt as the injustice able rights and contrary to fundamental rights constitutional courts are not duty bound to enforce them. Fundamental rights are constitutionally guaranteed rights and the constitutional courts are bound for the protection of fundamental rights. Public health is discussed under public policy heading in constitution and all these are the public policies drawn by the social contract of Pakistan. Through the social contract, constitution of Pakistan, the state authority has made it obligatory upon itself to ensure the basic facilities of life for its citizens.

Pakistan is an Islamic state and it has made a number of commitments to its inhabitants in the shape of policy matters. Policy matters are the basic guidelines for the state organs and machinery to ensure certain things according to the desires and needs of the citizens of Pakistan. Now, even if the policy matters, being injustice able rights cannot be enforced through the courts of law yet they are basic line of actions for the state departments to ensure them impliedly. Pakistan has taken a number of steps to ensure the public health up to the mark as its policy matter by establishing medical facilities around its territory and introduced a number of laws and regulations to organize its laws regarding providence of health.

Now, the issue of providence of essential medicine in the era of globalization of intellectual property rights by the advent of *World Trade Organization* and the international legislations

under its umbrella in the shape of *TRIPS* makes Pakistan on the juncture where it has to take two tasks at one time. First is to harmonize its laws to international commitments and other is to ensure the public health as it is one of the head under public policy matters enshrined in Constitution of Pakistan 1973.

TRIPS agreement under its introduction gives a number of concessions to its signatories to help its population improving their health and gives a clear provision in the its Article 27.2 gives the exception for the ordre public and mortality as exception to patentability and patent can be refused under this provision.[76] Article 30 gives a number of exceptions for research and experimentation, early working and it means to put generic drugs in market as soon as patent expires, bona fide use of invention by third party before the patent. Article 31 empowers the states to use the power of compulsory licensing under *TRIPS*. By the power of compulsory licensing a state can authorize any party to manufacture the patent product without authorization of the patent holder and in return government will pay to the patent holder the adequate compensation. Compulsory licensing can be used against the undue monopoly over patent and the general masses can be protected if the patent holder makes the invention away from public benefit.

Need of the time is to use all these legal concessions and by the proper utilization of them a system can be developed through which the providence of essential life saving drugs can be made without violation of international standards of patents.

4.5.4. Regulations for the Pharmaceutical Industry

Ministry of health is the basic regulatory institution which deals with the pharmaceutical industry using the powers conferred upon it by the way of drug act 1976, which provides a potent pharmaceutical pricing and market system and in addition to this a market recognition mechanism is being devised by the ministry of health which can be used to reject any new chemical from sale. Up till now the registration board of ministry of health has registered approximately 40,000 brand names of which 14,000 were molecules.

Recently in October, 2009, ministry of health cancelled the registration of 4,000 imported medicines in the result of objection by the local industrialists and this was in the wake of supporting pharmaceutical industry of Pakistan.

Intellectual property rights are now internationally recognized and Pakistan being the member of Berne convention, World intellectual property rights organization owes duty to make its intellectual property laws in accordance with the international agreements and moreover Pakistan as a member of *WTO* is the party to *Trade Related Intellectual Property Rights Agreement* (*TRIPS*) and under this it was due on Pakistan to uniform its laws in conformity with *WTO* agreements by the end of 2005 which is still in pipeline. The

[76] Article 27.2, *TRIPS* agreement

government of Pakistan has been criticized because of this on so many occasions but on the other side it has to protect the right of citizens of low price medicines as the patented medicine are away from the reach of not only low class but also of middle class. In the recent pharmaceutical report of 2010 it is shown that the basic consumers of patented drugs in Pakistan are the high class businessmen, bureaucrats and etc.

According to report of pharmaceutical industry 40 to 50% drugs available in market are fake and the industry in Pakistan is stuck between the counterfeit drugs and patenteted one. If the government of Pakistan ensures the world standards of patent than it makes the essential medicines out of the reach of common people and on the other side if it goes in the favor of local pharmaceutical industry than it has to face the strong criticism from the international community and moreover in the shape of trade sanctions but priority should be given to health care along with the harmonization of intellectual property laws with international standards.

One of the basic problems of Pakistan is that it is not having any concrete monitoring system to control the counterfeit drug and make the difference between life saving drugs which are essential for human life and other ordinary drugs. International agreements like *TRIPS* do not stop any country from providence of essential life saving medicines to public as it is the duty of a state to act for the welfare of state. In the positive development regarding counterfeit drugs, the government of Pakistan has increased the number of courts dealing the counterfeit drugs from nine to 20 and this will help the administration to control the fake medicine.

4.5.5. Patentability Issues in Pakistan

After the advent of *World Trade Organization* and a number of international agreements like *TRIPS*, Pakistan has introduced some five laws relating intellectual property rights including *Patent Ordinance 2000* and an amendment 2002.[77] Pakistan has introduced patent standards as are introduced by the global community but every country has the right to protect the public health and it is also duty of state to ensure international commitments. Era of globalization of intellectual property rights have double impact on the world, on one side it is beneficial for the global pharmaceutical industry of developed states and on the other side it is harmful for the developing and under-developing countries as the harmonization of domestic intellectual property rights with international standards make the public utility things out of the reach of common men. Pakistan being among the developing nations as is ascribed by the international community has made a number of moves for the harmonization of intellectual property law with international standards but unfortunately the efforts have not paid well in the shape of totally patent atmosphere and a number of causes are behind this in the shape of poverty, war on terror, natural calamities and etc. Indian patent system is also one of the parallel systems of intellectual property that deals very smartly in the form of

[77] Pakistan Pharmaceutical Healthcare Report 2010 (n-35)

protection to its own local interests and international standards. Pakistan also have done a number of moves to contend the international community by keeping in mind the local interests but the case of Pakistan is totally different as India is more successful in contending international community by its smart legislation and intellectual work in the field of intellectual property laws and specially in patent regime. Global intellectual property laws do not stop any country from the protection of its population from fatal diseases. In India the recent development is in the shape of Novartis case were the patent was rejected subject to its legislation in the shape of section 3(d) which stopped any new thing or substance to be patented if it does not increase in efficacy. By the rejection of this patent the right of life saving drugs was protected and it was justified by different writers and international community.[78]

In Pakistan, we have protected our local interests by different ways and they are the strict pricing system, market recognition (which is same as is in European patent system) and etc. after the advent of *TRIPS*, the other positive development in the field of pharmaceutical patents is the *Doha Declaration* which gives a safeguard against the unaffordable and much needed drugs. *Doha Declaration* gives the right to *WTO* members to protect the right of promoting public health and access to essential medicines.[79] In Pakistan about 40% of the population is earning less than one dollar a day and government is proving the health care facilities to only 20% of its population[80] and if the international standards are being applied in Pakistan without any improvement in government facilities than the situation of mortality of child/mother and deaths because of diseases will be common.

4.5.6. International Patent Standards and Local Needs in Pakistan

In Pakistan, patent laws have never been strict but after the advent of *TRIPS* agreement, the pressure was built against Pakistan to bring its laws in accordance with the international agreement and that is why the patent act 1911 was replaced by the *Patent Ordinance 2000* in December 2000 and it was deemed a positive move in the field of harmonization of patent laws of Pakistan with international agreements. After the strong criticism this act was amended in 2002.

The *TRIPS* compliance was certainly leading to the increase in the price of medicines and especially in the shape of increase in life saving drugs. According to the survey of World Health Organization (WHO) one third of global population does no t have access to essential drugs and same is the case with Pakistan. A flood of patent applications are waiting in the

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[78] Kd, Raju (n-15)

[79] Rehman, Hafiz, "*TRIPS* and public health: implications for Pakistan", Islamabad law review, p475, Vol 1:3&4

[80] Patent ordinance (n-3)

mail box and if patents are being granted to all of them than the situation will go worse and will create an atmosphere of costly drugs and it will increase mortality rate in Pakistan.

In this wake there are two basic challenges waiting for Pakistan and they are the providence of basic health care medicines to its citizens and on the same time the compliance in the shape of international agreements. Now it is the time for Pakistan to think wise and use all concessions being provided by international agreements to same its population from diseases. Pakistan should carefully draw its intention to the Indian patent model in the shape of patent amendment 2005 which stops the evergreening and other abuses of patents. Especially a wonderful model in the shape of section 3(d) which stops a new patent of already used salt or any substance unless and until it enhances the efficacy and is productive for the population. If it is not done than the patent can be used by international pharmaceutical companies to abuse the cheap medicine market of Pakistan. It is time to be vigilant and introduce smart legislation which equally contents international agreements and population of Pakistan.

Pakistan, being the developing country, lacks enough progress in the field of education and industry. So, the implementation of intellectual property rights, especially of patent rights is a challenge. There are number of factors involved in the fragileness of implementation of intellectual property laws in Pakistan and they are education, industrial backwardness and etc. Although, a number of moves have been made by the state to harmonize its intellectual property laws with the global standards but still more is demanded. After being the signatory to *TRIPS*, *Doha Declaration* and other global commitments under the umbrella of *World Trade Organization*, it is obligatory on Pakistan to make its intellectual property laws In accordance with the international standards set by international community of states.

In pursuance of its global commitments, Pakistan has introduced a modern legislation on Patent protection in the shape of *Patent Ordinance 2000* and an amendment in it during 2002. Through this law a number of global commitments are abided by Pakistan. Still we need to do more according to global community. In 2006, the representative of United States Office of Trade Mark moved Pakistan from its priority watch list to lower level because of its fragile implementation mechanism in the field of intellectual property and a large criticism was made for not protecting the global intellectual property rights.[81]

Pakistan at this juncture of time faces two fronts to fight in the shape of providence of essential life saving drugs to its poor population which is already hit by the war against terrorism, shaky economy, poor medical facilities and industrial backwardness and on the other hand Pakistan is indebted from the global commitments in the shape of *TRIPS* and etc to make its laws in accordance with international standards till the end of 2005 and the time is already elapsed.

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[81] Pakistan Pharmaceuticals & Healthcare Report Q3 2010

Implementation of *TRIPS* and other global commitments will be fatal to the right of public to good health if the enforcement mechanism is not dealt sharply. *Trade Related Intellectual Property Rights Agreement* has a wider scope to for the state to support its population in the field of providence of essential medicine and the same is highlighted in the *Doha Ministerial Declaration.*[82]

Pakistan is in need of taking both aspects of enforcement of international standards of intellectual property rights as well as using all modes being granted by international treaties to help its population in the field of intellectual property rights.

[82] Bently, Lionel, "Communication to Thing: Historical Aspects to the Conceptualization of Trade Marks as Property"<http://ssrn.com/abstract=1034177>, (21st May, 2011)

SUGGESTIONS AND RECOMMENDATIONS

Pakistan, being the developing country, is striving hard to harmonize its laws with the global intellectual standards. On the same time Pakistan has been trying to guarantee the essential life saving drugs to its masses. This task is a tricky and challenging. The divide in the world is between producers and consumer countries. Pakistan, being backward in the field of science and technology is facing problem in many field and the most important of all is the field of pharmaceutical where absence of life saving medicine is fatal for its inhabitants.

Globalization of intellectual property laws and their uniform implementation leads towards the price hike in medicine industry and the monopolist if not controlled can easily grab the lives of innocents. With the advent of international rules in the shape of TRIPS and other international legislations, it makes compulsion on Pakistan to harmonize its laws with the global standards. Now, in order to meet both demands of meeting international standards of patents and providence of essential medicines on public friendly rates, following are the suggestions and recommendations:

1- Patentability is a subject of relevant state to define it. Now, the patentability criteria should be drafted on strong patterns that it should help the providence of essential medicines and should help avoiding un-wanted patent grants. The best guidelines can be taken from the Indian Patent Act 1970 under Section 3(d).
2- Price control mechanism is also one of the ways to control the prices of life saving drugs. By the smart designing of it, the price of life saving drugs can be cheapened. Need is to draw a distinction between essential life saving drugs and ordinary drugs.
3- Compulsory licensing is another tool which can be used by the government to control the arbitrary use of monopoly over certain life saving drug. Rules enunciated in Pakistan are worthy enough to solve the issue of high priced drugs. But the need is to use the power of compulsory licensing. Pakistan should use this power which is given to it by its Patent Ordinance 2000 as well as TRIPS Agreement 1994 irrespective of any pressure of influential states.
4- Pakistan should show its vigilance in using the concessions being provided by the international legislations and declarations. This may invite global criticism in negative way but the intelligentsia and academicians should put their energies together to justify the acts of enjoying concessions by the country.

Patent system of Pakistan is not developed as compare to the systems of United States, United Kingdom and India. Pakistan needs a strong plan to develop the under developed patent system which should cover its health as well as academic needs. Actions to harmonize patent laws in Pakistan should be defended by the academicians and lawyers. So, it is the need of the time to put our energies together to build a robust patent regime which should cover all international standards as well as should help the poor fraction of society to maintain their health.

Aforementioned, suggestions and recommendation are based upon the comparative study of patent regimes in India, United States and Pakistan. Pakistan should make it clear to the world community that it will comply with global patent commitments and will also benefit from all concession being awarded to it though the same commitments. This can be done by the intellectual campaign in the shape of research developments in the field of patents. India has currently moved towards the use of compulsory licensing which is strongly supported by the academic intellect.

In my view, Indian patent model is best to be taken as guideline and the patentability criteria should be reshaped in a way that it should protect the public health and the global commitments. World is divided into two parts of developing and under developed countries, manufacturing and importing. Pharmaceutical manufacturing countries are of the view that they invest their resources and funds in research and developments of medicines; so, they should be paid back in the shape of monopolies. Developing and under developing countries should make it clear to the world that some of areas of patent grant should be excluded or should be given some concessions from strong patent regime in order to save the world population from fatal diseases.

Need of the time is to develop a patent system which is equally workable for the developing and developed countries. A patent regime should be developed which is equally beneficial for the patent holder and humanity of the globe. Pakistan and other developing countries should go on a step forward in intellectual field to convince the global pharmaceutical manufacturers that 'humanity first' should be the order of time.

Bibliography:

1. Legal Texts & Related Measures

1.1) Trade Related Intellectual Property Rights Agreement 1994

1.2) Doha Declarations

1.3) Patent Ordinance 2000 of Pakistan

1.4) Patent Act 1970 of India

1.5) Patent Act 2005 of India

2. PUBLICATIONS & PAPERS

- Kersnik J. Peklar J. Attitudes of Slovene general practitioners towards generic drug prescribing and comparison with international studies. J Clin harmTher. 2006; 1: 577-83.
- Santoro, Michael (1992) "Pfizer: Protecting Intellectual Property in a Global Marketplace," Harvard Business School Case Study no. N9-392-071.
- Tempest B. India: A global strategicasset for developed world market businesses. Journal
- Dilip K. Das; Intellectual property rights and Doha Round; The journal of world Intellectual Property, 33- 41
- Frederick M. Abbot; The Doha Declaration On The TRIPS Agreement And Public Health: Lighting A Dark corner At The WTO, Journal of International Economic Law, Oxford University Press; 469- 505.
- Gambardella, Alfonso (1995) Science and Innovation: The U.S. Phamaceutical Industry during the 1980s. (Cambridge: Cambridge University Press).
- Daniel Kahneman& Amos Tversky, Prospect Theory: An Analysis of Decision Under Risk, 47 ECONOMETRICA 263, 266 (1979)
- Viet D. Dinh, Yes to the Patent Reform Act, THE AMERICAN SPECTATOR (Dec. 3, 2007), available at

http://www.spectator.org/dsp_article.asp?art_id=12378 (last visited Oct. 6, 2008

- Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, „The Price of Innovation: New Estimates of Drug Development Costs□ (2003) 22 Journal of Health Economics 151.
- Michael Kremer and Rachel Glennerster, Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases (2004).
- Aidan Hollis, „A Comprehensive Advance Market Commitment: A Useful Supplement to the Patent System?□ (2008) 1 Public Health Ethics
-
- Philip J. Cook & Charles T. Clotfelter, The Peculiar Scale Economies of Lotto, 83 AM. ECON. REV. 634, 637-38 (1993
- Keayla, B. K. (1996) "New Patent Regime: Implications for Domestic Industry, Research and Development and Consumers," National Working Group on Patent Laws (Center for Study on GATT Laws). New DelhiHamied, Y. K. (1993)
- "Patents and the Pharmaceutical Industry: A Review," Presentation at the International Conferenc on Patent Regime Proposed in the Uruguay Round, New Delhi. Cipla, Ltd.

3). WEB SITES

- World Trade Organization (www.wto.org)
- World Intellectual Property Organization (www.wipo.int)
- World Health Organization (www.who.int)
- Social Scienced Research Network (www.ssrn.com)
- www.scribd.com
- www.ipo.gov.pk
- www.patentoffice.nic.in
- www.uspto.gov
- www.freepatentonline.com
- www.pakistanlaw.com
- www.irfanandirfan.com
- www.nclegal.com
- www.pakistanlawsite.com

4) List of Cases

1- Shire Biochem v English Pharmaceutical 2006 C L D 1038 (Lahore)
2- Pfizer Ltd v Wilson Pharma 2002 C L D 1653 (Karachi)
3- Merc& Co v Hilton Pharma 2003 C L D 407 (Karachi)
4- Glaxo Group v Evron Ltd 1992 C L C 2382 (Karachi)
5- Smith Kline & French Laboratories Lt . and another v. Feroze Sons Laboratories Ltd. and another 1992 MLD 2226
6- Glaxo Group Limited and 2 others v. Pakistan Pharmaceutical Products (Pvt.) Limited 1991 MLD 85
7- Rexona Proprietary Ltd. v. Majid Soap Works PLD 1956
8- Atco Lab.(Pvt.) Limited v. Pfizer Limited and others '2002 CLD 120
9- Glaxo Group v. Evron (Pvt.) Ltd. 1992 CLC 2382
10- Mere & Co. Ing. and others v. Hilton Pharma (Pvt.) Ltd. 2003 CLD 407