CHAPTER 3

PATENTS IN PHARMACEUTICAL

"The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death!"

*Indira Gandhi, former Prime Minister of India*

1.1 INTRODUCTION

A patent is an exclusive right or a title granted to an inventor by the state authority for an invention may be about a new product or process or significant improvement over an existing one. In short, the exclusive right to make, use or sell his invention will be with the patentee and all others are excluded from making or selling his invention. A patent is granted for a set period of time, in case of drug it is 20 years from the date of patent filing (TRIPS Agreement Annex 1C). A patent can attract benefits by way of royalty provided it is sold to or mortgaged or may be transferred to others by the patentee for the privilege granted. A patentee has the right to take a patent infringer to the court to stop him from future infringement or compel him to pay damages.

1.1.1 Patent - A Historical Perspective

The first patent was granted to an architect and engineer Filippo Brunelleschi for his industrial invention of equipment used in barge as hoisting gear to transport marble in the year 1421, in Florence, Italy (O'Connor J.&Robertson F. 2002). The patent was granted for three years. Patent then spread from Italy to other countries in Europe. Patent has started in England during the time of Queen Elizabeth I (reigned 1558–1603). Patent protection was then given for up to 14 years. France enacted its patent system during 1791. In the United States of America, the first patent act was passed by state congress in 1790. By 19th century end, most countries enacted patent laws across the world, due to which there are hundreds of separate jurisdiction available for patents in the world. However, Soviet Union was not recognised patents, but
inventors were issued patent certificates for their invention, which enabled them to receive some form of compensation for their inventive efforts. China, though followed Soviet Union earlier on patenting, has revised its patent law in 1985 on the European model (Encyclopaedia Britannica 2013).

1.1.2 Granting Patents
A patent, before granting approval, is examined by trained inspectors, who review and decide whether the inventions as described are truly novel. Though most countries adhere to a systematic pattern but, how rigorously one examine the invention is differed depending on the country in which it is filed. For instance, United States of America simply grant patents to the owner who can prove his claim as that of the first inventor irrespective whether the application is filed first or not. A patent when granted soon need to be commercially exploited as it will not allow patentee sitting on his invention for a long.

1.1.3 Pharmaceutical Patent
Pharmaceuticals are a significant industry, and it has a growing significance in the world because pharmaceuticals provides important health benefits to the humanity by way of inventing new products, new processes or new applications to existing products. It is this reason coupled with the extremely costly and time consuming nature of new drug development risen the growing importance of patent in pharmaceutical invention and to the devise proper intellectual property rights. TRIPS agreement is the result of this effort, which emphasizes a uniform intellectual property regulation across the world to safeguard pharmaceutical inventions from infringing and suggests product patent protection for twenty years from the date of filing an application.

1.1.4 Product and Process patent
In pharmaceuticals, there are two distinct types of patent available: (i) the product patent, by which a drug is produced and (ii) the process patent, through which the chemical formula for the drug is engineered. TRIPS 2005 stress both product as well as process patent protection to pharmaceutical inventions. It is this monopolistic nature of patent that allows pharmaceutical firms to quickly recover the cost of developing drugs. Patented drugs charges exorbitant price in the market and once the patent expire it becomes generic drug which normally priced lower due
to market competition. India plays a very important role in the production and marketing of
generic drugs and supplies quality drugs at affordable price to the entire world. However, this
privilege has been reversed with the introduction of WTO 2005 TRIPS agreement.

1.2 INDIAN PATENT ACT BEFORE 1970

Indian patent system originated with British before independence when they ruled India with the
introduction of Indian Patent & Designs Act, 1911 based on British Patent Law of 1856. The
Act recognized both product as well as process patent for pharmaceuticals, and granted 14 years
of exclusivity to new inventions (Thakur A.K. & Sharma N. 2007). The strong intellectual
property law has enjoyed complete market monopoly for patented drugs in India and the drug
price was the highest in the world (Senator Estes Kefauver 1961). MNCs had dominated Indian
drug market with importation of patented drugs and they never set up local drug manufacturing
units in the country.

1.3 INDIAN PATENT ACT 1970

Indian Patent Act, 1970 was enacted on April 20, 1972 replacing the old Patent and Designs Act,
1911. Indian patent act 1970 has abolished all previous legislations. The new patent legislation
was primarily to realize the core objectives to develop local drug production, to reduce import
dependence of drug and to make the country self-sufficient in bulk drugs and formulations
production and consumption.

The highlight of the Indian patent act, 1970 was that (i) it permitted only process patent for
chemicals and pharmaceuticals, (ii) the term of patent protection has reduced to 7 years, (iii)
introduced quick licensing mechanism. In short, only the process, i.e. the method of making the
product is patentable in India (Intellectual Property India 2013).

Further, the new patent law has excluded any product patent claims for pharmaceutical invention in
the country, at the same time created provision of automatic rights to produce life-saving drugs. The
patent law also had the provision of compulsory licensing, which are issued when situation
warranted in the interests of public health (Justice N. Rajagopala Ayyangar, 1959).
Owing to the absence of process patent protection, Indian pharmaceutical companies have made great progress in the area of drug production technology and mastering of process chemistry skills, which invariably helped industry to produce generic version of a number of patented drugs creating an atmosphere of affordable drugs not only for Indian consumers but the world over. This was an important milestone in the history of pharmaceuticals in India (Zacharias. N & Farias. S 2002).

1.4 INDIAN PATENT ACT AFTER 1970

Indian pharmaceutical industry, under process patent protection, has flourished for almost three decades until when India finally acceded to the TRIPS agreement in 1995. India’s obligations to TRIPS agreement saw many amendments taking place in the existing patent law in order to meet TRIPS regulations. This has made significant impacts on India’s otherwise successful bulk drug and formulation industry.

The reintroduction of TRIPS regulated product patent law in the country has virtually stopped Indian companies to the production of cheap generic version of patented drugs, on which Indian companies were heavily depended. This has forced Indian pharmaceutical companies to re-focus their business strategy with strong emphasis on research and development of new drug molecules to survive and grow in the pharmaceutical business. The alternate for them was to produce only off-patent drugs or produce patented drug under license by paying heavy royalty.

Diagram 3.1 represents various stages at which the Indian patent act has gone through before reaching to the present status.
1.5 AMENDMENTS TO INDIAN PATENT ACT, 1970

Indian patent act 1970 has undergone three important amendments during 1999, 2002 and 2005 in order to make Indian patent act fully TRIPS compliant.

1.5.1 1st Amendment in 1999

The first amendment to the existing process patent act 1970 was carried out in 1999 (Gazette of India 1999), which contained the provision of:
(i) Exclusive Marketing Rights (EMRs) and created a “Mail-box” system in which product patent applications can be filed effective 1st January 1995 for five years period or until patent is granted or disallowed whichever comes first. India will keep all these applications pending until it changes its existing patent law to comply the TRIPS regulations. These pending patent applications if found eligible later will qualify for product patent. In short, India has to grant patent to an applicant if he has already been granted a patent or an EMR for the invention which he or she had in any WTO member country on or after 01 January 1995 (Gazette of India 1999).

The Act encouraged significant number of foreign pharmaceutical companies to participate in the Indian market. By 2005, there were approximately 8,926 patent applications (Financial Express 2013) from foreign drug producers to cover their patented drugs sold as generics in the Indian market. Roche (Switzerland) became the first foreign company to win a patent under India’s new product patent regime. The company was granted patent in March 2006 for a drug that treats hepatitis C (Pegasys), which will be valid for 20 years from May 15, 1997 (Law360 2006). Among patent applications received, Pfizer (US) has submitted the maximum number of application (373) followed by Johnson & Johnson (262) and Procter & Gamble (187) (USITC 2007).

1.5.2 2nd Amendment Act in 2002

The second patent amendment act is done in the year 2002, which provided the incorporation of all applicable provisions except in the case of providing product patents (Gazette of India 2002). The important provisions under this amendment are:

(i) Redefining patentable subject matter;

(ii) Extension of patent term to 20 years i.e. for pharmaceutical inventions, the patent should be granted for a minimum period of 20 years whether it is product or process to fulfil the established criteria; and
(iii) In case of compulsory licensing provision, government will issue the compulsory licenses that complies with the TRIPS regulations only. Issuance of such licenses will entirely be based on the merit, and in each case the patent holder will be given an opportunity to put their view. Besides, there will not be any kind of discrimination between products imported and local products with respect to process patents, and the infringer has to bear the burden of proof (Gazette of India 2002).

1.5.3 3rd Amendment in 2005

The third amendment act is made in 2005 (Gazette of India 2005), which provide:

(i) Copying or reverse engineering of patented products is illegal in India effective 01 January 1995. Accordingly India became fully product patent compliant as per TRIPS agreement. Thus, a new patent regime has introduced in the country. The amendment act further clarifies that the Indian market will have only two versions of generic drugs: generics of off-patent drugs and generic drugs patented prior to 1995. India will not be affected with this act because most drugs (nearly 97 percent) are produced in the country are off patent (Sarda Rohit R. et.al, 2012).

(ii) Granting compulsory licenses in the case of exports to least developed countries (LDCs) with insufficient pharmaceutical manufacturing capacities.

1.6 THE INDIAN PATENT (AMENDMENT) ACT 2005

The Indian Patents (Amendment) Act 2005 was, in fact, the final step towards meeting India’s obligations to TRIPS agreement. The entire amendment exercise was an attempt to balance the interest of different competing stakeholders which include domestic pharmaceutical manufacturers, civil society groups concerned with access to affordable medicines, the research and development community, multinational pharmaceutical companies, intellectual property lawyers and various agencies and governments involved directly or indirectly to amendments and the compliance of TRIPS regulations.
India amended its patent law on April 04, 2005 (Gazette of India 2005), abolishing its existing “process patent” law and reintroduced the western style “product patent” law for pharmaceuticals, food, and chemicals in the country. The new patent act has deleted the exclusive marketing rights and restricted selling copycat drugs by pharmaceutical companies in India. They are also asked to pay royalty money to original patent holders for producing and selling copycat drugs in the market. The Amendment grants new patent holders a 20-year product patent monopoly starting from the date on which the patent is filed. During the patent no generic version of the drug or no compulsory license is entertained except where the provision under TRIPS is granted.

1.7 KEY PROVISIONS IN THE INDIAN PATENT ACT, 2005

Section 25(1), specifies that what invention can be qualified as patentable to grant patent right, and

Section 25(2), states that a patent claim is already granted to non-patentable inventions may need to either change or cancel.

Section 3(d), clearly mentions that patents will not be granted on the following grounds:

- Patent will not be granted to the discovery of an already known substance, unless the substance itself is new or it doesn’t result into enhanced efficiency of the known substance,

- Patent will not be granted to mere discovery of a new property or the new use of an already known substance, and;

- Patent will not be granted to the mere use of an existing process, equipment or device, unless the existing process leads to a new concept or at least it employs one new reactant.
Section 3(e) states that “a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance is not an invention” (IP India 2011).

For instance, a combination invention should be distinguishable from individual features. It means a relationship between two features must show a synergistic effect to be eligible for granting patent.

These two sections, in the Indian patent act 2005, considered to be the main obstacles for patenting drug substances in case of pharmaceutical inventions, unless and until the patentee show improved efficacy over the existing product or process.

1.7.1 Novartis AG’s Case

A recent patent case in reference to the section 3(d) of the Indian Patent (amendment) Act, 2005 was in the Indian Supreme Court, filed by Swiss drugmaker Novartis AG attempting to win patent protection for its cancer drug “Glivec”. The Supreme Court has refused protection for Glivec in its verdict on April 1, 2013 on the grounds that Glivec is not a new medicine but an amended version of a known compound called imatinib, which the company patented in 1993, therefore, not eligible for patent protection under Section 3 (d) of the Indian Patent Law 2005, which specifies that it require an incremental invention to possess both novelty and a significant increase in drug efficacy for it to be eligible for a patent in the country (TOI 2013).

1.7.2 Important Definitions Provided in the Patent Act 2005

2(j): Invention: it means a new product or a new process which involves an innovative step that is capable of industrial use.

2(ja): Inventive step: means it should have innovative features involving technical superiority or economic importance or both when compared to the known fact.

2(i): New Invention: it is a kind of innovation or technology which is not already published or used anywhere else in the world including the country where the application is being filed for
From this definition two types of claims can be made for protection of patentable invention: product claims and process claims. The product means claims to ‘things’. The product protection has wider scope in its application, which provides the right of absolute monopoly to the patentee, at the same time prevent others from making and selling the patented substance or article (Patent Daily, IPA Section 48).

On the contrary, process claim means claims to the method of processing an activity. This may further classify as a process used for the manufacturing or use of product or substance in a specific way. For instance, a particular product can generally be used or manufactured in more ways than one, but the protection remains rather limited under process patent. In other words, under process patent, the patent holder will have only the monopoly right for the method or the way of use for which the patent is granted, and patentee cannot prevent third parties from exploiting the invention (Patent Daily, IPA, section 48).

Interestingly, the process claim is not only differentiates the method for which the patent is granted, but it also infringes the patent process by producing and selling the invention to which the product obtained directly by that process.’ To put it differently, the law permit others the exclusive right to use their patented process for commercial exploitation.

1.8 PROVISION OF SAFEGUARDS AND FLEXIBILITIES IN TRIPS AGREEMENT
TRIPS Agreement contains certain flexibilities as well as some safeguards to a limited extent, which are mainly provided with an objective to mitigate the anticipated negative impacts on accessibility and affordability of drugs, particularly in a developing country like India. The most important safeguards are:

- **Compulsory License** - is a license to use an invention, which has been granted without the permission of the patent holder. A compulsory license can be used to allow the
production and sale of generic drugs before expiry of the patent, thereby increasing opportunities for competition. The basic rationale for a compulsory license is that since a patent is a privilege granted by the Government, the Government retains the right to limit that privilege, if necessary. Many countries, including developed countries, have provisions for compulsory licenses in their national laws. Compulsory licenses are allowed under TRIPS (TRIPS Agreement Annex 1C).

Compulsory licensing has been available in India ever since India introduced the Indian Patents Act 1970. The revised act, as amended in 2005, retains the compulsory licensing provisions in the new patent regime in order to promote competition and safeguard public interest, including making medicines widely available at low prices.

- **Parallel Importation** - refers to importation, without the consent of the patent holder, of a patented product that is marketed in another country. Parallel importation allows one to 'shop around' for a good price. The TRIPS Agreement states that parallel importation cannot be challenged under the WTO dispute settlement mechanism, thus, de facto, leaving countries the freedom to choose whether or not to allow parallel importation (TRIPS Agreement Annex 1C).

- **The “Bolar Provision”** - allows testing and regulatory approval of generic versions of a drug before its patent expires; thus, it allows generic producers to get ready, so that they can start the production and sale of a generic drug as soon as its patent expires. In this way, Bolar Provision facilitates generic competition (UNAIDS, WHO and UNDP Policy Brief 2010).

### 1.9 THE IMPACT OF PRODUCT PATENT ON INDIAN PHARMACEUTICAL INDUSTRY

**On Product Patent:** With product patent in place, companies can no longer use reverse chemical process engineering to manufacture patented drugs. Indian market will have only two versions of generic drugs: generics of off-patent drugs and generic drugs patented prior to 1995. Indian companies will have to either wait until the product goes off-patent in the market or
discover new drug molecules to stay competitive in the international market. Another factor is that product patent protection proliferate monopoly, rise medicine prices, and impacts survival of small and medium scale companies. There are also chances of increase in patent litigation cases. On the flip side, Indian companies will have to invest more in the development-led drug research, discover new molecule regularly to stay alive. The act does encourage significant number of foreign companies to participate in the Indian market.

**On Patent Infringement:** Patent protection is very important, companies can generate revenue for future research and development of new drugs to sustain and grow their business. IPR protection safeguards the staggering developmental cost of new chemical entity (NCE) and high attrition rate in development cycle. Without strong patent protection, pharmaceutical companies cannot raise the investment needed to conduct expensive, high-risk clinical research that too with no guaranteed return. Therefore, it is assumed that without strong patent protection, there will be fewer drug developments so also the flow of drugs to the people would greatly be reduced to the extent it will harm the patients as well as world public health.

**On Access to Cheaper Drugs:** Patent protection leads to monopoly, it prevents market competition, which results into increase in drug prices thereby reducing access to cheaper drugs. The rationale for patent protection may be to encourage innovation but, the possibility of abusing monopoly rights and taking unfair advantage on price in the absence of competition is a crime against the poor in the world especially of life-saving drugs. Conferring monopoly rights over life-saving drugs a highly contentious issue because there should be no profiteering from life and death. Hence, limiting patent rights can help bring down the cost of drug acquisition and access. The other way to bring down the drug price is to use the provision of compulsory licensing embedded in the TRIPS agreement by the government or enter into price negotiation with public procurement. Developing countries need cheaper medicines for fighting endemic diseases like HIV/AIDS, TB, and Malaria etc.

**On Compulsory Licensing:** It is yet to prove that the effective use of compulsory licensing provisions or otherwise limiting patent rights will curb innovative instinct of the people, because every nation aspires to be a developed one, and that is possible only with development of
innovation not only in pharmaceuticals but in every other industries. Therefore, no nation would want to prevent, but progress towards a strong and innovative pharmaceutical industry. However, to protect the larger interests of nations public health, particularly when there is an emergency situation; country adopts measures to replace the paradigm of strict patent regimes.

1.10 PRODUCT V/S PROCESS PATENT

Table 3.1: Product v/s Process Patent

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<tr>
<td>2. Under international patent law</td>
<td>2. Under domestic patent law</td>
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<tr>
<td>3. Only large companies will find the foothold.</td>
<td>3. Major boost to domestic pharmaceutical industry.</td>
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<td>4. Only off-patent product can produce.</td>
<td>4. Can produce generic version of patent protected drugs.</td>
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<td>5. Patent life 20 years</td>
<td>5. Patent life only 7 years</td>
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<tr>
<td>6. Only Compulsory Licenses issued under certain terms and condition.</td>
<td>6. Automatic licenses of right issued after 3 years of granting patent.</td>
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<td>7. Under product patent the burden of proof lies with alleged infringer.</td>
<td>7. In case of process patent the burden of proof lies with patentee.</td>
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<tr>
<td>8. Innovative</td>
<td>8. Imitative</td>
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<tr>
<td>9. Higher capital investment in R &amp; D.</td>
<td>9. Meagre capital investment in R &amp; D.</td>
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<tr>
<td>10. Focus on new drug research</td>
<td>10. Focus on reverse process engineering</td>
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<tr>
<td>11. Exclusive market rights (EMR) for 5 years for patents in any other country.</td>
<td>11. Enable to manufacture and supply medicine at affordable cost</td>
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<td>12. Prices of drugs will increase multifold, beyond the reach of</td>
<td>12. Protects inventor as well as consumers interested in a well-balanced manner.</td>
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common man.

| 13. | Cost of production will increase due to royalty payment to the inventor. | 13. | Quality producer of affordable drugs in the world. |
| 15. | Will move up the value chain | 15. | Remain a copy-cat |
| 16. | Collaborative R & D with PPP mode | 16. | Limited R & D |
| 17. | Wider scope of India inventing its first commercial grade new compound. | 17. | Limited or no scope |
| 18. | Encourage MNCs to launch their patented products. | 18. | Discourage MNCs from launching their new products in India. |
| 19. | Boost Foreign Direct Investments by MNCs | 19. | Reluctant to invest under weak patent protection in domestic market |
| 20. | Domestic competition will increase | 20. | Limited competition from MNCs |

1.11 PATENT LAWS IN MAJOR COUNTRIES

**United States:** US Patent Law (USPTO 2014) considers that a patent is an exclusive intellectual property right granted to the inventor for his invention. The law states that an invention under patent provides monopoly status and the same is prohibited from using, producing and selling by others in the entire state of America.

In the United States, three types of patents are granted to an invention:

i. **Utility patents:** are granted to any person whose inventions, whether it is products or processes, are new or at least have useful improvements thereof to the already existing knowledge or known facts. Utility patents are the most prevailing type of patent available in the United States, and it is granted for a period of 20 years from filing date.
ii. **Design patents**: are granted to any person whose inventions are new, original and attractive in terms of design and workmanship for an article of production. Design patent protects the ornamental designs.

iii. **Plant patents**: are granted to any person who create and asexually reproduce a distinct or a new breed of plant. Plant patents safeguards this distinct variety of plant from asexually reproducing.

The U.S. patent is administered by the Patent Act (US Code 35), through which the U.S. Patent & Trademark Office (USPTO) is established. Applicants who wish to obtain a patent protection must submit their request to the USPTO Office. Competent officers from USPTO office will verify such application to decide whether the discovery is patentable. U.S. patent law authorise the patentee to be the sole owner of the invention, which exclude others from using, producing and selling a patented invention.

**Europe**: A uniform system of protection against inventions whether it relates to industrial property, copyright or other related rights, constitutes the foundation of intellectual property rights within the European Union. European Union possesses two important bodies to carry out its mission: the European Patent Office (EPO) and the Office for Harmonisation in the Internal Market (OHIM), which is responsible for the registration of community trademarks and designs.

They believe the community patent system is more effective will give inventors the option of obtaining a single patent which is legally valid throughout the European Union. It substantially reduces the patenting costs (in particular those relating to translation and filing), simplifies protection of inventions throughout the European territory as the result of one single procedure, and the establishment of a single centralised system of litigation. Finally, the protection of these rights also entails protecting them against piracy, illegal trade and counterfeiting.

**Japan**: The Japan patent act stipulates that an invention must be high in quality and technologically superior in order to qualify for patent protection. The specific purpose of the
patent act in Japan is to promote inventions, which invariably lead to the development of the local industry, for which, the consider protection, and the utilization of invention is a must.

The patent protection under Japanese act is granted for a period of 20 years from the date of application. For pharmaceutical and agricultural inventions, the patent period is further extended up to five more years (Japan Patent Office (JPO)).