IMPLICATIONS OF PATENTS ORDINANCE 2000 ON THE PHARMACEUTICAL INDUSTRY IN PAKISTAN

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A thesis submitted in partial fulfillment
of the requirement for the degree of Master of Law
(Faculty of Shari'ah and Law)
International Islamic University Islamabad

2005

1- Patents- Pakistan
2- Patent Laws and legislation. Pakistan

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Dedicated

to

My Parents

for leading me into intellectual pursuits

My Wife

for her support and cooperation

My Children

for making life a pleasure

ACKNOWLEDGMENTS

I only have been able to complete this dissertation because of the special blessing of Almighty ALLAH. First of all I wish to thank to Almighty ALLAH for the courage, power and resources HE granted me to complete this dissertation.

I also wish to acknowledge my debt to all my teachers of LLM, specially Hafiz Aziz-ur-Rehman.

I am particularly grateful to my Dr M. M. Mirza for his moral support, time and discussions I made with them on different points.

Finally, in the last my special thanks are for all those people and institutions who have placed valuable data and information on the internet to help the students undertaking research work.

INTRODUCTION

The information and original expressions of creative individuals i.e. inventions, literary and artistic works, and symbols, images, names, and designs used in commerce, is known as intellectual property (IP).

Safeguarding these property rights fosters economic growth, provides incentives for technological innovation, and attracts investment that will create new jobs and opportunities Artists, authors, inventors, and others unable to rely on locks and fences to protect their work turn to IP rights to keep others from harvesting the fruits of their labour. Copyrights, patents, trade secrets and trade marks are different forms of intellectual property.

Pakistan is among one of the 149 member countries in the world who have signed the 1994 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), the treaty to strengthened legal protection for patents. In accordance with the TRIPS agreement, Patents and Design Act 1911 was repealed and Patents Ordinance, further amended in 2002, was promulgated in Pakistan.

In order to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barrier to legitimate business. Patents Ordinance 2000 was promulgated which, however, has resulted in increased litigation.

1.1 STATEMENT OF THE PROBLEM

Patents Ordinance 2000 and the Patents (Amendment) Ordinance 2002 have adversely affected the pharmaceutical industry in Pakistan.

1.2 AIM OF THE STUDY

In the present study, the research's aim is to study thoroughly the intellectual property as well as other matters relating to the infringement of patents. During the study the researcher has come across the abuse of patent rights by patent holders, where they unlawfully threaten with the proceedings for infringement of a patent.

The Patents Ordinance 2000 was promulgated on 2nd December 2000 by the then President of Pakistan at a time when the Chief of Army Staff took over as Chief Executive of Pakistan. Afterwards this Ordinance became the part and parcel of the 17th Amendment in the Constitution of 1973. Although the Government of Pakistan has made certain amendments in the Patents Ordinance 2000 in order to safeguard the national interest within the framework of guidelines laid down in the TRIPs agreement, there is still much to be done in the Patent Amendment Ordinance 2002 to make it a truly balanced Ordinance which not only provides protection to the Patent right holders but guarantees that the law does not itself become a barrier to the legitimate business.

In this study the ambiguity, incompleteness and inconsistency in the Patents Ordinance 2000 will be discussed thoroughly in the following pages. In this thesis the researcher has studied a few cases relating to Patent infringement in Pakistan prior to the promulgation of Patents Ordinance 2000 and found the increased

trends of litigations in the Pharmaceuticals industry after the issuance of Patents Ordinance 2000.

The aim of my study is to find out whether by virtue of Patent Ordinance 2000, and an Amended Patents Ordinance 2002. It has adversely affected the pharmaceutical industry in Pakistan whereby the attention of industrialists have been reverted toward the courts of law in order to either protect their Intellectual Property Rights or defend alleged infringements.

1.3 METHODOLOGY

The present study is descriptive in nature and the researcher has discussed the patent laws, both the existing and repealed ones, with reference to increase the litigation in the pharmaceutical industry in Pakistan because it has badly affected the pharmaceutical industry. In this research, the researcher has identified the relevant areas in the Patents Ordinance 2000 critically, and Patents Amendment Ordinance 2002.

1.4 DATA COLLECTION

In the course of my research, I researcher has visited various Libraries of Islamabad, Rawalpindi, Lahore, particularly, Dr. Muhammad Hamidullah Library, Islamic Research Institute, Islamabad. Central Library, International Islamic University, Islamabad and National Library, Islamabad. As we are living in the first decade of the 21st century, the internet is very frequently used in research. The researcher has used very frequently various websites of the Internet for the collection of relevant material for his thesis.

CHAPTER TWO

LITERATURE REVIEW

There are a number of books on law in each library, but a few books are available on Patents Law in Pakistani Libraries, therefore, the collection of the relevant material for the researcher was not an easy job. Even the selection of the collected material was also more difficult job for the thesis writer. So far there is a lack of literature available on the topic especially with reference to patents and pharmaceutical industry in Pakistan, because of very little awareness of the masses on the subject Research will be based on study of the implication of prevailing Patents Law on pharmaceutical industry due to increase in litigation in Pakistani courts.

Laws of Trade Mark, second edition, by Salil K. Roy Chouwdhury, came out of the press in 1999 from Kamal Law House Calcutta, India. It deals with the History and Definition of Patent. The writer has traced the origin of the Patents Laws in British India and has given the history of the Patents Laws in British India and thus has traced the date when these patents law were repealed through Patents and Designs Act 1911.

Trade Marks Act and Rules, first edition 2001, by Ali Asghar. This work is published by Pioneer Book House, Karachi. The book is about the Meaning of Patent and described invention with reference to process, preparing or making, or produced through manufacture.

The World Trade Organization (WTO), located in Geneva, deals with the rules of trade between nations at a global or near-global level. It's an organization

for liberalizing trade, a forum for governments to negotiate trade agreements and a place for them to settle trade disputes.

Patents Ordinance, 2000 (Ordinance No. LXI of 2000): An Ordinance to amend and consolidate law relating to the protection inventions, Gazette of Pakistan, Extraordinary, 2nd December 2000. Prior to the introduction of this Patents Ordinance the Patents and Designs Act 1911 was repealed by Patents Ordinance 2000. In fact the Government of Pakistan had signed Trade Related Aspects of Intellectual Property Rights (TRIPS) in 1995, therefore, it was necessary to promulgate new ordinance in accordance with TRIPS agreement. Under TRIPS agreement, member countries, WTO members have to provide patent protection for any invention, whether a product (such as a medicine) or a process (such as a method of producing the chemical ingredients for a medicine), while allowing certain exceptions. Patent protection has to last at least 20 years from the date the patent application was filed. Members cannot discriminate between different fields of technology in their patent regimes. Nor can they discriminate between the place of invention and whether products are imported or locally produced. However, the governments can refuse to grant patents for three reasons that may relate to public health:

- inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health
- diagnostic, therapeutic and surgical methods for treating humans or animals
- certain plant and animal inventions.

Under the TRIPS Agreement, governments can make limited exceptions to patent rights, provided certain conditions are met. For example, the exceptions must not "unreasonably" conflict with the "normal" exploitation of the patent[1]. Many countries use this provision to advance science and technology. They allow researchers to use a patented invention for research, in order to understand the invention more fully. In addition, some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval — for example from public health authorities — without the patent owner's permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision[2].

Governments can also act, again subject to certain conditions, to prevent patent owners and other holders of intellectual property rights from abusing intellectual property rights, "unreasonably" restraining trade, or hampering the international transfer of technology[3].

There is another very important exception in the agreement that allows compulsory licensing as part of the agreement's overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs. Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of

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[1] Articles 27.2, 27.3a, 27.3b TRIPS Agreement

[2] Articles 8 TRIPS Agreement

[3] Articles 8 and 40 0f TRIPS Agreement

the patent owner. In current public discussion, this is usually associated with pharmaceuticals, but it could also apply to patents in any field — and the TRIPS Agreement does prohibit discrimination between fields of technology. Compulsory licensing and government use of a patent without the authorization of its owner can only be done under a number of conditions aimed at protecting the legitimate interests of the patent holder.

In addition, the agreement also provides exceptions of parallel imports/grey imports which allows imports of products made and marketed by the patent owner (or trademark- or copyright-owner, etc) into another country without the approval of the patent owner.

However, for pharmaceuticals and agricultural chemicals, countries eligible to use this provision (i.e. countries that did not provide protection on 1 January 1995) had two obligations. They had to allow inventors to file patent applications from 1 January 1995, even though the decision on whether or not to grant any patent itself needed not be taken until the end of that period. This is sometimes called the "mailbox" provision (a metaphorical "mailbox" is created to receive and store the applications). The date of filing is significant, which is why the mailbox provisions were set up. It was used for assessing whether the application meets the criteria for patenting, including novelty ("newness"). The governments also allowed the relevant pharmaceutical or agricultural chemical product to be marketed during the transition period, subject to certain conditions an exclusive marketing right for the product for five years, or until a decision on a product patent was taken.

Thirteen WTO members — Argentina, Brazil, Cuba, Egypt, India, Kuwait, Morocco, Pakistan, Paraguay, Tunisia, Turkey, United Arab Emirates and Uruguay notified "mailbox" systems to the TRIPS Council, indicating that at that time they did not grant patent protection to pharmaceutical products. Some of these have now introduced pharmaceutical patent protection — such as Argentina, Brazil, Guatemala, Morocco and Turkey.

Patents Amendments Ordinance 2002, this ordinance was an amendment in Patents Ordinance 2000, by substitution and edition of some sections. The amendments of the ordinance made it a balanced ordinance.

GATT Agreement: General Agreement on Tariffs and Trade (GATT) had provided the rules for the system. It did not take long for the General Agreement to give birth to an unofficial, *de facto* international organization, also known informally as GATT. The purpose of this agreement was to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.[4]

After the promulgation of Patents Ordinance 2000 thereby making the Patent laws in accordance with the guidelines laid down by the TRIPS agreement, certain confusions have arisen. According to the point of view of multinational patent holders, in order to implement Patent laws, certain amendments may be required in the Drugs Act 1976. According to this point of view, any medicine

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[4] Trade Marks Act & Rules. First Edition. Ali Asghar. (Karachi: Pioneer Book House, 2001), p. 285.

allegedly infringing the patent holders' right may not be registered, allowed to be imported, marketed or sold in the country.

CHAPTER THREE

HISTORY AND DEFINITION OF PATENT:

Intellectual property refers to creations of the mind: inventions, literary and artistic works, and symbols, names, images, and designs used in commerce[5]. Intellectual property is divided into two categories:[6]

- Industrial property, which includes inventions (patents), trademarks, industrial designs, and geographic indications of source; and
- Copyright, which includes literary and artistic works such as novels, poems and plays, films, musical works, artistic works such as drawings, paintings, photographs and sculptures, and architectural designs.

In the United States, patent law dates to 1641, when the first patents for inventions were issued by the Massachusetts Bay Colony for the manufacture of salt[7].

As trade increased in the 19th century, many countries adopted laws recognizing the legal rights of trademark owners. These laws prohibited other

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[5] Facts Sheet. TRIPs and Pharmaceutical Patents- Obligations & Exceptions.WTO. Geneva 21-Switzerland

[6] Facts Sheet. TRIPs and Pharmaceutical Patents- Philosophy-TRIPs Attempts to Strike a Balance. Geneva 21-Switzerland

[7] Manual of Trade Marks, Merchandize Marks and Patents and Design.1998- Abdul Wahid Chaudhry. Nadeem Law Book House- Lahore.

sellers from using similar marks that might confuse the public about the source of a product. In United States, Congress passed the first federal trademark law in 1870 and has made major revisions in the law since then. The first ever international agreement dealing with trademark laws was a treaty known as the Paris Convention. Adopted in 1883, it required members to recognize the trademark rights of foreign producers[8]. This agreement provided the basic guideline to different international treaties and agreement for the global safeguard of patent rights.

MEANING OF PATENT:

The word "Patent" is used as a monopoly right in respect of any invention[9]. It is also defined as a grant made by a government that, confers upon the creator of an invention, the sole right to make, use, and sell that invention for a set period of time. It is "a legal document granted by the government giving an inventor the exclusive right to make use and sell an invention for a specified number of years"[10].

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[8] Paris Convention for the Protection of Industrial Property of March 20, 1883. Trade Marks Acts & Rules Ali Asghar. First Edition 2001. Pioneer Book House, Karachi.

[9] Laws of Trade Mark, Copyright, Patents and Designs. Salil K. Roy Chowdhury. 2nd Edition 1999. Kamal Law House Calcutta

[10] Microsoft ® Encarta ® Encylopedia 2005©. 1993-2004 Microsoft Corporation.

The Patent can be granted in respect of a new invention that has not been obvious to a person prior to the date of application for patent and not of discovery. It should involve an inventive step which is capable of industrial application[11].

A patent only gives an inventor the right to prevent others from using the patented invention. It says nothing about whether the product is safe for consumers and whether it can be supplied. Patented pharmaceuticals still have to go through rigorous testing and approval before they can be put on the market. As trade increased in the 19th century, many countries adopted laws recognizing the legal rights of trademark owners. These laws prohibited other sellers from using similar marks that might confuse the public about the source of a product. In United States, Congress passed the first federal trademark law in 1870 and has made major revisions in the law since then[12].

At the time of independence, the Patents and Designs Act, 1911 was in force which was amended from time to time. Since Pakistan is among one of the around 150 member countries[13] in the world who have signed the 1994 agreement on TRIPS, the Patents and Designs Act, 1911 was repealed by an Ordinance promulgated by the President of Pakistan on 2nd December 2000, which was

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[11] Patents Amendment Ordinance 2002., Sections 9 & 10

[12] www.sba.gov/hotlist/tmdef.html.

[13] Understanding the WTO. Written and Published By World Trade Organization, Information and Media Relation Division. 3rd Edition, 2005. Geneva Switzerland.

further amended on 26 October 2002 and called as Patents Amendment Ordinance 2002[14], in accordance with the TRIPS agreement obligations.

WTO:

The World Trade Organization (WTO), located in Geneva, deals with the rules of trade between nations at a global or near-global level. It's an organization for liberalizing trade, a forum for governments to negotiate trade agreements and a place for them to settle trade disputes. The WTO began life on 1 January 1995, but its trading system is half a century older. Since 1948, the General Agreement on Tariffs and Trade (GATT) had provided the rules for the system. It did not take long for the General Agreement to give birth to an unofficial, de facto international organization, also known informally as GATT. Over the years GATT evolved through several rounds of negotiations[15].

The WTO has nearly 150 members, accounting for over 97% of world trade. Around 30 others are negotiating membership. Decisions are made by the entire membership. This is typically by consensus. A majority vote is also possible but it has never been used in the WTO, and was extremely rare under the WTO's predecessor, GATT. The WTO's agreements have been ratified in all members' parliaments.

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[14] Patents Ordinance, 2000 (Ordinance No. LXI of 2000). Gazette of Pakistan, Extraordinary, 2nd December 2000. F. No. 2(1)/2000-Pub.

[15] TRIPS and Pharmaceutical Patents. WTO OMC Facts Sheet. 2001. Information and Media Relations Division. Geneva, Switzerland

The WTO's top level decision-making body is the Ministerial Conference which meets at least once every two years. The Fifth WTO Ministerial Conference will be held in Cancún, Mexico from 10 to 14 September 2003.

The General Council (normally ambassadors and heads of delegation in Geneva, but sometimes officials sent from members' capitals) which meets several times a year in the Geneva headquarters. The General Council also meets as the Trade Policy Review Body and the Dispute Settlement Body.

At the next level, the Goods Council, Services Council and Intellectual Property (TRIPS) Council report to the General Council. Numerous specialized committees, working groups and working parties deal with the individual agreements and other areas such as the environment, development, membership applications and regional trade agreements.

The Uruguay Round which lasted from 1986 to 1994 and led to the WTO's creation[16]. Whereas GATT had mainly dealt with trade in goods, the WTO and its agreements now cover trade in services, and in traded inventions, creations and designs.

GATT AGREEMENT:

The General Agreement on Tariffs and Trade (GATT) was first signed in 1947. The agreement was designed to provide an international forum that encouraged free trade between member states by regulating and reducing tariffs on traded

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[16] Patents Ordinance, 2000 (Ordinance No. LXI of 2000). Gazette of Pakistan, Extraordinary, 2nd December 2000. F. No. 2(1)/2000-Pub

goods and by providing a common mechanism for resolving trade disputes. GATT membership now includes more than 110 countries[17].

The GATS covers all internationally-traded services with two exceptions: services provided to the public in the exercise of governmental authority, and, in the air transport sector, traffic rights and all services directly related to the exercise of traffic rights. The GATS also defines four ways in which a service can be traded, known as "modes of supply":

1. services supplied from one country to another (e.g. international telephone calls), officially known as "cross-border supply";

2. consumers from one country making use of a service in another country (e.g. tourism), officially known as "consumption abroad";

3. a company from one country setting up subsidiaries or branches to provide services in another country (e.g. a bank from one country setting up operations in another country), officially known as "commercial presence"; and

4. individuals traveling from their own country to supply services in another (e.g. an actress or construction worker), officially known as "movement of natural persons".

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[17] TRIPS and Pharmaceutical Patents. WTO OMC Facts Sheet. 2001. Information and Media Relations Division. Geneva, Switzerland

TRIPS AGREEMENT:

The General Agreement on Trade in Services (GATS) is among the World Trade Organization's most important agreements. The accord, which came into force in January 1995, is the first and only set of multilateral rules covering international trade in services. It has been negotiated by the Governments themselves, and it sets the framework within which firms and individuals can operate. The GATS has two parts: the framework agreement containing the general rules and disciplines; and the national "schedules" which list individual countries' specific commitments on access to their domestic markets by foreign suppliers.

Most of the WTO agreements are the result of the 1986–94 Uruguay Round negotiations, signed at the Marrakesh ministerial meeting in April 1994. The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) attempts to strike a balance between the long term social objective of providing incentives for future inventions and creations, and the short term objective of allowing people to use existing inventions and creations.

The basic philosophy of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is that it attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations. The agreement covers a wide range of subjects, from copyright and trademarks, to integrated circuit designs and trade secrets. Patents for pharmaceuticals and other products are only part of the agreement.

The balance works in three ways:

- Invention and creativity in themselves should provide social and technological benefits. Intellectual property protection encourages inventors and creators because they can expect to earn some future benefits from their creativity. This encourages new inventions, such as new drugs, whose development costs can sometimes be extremely high, so private rights also bring social benefits.

- The way intellectual property is protected can also serve social goals. For example, patented inventions have to be disclosed, allowing others to study the invention even while its patent is being protected. This helps technological progress and technology dissemination and transfer. After a period, the protection expires, which means that the invention becomes available for others to use. All of this avoids "re-inventing the wheel".

- The TRIPS Agreement provides flexibility for governments to fine tune the protection granted in order to meet social goals. For patents, it allows governments to make exceptions to patent holders' rights such as in national emergencies, anti-competitive practices, or if the right-holder does not supply the invention, provided certain conditions are fulfilled.

INTERNATIONAL OBLIGATIONS OF MEMBER COUNTRIES:

Under TRIPS agreement, member countries, WTO members have to provide patent protection for any invention, whether a product (such as a medicine) or a process (such as a method of producing the chemical ingredients for a medicine), while allowing certain exceptions. Patent protection has to last at least 20 years

from the date the patent application was filed. Members cannot discriminate between different fields of technology in their patent regimes. Nor can they discriminate between the place of invention and whether products are imported or locally produced.

However, the governments can refuse to grant patents for three reasons that may relate to public health:

- inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health
- diagnostic, therapeutic and surgical methods for treating humans or animals
- certain plant and animal inventions

Under the TRIPS Agreement, governments can make limited exceptions to patent rights, provided certain conditions are met. For example, the exceptions must not "unreasonably" conflict with the "normal" exploitation of the patent[18].

Many countries use this provision to advance science and technology. They allow researchers to use a patented invention for research, in order to understand the invention more fully. In addition, some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval — for example from public health authorities — without the patent owner's permission and before the patent protection expires. The generic

[18] Articles 27.2, 27.3a, 27.3b TRIPS Agreement

producers can then market their versions as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision[19].

Governments can also act, again subject to certain conditions, to prevent patent owners and other holders of intellectual property rights from abusing intellectual property rights, "unreasonably" restraining trade, or hampering the international transfer of technology[20].

There is another very important exception in the agreement that allows compulsory licensing as part of the agreement's overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs. Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. In current public discussion, this is usually associated with pharmaceuticals, but it could also apply to patents in any field — and the TRIPS Agreement does prohibit discrimination between fields of technology. Compulsory licensing and government use of a patent without the authorization of its owner can only be done under a number of conditions aimed at protecting the legitimate interests of the patent holder.

In addition, the agreement also provides exceptions of parallel imports/grey imports which allows imports of products made and marketed by the

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[19] Articles 8 TRIPS Agreement

[20] Articles 8 and 40 0f TRIPS Agreement

patent owner (or trademark- or copyright-owner, etc) into another country without the approval of the patent owner.

However, for pharmaceuticals and agricultural chemicals, countries eligible to use this provision (i.e. countries that did not provide protection on 1 January 1995) had two obligations. They had to allow inventors to file patent applications from 1 January 1995, even though the decision on whether or not to grant any patent itself needed not be taken until the end of that period. This is sometimes called the "mailbox" provision (a metaphorical "mailbox" is created to receive and store the applications). The date of filing is significant, which is why the mailbox provisions were set up. It was used for assessing whether the application meets the criteria for patenting, including novelty ("newness"). The governments also allowed the relevant pharmaceutical or agricultural chemical product to be marketed during the transition period, subject to certain conditions an exclusive marketing right for the product for five years, or until a decision on a product patent was taken.

Thirteen WTO members — Argentina, Brazil, Cuba, Egypt, India, Kuwait, Morocco, Pakistan, Paraguay, Tunisia, Turkey, United Arab Emirates and Uruguay notified "mailbox" systems to the TRIPS Council, indicating that at that time they did not grant patent protection to pharmaceutical products. Some of these have now introduced pharmaceutical patent protection — such as Argentina, Brazil, Guatemala, Morocco and Turkey.

DEVELOPMENT OF PHARMACEUTICAL INDUSTRY IN PAKISTAN:

Although in the beginning, local manufacturers did not pay much attention on quality and presentation of their products, but with the passage of time, local companies gained the confidence of medical profession and hence started getting more and more share in the sales of medicines. As to date, there are 428 pharmaceutical manufacturers actively involved in active manufacturing/import of pharmaceutical products (medicines for human use) in Pakistan, out of which only 19 are multinational[21].

Since the raw materials of expensive medicines were easily available from countries of South America, China, India and some European countries, many pharmaceuticals companies started manufacturing those medicines in Pakistan which invoked many multinational companies to institute cases against those manufacturers.

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[21] Pakistan Drug Manual., December 05-2006. A Therapeutic Drug System. Medical Channel Karachi

TABLE NO. 1

COMPARISON OF PRICES OF MULTINATIONALS VS LOCAL MEDICINES[22]

	BRAND LEADER PRICE	GENERIC PRICE	REMARKS
Ranitidine	Zantac 150 mg Rs. 88.20	Ranitdine 150 mg Rs. 40.00	121 % Expensive
Famotidine	Pepcidine 40 mg Rs. 263.70	Peptiban 40 mg Rs. 156.84	68 % Expensive

[22]. Pharma Guide 20th Edition. 2006

TABLE NO. 2

NUMBER OF PHARMACEUTICALS MANUFACTURERS[23]

	MULTINATIONAL PHARMACEUTICALS	LOCAL PHARMACEUTICALS
TOTAL NUMBER	19	428
PERCENTAGE	4.25	95.75

[23] IMS. 2006.

TABLE NO. 3

MARKET SHARE MNCs Vs LOCAL PHARMACEUTICALS[24]

	MULTINATIONAL PHARMACEUTICALS	LOCAL PHARMACEUTICALS
SALES IN BILLION	81.01	48.56
PERCENTAGE OF SALES	62.50	37.50

[24] IMS. 2006

TABLE NO. 4

GROWTH WORLDWIDE VS PAKISTAN[25]

	WORLDWIDE	PAKISTAN
TOTAL NUMBER	80 %	11.64 %

[25] IMS. 2006

TABLE NO. 5

CONTRIBUTION OF DIFFERENT CATAGORIES OF DOCTORS IN PHARMACEUTICALS IN PAKISTAN[26]

CATEGORY	PERCENTAGE
GENERAL PRACTIONERS	66
MEDICAL OFFICER/RESIDENT MEDICAL OFFICERS BASED IN HOSPITALS	22
CONSULTANTS	18

[26] IMS.2006

CHAPTER FOUR

PATENT LAWS IN PAKISTAN

Overview of Relevant Sections of Repealed and Existing Laws

In this study, the research has tried to compare the repealed and the existing Patents Law in Pakistan. The Patents and Design Act 1911 came into force on the first day of January 1912 in the British India. Pakistan got independence by the British Ruler in 1947 and therefore, Pakistan opted the same Act afterwards with the omission of the word "Indian" in 1949.[27]

The Patent and Design Act 1911 was repealed after the promulgation of Patents Ordinance 2000 on 2nd December 2000.[28]

Any suit for infringement of patent, or any proceeding of revocation of a patent, pending in any court on the commencement of this ordinance was to be continued and disposed of under the Patents and Design Act 1911[29].

The amendment had become necessary in order to make new laws and rules concerning the applicability of basic principles of TRIPs agreements signed by the Government of Pakistan .

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[27] The Patents and Design Act 1911.

[28] Section 106 Patents Ordinance 2000

[29] Section 106 Patents Ordinance 2000

Comparison of Relevant Sections of Repealed and Existing Laws

When Pakistan came into existence, Patents and Design Act 1911 was in force in Indo-Pak subcontinent since its promulgation. This law was adopted as such and amended from time to time as per requirements. Afterwards it was repealed in 2000 and a new Patents Ordinance 2000 promulgated to make the existing laws in accordance with the international obligations like TRIPs.

1. Definitions pertaining to Patents and Designs.

- The definition of "invention"[30] which was deficient in The Patents and Design Act 1911 and was improved in Patents Amendment Ordinance 2002 and made comprehensive[31] by including the words "new and useful product, art, process, method or manner of manufacture, machine, apparatus or other article, substance or article or product produced by manufacture and any new and useful improvement of any of them.".

- Certain new definitions have also been added in the Patents Amendment Ordinance 2002. For example "process, product, person interested"[32].

Through these additions the scope of invention has been widened by including chemical product and process into it which has bestowed more rights to the inventors. Previously same end product could be manufactured by more than one manufacturer by using different processes but with this definition, the products

[30] The Patents and Design Act 1911. Section.2 (8).

[31] Patent Ordinance 2000. Section 2(i)

[32] Patent Ordinance 2000. Section 2 (s)(t)

have also been protected by the law. This protection has resulted into increased litigation as the probability of "infringement" has increased manifolds.

2. "Novelty which describes the newness or being novel of a product or process not known to the public prior to the filing of its application for its protection" had not been mentioned by the Patents and Design Act 1911 whereas it has been dealt with in the Patents Ordinance 2000[33]. This section has put restriction on unscrupulous elements to get patent protection and obviously ended up in increased litigation also.

3. Application for Patent

a) The section relating to application for protection of an invention in convention countries has been reworded and changed as follows. This sub-section[34] reads as "where applications for protection have been made in one or more Convention countries in respect of two or more inventions which are cognate or of which one is"

b) modification of another, a single convention applicant may, subject to the provisions of section 15, be made in respect of those inventions at any time within twelve months from the date of the earliest of the said applications for protection" This was further amended in Patents Amendment Ordinance 2002 as , "Where an application for protection has been made in one or more convention countries in respect of an invention, subject to the provisions of section 15, application shall

[33] Patents Ordinance 2000. Section 8.

[34] Patents Ordinance 2000. Section 13 (2)

be made in respect of that invention at any time within 12 months from the date of earliest application filed in any convention country". The reason for amendment was an application for a patent is made for a single invention and application is to be filed, everywhere where protection is sought, within 12 months of filing first application for the invention in any invention country and secondly this provision is in conflict with section 13(3) and 15 (4).

c) Subsection (3) Patents Ordinance 2000 specifies the limitation of each application to single invention only or to a group of inventions so linked as to form a single general inventive concept. This sub-section did not exist in the Part 1 of Patents and Design Act 1911 which deals with application for and grant of patent.

This sub-section resulted into increased in litigation where the patentees exploited it by adding varied claims in their application for patents and envisaged more than one inventions in one application. This not only created confusion to the Patent Office, courts of law and interested parties but also provided a ground to the patentee to instigate un-necessary litigation. Section 13(3) was further amended in Patents Amendment Ordinance 2002 by deletion of "or to a group of inventions so linked as to form a single general inventive concept" which limited single application to a single invention only. I would refer to the example of cases Rofecoxib pending in the court of law. By allowing group of inventions to be considered under one application provide a blanket protection to a large number of inventions as a group which otherwise require separate applications. Secondly it will debar others from conducing R&D and to invent in related areas which are

covered under this blanket group of inventions. The provision in its present debar others to carry work on the general inventive concepts that are covered under the group inventions applied for.

4. Claims related to specifications for patent application.

a) Section 15 relates to the claims made therein the specifications of application for patents. Sub-section 4 has been widely exploited in such a way that multiple claims are claimed in a single application for an invention which consequently protects many variants of a single invention. Once the inventor is granted protection of his invention, the patentee institutes legal proceeding against anyone in the light of varied claims made in the application for patent. This sort of protection which covers many inventions in one application has resulted into increased litigation in the court of law.

Whereas it was the clearly mentioned[35] in Patent and Design Act 1911 that in the case of a complete specification, it must end with a distinct statement of the invention claimed. Through the introduction of a section[36] in Patents Ordinance 2000 a loophole was created for the benefits of the patent holders.

5. The effect of acceptance of complete specification.

This section[37] entitles the patentee the like privileges and rights as if a patent for the invention had been sealed on the date of advertisement of the complete

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[35] Section 4(4) Patents and Design Act 1911

[36] Section 15 (4) Patents Ordinance 2000

[37] Section 22 Patents Ordinance 2000

specification. The applicant may institute any proceedings for infringement of the patent without waiting for its acceptance and sealing, and a court may grant such relief by way of an injunction restraining the alleged infringement. It grants full rights to the patentee[38] on mere filing of an application in the Patent Officer, even the fate of application still has to be decided. Similar protection was also granted to the patentee in Section 7 of Patents and Design Act 1911 but it was subject to the condition that the applicant shall not be entitled to institute any proceedings for infringement until the patent has been sealed.

6. Remedy in case of groundless threats of infringement proceedings[39].

This section is also ambiguous and incomplete where any interested person who threats through circular or advertisement or otherwise with proceedings for infringement of a patent, the aggrieved person could file suit against him for a declaration to the effect that the threats are unjustifiable alongwith injunction and damages. Section 36 of Patents and Design Act 1911 also deals with the same situation.

A SUMMARY OF RELEVANT SECTIONS AMENDED IN PATENTS ORDINANCE 2000

Purpose of promulgation of Patents Ordinance 2000 was to change the Patents and Design Act 1911 in accordance with TRIPs agreement. Since Patents Ordinance was promulgated without consultation of Ministry of Industries and Production, Ministry of Health, Ministry of Agriculture, Pharmaceutical Industry,

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[38] Section 7 Patents and Design Act 1911

[39] Section 66 Patents Ordinance 2000

Pakistan Druggist Association and law firms dealing with Intellectual Property Rights. It was deeply felt that certain amendments were made to make it more compliant with TRIPs and undo the TRIPs plus sections/sub-sections of Patents Ordinance 2000.

DATE OF FILING OF PATENT APPLICATION

In the Patents Ordinance 2000, the date of filing of an application for the grant of patent was considered from the date it was so dispatched to the Patent Office or its branch office[40].

Effects of Amendment

According to the existing provision, the date on which an application is sent is considered as the "date of filing". Sending of a document to the patent office does not necessarily mean that the document has been received at the office. This can lead to unwanted manipulation, resulting in multiplicity of litigation, disputes and confrontations and in most of the cases, patent office shall be at the receiving end. The subsection was amended and the filing date was considered to be the date on which the application was filed at the patent office or its branch office[41].

It is interesting to note that the Section 13 (1) requires filing of applications at patent office. Therefore, existing provision of 2(f)(ii) was contrary to 13(1).

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[40] Section 2(f) Patents Ordinance 2000

[41] Section 2(f) of Patents Amendment Ordinance 2002

DEFINITION OF "PROCESS"

The definition of "process" was also misleading. In the Patents Ordinance 2000 it was defined as means any art, process or method or manner of new manufacture of a product and includes a new use of anon process or a product[42]. It was hence amended and a new use of anon process or product was excluded from the definition[43].

EFFECTS OF AMENDMENT

There is no clause in the TRIPs agreement which bounds the member countries to add the condition of "a new use of anon process or product" and the TRIPs agreement is silent on this issue so the inclusion of this condition in the Patents Ordinance 2000 was 'TRIPS plus". Before the amendment, this section was a potential reason to an increased litigation because under its cover, a patentee could get his invention patented again for another period of 20 years by merely introducing a new use of known product or process. This was contrary to basic norms of the law and such law did not exist in any country of the world

PATENTABLE INVENTION.

According to the provisions of Patents Ordinance 2000, any invention is patentable, if it is new, involves an inventive step and is capable of industrial application[44]. A proviso was added to the subsection wherein few exceptions[45]

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[42] Section 2(s) Patents Ordinance 2000

[43] Section 2(s) Patents Amendment Ordinance 2002

[44] Section 7(1) Patents Ordinance 2000

were added to it such as a discovery, scientific theory or mathematical method[46], a literary, dramatic, musical or artistic work or any other creation of purely aesthetic character whatsoever[47], a scheme, rule or method for performing a mental act, playing a game or doing business[48], and the presentation of information[49].

Similarly another provision of this section prevents anything from being treated as an invention for the purposes of Ordinance, only to the extent or an application for a patent relates to that thing as such[50]. Another subsection of puts a bar regarding the grant of patent for the for an invention the publication or exploitation of which would be contrary to the public order or morality, provided that the exploitation shall not be considered to be so contrary merely because it is prohibited by any law for the time being in force, for animals or plants other than micro-organisms and essentially biological process for the production of animals or plants, but this prohibition shall not apply to micro-biological processes or products of such processes and for diagnostic therapeutic and surgical methods for the treatment of humans or animals[51].

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[45] Section 7(2) Patents Ordinance 2000

[46] Section 7(2)(a) Patents Ordinance 2000

[47] Section 7(2)(b) Patents Ordinance 2000

[48] Section 7(2)(c) Patents Ordinance 2000

[49] Section 7(2)(d) Patents Ordinance 2000

[50] Section 7(3) Patents Ordinance 2000

[51] Section 7(4)(a)(b)(c) Patents Ordinance 2000

A new clause was inserted in the Section 7 where the substances existing in nature or if isolated there from were included in it[52].

Justification of Adding Section 7(2)(E):

Nothing in TRIPS requires natural substances, even in isolated or purified form, to be considered an invention. Even otherwise, isolation of a new substance (product) from a natural material is discovery and not invention. Inclusion of this Sub-section will also help prevent biopiracy. Such as exclusion however, does not debar development of new products or processes which involve an inventive step e.g. in case the research in the field of biotechnology. Microorginism however, can be patented under section 7(4)(c) of the Patent Ordinance 2000, in accordance with the TRIPS agreement requirements. Such provisions of TRIPS agreement are under review by WTO as there is a strong objection to the related Article 27 (3)(b) by most countries. Certain industrialized countries have specifically allowed patenting of biotechnological inventions if they concern isolated biological material by means of a technological process (which specifically excluded plant or animal variety) but such patent protection is granted to the invention and not to naturally occurring materials even if isolated there from.

COMMERCIAL EXPLOITATION OF INVENTIONS:

Section 7(4) deals with prevention of commercial exploitation of invention which would be necessary to protect "order public" or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the

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[52] Section 7(2)(e) Patents Amendment Ordinance 2002

exploitation is prohibited by domestic law for the time being in force. Certain amendments were necessary to protect the rights of general public[53] as it has been guaranteed in the TRIPs agreement[54].

New subsections were added regarding genetically modified microorganisms[55], new or subsequent uses of a known product or process[56] and a mere change in physical appearance of a chemical product shall not constitute a patentable invention where the chemical formula or process of manufacture remains the same[57].

There is a malicious tendency of getting patent rights for mere changes in physical appearance in chemical products without any significant improvement (therapeutic or otherwise) or addition in the invention, so as to be regarded as improvement for "patent of addition". Such tendencies increase the litigation in the court of law.

NOVELTY IN AN INVENTION:

Section 8 of Patents Ordinance 2000 deals with 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,

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[53] Section 7(4)(b)

[54] Article 30 and 31. TRIPs agreement.

[55] Section 7(4)(d) Patents Amendment Ordinance 2002

[56] Section 7(4)(e) Patents Amendment Ordinance 2002

[57] Section 7(4)(f) Patents Amendment Ordinance 2002

of the application claiming the invention[58] and contents of the complete specification and priority documents published under section 21 of an application filed in Pakistan[59].

Another subsection dealing with traditionally developed or existing knowledge available or in possession of a local or indigenous community or region" has been added into the Patents Amendment Ordinance 2002[60].

Effects of Amendment

This word "and" makes it compulsory to comply with both the provisions to make them "state of the art". This makes the provision meaningless resulting in patenting of anything that is already known. Traditional knowledge is to be acknowledged as "state of the art". Knowledge covered under Section8 (2)(a) is not being interpreted, by different judicial authorities, to allow traditional knowledge. This section was previously exploited by many people and ended up in increased litigation.

APPLICATION FOR PATENT:

Section 13 deals with the application for patent. It describes that each application shall relate to one invention only or to a group of inventions so linked as to form a

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[58] Section 8(2)(a) Patents Ordinance 2000

[59] Section 8(2)(b) Patents Ordinance 2000

[60] Section 8(2)(c) Patents Amendment Ordinance 2002

single general inventive concept[61]. Amendment was made in it and restricted application to relate to one invention only[62].

Justification:

By allowing group of inventions to be considered under one application provide a blanket protection to a large number of inventions as a group which otherwise require separate applications. Secondly it debarred others from conducing R&D and to invent in related areas which are covered under this blanket group of inventions.

The provision in its present form debars others to carry work on the general inventive concepts that are covered under the group inventions applied for.

SPECIFICATIONS OF APPLICATION FOR A PATENT:

Section 15 of Patents Ordinance 2000 deals with the contents of application for the grant of a patent. According to the Patents Ordinance 2000 every specification, whether complete or provisional, shall describe the invention, and shall begin with a title indicating the subject to which the invention relates. Subject to any rules made in this behalf, drawings may, and shall if the Controller so requires, be supplied for the purposes of any specification, whether complete or provisional, and any drawings so supplied shall, unless the Controller otherwise directs, be deemed to form part of the specification and reference in this

[61] Section 13(3) Patents Ordinance 2000

[62] Section 13(3) Patents Amendment Ordinance 2002

Ordinance to a specification shall be construed accordingly. Every complete specification shall fully and particularly describe the invention and the method by which it is to be performed[63], disclose the invention which is known to the applicant and for which he is entitled to claim protection[64], and end with a claim or claims defining the scope of the invention for which protection is claimed[65].

Certain changes were also made in Section 15(1) which was reworded and made TRIPs compliant[66]. Restriction was put to the applicant regarding claim or claims which shall be specific single invention for which the application is being made[67].

A sub-section was also added pertaining to a chemical product intended for use in medicine or agriculture, the invention sought for shall be specific to one chemical product only[68].

Effects of Amendment

According to present practice and the interpretation which can be made from the existing provision of Patent Ordinance 2000 the broad title covering an entire range of products in particular the group or that class or the category is covered

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[63] Section 15(3)(a) Patents Ordinance 2000

[64] Section 15(3)(b) Patents Ordinance 2000

[65] Section 15(3)(c) Patents Ordinance 2000

[66] Article 7 & 8. TRIPs Agreement.

[67] Section 15(1) Patents Ordinance 2000

[68] Section 15(3)(d) Patents Amendment Ordinance 2002

under one patent application which is not desired. Such wording leads to increased litigation by unnecessarily dragging the innocent people to the court of law.

ACCEPTANCE OF COMPLETE SPECIFICATION

On and from the date of advertisement of the acceptance of a complete specification and until the date of sealing of a patent in respect thereof, the applicant shall have the like privileges and rights as if a patent for the invention had been sealed on the date of advertisement of acceptance of the complete specification, provided that the applicant may institute any proceedings for infringement of the patent without waiting for its acceptance and sealing, and a court may grant such relief by way of an injunction restraining the infringement, if the court is satisfied that the applicant is the true proprietor of the invention and shall be properly registered as a patentee and shall suffer irreparable loss if infringement of its patent is not stopped, Provided further that the applicant shall not be able to recover any damages against the infringer for any infringement of its invention taking place before the sealing of the patent[69].

Effects of Amendment

Before the grant of patent specifications are advertised for calling objection from interested persons. Existing provisions give privileges and right to the applicant of Patent as if a Patent for the invention has been sealed and also to allow the applicant file infringement suit even before the patent has been approved. And in

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[69] Section 22. Patents Ordinance 2000

this case the Ordinance allows the court to grant relief. At this stage grant of right to file a suit is not justified. It is not required by TRIPS and is also against the norms of justice. It shall lead to multiplicity of litigation without any justification.

REMEDY FOR GROUNDLESS THREATS OF PROCEEDINGS

According to the provisions of Patents Ordinance 2000 any person, whether entitled to or interested in a patent or an application for a patent or not, threatens any other person by circulars, advertisements or otherwise with proceedings for infringement of a patent, any other person aggrieved thereby may bring suit against him for any such relief[70]. Unless in any suit under Section 66(1) the defendant proves that the acts in respect of which proceedings were threatened constitute or, if done, would constitute, an infringement of a patent or of rights arising from the publication of a complete specification in respect of a claim of the specification not shown by the plaintiff to be invalid, the plaintiff shall be entitled to the following relieves, namely a declaration to the effect that the threats are unjustifiable[71], an injunction against the continuance of the threats[72] and such damages, if any, as he has sustained thereby[73].

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[70] Section 66(2) Patents Ordinance 2000

[71] Section 66(2)(a)Patents Ordinance 2000

[72] Section 66(2)(b) Patents Ordinance 2000

[73] Section 66(2)(c) Patents Ordinance 2000

Effects of Amendment

This section encouraged the litigants to file suits based on threatening advertisements whereas to give threat, in the general law is a subject of criminal proceedings. An injunction has been sought by restraining the defendants to float their product in the market. This would in turn end up in litigation.

INCONSISTENCY BETWEEN PATENT ORDINANCE 2000 AND THE DRUG ACT 1976

After the promulgation of Patents Ordinance 2000 thereby making the Patent laws in accordance with the guidelines laid down by the TRIPs agreement, certain confusions have arisen. According to the point of view of multinational patent holders, in order to implement Patent laws, certain amendments may be required in the Drugs Act 1976. According to this point of view, any medicine allegedly infringing the patent holders' right may not be registered, allowed to be imported, marketed or sold in the country. According a judgment in a case Glaxo Group Ltd versus Evron Pvt Ltd, registration under the Drugs Act 1976 would not constitute defense against infringement regulated by the Patents and Design Act 1911, two statutes covering different fields and controlling classes of activities[74].

A brief mention of different Sections of the Drugs Act which could raise conflict of interest with reference to the Patents Ordinance:

PROMULGATION OF LAW:

As per preamble of the Drugs Act 1976, "it is expedient to regulate the import, export, manufacture, storage, distribution and sale of drugs"[75]. Whereas at the time of enactment of this law, the issue of patent was not so important and secondly the government was not obliged to protect the worldwide patent rights to such an extent. In fact the import, export, manufacture, storage, distribution and sale of drug are directly affected by the provisions of Patents Ordinance with reference to the rights conferred upon the patent holders.

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[74] PLD 1991 Karachi – 252.

[75] The Drugs Act (XXXI of 1976)

Prohibition for the import of drugs:

The Federal Government shall regulate the import and export of drugs in the prescribed manner and for that purpose may make such orders and issue such directions to the importers and exporters as it may deem fit[76]. If in the opinion of the Federal Government the public interest so requires, the Federal Government may, by notification in the official Gazette, direct that a drug or a class of drugs specified in the notification, or drugs generally, shall not be imported or exported otherwise than under the authority of 'a license issued under this Act or except by an importer or exporter or through an indentor registered in accordance with the rules or direct that a drug or class of drugs specified in the notification shall not be imported except by an agency of Government so specified, or prohibit the import or export of any drug or class of drugs specified in the notification.

This Section of the Drugs Act 1976 deals with the imports etc of the drugs. In this section there is no provision which hinders or stops or binds the importer to import only those medicines which do not in any manner infringe the rights of a patent holder. So question arises

- whether it is possible for the Ministry of Health to grant permission to only those importers who are supposedly importing the medicines without infringing the rights of a patent holder.
- Secondly whether is possible to formulate a mechanism which could ensure that such an alleged infringement will not take place by the import of a medicine.

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[76] Section 4 of The Drugs Act 1976.

- Thirdly whether Ministry of Health has the authority to decide whether a medicine being imported is or is not infringing the rights of a lawful patent holder. The logical answer is that the ministry in no way can give any verdict on the subject which purely a discretion of a competent court to decide. So logically Ministry of health can not put an embargo on import of any medicine, provided it fulfils the criteria laid down for its import. Hence the claim made by the patent holders in this respect cannot be accepted due to the fact that it could result into increased the litigation.

Regulation of manufacture of drugs:

(1) The grant of licenses to manufacture drugs shall be regulated in accordance with such conditions and procedure as may be prescribed, by a Central Licensing Board to be set up by the Federal Government and consisting of such representatives of the Federal Government and the Provincial Governments as may be prescribed.

(2) The members of the Central Licensing Board shall exercise such powers, including the powers of an Inspector, as may be prescribed.

(3) The Central Licensing Board shall make regulations to regulate the conduct of its business.

(4) Any member of the Central Licensing Board may, at any time, by writing under his hand addressed to the Federal Government, resign his office or shall vacate his office if the Federal Government, being of opinion that in the public interest it is necessary so to do, so directs.

(5) Subject to sub-section (4), a member of the Central Licensing Board shall hold office for the prescribed period[77].

This section speaks of setting up a central licensing board, whose responsibility is to grant licenses to manufacture drugs. The issuing of drugs manufacturing license depends upon fulfilling the prescribed procedure and conditions by such manners of drugs. Every manufacturers of drugs must obtain this license as a pre-requisite.

Regulation of sale of drugs :

The Provincial Governments shall regulate the sale of drugs in the prescribed manner and may for that purpose make such orders, and issue such directions to the importers, manufacturers, stockists, retailers or other dealers of drugs, as they may deem fit[78].

The criteria for prescribing terms and conditions of issuance of license to regulate trade or business should be such that has logical nexus with the object of the law[79].

Manufacture and sale of any registered medicine in Pakistan.

As discussed earlier, it is beyond the scope of Ministry of Health to declare or assess that any medicine being manufacture in Pakistan, which has already been granted registration certificate does not infringe the rights of lawful patent holder. On the other a patent holder would always like that Ministry of Health should not allow any law manufacturer to manufacture a medicine which in any way,

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[77] Section 5. The Drugs Act 1976

[78] Section 6. The Drugs Act 1976

[79] PLD 1992- Lahore 415.

according to the opinion of a patent holder, infringes his patent rights. If such an assertion of a patent holder is accepted, it could end up an increased litigation.

7. Registration of Drugs[80]:

(1) The Federal Government shall cause all drugs to be registered in-accordance with such conditions and procedure as may be prescribed and for that purpose set up a Registration Board, consisting of such number of persons, possessing such qualifications, as may be prescribed.

(2) The members of the Registration Board shall exercise such powers, including the powers of an Inspector, as may be prescribed.

(3) The Registration Board shall make regulations to regulate the conduct of its business.

(4) Any member of the Registration Board may, at any time, by writing under his hand addressed to the Federal Government, resign .his office or shall vacate his office if the Federal Government, being of opinion that in the public interest it is necessary so to do, so directs.

(5) Subject to sub-section (4), the members of the Registration Board shall hold office for the prescribed period.

(6) The Federal Government shall, by notification in the official Gazette, fix the date after which no drug which is not registered shall be allowed to be exported, imported, manufactured, stored, distributed or sold.

(7) A person applying for the registration of a drug shall furnish such information in respect of the drug as may be prescribed, including information

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[80] Section 7. The Drugs Act 1976

relating to its efficacy, safety, and quality, or as may be required by the Registration Board for the purpose of the evaluation of the drug.

(8) Single-ingredient drugs shall be registered generally by their generic names while compound drugs shall be registered generally by their proprietary names.

(9) The registration of a drug shall be subject to such conditions, if any, as the Registration Board may specify at the time of its registration.

(10) Where the Registration Board registers a drug, it shall inform the person applying for its registration and the Provincial Governments of its having done so and of the conditions subject to which it has been registered.

(11) If the Registration Board, on the basis of information received or an inquiry conducted by it, is of opinion that-

a. the registration of a drug was procured by fraud or misrepresentation; or

b. the circumstances in which a drug was registered no longer exist; or

Section 7 of the Drugs Act 1976.

c. there has been a violation of the conditions subject to which a drug was registered; or

d. it is necessary in the public interest so to do;

the Registration Board may, after affording to the person on whose application the drug was registered an opportunity of showing cause against the action proposed to be taken, cancel or suspend the registration or specify any further conditions to

which the registration shall be subject and inform such person and the Provincial Governments accordingly.

12. The Provincial Governments shall take all such steps as may be necessary to ensure compliance with the conditions subject to which a drug is registered and to prevent the manufacture or sale of a drug-

a. which has not been registered; or

b. the registration of which has been cancelled or stands suspended.

This is a very important section as far as the Patent Ordinance and rights of patent holders is concerned. Apparently a medicine should not be granted a registration or permission to be manufactured in Pakistan if it infringes the rights a patent holder in any manner. But at the same time, as mentioned earlier, how would decide that a particular medicine will cause infringement of rights of a patent holder. The same thing was decided by the honourable court is the following decision.

"The contention that the drug has been registered under Drugs Act, 1976 and registration certificate under Section -7 of the Act has been issued by the Ministry-of-Health Held, mere registration of the Drug with the Ministry of Health under the Drugs Act cannot immunise the Defendants against claims of aggrieved parties under the Patent and Design Act, 1911[81].

However the registration of the drugs is not automatic but requires fulfillment of specified conditions[82].

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[81] 1987 C L C 1571

[82] PLJ 1978. Karachi. 216

CHAPTER FIVE

LAW CASES WITH REGARDS TO ALLEGED INFRINGEMENT OF PATENTS

In Pakistan, there are two different way to file a suit regarding the infringement of the Patents and Designs under the provisions of Patents and Designs Act 1911 and Patents Ordinance 2000. In the Province Sindh, the original suit regarding the Patents shall be instituted before the Sindh Higher Court, while in the Province Punjab, the same cases shall be instituted before the Respective District Judge. The chapter is based on the collected materials of the researcher and a few cases of the multinational pharmaceutical companies, who exploited the various Sections of the patents Ordinance 2000 and started harassing the local pharmaceutical Industry by filing unnecessary cases and got stay orders from the courts for a long time just to enjoy the monopoly in the market.

The example of a Multinational company who has obtained the Pakistani patent and the company claims that it covers all processes for the preparation of solid dosage forms of bi-sphosphonic acids and salts thereof.

The specification of this patent describe pharmaceutically acceptable salts of bisphosphonic acids such as ammonium salts, alkalimetal salts such as sodium and potassium (including mono-di- and tri sodium) salts, alkaline earth metal salts such as calcium and magnesium salts, salts with organic bases such as dicyclohcxylaminc salts, N-mcthyl-D-glucaminc and salts with amino acids such as arginine, lysinc etc.

It also cover pharmaceutical compositions of oral solutions of Alendronate along with compositions for reducing the risk of vertebral or non-vertebral fractures in an osteoporotic female by administering a therapcutically effective amount of Alendronate.

Due to this fact the researcher has selected some law cases alongwith all the relevant details in order to know how protection has been bought in regard to all relating salts of the compound by exploiting the Patents Ordinance 2000.

Case No. 1

ATCO LAB. (PVT) LIMITED—Applicant

Verses

Pfizer Limited and others--Respondents[83]

Monopoly of plaintiff after grant of injunction—Patented pharmaceutical compound of the plaintiffs and similar other compounds manufactured by other pharmaceutical companies were mainly used for treatment of high blood pressure—Monopoly in the patented medicine in Pakistan was being exploited by the plaintiffs company to the prejudice of the poor people of the country in need of their medicine, which was against public interest.[84]

The Suit number of this case is 1024 of 1998, filed by ATCO LAB. (PVT) LIMITED—Applicant Verses Pfizer Limited and others—Respondents in the Sindh High Court, Karachi, and was decided on 23rd August 2001.

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[83] 2002 CLD Karachi, pp. 120-137.

[84] *Ibid.*, p. 120

DECISION:

The court decided that the respondents Messrs Pfizer Limited are availing the benefits of registration of Patent No. 130621 in their favour since 1986 and before commencement of present round of litigation in the year 1998, the petitioners or anybody else had not challenged registration of their Patent No. 130621. The respondents under section 12 of the Patents and Designs Act, 1911 are entitled to avail the benefit of this patent for a period of 16 years from 1986 and uptil now they have already availed such benefit for more than 15 years. Thus at this belated stage no case for suspension of their registration and grant of relief prayed in C.M.A. No. 3609 of 1999 is made out by the petitioners, in addition to this the factual controversy raised by the parties cannot be resolved without recording of evidence and therefore, at this stage, the petitioners have no prima facie case for grant of interim relief.[85]

FACTS:

The plaintiffs in the referred suit have taken the plea that they are holder of Pakistan Patent No. 130621, for which they had applied in the year 1986 and sealed in 1989. This patent relates to a pharmaceutical compound called 'Amlodipine Besylate', sold by the plaintiffs under the trade named 'Norvasc'.Under Section 12 of the Act of 1911, the plaintiffs have the exclusive

[85] Ibid., pp. 136-137.

right to use, sell and manufacture their patent for a period of 16 years from 1986.[86]

The defendants stressed on this point, that the Patent No. 130621 was obtained by the plaintiffs through misrepresentation and concealment of full facts as the same was subject-matter of earlier Patent No. 128705 of the plaintiffs' company which expired on 11.03.1998 thus the disputed Patent No. 130621 is a mere duplication of the earlier one to seek extension of time for enjoyment of monopoly.[87]

Case No. 2

Suit No. 508 of 1986, decided on 30th April 1987.

Sandoz Limited and another—Plaintiff

Versus

Pakistan Pharmaceutical Products Limited.

"Mere registration of drug with Ministry of Health under Drug Act 1976 could not immunize the defendant against claims of aggrieved party under the Patents and Designs Act 1911".

Decision:

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[86] Ibid., p. 123.

[87] Ibid., p. 126.

"That the defendant should be restrained from importing, marketing or publicizing any product under the name 'Ketotifen' or reproducing the chemical or structural formula of the drug on any of their products in any form".[88]

FACTS

Plaintiffs filed the suit for infringement of their patent bearing nos: 123776, 123990 and 124546, the patent covers the production of drug 'Ketotifen' which is selling under the trade name 'Zaditen'. The prayer is that defendants should not put in the market either in the capsule form or in the syrup form or in any other form, thereby creating an impression that the drug of the defendants contains 'Ketotifen' with hydrogen pumerate.

The drug of the defendants has been registered under the drug Act 1976. This registration certificate has been issued under Section 7 of the Drugs Act by the Ministry of Health, Government of Pakistan informing the defendants that drug 'Ketotifen' capsule has been registered with them.

Case No. 3

C.M. No. 1 of 2005 Khawaja Tahir Jamal---Plaintiff/Applicant

Versus

M/s A. R. Rehman Glass—Defendant/Respondent

Decided on 25.02.2005.

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[88] 1987 CLC, p. 1575.

Question of novelty and invention has to be seen and judged, keeping in view the provisions of Section 2 (i) of Patents Ordinance 2000.

Decision:

The defendant instead of seeking revocation of the Patent, opted to establish its projects and took risk, consequently, the instant application of the plaintiff is allowed and the defendant is restrained from manufacturing, importing, launching or affirming for sale its disputed sheet-glass products.

FACTS

That Plaintiff has a right/privilege for exclusive use of invention by virtue of provisions of Section 30 of the Patents Ordinance 2000 and the defendant are committing infringement of Plaintiff's patent/process. Hence instituted the suit for permanent injunction. The defendants envisaged that the Patent No. 133253 has been obtained by fraud and Patent of Plaintiff lacks the element of novelty.

Case No. 4

Suit No. 1402 Civil Miscellaneous Nos. 8832 of 1989 and 3201 of 1990, decided on 4th September 1990

"Effect of registration with Minsitry of Health—Registration of a drug with the Ministry of Health and permission to manufacture the same could not take out the drug from the purview of this provisions of Patents and Designs Act 1911, if the same amounted to infringement of a patent registered thereunder. [p. 89] B".[89]

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[89] 1991 M.L.D. 85.

DECISION:

"... The Pharmaceutical Expert Dr. I. H. Qureshi had opined that it was not possible to state that whether the method and process of the drug of the defendant was similar to the plaintiff's still the Court granted interim injunction, while in the case in the hand the opinion of the Pharmaceutical Expert Dr. woodhouse is in favour of the Plaintiff and has not been satisfactorily rebutted by the defendant by producing the evidence of any of the pharmaceutical expert against the same. I am, therefore, satisfied that the plaintiff has a strong prime facie case the balance of convenience is in his favour and he would suffer irreparable loss if interim injunction is not granted".[90]

FACTS

"... A drug or compound known as 'Ranitidine', was discovered and developed by the Plaintiff and is marketed in Pakistan in the form of 'hydrochloride salt', under the brand name 'Zantac'. Pakistan Patent No. 126632 relates to the processes for preparing ranitidine'/ranitidine hydrochloride and pharmaceutical compositions containing the same ... It is alleged that the Defendants have flagrantly violated the plaintiffs' patents mentioned above and are openly selling a drug containing ranitidine as its hydrochloride salt, which has also serious implications for plaintiff".[91]

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[90] Ibid. p. 90.

[91] Ibid., p. 87.

The defendants have contested the suit and application. Their main plea is that the drug manufactured and sold by them differs from the drug under patent manufactured and sold by the plaintiffs. The defendants have obtained their registration of 'Rantid tablets' with the Director-General, Ministry of Health, Government of Pakistan on 10.12.1984. Eve at the time of the registration the plaintiffs had lodged and objection, but the same was overruled. Besides this it was contended that the plaintiffs would not suffer irreparable loss, nor was the balance of convenience in their favour.[92]

Case No. 5

Suit No. 855 of 2000, decided on 5th August 2002.

MERC & CO. ING. And others ... Plaintiffs

Versus

HILTON PHARMA (PVT.) LTD. ... Respondent

"Threatened action ... Interim relief grant of—Court would not wait for actual infringement, but threatened action of infringement would also entitle patentee for grant of interim relief to safeguard his patent rights and to avoid its infringement. [p. 418]E.[93]

DECISION:

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[92] Ibid., p. 87.

[93] 2003 C L D 407, Karachi, p. 409.

"... the difference in sale price is negligible, rather considering the cost of production based on the imported raw material it appears that defendant will be making much more profit if their product is allowed to be marketed n Pakistan. To sum up, it will be seen that the pleas of prior use, knowledge and lack of novelty, use of different process, premature nature of suit and difference in pricing raised by defendant are on weak footing, therefore, plaintiffs cannot be non-suited from grant of injunction.[94]

FACTS:

The plaintiff who is engaged in the business of manufacturing, formulating and selling pharmaceutical products, inter alia, including Alendronate and Alendronate Sodium, which is a newly invented drug found particularly effective against the disease of osteoporosls, which results in thinking and weakening of bones. Further case of the plaintiffs is that they have been successful in discovering, and developing new chemical and pharmaceutical entities of major significance and in the last 5 years they have developed 15 drugs and vaccines and this process of research is continued at high cost.[95] On the other hand, case of defendant-company Messrs Hilton Pharma (Pvt.) Ltd., is that they are leading pharmaceutical concern engaged n the manufacturing and marketing of medicines and other pharmaceutical products in Pakistan. Since 1976 they have made substantial investment in this field and have earned considerable goodwill and

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[94] Ibid., p. 419.

[95] Ibid., p. 410.

sizeable share in the market. In the year 1999 they have got registered their pharmaceutical product "OSTAD" with the Ministry o Health. Government of Pakistan, and have also incurred huge expenditures in publicizing the said product in the market. This new product of defendants-company, which is yet to be introduced in Pakistani market, contains chemicals ingredient "Alendronate Sodium" manufactured from one of the many other known processes for manufacturing the said chemical ingredient.[96]

Case No. 6

Suit No. 42 of 2003, MERCK & CO., Inc., and Others Versus Ferozesons Laboratories Limited.

Precisely, the plaintiffs have filed a Suit for permanent injunction restraining the Defendant perpetually-from infringing the Plaintiffs' copyrights and Passing off Defendant's products as and for the products of the Plaintiffs and for damages, plaintiffs are strongly committed to research and development in an effort to discover, invent and develop, interalia, new chemical and pharmaceutical products and compounds, including processes for their manufacture and formulations thereof.That amongst the completely novel invented products of substantial therapeutic importance, which has been developed and patented by the Plaintiffs in large number of countries, is a Compound (including its processes of manufacture and formulations compositions) now known by the International Non-Proprietary name of Montelukast.

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[96] Ibid., p. 411.

That at this stage it would be relevant to briefly describe various steps involved in connection with the generic naming of a pharmaceutical and chemical product or a drug such as Montelukast. Any product at the time of its discovery and early development is initially designated by its molecular structure or chemical formula. that since the molecular structure or chemical formula of compounds is cumbersome, complicated, lengthy and complex for normal day to day usage; a non-proprietary name is also given to a compound or a drug. The name **Montelukast** was proposed by t Plaintiff and approved by the World Health Organization as a Non-Proprietary name. The name **Montelukast** therefore, appears in official publications. That lastly a trademark was developed by First Plaintiff for Montelukast. This is the name under which a manufacturer and/or seller sells the product (i.e., the finished product) in which the active ingredient is the patented drug or pharmaceutical compound, or composition. In the present case the trademark **SINGULAIR** is used under which the products containing Monteliskast as the active ingredient as its sodium salt i.e. Montclukast Sodium.

Containing Montelukast apart from being very effective for treatment of asthma etc., among adults are equally effective and safe for use by children even as young as the age of two (2) years Symposiums in various cities of Pakistan in which large number of Pakistani physicians other people from medical profession participated. Further, Monteiukast product Literature was also developed, get printed and circulated by Plaintiffs throughout Pakistan for and or behalf of Plaintiff who enjoy copyright in some of the Product literature created by and/or on its behalf, as also mentioned on such Publications. In other literature Plaintiff enjoy copyright therein. That the Plaintiff have continuously promoted their

Monteiukast containing products through various customary means in Pakistan. That all the information disclosed and revealed to the physicians or other concerned people in the product literature, specifically and exclusively related to the Plaintiffs' Montelukast containing products whereby an assurance was conveyed by the Plaintiffs to the physicians and other people concerned that Plaintiffs' Montelukast containing products will bring the results as disclosed in the Product Literature.Plaintiffs SINGULAIR products active ingredient is referred to and written on **the** packaging, promotional as Montelukast Sodium, MSD and therefore, on this score also products containing Montelukast are exclusively associated with the Plaintiffs only

The inserts of Montelukast products and promotional material etc., as detailed above are original literature works, they were first published in Pakistan in the years 2000, 2001 and 2002 as (he case may, as mentioned hereon the authors thereof being Pakistani nationals and residents, as such all such works enjoy copyright protection in Pakistan by virtue of the provisions of the Copyright Ordinance 1962 and no one else, except Plaintiff respectively or their authorized persons have the right to produce or copy or imitate wholly or in part the said product inserts and promotional material etc.

That by virtue membership United States of America and Pakistan of the Berne Convention for the Protection of Artistic and Literary Works, 1884 and the Universal | Copyright Convention, 1952 as well as Section 54, of. the Pakistan Copyright Ordinance, 1962, as amended by the Copyright Ordinance, 2000, read with the International Copyright Order, 1968, the Products Inserts, printed material

as used by Plaintiffs in other countries, the literary contents of the website www.singular.com as well the Clinical Studies, Efficacy And Safety Results in relation to Montelukast containing products owned by Plaintiff No. 1 shall be deemed to be first published in Pakistan like manner and enjoy copyright protection in Pakistan such printed material, website contents and description, the. Clinical Studies, Efficacy And Safety Results for Montelukast and their individual features being original literary works protected in all Berne Convention and Universal Copyright Convention Member Countries, are likewise protected in Pakistan as of the years of their first publication by virtue of Section 54 of the Pakistan copy right Ordinance 1962 read with the International Copyright Ordinance 1968, paragraphs 3(a), 3(b) & 3(d) in particular, read

With Sections 10, 9, 4 and 2 of the Copyright Ordinance, 1962, hence any person, who amongst others, reproduces in a material forms, publishes or copies or counterfeits *such* original inserts, printed material, website contents and description. Clinical Studies, Efficacy And Safety Results without the authorization, permission, consent or license of their owners would commit an infringement of Copyrights" in the said, inserts, printed material, website contents and description, Clinical Studies, etc., for Montelukast containing products.

Thus the Montelukast products under the trademark "SINGULAIR" have acquired a high reputation and goodwill in Pakistan... which belongs to the Plaintiffs and the manufacture and/or sale of any Montetukast containing products by third persons with direct or indirect impression or representation that such Montelukast manufactured and/or formulated by sources unrelated to the Plaintiffs

will have the same effect as that of Plaintiffs' containing products could result in misrepresentation made during the course of trade to potential customers of Plaintiffs would amount to the commission of tort of passing off and which words he calculated to injure the business or goodwill of the Plaintiffs and which would .'dually cause damage to the said business or goodwill of the Plaintiffs in Pakistan. Montelukast products have been invented, **developed, produced, launched and** popularized throughout the world including Pakistan by and/or on behalf of Plaintiffs, and were marketed for the first time in 1997. There is no third party which is selling any Monleliskast containing product in Pakistan originating from the Plaintiffs, particularly with the indication or impression that the same will give results or will otherwise have the therapeutic effects as that of Plaintiffs' Montelukast containing products, which have established their reputation and goodwill on the strength of their quality, efficacy and safety. Therefore sale of any products containing Montelukast by any third party with the impression, indication or representation that such Montelukast products may have the same therapeutic effect, efficacy and safety as that of Plaintiffs' Montelukast products may be motivated by an attempt So deceive or confuse the public into believing that such company or person's Montelukast containing products are the same as that of the Plaintiffs.

Plaintiffs came to know vide market sources that Defendant alleged to have obtained a Drug Registration from Ministry of Health, Government of Pakistan for manufacturing and marketing pharmaceutical products containing **Montelukast** as its sodium salt under the trademark 'MONTE KAST and its representatives and employees are canvassing and announcing to the doctors and

people in the medical and pharmaceutical trade that having obtained registration from the Ministry of Health they would soon introduce their MONTEKAST products containing Montelukast as the active ingredient, in the market. Defendant's representatives are advertising and misrepresenting to the physicians and other people in the medical and pharmaceutical trade that Defendant's products under the trademark MONTEKAST containing Montelukast as the active ingredient are the same and will have the same therapeutic effect, efficacy and lever of safety as that of Plaintiffs' Montelukast products,. It is submitted that it is common knowledge in Pakistan that companies intending to market copy/imitation products of the research molecules such as Montelukast, use and rely it on clinical studies and trials, efficacy and safety studies carried out on research molecules to support and/or obtain their own drug registrations from the Ministry of Health as such companies and expertise for conducting such tests/trials and carrying of the studies and are not willing to spend enormous amounts of money required for such purposes.

Plaintiffs therefore, have reasons to believe that the Defendant has copied and/or imitated and/or produced the information, description, report of results, analysis and tests conducted by or on behalf of Plaintiff using Montelukast products originating from (he Plaintiff company to show (and to misrepresent) to the Ministry of Health. Defendant through their pre-launch promotional campaign for Montelukast containing products are solely relying upon and referring to the reports, studies, analysis results given by Montelukast containing products of the Plaintiffs, as the Plaintiffs' Montelukast products have achieved high levels of success due to their quality, superior therapeutic effects as well as the safety and efficacy standards maintained by the Plaintiffs, which it is believed the Defendant

may neither achieve nor maintain in relation to their Montelukast containing product.

The sales promotion staff of the Defendant is distributing to doctors and the trade, material consisting of and referring to the studies etc. and results obtained by using Montelukast products of the Plaintiffs, as if constituting the studies and results given by Defendant's Montelukast products. The Defendant by its said (misrepresentation are seeking to induce the doctors to prescribe, and the trade and the public to purchase and dispense, Montelukast product originating from them to be sold under the trademark MONTEKAST in the impression to get Montelukast products from the commercial source which had manufactured and sold the Montelukast products which had given the results and therapeutic effect shown in the Defendant's (promotional) material. If a doctor prescribed, and/or rallied and the public purchased, Defendant's Montelukast products in response to Defendant's (promotional) material, the Defendant would supply, and/or the trade and the public would buy, Montelukast/products not of that commercial source of Defendant manufactured and/or origin. This clearly constitutes and will constitute the commission of the tort of Passing Off.

That the manner in which the Defendant has copied and description. Clinical Studies, Efficacy And Safety Results, product insert of Plaintiffs' Montelukast products as well as the way the Defendant is canvassing and assuring people in medical profession about the therapeutic effect and results **of their Montelukast** products, the same is likely to be understood by the trade and public, and more particularly by the unwary purchasers as indicating origin of such

products of the Defendant with the Plaintiffs and Defendant's products shall be likely to be taken to be emanating from the Plaintiffs and therefore, confusion, will be most likely to result. The Defendant's aforesaid activities are otherwise generally likely to cause confusion and deception amongst the trade and the public and adversely affect the Plaintiffs in their business, custom and goodwill.

That aforementioned acts are clearly acts of fraud on the part of the Defendant who have no justification or reason for doing so. The aforesaid violation or intended violation by Defendant of Plaintiffs' copyrights and common law rights as described above is of utmost concern to the Plaintiffs and poses a serious threat to the substantial investments made by the Plaintiffs in their business as well as the reputation and goodwill enjoyed by the Plaintiffs in their Montelukast product.

That in view of the above, it is respectfully prayed that this Honorable Court may be pleased to pass a decree against the Defendant:

(a) a decree for permanent injunction restraining the Defendant perpetually from infringing and violating Plaintiffs' respective copyrights in the and description, studies, reports, results, product inserts and promotional literature and from launching, promoting, marketing, offering for sale and selling Defendant products containing Montehkast in any form under any name as and for Montelukast products of the Plaintiffs by, inter alia, referring to the clinical trials, studies, reports, results conducted and/or carried out on Plaintiffs' Montelukast products.

(b) a decree for permanent injunction restraining the Defendant perpetually from using the Plaintiff respective copyrights in any manner and from

canvassing, advertising or other promoting their Montelukast containing products with the indication, whether direct or indirect, and misrepresentations that Defendant's Montelukast products will have i.e. same therapeutic effect, efficacy and safety results as that of (lie Plaintiffs' Montelukast containing products sold under the trademark SINGUI.AIR or otherwise Passing Off, or intending to Pass Off and enabling others to Pass Off Defendant's Montelukast containing products as those of the Plaintiffs and otherwise in any manner or form use, refer to or indicate to clinical studies, reports, test etc., conducted on Plaintiffs Montelukast products or to Plaintiffs copyright literary works.

(c) a money decree against the Defendant for payment of Rs. 10,000,000/- (rupees ten million) to the Plaintiffs as damages on account of partial compensation for the loss and damage for .injury the goodwill and reputation of the Plaintiffs.

The defendant filed Written Statement along with Reply to the stay application and the following arguments were discussed.

1. That the averment of the plaint does not disclose any cause of action. That no cause of action has accrued to the plaintiffs as there is no copyright registration granted by the competent authority, the defendant has not committed any infringement of the alleged copyright. And that suit has been filed on false and fabricated grounds as no case of infringement of alleged copyright has been made out.

2. That the First plaintiff is a corporation organized and consisting the laws of the State of New Jersey, United States of America vide Para No 1 and 1.1 of the plaint, Merk & Co, Inc and Merck Frosst Canada & Co are Foreign Companies existing under the laws of the State of New Jersey USA and laws of the Province Of Novo Scotia , Canada, do not have registered office at Pakistan under Section 541 and 452 Companies Ordinance 1984. Under Section 456 Company Ordinance 1984, the First and Second Plaintiffs Shall not be entitled to bring any suit or institute any legal proceeding until it has complied with the provisions of Section 451 and 452 Companies Ordinance 1984.

3. That the plaintiff i.e. Merck Frosst Canada & Co has given Power of Attorney to Mr,Naveed Afzal Qari relating to infringement of patent, exclusive market right of patent whereas in the said Attorney no power has been given in relate to copyright, literature and insert of their product Singulair containing Montelukast. That the plaintiffs Annexed in their plaint as Annexture -3 a Special Power of Attorney where Mr. Muhammad Tahir Iqbal is a Attorney of Merck & Co Inc i.e. first Plaintiff sub-delegated the power of Attorney to Syed Mukkaram Ali and Mr.Naveed Afzal Qari in regard to Patents Trademarks and intellectual Property Rights whereas the Merck & Co i.e. first plaintiff has given power of Attorney pertaining to Sodium Aldoronate hence Mr. Naveed Afzal Qari do not have any right to sign and verify the plaint.

4. That it is pertinent to mention here that vide para 2.5 of the plaint the plaintiffs themselves admitted that third Plaintiff is a Pakistani Company engaged in the import and the distribution of pharmaceutical product is responsible for product registration import and distribution of plaintiffs Montelukast product whereas the said Pakistani Company i.e. Muller and Phipps i.e. third Plaintiff is not entitled to file a suit on behalf of the Plaintiff No.1 & 2 being a foreign companies under Sections 451,452 & 456 of Companies Ordinance 1984. Whereby the Foreign company who establish a place of business in Pakistan shall within 30 days of the establishment of the place of business, deliver to Registrar a certified copy of the Charter, Statute and Article of the company etc. The suit is barred by law. That under Section 206 Sub Section 3, Companies Ordinance 1984, no company whether incorporated in Pakistan or out side Pakistan which is carrying business in Pakistan shall without the approval of authority appoint any sole purchase, sale or distribution agent as already stated above the plaintiffs have got no approval from the authority i.e. Corporate Law Authority under Section 11 of the Companies Ordinance 1984

5. That vide para 4.1 the plaintiffs got patented their drug vide patent No. US 5,565,473 & EP 0480717B1 in USA but the plaintiffs do not obtained patent in respect of Montelukast in Pakistan hence got no right to manufacture or distribute their drug. That the plaintiffs fraudulently made a literature and insert of the defendant's drug

Montekast by themselves and showed the similarity with the plaintiffs literature and annexed with the plaint as Annexure K & L whereas the defendant's literature is entirely different and insert is different as of plaintiffs Literature and insert.

6. That the plaintiffs filed an application for registration of imported drug through their sole agent in Pakistan i.e. Muller & Phipps Pakistan Private Limited Plaintiff No.3 whereas under the provision of Section 206 sub section 3 Companies Ordinance 1984, no company whether incorporated in Pakistan or out side Pakistan which is carrying business in Pakistan shall without the approval of authority appoint any sole purchase, sale or distribution agent as already stated above the plaintiffs have got no approval from the authority i.e. Corporate Law Authority under section 11 of the Companies Ordinance 1984.

7. That the plaintiffs have filed a suit only to create harassment and put pressure on the defendant by mentioning concocted stories which have got no concern with the defendant's product. That the plaintiffs have got no cause of action to file the instant suit as the suit is premature and based on presumptions and conjectures, hence the suit is liable to be dismissed under Order 7 Rule 11 CPC.

That the arguments and record perused carefully and on carefully scanning of the record transpires that though the existence of the copy right in respect of the product subject matter of the suit is asserted in the plaint by

the plaintiffs, but there s no proof in this regard as to when alleged copy rights were granted to the plaintiffs and in this regard a vague and compound assertion is pleaded by mentioning that some of the products are result of certain copy right, but those products have not been specially defined. Therefore, for the reasons discussed the application for interim relief moved by the plaintiffs is hereby dismissed. The main case is pending in the court.

Case No. 7

First Regular Appeal before the Lahore High Court Rawalpindi Bench Rawalpindi.

FACTUAL BACKGROUND OF APPEAL:

The Appellant filed Regular First Appeal Against Order under section 96 CPC, challenging the order of dismissal of Application for interim injunction, application under Order 11 Rules 14 & 15 CPC, and Decree dated January 21, 2002 passed by the learned District Judge,_Islamabad. Restraining the Respondents/Defendants from using in any manner and selling Rosiglitazone itself and/or Rosiglitazone in the form of any of its pharmaceutically acceptable salts and/or Rosiglitazone with addition of any other pharmaceutical ingredient/element/compound containing products or any colourable imitation of Appellants/Plaintiffs' Rosiglitazone and its various pharmaceutically acceptable salts products **Rosiglitazone Products** which is manufactured and/or formulated by using or adopting in any manner any process identical to or equivalent to or substantially similar to or incorporating the essential steps of any of the processes

and formulations/compositions subject matter of claims of Appellants'/Plaintiffs' Pakistani Patent Nos. 133856, 136289, 136428 and 136429 hereinafter collectively referred to as the **Appellants'/Plaintiffs' Patents).** That alongwith the Suit, the Appellants/Plaintiffs also filed an application under Order 39 Rules 1 and 2 CPC (hereinafter referred to as the **Stay Application)** to restrain the Respondent/Defendant from manufacturing and/or importing and/or formulating and/or launching and/or offering for sale and/or selling their disputed **Rosiglitazone containing products** till disposal of the Suit.

That the grant of the aforesaid Patents to the Appellants/Plaintiffs in terms of Section 30 of the Patents Ordinance, 2000 (hereinafter referred to as **the Patents Ordinance)** gives them the exclusive proprietary rights to and in respect of:

a) all the processes of manufacture of Rosiglitazone and its various pharmaceutically acceptable salts including hydrochloride claimed therein;

b) the formulations of Rosiglitazone and its various pharmaceutically acceptable salts including hydrochloride claimed therein;

c) Rosiglitazone and its various pharmaceutically acceptable salts including hydrochloride when manufactured by the said claimed processes; and

d) different compositions and dosage forms of Rosiglitazone and its various pharmaceutically acceptable salts including hydrochloride. The rights granted to the Appellants/Plaintiffs also included right to prevent any person, not authorized by the Appellants/Plaintiffs from using, imitating and counterfeiting such inventions (Patents) in terms of Section 60 of the Patents Ordinance.

3. That the learned Trial Court on the date of the filing of the Suit (October 20, 2001), being prima facie convinced with the claim of the Appellants/Plaintiffs as contained in the Suit, was pleased to register the Suit, issued summons and notices to the Respondents/Defendants and an order was also passed restraining the Respondents/Defendants from launching any disputed Rosiglitazone Products. Relevant extract of the order dated October 22, 2001 is reproduced hereinafter:

"In view of Section 61(2) of the Patents Ordinance 2000, as an effective provisional measure, the respondents are prevented from infringing the patents of the Plaintiffs and making importing and offering for sale, the patented Rosiglitazone containing products of the petitioners, till next date of hearing. To come up on 31.10.2001."

3. .That the Respondents/Defendants appeared in the Suit on the very next date of hearing i.e., October 31, 2001 and filed their written

statement to the Suit and reply to the Appellants'/Plaintiffs' Stay Application. That apart from raising certain irrelevant preliminary objections, the Respondents/Defendants in their written statement raised various defenses on merits to the Suit as well as Stay Application. Salient points of defenses raised by the Respondents/Defendants in their written statement to the Suit and reply to Stay Application are mentioned hereinafter:

i) That the Respondents'/Defendants' product **Roziglitazone Hydrochloride (HCI)** [hydrochloride salt of Rosiglitazone], is different from Appellants'/Plaintiffs' Patented product **Rosiglitazone Maleate.**

ii) That the Respondents'/Defendants' **"Process"** to produce **Roziglitazone** containing product is different from those covered by Appellants'/Plaintiffs' Patents.

iii) That Ministry of the Health, Government of Pakistan has granted Semi-Basic Manufacturing License to the Respondents/Defendants to produce Rosiglitazone containing products.

iv) That the Respondents/Defendants have filed Black Box Patent Application No. 546/2001 dated September 11, 2001 before the Controller of Patents and Designs, Karachi.

An Application under Order 11 Rules 14 and 15 read with Section 151 CPC for a direction to the Respondents/Defendants to produce their Black Box Patent Application No. 546/2001 dated September 11, 2001 which the Respondents/Defendants had not produced, except the title page thereof, carrying the chemical name of Rosiglitazone and Respondents'/Defendants' name.

4 After filing of aforementioned Applications by the Appellants/Plaintiffs before the learned Trial Court on **November 06, 2001,** arguments were partly heard on the Stay Application and proceedings were adjourned to November 15, 2001 for hearing of further arguments on the Stay Application.

5. That on January 19, 2002 the learned Judge was pleased to put few questions to Counsel for both the parties with regard to certain issues of grant of interim injunction and was pleased to observe that orders will be pronounced on the Stay Application on the same date before the closing hour of the day.

6. That finally, the learned Trial Court, to the utmost shock and surprise of the Appellants/Plaintiffs, rather than pronouncing orders on the Appellants'/Plaintiffs' Stay Application (only upon which proceedings were conducted), through its Order and Decree dated 21, 2002 (hereinafter referred to as the **Impugned Order**), dismissed (i) Stay Application, (ii)

Application under Order 11 Rules 14 & 15 CPC as well as (iii) the Suit itself. Relevant extract of the Impugned Order is reproduced hereinafter:

"The suit of the plaintiffs in respect of a decree for permanent injunction restraining the defendants perpetually from infringing their patents rights as well as damages is held to be pre-mature and the same is accordingly dismissed with costs"

"Consequently, application of the plaintiffs/Petitioners under Order 39 Rule 1-2 read with Section 151 CPC for grant of interim injunction is rejected."

7. That the Impugned Order, dismissing the Stay Application is erroneous, illegal, improper, unwarranted by the circumstances of the case, arbitrary, harsh, nullity in the eyes of law, affected by excess of jurisdiction and misreading and non reading of record and mis-appreciation and mis-application of law is therefore, liable to be set-aside on the following amongst other:-

Grounds of Appeal

a) That the learned Trial Court has failed to apply its judicial mind to the facts of the case in general and law on the subject in particular, therefore, the Impugned Order is liable to be set-aside.

b) That the learned Trial Court has committed serious error while dismissing Appellants'/Plaintiffs' Application under Order 11 Rules 14 & 15 CPC

(which order has been set aside by the learned Division Bench of this Honorable Court in RFA) seeking direction to the Respondents/Defendants to produce their Black Box Patent Application No. 546/2001. The learned Trial Court has misinterpreted and mis-applied the law as there is no prohibition in the Patents Ordinance which prevents a court of law from directing submission of specifications and claims of any pending patent application, whether Black Box or Ordinary.

c) The learned Trial Court has erred not to appreciate that Respondents'/Defendants' Black Box Patent Application was the solitary document upon which they entirely based their defence, which they had also mentioned in their written statement and reply to Stay Application, however, with utter malafide and with intention to practice fraud upon the learned Trial Court (in which the Respondents/Defendants were successful), the Respondents/Defendants did not file complete copy of their Black Box Patent Application and rather only filed cover sheet of same ***which neither disclosed Respondents'/Defendants' alleged invention and the method by which it was to be performed nor the process or formula or composition of making Rosiglitawne and converting Rosiglitazone to its hydrochloride salt (Rosiglitazone hydrocliloride).*** In this manner, the Respondents/Defendants malafidely and purposefully withheld the entire document from the learned Trial Court therefore, dismissal by the learned Trial Court of appellants/Plaintiffs Application under Order 11,Rules 14 and 15 CPC was wholly unjustified and illegal whereby the learned Trial Court eliminated its own position to prima facie reach correct

conclusion. In fact, the illegal dismissal of this Application was one of the basic illegalities which resulted in dismissal of the Stay Application through the Impugned Order.

d) In these circumstances, attention of the learned Trial Court was drawn to various judgments by the superior Courts of the country, more particularly, 1986 **MLD** 1535 and 1996 **MLD** 1123

e) In the above manner, the learned Trial Court rather than drawing adverse presumption against the Respondents/Defendants for withholding the Best Evidence (their alleged Black Box Patent Application) erroneously treated their false allegations (without any proof) as ***"Proven Facts",*** when in fact no evidence was recorded wherefor serious error has been committed by the learned Trial Court rendering the Impugned Order a mere nullity in the eyes of law, which is accordingly liable to be set-aside.

e) That the Impugned Order is self contradictory and shows lack of application of judicial mind by the learned Trial Court to the facts of the case.

f) The learned Trial Court thus made a very serious error, going to the root of the matter, in not appreciating that when it had itself refused to direct the Respondents/Defendants to produce complete copy of their Black Box Patent Application, and neither the Respondents/Defendants produced that, comprising of specifications and claims (the process)es), formulations/compositions etc., for making Roziglitazone), as is mandatory

by virtue of Section 15 (1) and (3) of the Patent Ordinance, it could not hold in the same breath that:

"If we compare, the composition specification of the patents and the Black Box application of the plaintiffs with that of the defendants, it transpires that **the composition as well as manufacturing process of the medicines being manufactured by the parties, prima facie, seems to be different."**

g) It is respectfully submitted that since Respondents'/Defendants' alleged process, formula and formulation/composition were not before the learned Trial Court, it could not compare the process or the composition or the formulation of the Appellants'/Plaintiffs' Patents with that of Respondents'/Defendants' and could not hold that " **the composition as well as manufacturing process of the medicines being manufactured by the parties, prima facie, seems to be different."**

It is respectfully submitted that the Appellants'/Plaintiffs' aforementioned Black Box Patent Applications were of significant importance as the same relate to Appellants'/Plaintiffs' invention with regard to **Rosiglitazone Hydrochloride Monohydrate** and **Rosiglitazone Hydrochloride Dihydrate**

The Respondents'/Defendants' main defence was that their disputed product being Roziglitazone HC1 (Roziglitazone Hydrochloride) is different from

Appellants'/Plaintiffs' product. To support the above contentions the Respondents/Defendants had relied on their Black Box Application No. 546/2001 filed on September 11, 2001 (after almost 17-months of Appellants'/Plaintiffs' inventions as disclosed in Appellants'/Plaintiffs' Black Box Patent Application Nos. 341 and 342 of 2000).

h) In above view of the matter, the Appellants'/Plaintiffs' inventions duly related to ***Roziglitazone Hydrochloride,*** without prejudice to the fact that alleged addition of Hydrochloride by Respondents/Defendants to Appellants'/Plaintiffs' patented product Roziglitazone was immaterial and insignificant.

i) It is respectfully submitted that under law, the Respondents'/Defendants' cannot be considered to be inventors of Roziglitazone HCI as the same has already been invented by the Appellants/Plaintiffs and they had their Patent No. 133856 dated September 05, 1992 as well as their other Patents in Pakistan.

j) Further, the Appellants'/Plaintiffs' Black Box Patent Applications No. 341 and 342 of 2000 both dated April 19, 2000 additionally related to **Rosiglitazone Hydrochloride Monohydrate** and **Rosiglitazone Hydrochloride Dihydrate** therefore, clearly, under law, the Respondents'/Defendants' alleged false invention (in fact imitation and counterfeit) of Roziglitazone Hydrochloride lacked *"Novelty* " in terms of Sections'7 and 8 of the Patents Ordinance. In this view of the matter, the Impugned Order is liable to be set aside.

f) Attention of this Honorable Court is drawn to contents of Paragraph No. 19 of the Impugned Order, more specifically the first 5 lines of paragraph No. 19, relevant extract whereof is reproduced hereinafter:

"As observed above, the defendants have obtained marketing approval from the Ministry of Health, Government of Pakistan and their Black Box application in respect of the chemical product is pending adjudication in the Patent Office. Therefore, the prayer of the plaintiffs is pre-mature and not maintainable."

k) With regard to above, it is respectfully submitted that Superior Courts of the country have consistently and clearly held that obtaining of any marketing approval or a drug registration from the Ministry of Health, Government of Pakistan for production or sale of any drug or pharmaceutical product in Pakistan, cannot be pleaded as a defence to an action for infringement of a patent.

l) In this regard, attention of the learned Trial Court was drawn to various reported judgments by Superior Courts of the country, more specifically, judgments reported as 1992 CLC 2382 (DB), 1991 CLC Note 168 Page 52,1991 MLD 85 and 1987 CLC 1571.

Most importantly the Judgment reported as 1992 **CLC** 2382 was by a learned Division Bench of Honorable Sindh High Court. For convenience of this Honorable Court relevant extracts of two of the aforementioned judgments are reproduced hereinafter

"There is no controversy on the point that respondents' product **'Melfax' is registered with the Director General, Health,** Government of Pakistan. However, the question whether the respondents have infringed the appellants' patent is altogether a distinct question and the same has to be determined in accordance with the law relating to patents. **Consequently, registration of respondents' product with the Director General cannot be successfully pleaded as a defence against the alleged infringement. "**

1987 CLC 1571

"Mere registration of the drug with the Ministry of Health under the Drugs Act cannot immunize the Defendants against claims of aggrieved parties under the Patent Act."

g-iii) The learned Trial Court also erred to overlook and not consider clear statutory provisions of Sections 30 (3) and 60 (1) of the Patents Ordinance.

m) In view of aforequoted binding law laid down by the learned Division Bench of Honorable Sindh High Court, there was no justification for the learned Trial Court to hold that either the Suit or resultantly, the Stay Application were premature or not maintainable for the reason that the Respondents'/Defendants' had clearly ***"threatened to infringe"*** Appellants'/Plaintiffs' patents wherefor the Suit as well as the Stay Application were fully competent and could not be summarily dismissed by

the learned Trial Court through the Impugned Order which is liable to be set-aside

On evidence, as it stands, there is ground for saying that 'Melfax' is medically equivalent to 'Zantac'. As soon as it is put into the human body, it does have the same effect as 'Zantac'. In these circumstances, we think there is a prima facie case for saying that there was an infringement. So we would hold, departing in this respect from the learned Judge, that there is prima facie evidence of infringement of these Pakistan patents by the importation and sale in this country of the medicine 'Melfax'.

k) It is respectfully submitted that while passing the Impugned Order dated January 21, 2002, the learned Trial Court has mis-interpreted the provisions of Section 61, more specifically Section 61(2) of the Patents Ordinance, 2000.

1) Attention of this Honorable Court is drawn to contents of paragraph No. 12 of the Impugned Order as appearing on pages 10 to 12 thereof wherein the learned Trial Court has reproduced and discussed various formulas of various Patents and Black Box Patents Applications of the Appellants/Plaintiffs which are in fact only the ***Titles Of Inventions*** and **chemical names** of various compounds and **not** ***"Processes"*** or ***"compositions".***

With regard to above, it is respectfully submitted that the learned Trial Court has altogether ignored these issues of significant importance and reached an illogical

conclusion that the Respondents'/Defendants' Product and Process is different from that of the Appellants'/Plaintiffs' Product and Process which conclusion is wholly incorrect and not based on any material, and a pure nullity in the eyes of law wherefor the Impugned Order, ***treating a mere "chemical name" as a "Process",*** is liable to be set-aside.

The appellant, in view of the above it is respectfully prayed that this Honorable Court may be pleased to:

i) set-aside the Impugned Order dated January 21, 2002 to the extent that it has dismissed the Appellants'/Plaintiffs' Application under Order 39 Rules 1 and 2 read with Section 151 CPC for grant of interim injunction and grant the same till disposal of the Suit by the learned Trial Court on merits;

ii) suspend the operation of the Impugned Order dated January 21, 2002 during the pendency of the titled appeal; and

iii) restrain the Respondents/Defendants from importing, making, formulating, launching and selling **Rosiglitazone itself** and/or **Rosiglitazone in the form of any of its pharmaceutically acceptable salts** and/or **Rosiglitazone with addition of any other pharmaceutical** ingredient/element/compound containing products or any colourable imitation of Appellants/Plaintiffs' Rosiglitazone and its various pharmaceutically acceptable salts products, during the pendency of this appeal.

The appeal was heard for two days and finally dismissed by the court.

CONCLUSION

Going through the facts and data collected it can be undoubtedly said that after the promulgation of Patents Ordinance 2000;

- the number of cases filed in the court of law has increased manifolds
- Patent holders have started instituting unlawful cases to harass the ordinary traders/manufactures to monopolize their products
- Patent holders have started getting undue protections in the wake of some sections of Patent Ordinance hence one patent would block the way for others to future research and developments
- Certain Sections of the Patent Ordinance gave the liberty to the patent holders to get temporary injunctions even by merely filing a suit against anyone without going into the substance of the case
- Defendants, in case of suits filed by the patent holders, did not have much rights and were likely to suffer till the decision of the cases which could take a long time