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Abstract: Intellectual Property Right (IPR) is a lawful right given by government to inventors for their intellectual work. IP rights are necessary to prevent copying and misuse of original work. IP includes Patents, Copyrights, Trademarks, Plant varieties, Trade secrets, Industrial designs and Geographical indicators. In India in the year 2013-14 maximum numbers of applications filed and granted were for Trademarks. More than 42000 applications were applied for patent while only 10% (4200) got the approval. IIT tops the list in patent filing while CSIR is leading organization in getting maximum number of patent grants. Indian government has taken various initiatives to make the patenting process easier. Patent can be filed in all four metro cities. For international patenting, patent cooperation treaty (PCT) and convention application filing is done to protect the invention at international level and India is one of the member countries of these group. IP rights provide monetary benefit to inventors, further it creates environment of competition which is good for the growth of the economy. As India is a growing economy and competing with many countries out of which some are involved in reverse engineering and copying many of the original work, hence the role of IPR becomes even more crucial. It is also believed that IPR creates monopoly and could increase the price of essential commodities thus affecting poor people. All in all IPR is needs for today's world. A balance is required for its use to misuse which will only be made by making careful law and its effective implementation. [P. Ishwar Bhat, Historical evolution and development of Intellectual Property rights: A focus of some themes, Journal of development and social change, Volume 6, no 1 and2 Jan-Mar, 2009]

1. Introduction

Patent is a universally acclaimed name for monopoly or exclusive right granted by State in favour of an inventor in respect of an invention and excludes the rights of others for a limited duration to do certain acts in relation to an invention. This right is granted to the person who fulfills the prescribed conditions laid down by the government of a particular country. Thus the patentee becomes the sole owner of the invention.

The Patent is granted protection not only under the respective laws of the various countries in the world. But, there is an effort on the International level to protect the inventor.

The World Trade Organization (WTO) is the successor to the General Agreement on Tariffs and Trade (GATT) established in the wake of the Second World War. The WTO is the governing body at the international level, which covers Trade Related Aspects of Intellectual Property Rights (TRIPs) and several allied agreements. The WTO is known to grant flexibilities to the developing member countries in implementing the obligations under the agreement. The WTO’s intellectual property agreements prescribe rules for trade and investment in ideas and creativity. These rules state how Intellectual Property Rights (IPR’s) should be protected where trade is involved.1

The World Intellectual Property Organisation (WIPO) is another international organization dedicated to help ensure that the rights of creators and owners of Intellectual Property are protected worldwide and that inventors thus, recognized and rewarded for their ingenuity. It administers 23 International Treaties dealing with different aspects of Intellectual Property protection. These Treaties and Agreements seek to harmonize national intellectual property legislation and procedures, provide services for international applications for industrial property rights, exchange Intellectual Property information, provide legal and technical assistance to developing and other countries and also facilitate resolution of private Intellectual Property disputes.

The TRIPs Council (which consists of members of the WTO that is responsible for administering the TRIPS Agreement, in particular monitoring the operation of the Agreement) and the WIPO have agreed to cooperate under an agreement that helps the council implement the provisions under the TRIPS agreement.

2. Patents in the Indian Scenario

The laws pertaining to Patent in India is governed by the Patents Act, 1970 which has been amended twice by The Patents (Amendment) Act, 1999 and The Patents (Amendment) Act, 2002. The new Patent Act, 2002 has although been notified on June 25th 2002, however, currently only limited sections of it have been made applicable vide Gazette Notification from the Government of India, dated May 20, 2003. Although, it is being implemented in phased manner, however, it is a matter of time before the new Act shall be applicable in its entirety.2

In the current scenario, the old Acts i.e. The Patent Act, 1970 and The Patent Rules, 2003 are applicable except for the sections made applicable through the Gazette Notification, as stated above.3

What is Patentable

Patents are granted in respect of any invention in goods. An invention means any new and useful art, process, method or manner of manufacture, machine, apparatus or other article, or substance produced by manufacture, and includes any new and useful improvement in any of them. No patent is

1 http://www.en.wikipedia.org/wiki/patents

2 Mr. Shambhu Ghatak authors the article. Patents: A Case History of Indian Drugs and Pharmaceutical Industry “at: shambughatak@yahoo.com visited on 15th December 2009.

3 Needham, J., the Grand Titration, 1969.
granted in respect of claims for the substances themselves; however, claims for the methods or processes of manufacture are patentable. However, in compliance with its commitment under the TRIPS agreement, India has been given time to introduce product patent by the year 2005.

Who Can Apply
Both the Indian nationals and foreigners can make an application for patent in India. But, in case of foreigners applying for patent in India, it is necessary that the country of such applicant should also be providing such reciprocal rights to the Indian nationals.

Application for patents can be made by any person claiming to be the true and first inventor of the invention or by his assignee or legal representative. An application for patent can be made by any of these persons either alone or jointly with any other person. Two or more companies as assignees may also make an application jointly.

Steps Involved in Grant of Patent:
1) Filing of an application for grant of a patent accompanied by either a provisional specification or a complete specification before any public disclosure of the invention.
2) In case provisional specification accompanies the original application, then filing of the complete specification within 12 months from the date of filing of the provisional specification. The said period may be extended by a further period of 3 months by paying appropriate fee for extension.
3) Over coming objections, if any laid by the examiner after the technical examination of the application by the patent office.
4) Acceptance of the application and advertisement of such acceptance in the official gazette.
5) Overcoming opposition, if any, to the grant of a patent.
6) Grant and sealing of the patent.
7) Maintenance of patent by payment of renewal fee.
8) Enforcement/revocation.

Patent Cooperation Treaty:
Patent Cooperation Treaty is the sister treaty of the Paris Convention, which is administered by the World Intellectual Property Organization (WIPO). The PCT facilitates filing of patent applications under a single umbrella and provides for simplified procedure for the search and examination of such applications.

Under the Paris convention an inventor gets a grace period of 12-months to file a patent application in other member countries after filing in the home country. This period of grace is extended to 30-months under the PCT, whereby an inventor can file an "international patent application" in each of the PCT member countries within this prescribed period. In India a grace period of 31 months is granted for such "international patent application".

Protection available to a Patentee
A Patentee has the exclusive right to make, use, exercise, sell or distribute the patented article or substance in India or to use or exercise the method or process. He can assign or give licence and can even surrender his patent. After the Patents (Amendment) Act, 1999, the provisions relating to the grant of Exclusive Marketing Rights (EMR) to the patentee were incorporated. These rights can be exercised either by the patentee himself or by his agents or licensees during the term of patent. In addition to the above privileges the patentee has a statutory right to protect his patent right from being infringed by others. In case of such violation of rights the patentee has civil remedies at his disposal. The civil remedies are in the nature of- Injunction; Damages or Account of profits and Seizure, forfeiture or destruction of infringing material.

Important Amendments in the Patent Act:
The Amendment to the Patents Act, 1970 namely, the Patent (Amendment) Act, 2002 has been notified in the Gazette of India as on 25/06/2002. This Act makes the Indian patent law not only TRIPs compliant but also incorporates safeguards for the protection of public interest, national security, bio-diversity, traditional knowledge, etc. The opportunity has also been utilised to harmonise the patent granting procedures with international practices and to make the system user friendly.

3. Historical Background

- In 1872, the Act of 1859 was consolidated to provide protection relating to designs. It was renamed as “The Patterns and Designs Protection Act” under Act XIII of 1872. The Act of 1872 was further amended in 1883 (XVI of 1883) to introduce a provision to protect novelty of the invention, which prior to making application for their protection were disclosed in the Exhibition of India. A grace period of 6 months was provided for filing such applications after the date of the opening of such Exhibition.

- This Act remained in force for about 30 years without any change but in the year 1883, certain modifications in the patent law were made in United Kingdom and it was considered that those modifications should also be incorporated in the Indian law. In 1888, an Act was introduced to consolidate and amend the law relating to invention and designs in conformity with the amendments made in the U.K. law.

- The Indian Patents and Designs Act, 1911. (Act II of 1911) replaced all the previous Acts. This Act brought patent administration under the management of Controller of Patents for the first time. This Act was

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4 Quoted in Jean Lanjow, “The Introduction of Pharmaceutical Product Patents in India: ‘Heartless Exploitation of the Poor and Suffering’”, Economic Growth Centre, Yale University, August 26, 1997, p. 1


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further amended in 1920 to enter into reciprocal arrangements with UK and other countries for securing priority. In 1930, further amendments were made to incorporate, inter-alia, provisions relating to grant of secret patents, patent of addition, use of invention by Government, powers of the Controller to rectify register of patent and increase of term of the patent from 14 years to 16 years. In 1945, an amendment was made to provide for filing of provisional specification and submission of complete specification within nine months.

- After Independence, it was felt that the Indian Patents & Designs Act, 1911 was not fulfilling its objective. It was found desirable to enact comprehensive patent law owing to substantial changes in political and economic conditions in the country. Accordingly, the Government of India constituted a committee under the Chairmanship of Justice (Dr.) Bakshi Tek Chand, a retired Judge of Lahore High Court, in 1949 to review the patent law in India in order to ensure that the patent system is conducive to the national interest.8

**Patents Rules**

Under the provisions of section 159 of the Patents Act, 1970 the Central Government is empowered to make rules for implementing the Act and regulating patent administration. Accordingly, the Patents Rules, 1972 were notified and brought into force w.e.f. 20.4.1972. These Rules were amended from time to time till 20 May 2003 when new Patents Rules, 2003 were brought into force by replacing the 1972 rules. These rules were further amended by the Patents (Amendment) Rules, 2005 and the Patents (Amendment) Rules, 2006. The last amendments are made effective from 5th May 2006.

**India’s Patent Policy**

India has a long history of patent policy which was framed after enormous study. India’s approach to patents differs from those of industrialized countries in that India sees patents as a tool of public policy. India’s policy is being challenged by the demand to reform IPR laws to conform to TRIPS. This section provides an overview of India’s patent policy.9

**India’s Patent Policy in Pre-TRIPS Period**

India’s patent policy focused on balancing developmental concerns with the need for promoting innovations. India viewed patents as a tool for economic development and restricted the scope and term of patents. The sentiment in India on the issue of patents, especially on pharmaceuticals, is illustrated by an oft-quoted statement made by Indira Gandhi at the World Health Assembly in 1982:

“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”.10

The Original Indian Patents Act, 197011

1) The Act tries to strike a balance between the rights of the patent holder and his obligation to the society that grants him such rights.

2) The basic philosophy of the Act, as laid down in Section 83, is that patents are granted to encourage inventions to accelerate indigenous industrial growth by securing their working in India on a commercial scale. And, those patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.

3) The Act totally excludes atomic energy and methods of agriculture from patentability. One cannot obtain any sort of patent whatsoever in these fields (Section 3).

4) The Act permits product patents for all inventions except food, medicines, drugs and Substances produced by chemical processes; in these fields only process patent is available because food and health are crucial for the well-being of the people. Process patents in these areas enable the other competitors to find new, improved and economical processes for producing the same product.

5) Section 53 provides patent protection for a period of 14 years from the date of filing. In case of food and medical drugs the period of protection is limited to seven years from the date of filing the patent or five years from the date of sealing, whichever is earlier. This shorter period of protection in case of food and medicines is believed to be necessary to prevent the patentee from exploiting the needs of society by charging exorbitant prices for the patented article. Further, in the field of medicine, the rate of obsolescence is high as new and improved molecules keep replacing the existing ones.

6) The Act contains provisions for compulsory working of a patent. The Working of a patent means manufacturing the product in India. The patentee cannot hold the patent in India and import the product from another country, thereby compelling the Indian consumer to pay an excessive price.11

7) In public interest, patents are subject to strict and extensive governmental control and use. The provision on Compulsory Licensing under Section 84 of the Act ensures the working of the patent after three years from the date of sealing. If the patent holder ignores this provision, any person may apply for compulsory license and he shall be licensed to manufacture the product. The rationale of compulsory license is that the state undertakes to protect IPRs only to ensure that new products are available cheaply and in abundance. Hence compulsory license is issued if it is in public interest or if the manufacturer does not work the patent.

8) Every patent for an invention relating to a method or process for manufacture of Substances intended for use, or capable of being used, as food, medicines, or drugs, or relating to substances prepared or produced by chemical process (including alloys, optical glass, semiconductors and inter-metallic compounds) shall be deemed to be endorsed “Licensces of Right” from the

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8 Justice (Dr.) Bakshi Tek Chand retired Judge of Lahore High Court, in 1949


10 Quoted in Jean Lanjow, “The Introduction of Pharmaceutical Product Patents in India: ‘Heartless Exploitation of the Poor and Suffering’”, Economic Growth Centre, Yale University, August 26, 1997, p. 1

date of expiry of three years after the sealing of the patent.

The Influence of England on Indian Patent Law

Patent law in India had its origins in the patent system introduced by Great Britain which ruled India for almost four centuries. It is well documented that the British influence in India had its beginning in 1600 with Queen Elizabeth I’s chartering of the “Governor and Company of Merchants of London trading into the East Indies.” The English East India Company (“The Company”), which first came to India in 1608 and laid the foundation for British rule over the next three decades. The British Crown was eventually forced to take full control of India from the Company in 1858 as a result of a massive revolt against the Company, which is also known as India’s First War of Independence.

Amendments in India after Trips Agreement

TRIPs provided a three-stage frame for countries such as India which did not grant product patent rights in pharmaceuticals, when TRIPs came into force on 1 January, 1995:

1) Introduction of a facility (“mail box”) from January 1, 1995 to receive and hold product patent applications in the fields of pharmaceuticals (and agricultural chemicals). Such applications will not be processed for the grant of a patent until the end of 2004. But Exclusive Marketing Rights (EMRs) can be obtained for that application if a patent has been granted in some other WTO member country and the application has not been rejected in the country as not being an invention.

2) Compliance, from January 1, 2000 with other obligations of TRIPs, namely, those related to rights of patentee, term of patent protection, compulsory licensing, reversal of burden of proof and so on, and

3) Introduction of full product patent protection in all fields including pharmaceuticals from January 1, 2005. All the product patent applications held in the mail box are also required to be taken up for examination from January 1, 2005.

Patents Amendment Act, 1999

Even though India was given exemptions from implementing pharmaceutical/ agrochemical product patents until 2005, it was mandated to set up a mailbox facility for such product patent applications filed during the TRIPs transition period and to assign each application a filing date.

Another obligation under TRIPs was the provision dealing with the grant of EMRs for mailbox applications that met specified conditions during the transition period. India initially tried to implement the mailbox facility and grant EMRs by way of a presidential order. For various reasons the Indian parliament failed to pass the law dealing with mailbox facility and EMRs. This prompted the United States to utilize the WTO’s dispute resolution mechanism to address India’s failure to enact the mailbox and EMR regime into a law.

4. Conclusion

India had a Patent Act which was a master piece legislation on Indian soil with deep rooted sentiments of Indian culture and traditions which did not provide for the product patents until 2005. It stood as an example to many countries which was able to protect Intellectual property and also balanced the public interest which put the Indian Pharmaceutical companies to take advantage and helped in manufacturing the medicines at a very low cost of production which ensured that the prices of medicines are within the reach of the general public and the manufacturers were free to utilize the technologies within the limitations for the welfare of the society and for suffering patients it was a God sent gift. The problem was first initiated when the developing and underdeveloped countries were asked to comply with the strict implementation of TRIPs Agreement beginning with grant of process patents, exclusive marketing and mail box applications initiating in the year 1995-2005 during which India witnessed that the prices of the drugs were increased by the process patent holders but due to the reason of adopting reverse engineering the other manufacturers were able to produce the same medicines by different methodology. Hence this ensured that there were other alternatives available in the market which probably might not be possible under product patent regime and the affordability to life saving drugs and enforce right to health would be a distant dream for the poorer sections of the society and puts an extra burden on the middle class families. The health protection is very much essential and hence there is a binding on the patients to have those medicines which has been prescribed to them they don’t have any kind of choice before them. Though there were efforts taken to provide certain flexibilities as a measure for controlling the prices and affordability of medicines. There is a need to balance the issue of public health and IP protection by properly utilizing the flexibilities.

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[3] Mr. Shambhu Ghatak authors the article. Patents: A Case History of Indian Drugs and Pharmaceutical Industry “at: shambhughatak@yahoo.com visited on 15th December 2009.

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[11] Id. at 10, 12-17.