INDIAN PATENTS ACT

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INTRODUCTION

India is a unique country having its own riches blessed with treasures of wealth, spirituality, moral values where people practiced and adopted the principles of nonviolence and peace. Spiritual elevation was sought not for the sake of individual's attainment of self realization and enlightenment but to serve for the service of the mankind. Social welfare was given much precedence over that of individual's vested interest. We get a large number of instances in this regard where people had an ulterior motive were denied with getting the knowledge. The spiritual gurus have made it a condition that they would impart education or a secret only on getting the assurance that education or knowledge should not be used for the self benefit or for doing the business. This type of practice is still in existence in many of the villages in India.

One such practice can be seen in village Kalagi of Chitapur taluka in Gulbarga district, where the medicine for the fractured broken bone is prepared by the leaves given to the needy patients which is unique medicine which joins the bones by mere application of the medicine, this ensures that the patient does not require any kind of plaster and to hold the broken part of the body still without making any movement and the person who gives the medicine does so at free of cost not a single pie is charged from him. The secret of producing that medicine is currently practiced and this knowledge is transferred by their ancestors subject to the condition that to whom such knowledge is given should take an oath not to use that medicine for making a lively hood or for commercial purpose. It is a concept and spiritual belief in Indians that the secret so disclosed by the Gurus works only if it is utilized for the welfare of the people similarly the antidote for the snake bite to neutralize the snakes poison and for curing jaundice is still in practice in few of the villages where in allopathic medicines does not cure the disease cent percent.

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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".[2]

The philosophy of India's Patents Act of 1970 varies enormously from the framework being established under TRIPs. There are several knowledge and information areas which India considers non-patentable. India has a large community of scientists and researchers among whom publication rather than gaining patents has been a concern. G.V. Ramakrishna, Chairman of the Disinvestment Commission points out that in India, "We (Indians) are accustomed to the notion that knowledge is free. Our whole orientation has to change from one that stresses intellectual attainment to one that protects intellectual property. [3] Industrialised nations conceive of patents as a fundamental right comparable to the right of physical property, whereas developing nations view it as "fundamentally as an economic policy question.[4]

From the perspective of developed countries, intellectual property is a private right that should be protected as any other tangible property, but for developing nations, intellectual property is a public good that should be used to promote economic development.[5]

India has always believed in the Principle of Dharma and wanted that this Principle be envisaged in the Laws that it enacts. On this basis Patents Law was legislated so that the

[2] 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

[3] Rukmini Parthasarthy, "The CEO's Guide to The New Patents Regime "Business Today (Bombay), September 22, 1998, p. 58

[4] R. Gadbow and Richards, eds., Intellectual Property Rights: Global Consensus, Global Conflict?, (Boulder, 1988), p. 2

[5] Terence P. Stewart, ed., The GATT Uruguay Round: A Negotiating History 1986-1992, vol. 2 Commentary (Netherlands, 1993), p. 2255

fruits of innovation be reached to the least person and no person is deprived of it as India was against the commericialization of ones own intellect.

THE MAIN FEATURES OF THE ORIGINAL INDIAN PATENTS ACT, 1970[6]

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] Chandiramani, Nilima.. "Legal Factors in TRIPs": Economic and Political Weekly. Centre for Civil Society 8. January 19, 2002.

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.

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, semi-conductors and inter-metallic compounds) shall be deemed to be endorsed "Licenses of Right" from the date of expiry of three years after the sealing of the patent.

This patent law which was a model for other developing countries like Argentina, Mexico, Egypt, Brazil and Chile, has been replaced by the Indian Patent Act, 1999, which is modeled on the basis of the TRIPs (Trade-Related Aspects of Intellectual Property Rights) Agreement. This amendment seeks to implement the obligations that India has taken in the field of patents by signing the TRIPs Agreement. The bill generally aims at making the 1970 Patents Act as TRIPs compliant as possible.

Besides TRIPs, India is also a member of the following international treaties related to intellectual property rights:

- Convention establishing World Intellectual Property Organization (WIPO)
- Paris Convention for the protection of Industrial Property with effect from December 7, 1998
- Patent Cooperation Treaty (PCT) with effective from December 7, 1998

HISTORY OF INDIAN PATENT 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 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 and 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. The terms of reference of this Committee includes as follows:

- to survey and report on the working of the patent system in India;
- to examine the existing patent legislation in India and to make recommendations for improving it, particularly with reference to the provisions concerned with the prevention of abuse of patent rights;
- to consider whether any special restrictions should be imposed on patent regarding food and medicine;
- to suggest steps for ensuring effective publicity to the patent system and to patent literature, particularly as regards patents obtained by Indian inventors;
- to consider the necessity and feasibility of setting up a National Patents Trust;
- to consider the desirability or otherwise of regulating the profession of patent agents
- to examine the working of the Patent Office and the services rendered by it to the public and make suitable recommendations for improvement;

- to report generally on any improvement that the Committee thinks fit to recommend for enabling the Indian Patent System to be more conducive to national interest by encouraging invention and the commercial development and use of inventions.

The committee submitted its interim report on 4th August, 1949 with recommendations for prevention of misuse or abuse of patent right in India and suggested amendments to sections 22, 23 and 23A of the Patents and Designs Act, 1911 on the lines of the United Kingdom Acts 1919 and 1949. The committee also observed that the Patents Act should contain clear indication to ensure that food and medicine and surgical and curative devices are made available to the public at the cheapest price commensurate with giving reasonable compensation to the patentee.

Based on the above recommendations of the Committee, the 1911 Act was amended in 1950 (Act XXXII of 1950) relating to working of inventions and compulsory license/revocation. Other provisions were related to endorsement of the patent with the words 'license of right' on an application by the Government so that the Controller could grant licenses.

This Act remained in force for about 24 years without any change till December 1994. However, the Act of 1970 was amendment to comply with TRIPs Agreement. An ordinance effecting certain changes in the Act was issued on 31st December 1994, which ceased to operate after six months. Subsequently, another ordinance was issued in 1999. This ordinance was subsequently replaced by the Patents (Amendment) Act, 1999 that was brought into force retrospectively from 1st January, 1995. The amended Act provided for filing of applications for product patents in the areas of drugs, pharmaceuticals and agro chemicals though such patents were not allowed. However, such applications were to be examined only after 31-12-2004. Meanwhile, the applicants could be allowed Exclusive Marketing Rights (EMR) to sell or distribute these products in India, subject to fulfillment of certain conditions.

The second amendment to the 1970 Act was made through the Patents (Amendment) Act, 2002 (Act 38 0f 2002). This Act came into force on 20th May 2003 with the introduction of the new Patent Rules, 2003 by replacing the earlier Patents Rules, 1972.

The third amendment to the Patents Act 1970 was introduced through the Patents (Amendment) Ordinance, 2004 with effect from 1st January, 2005. This Ordinance was later replaced by the Patents (Amendment) Act 2005 (Act 15 of 2005) on 4th April, 2005 which was brought into force from 1-1-2005.

The Patents Act, 1970, was very weak for particular inventions, especially pharmaceuticals. The Act did not provide protection for products vital to the Indian economy, such as agricultural and horticultural products, atomic energy inventions, and all living things.[7] A "stated objective of the Indian Patents Act, 1970, was the development of an independent Indian pharmaceutical industry. The abolition of pharmaceutical product protection from the inherited British colonial law was seen as the key element in advancing this objective."

Under the Patents Act, 1970, the examination and opposition procedures were lengthy. Patent examiners had to ensure that applications were in compliance with the procedural requirements of the Patent Act, and to determine whether there was any "lawful ground of objection to the grant of the patent" Patent examiners had to file a report with the Controller of Patents listing any objections to the grant of the patent within eighteen months after receiving a patent application. Objections could relate to the claims and the specification or anticipation of any claims. The Controller had to report any objections to the applicant and give the applicant an opportunity to amend its application. If the applicant fixed all of the objections and the Controller accepted the complete specification, it was then advertised in the Official Gazette.[8]

PATENT 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

[7] http://www .patent office.nic.in/ipr/patent/manual-2052005.pdf. visited on 16th April,2010, at 11am

[8] Sec 23 of Indian Patent Act , 1970

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.[9]

An Ordinance was actually introduced a day before TRIPs came into effect. But the Ordinance lapsed because it could not be followed up with the necessary legislation within the stipulated time required. Then the government introduced a Bill and it was passed in the Lok Sabha. But in the Rajya Sabha, where the opposition was in a majority, the Bill was stalled (the Bill was referred to a Parliamentary Select Committee) and the report could not be submitted by the time the Parliament was dissolved in May 1996, and India had to comply with the requirements of the TRIPs agreement by April 1999. Again a Bill was introduced, and this time it was passed in the Rajya Sabha on 22 December 1998, but the Bill could not come up for consideration in the Lok Sabha. Ultimately an Ordinance was promulgated followed by an Act passed in March 1999.[10] The Patents (Amendment) Act, 1999.[11]

Main Provisions of Patents (Amendment) Act, 2005

The Patents (Amendment) Act, 2005, ("Patents Act, 2005") was signed into law by the President of India on April 4, 2005, published in the Gazette of India, and brought India's

[9] See "Amendments to the Patents Act, 1970: Background Note," Department of Industrial Policy and Promotion, Ministry of Commerce, New Delhi. See also the website of the Controller General of Patents, Designs and Trademarks, Government of India (www.patentoffice.nic.in).

[10] For a discussion of the background and the delay, see Peoples' Commission on Patent Laws for India 2003, pp. 17-20.

[11] The text was accessed from www.patentoffice.nic.in. visited on 11th May 2011.

patent laws fully into compliance with TRIPs. "This bill amends India's previous Patents Act to incorporate stricter patent laws, while simultaneously continuing to protect India's domestic pharmaceutical sector and the public health of her citizens."The Patents Act, 2005, altered the former definition of "pharmaceutical substances" to "any new entity involving one or more inventive steps."This means that the pharmaceutical must be new and not just an insignificant change from a previously patented entity. The new law states:

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

Several provisions in the Patents Act, 2005 speed up the process of reviewing and granting patents. The time frame for examination of patent applications was substantially changed by the new law. Earlier, the time period to put the application in order for acceptance was 12 months from the date of the first office action. In the meantime, the first office action had to be replied to within four months of its receipt. The new Rules prescribe a total time period of six months to put the application in order for grant. This period is extendable by three months. Upon filing the Request for Examination, the Controller of Patents will refer the application to an Examiner[12]. The law does not prescribe a time limit to do so. The Examiner, on receipt of such reference, must issue an Office Action within one month and not later than three months from the date of reference.

In addition, "provisions relating to acceptance of complete specification, advertisements of acceptance of complete specification and effect of acceptance of complete specification have been omitted. There will now be direct grant of Patent." The old provisions which dealt with the requirement of sealing of Patent were also omitted by the new Act. Indian legal officials have also recently opened at least ten new regional patent offices in order to speed up the patent process. The processing time limits for examination of patents have been

[12] The Indian Patent Law of 1970 and the Amendment of 2005 are available on-line at the Indian Patent Office Website at: http://patentoffice.nic.in/ipr/patent/patents.htm and http://patentoffice.nic.in/

reduced from forty-eight months to thirty-six months. "Apart from major changes, one of the positive aspects of the present Act is that by amending the various sections rigidity in the time-line is replaced by greater flexibility."[13] When India joined the WTO in 1995, India was forced to create a means for filing pharmaceutical product applications. However, India did not have to review these applications until January 1, 2005, when the developing member transition period ended. To satisfy this requirement, India set up a "mailbox" system to receive, but not review, pharmaceutical applications. Under the Patents Act, 2005, patent applications in the mailbox before January 1, 2005, receive patent rights only from the date of the patent grant, not from the date of filing. Because the 20-year patent protection period begins from the date of filing, however, some pharmaceutical patents will have a short patent life once issued. In addition, after a patent is granted, patent-holders are only entitled to receive reasonable royalties from enterprises which have made significant investments and were producing and marketing the newly patented product prior to January 1, 2005, and which continue to manufacture the product even after grant of the patent, and no infringement actions can be brought against such companies. "Royalty payments commence on the date of the patent grant aid . . . no retroactive royalty's from the patent's filing date having to be paid." "This 'means Indian companies have got compulsory licenses for the 200-odd new molecules that have been patented in the past five years."[14] The Patents Act, 2005, also provides compulsory licensing for the manufacture and export of pharmaceutical products to any country having insufficient or no manufacturing capacity of its own to address public health problems. This allows the Indian government to license the use of a patent to a third party, without the patent owner's consent, for domestic production in India. Before granting the compulsory license, the applicant must only make efforts to obtain a license from the patent holder for a "reasonable period," which is "construed as a period not ordinarily exceeding a period of six months." If the "compulsory license is granted with a pre-dominant purpose of supply in Indian market the licensee may also export the patented product, if need be" "Finally, a compulsory license may be issued that

[13] Jeffrey Colin, Coming into compliance with TRIPs: A Discussion of India's New Patent Laws Cardozo Arts and Entertainment Law Journal; J.D.Candidate, 2008, Benjamin N. Cardozo School of Law; B.S., , Columbia University School of Engineering and Applied Science. 2005.

[14] Martin J. Adelman and Sonia Baldia, Prospects and Limits of the Patent Provision in the TRIPs Agreement: The Case of India, 29 VAND. J. TRANSNAT'L L. 507, 518 (1996).

allows a patented product to be exported in order to remedy an anticompetitive practice. These provisions benefit India's generic pharmaceutical companies, encourage domestic production, and protect the public health of her citizens by preventing abuse of an invention's patent protection."

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.