PATENT PROTECTION AND INDIAN PHARMACEUTICAL INDUSTRY

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ABSTRACT

Patents, copyrights, trademarks, geographical indicators, protection of undisclosed information, layout designs of integrated circuits, industrial designs and traditional knowledge are recognized internationally by the trade related intellectual property rights agreement (TRIPS) governed by the WTO. In the present article, a brief historical background of intellectual property rights in relation to the Indian pharmaceutical sector is represented. The effect of patent policy of 1970 upon the Indian industry is described as a revolution for the Indian economic. The concept of compulsory licensing is briefly discussed. Finally, trade mark as the intellectual property right is discussed according to the Indian pharmaceutical market.

Keywords: Patents, Trade related intellectual property rights, Indian pharmaceutical sector, compulsory licensing, Trade mark.

INTRODUCTION

The existing frame work of intellectual property laws recognized internationally are those identified by the trade related intellectual property rights agreement (TRIPS) governed by the WTO. They are patents, copyrights, trademarks, geographical indicators, protection of undisclosed information, layout designs of integrated circuits, industrial designs. Another area for protection that is interesting for the India is the protection of traditional knowledge as intellectual property. Several pros and cons have been considered for agreement on trade related aspects of intellectual property rights, April 15, 1994, Marrakesh agreement establishing the World Trade Organization (WTO Agreement), states that "patents shall be available for any inventions, whether product or process, in all fields of technology provided that they are new, involve an inventive step, and are capable of industrial application".[1]

A patent is a government granted exclusive right, or a set of specified rights, to an inventor, or a person who claims to be the true and first inventor (or the discoverer of a new process) to make, use or sell an invention, usually for a specified term.

A patent for an invention is the grant of a property right to the inventor, issued by the Patent and Trademark Office (PTO). Patents are used to protect new product, process, apparatus, and uses providing the invention is not obvious in light of what has been done before, is not in the public domain, and has not been disclosed anywhere in the world at the time of the application. The invention must have a practical purpose. Patents are registrable nationally. Registration provides a patentee the right to prevent anyone making, using, selling, or importing the invention for 20 years from the date on which the application for the patent was filed or, in special cases, from the date an earlier related application was filed, subject to the payment of maintenance fees. Patents are enforced by court proceedings. In addition, the Regulation on Supplementary Protection Certificates (SPCs), grants “patent extensions” of up to 5 years to pharmaceutical and plant products, providing as much as 25 years of patent life for originator medicines.

Patents of living organisms, that can include plant and animal species, and related biological and biotechnology-enabled inventions, are classified as patents on life forms, or bio-patents.

The historical background of Indian IPR

The patent policy of India in the 1950 was to ensure that there was local production of drugs. In 1950, foreign multinational made the entire drugs supply in India. Foreign multinationals controlled more than 90% of the Indian pharmaceutical industry and hence determined supply and availability of drugs. Drugs were manufactured outside India and imported for a higher cost. The cost of drugs in India was amongst the highest in the world. The drug prices were so high that in 1961, the US senate committee headed by Senator Estes Kefauver observed that India ranked among the highest priced nations in the world for drugs.

Around the same period the government of India made the first five year plan to carve India’s development path. Statistics reveal that income from industries was as low as a mere 6.6% of the total national income. A mere 8% of the total labor force was working in industrial establishment. Epidemic diseases accounted for 5.1% of the total mortality. The first five-year plan recorded that India was the largest reservoir of epidemic diseases. Poverty was also at its peak in India. Around 50% of India’s population were living under poverty and were unable to afford the cost of drugs. Consequently, life expectancy was very low and mortality rate due to diseases was very high. The central government under the Drugs Act of 1940 imported required drugs since India had local production of bulk drugs.

Unable to control the expenditure on drugs the government of India took two significant steps to remedy the situation. First, the government signed an agreement with UNICEF to set up a factory for manufacturing of penicillin and other antibiotics. This resulted in the establishment of Hindustan Antibiotic Limited in 1957 to

manufacture drugs at a cheaper rate for the public. Next, the government appointed justice Rajagopala-Ayyangar Committee in 1957 to recommend revision to the patent law to suit industrial needs. The object of the committee was to ensure India developed a locally sustainable pharmaceutical market. The committee submitted its report in 1959.

The report submitted that the patent legislation needed a clear directive. In recommending changes, the Ayyanger committee was bound by the provisions of the Indian constitution. Article 21 of the constitution guarantees right of life, which include the right to good health. The preamble of the Constitution requires policies to balance social and economics rights. Hence public health concerns need to be weighed with business interests in amending the patent legislation. The Ayyanger report argued that a patent policy vesting unrestrained monopoly would deny a vast section of India's population from access to medicines.

The report concluded that a policy with unfettered monopoly rights would violate the preamble of the Indian Constitution. The report studied the patent systems of U.K, Germany and the U.S and pointed that Germany's weakened patent protection encouraged the growth of chemical industry. Hence the report recommended a compulsory licensing system and process patenting of drugs. The act based on the Ayyanger report and the rules came into force in 1972.

Since health care was a major concern, the Drug Price Control Order was also passed in 1970. The order gave control over the price of drugs to the government thus complimenting the compulsory license provisions in the Indian legislation. After the Drug Price Control Order was passed, the government of India placed most drugs under price control.

The economic brunt of the 1970 patent policy has not escaped India. Multinational companies, once major players, became reluctant to sell in India. By 1997, multinationals accounted for less than 30 percent of bulks and 20 percent of locally produced formulations. Most multinational complied with the minimum requirements necessary to maintain presence in the Indian market (such as producing simple formulations from imported bulks), while awaiting stronger patent protection. The government responded by steadily reducing price control on drugs. In 1970 most drugs were under price control, by 1984 this was reduced to 347 drugs, and to 163 drugs in 1987. In 1994 only 73 drugs remained under price control. The drug policy was established in the year 1978.

In 1986 India debated on whether to join the Paris Convention, The Indian Drug Manufacturers Association (IDMA) was at the forefront of the debate highlighting the risks of joining the Convention before India eventually relented to severe international pressure. During that time the IDMA was said to have been advised by retired judges and had a lot of support from the judiciary as well.[3]

India was very actively involved in opposing the TRIPs component of the GATT agreement, especially the proposal for product patents on pharmaceutical innovations. Indira Gandhi succinctly summed up the national sentiment 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." Now that India has signed the treaty, though most unwillingly, it is committed to introducing pharmaceutical product patents 2004, a value analysis i.e. cost-benefit analysis of this move is essential for India.

The revolution in Indian pharmaceutical sector

The patent policy pursued by India enabled it to become a big international player in the generic drug market. The patent policy of 1970 dramatically changed India's condition. In 30 years, the Indian pharmaceutical industry is valued at USD 70 billion compared to a mere USD 2.1 million before 1970. Currently 24000 pharmaceutical companies are licensed in India. Of the 465 bulk drugs used in India, approximately 425 are manufactured within the country. Indian industry has emerged as a world leader in the production of several bulk drugs. Indian industry has emerged as a leader for the production of bulk drugs like sulphamethoxazole and ethambutol. Indian production accounts for nearly 50% of the world production. Several companies like Ranbaxy, Dr Reddy's and Cipla have the potential to become billion dollar companies within the next few years.

Other than developing indigenous pharmaceuticals, India has grown as a major player in the international generic drugs market. The U.S during the Anthrax scare considered importing cheap generic drugs from India. India emerged as a reliable exporter of the generic AIDS drugs in South African AIDS crises.

Some other examples, the cost of ciprofloxacin were Rs. 27 (60 cents) per tablet eight year ago in India. The cost of ciprofloxacin currently is Rs. 1.50 (4 cents). Indian drug-makers export the generic version of ciprofloxacin to Russia, Brazil, Southeast Asia and Middle East at highly competitive prices.[4]

In spite of such aggressive development of the indigenous pharmaceutical industry, only a mere 30% of Indian population has secured access to modern medications. Until the entire population has access to drugs India has to follow the pre-TRIPS patent policy.

TRIPS patent policy requires developing countries to only award product patents. Novel processes will not be patentable in developing countries since these countries do not use process by product claims. Consequentially, inventions patentable in developed nations by use of process by product claim will fall outside TRIPS compliant patent legislation of developing nations. Some generic drugs patentable in developed nation using process by product claim will be unprotected in developing nations.

TRIPS, the intellectual property component of the Uruguay round of the GATT Treaty, have given rise to an acrimonious debate between the developed countries and less developed countries (LDCs). Business interests in the developed world claimed large losses from the imitation and use of their innovations in LDCs. They also asserted that IPRs would benefit the developing countries like India

by encouraging foreign investment, by enabling transfer of technology and greater domestic research and development (R&D). On the other side, LDC governments were worried about the higher prices that stronger IPRs would entail and about the harm that their introduction might cause to infant high tech industries.

Indian drug manufacturers believed exclusive marketing rights (EMR) would lead to the destruction of the local drug industry and that it was more restrictive than even the product patent regime. They argued that foreign drug companies would get the right for exclusive marketing in India before going through an examination in India. Indian manufacturers also felt that EMRs did not foreign multinationals to take over the market. However, the biggest impediment to the implementation of the EMR legislation was the fear that the cost of medicines would increase substantially. It was also feared that the Indian drug companies would be driven out of business.

The present Status of Indian IPR

The patent policy of 1970 has catered to the needs of the Indian poor. Drug price in India are one of the cheapest in the world today and are affordable to the population. On an average, drugs manufactured in India are more than 100% cheaper than the same drug in U.S. The government of India has achieved the Constitutional mandate of social economic balance by setting a maximum sale price while still leaving a reasonable profit.

TRIPS 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.

In the area of patents, TRIPS references the key articles of the Paris Convention and requires members to comply with them. It requires both national treatment and most-favored-nation treatment. It provides that no nation may discriminate in its patent system based on field of technology, a provision extremely important to the pharmaceutical and biotechnology industries whose drugs were not patentable in several member states.

For pharmaceutical patents, the flexibility has been clarified and enhanced by the 2001 Doha Declaration on TRIPS and Public Health. The enhancement was put into practice in 2003 with a decision enabling countries that cannot make medicines themselves, to import pharmaceuticals made under compulsory license. In 2005, members agreed to make this decision a permanent amendment to the TRIPS Agreement.

A patent may be granted for a product, or a process. In the case of a product, the patent is in the end product. In the case of a process the patent does not lie in the end product but only in the process of production. The act merely awards process patents for inventions relating to food, drugs, medicines and chemical processes. The implication is that the grant of patents is limited to the process or the method of making for inventions falling within the classification mentioned above. By changing the process, the same product can be a subject of a new process patent.

Patenting: 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.

The TRIPS Agreement is remarkable for not merely stating the rights, which Members must protect, but also defining in great detail the national civil and criminal procedures by which they are to be enforced.

Patentability of inventions

The subject matter that is patentable under the TRIPS is broadly defined. The agreement provides that "patents shall be available for any inventions, whether products or processes, in all fields of technology including pharmaceutics." Member countries must now offer patent protection to both product and process innovations, as long as they are new and non-obvious. This change generally will require less-developed countries to adopt broader definitions of what is patentable, consistent with the laws of developed countries.

India for instance did not provide product patents for pharmaceutical drugs. It only provided for process patents. The laws in India gave rise to a thriving generic drug industry wherein practically every foreign drug was reverse engineered without fear of any sanction. The pharmaceutical industry was greatly affected by this practice and reversing this trend among developing countries was top priority for the US as TRIPS negotiations were being conducted. However developing countries rebelled against a strict imposition of this norm without having the requisite infrastructure to implement it. They sought some compromise whereby the Article 27:1 states as follows: “Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced”.

Level of protection that the US demanded would eventually be provided but it would be granted in a phased manner.

The compromise resulted for developing and least developed countries respectively. Developing countries like India have until January 1, 2005 to fully implement the whole gamut of TRIPS provisions and least developed countries have until January 1, 2015. Developing countries got a grace period of 5 years to implement the agreement and a further period of five years to grant product patents to those areas of technology in which product patents were not granted. They had to however provide for EMR to pharmaceutical companies. This is essentially an exclusive right for marketing a drug in the member nation for five years or until a product patent is granted or rejected, whichever period is shorter. Due to this it is possible for companies that develop such inventions to file patent applications in developing countries prior to their implementing the TRIPS provisions in full. Applicants can also claim the date of filing as the priority date. Under

TRIPS, even though a patent may not be granted until the end of the grace period, the invention must be afforded patent protection for the remainder of the patent term, as measured from the filing date.

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.

Members may also exclude from patentability

(a) Diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) Plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed **four** years after the date of entry into force of the WTO Agreement.

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 expire. 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.

This has been upheld as conforming to the TRIPS Agreement in a WTO dispute ruling. In its report adopted on 7 April 2000, a WTO dispute settlement panel said Canadian law conforms to the TRIPS Agreement in allowing manufacturers to do this. (The case was titled "Canada-Patent Protection for Pharmaceutical Products").

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.

The agreement 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. But the term "compulsory licensing" does not appear in the TRIPS Agreement. Instead, the phrase "other use without authorization of the right holder" appears in the title of Article 31. Compulsory licensing is only part of this since "other use" includes use by governments for their own purposes.

In the main Doha Ministerial Declaration of 14 November 2001, WTO member governments stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health-by promoting both access to existing medicines and the creation of new medicines. They therefore adopted a separate declaration on TRIPS and Public Health. They agreed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. They underscored countries' ability to use the flexibilities that are built into the TRIPS Agreement, including compulsory licensing and parallel importing. And they agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016.

Article 31(f) of the TRIPS Agreement says products made under compulsory licensing must be "predominantly for the supply of the domestic market". This applies to countries that can manufacture drugs-it limits the amount they can export when the drug is made under compulsory license. And it has an impact on countries unable to make medicines and therefore wanting to import generics. They would find it difficult to find countries that can supply them with drugs made under compulsory licensing.

The legal problem for exporting countries was resolved on 30 August 2003 when WTO members agreed on legal changes to make it easier for countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves. When members agreed on the decision, the General Council chairperson also read out a statement setting out members shared understandings on how the decision would be interpreted and implemented. This was designed to assure governments that the decision will not be abused.

The decision actually contains three waivers:

- Exporting countries obligations under Article 31(f) are waived-any member country can export generic pharmaceutical products made under compulsory licenses to meet the needs of importing countries.
- Importing countries obligations on remuneration to the patent holder under compulsory licensing are waived to avoid double payment. Remuneration is only required on the export side.
- Exporting constraints are waived for developing and least-developed countries so that they can export within a regional trade agreement, when at least half of the members were categorized as least-developed countries at the time of the decision. That way, developing countries can make use of economies of scale.

Carefully negotiated conditions apply to pharmaceutical products imported under the system. These conditions aim to ensure that beneficiary countries can import the generics without undermining patent systems, particularly in rich countries. They include measures to prevent the medicines from being diverted to the wrong markets. And they require governments using the system to keep all other members informed each time they use the system, although WTO approval is not required. At the same time phrases such as "reasonable measures within their means" and "proportionate to their administrative capacities" are included to prevent the conditions becoming burdensome and impractical for the importing countries.

TRADE MARKS

A symbol (logo, words, shapes, a celebrity name, and jingles) used to provide a product or service with a recognizable identity to distinguish it from competing products. Trademarks protect the distinctive components which make up the marketing identity of a brand, including pharmaceuticals. They can be registered nationally or internationally, enabling the use of the symbol ®. Trade mark rights are enforced by court proceedings in which injunctions and/or damages are available. In counterfeiting cases, authorities such as Customs, the police, or consumer protection can assist. An unregistered trade mark is followed by the letters ™. This is enforced in court if a competitor uses the same or similar name to trade in the same or a similar field.

A service mark is the same as a trademark except that it identifies and distinguishes the source of a service rather than a product. The terms "trademark" and "mark" are commonly used to refer to both trademarks and servicemarks.[2]

Trademark rights may be used to prevent others from using a confusingly similar mark, but not to prevent others from making the same goods or from selling the same goods or services under a clearly different mark. For example, in the case of pharmaceutical industry, the court considers the type of the drug and the purchaser and such other aspects before it reaches a decision. In the case of Win-Medicare Ltd V. DUA Pharmaceuticals Pvt Ltd, **Diclomol** was used by the plaintiff and **Dicamol** was used by the defendant. The court held that the two products were similar and considered the factor that these drugs are sold without prescription. Therefore these drugs can be bought off the counter by illiterate customer and therefore restrained the use of the trademark by holding that they are similar.

Similarly, the Delhi High Court granted an ex-prate injunction to SmithKline Beecham Ltd which was the registered owner of the mark **Crocin** against the use by Apar Pharma of Hyderabad and Cyper Pharma of Delhi against the use of the word **Crocinex**. Both the marks were sought to be used for paracetamol tablets. The Court held that the words were so similar that the attempt was to deliberately mislead the public.

On the other hand, in Calida Lab v. Dabur Pharma Ltd, Calida alleged that **Zexate** was deceptively similar to **Mexate** in respect of a particular injection used to treat cancer. The Court based its conclusions only on the fact that the drugs were specialized drugs which could only be purchased showing the prescription of a **cancer** specialist. It was felt that the prescriptions were made by specialist doctors who are knowledgeable and are capable of distinguishing the names and therefore court held that the trademarks can be allowed.

The same logic was followed in the case of Biofarma V. Sanjay Medical Store; the question was with reference to **Flavedon** and **Trivedon** for a drug that was prescribed for heart disease. The court gave importance to the fact that the drug was a **Schedule H drug** under the Drugs and Cosmetics Act, which meant that the drug cannot be bought off the counter. The Court held that the two drugs need not be considered to be deceptively similar on the same logic followed in the above mentioned case.

In Biochem Pharmaceutical Industries V. Biochem Synergy Ltd, both companies were engaged in the business of selling pharma and medical products. **Biochem** Synergy was engaged in bulk drugs whereas Biochem Pharma was selling their drugs in strips of 10 which were available with the chemist and druggist. Here it was argued that the name Biochem was a combination of BIO and CHEM and therefore was not distinctive. The court considered that the name Biochem was registered by Biochem Pharma and that there were 28 trademarks of the company beginning with that name. Biochem Pharma had also been in the business for the past 35 years, thereby acquiring a reputation. Hence the court held that Biochem Synergy desist the use of the word Biochem in order to ensure that the consumers are not unnecessarily avoid.

Recently in, Allergen Inc V. Milment Optho, the Supreme Court of India considered the issue of trans-border reputation. Allergen Inc was the manufacturer of eye care products under the trademarks **Ocuflox**, and has registered the mark in over nine countries. Allergen had applied for registration of its mark in India. It contended that Milment Optho which also manufacturers eye care products was using the same mark in India for similar goods. The Single Judge of the Calcutta High Court had issued an interim order restraining Milment from using the mark, which was vacated after hearing the Indian Company. The case went on appeal to the Supreme Court. The Court considered certain remarks that were made by the Division Bench of the Calcutta High

Court where the Calcutta High Court had mentioned that these foreign brand names were no more alien to the Indians on account of the higher rate of travel and the increased advertisement in India. Eventually, Milment has offered to change its name in the Supreme Court.

However, even in cases where the trade mark has been registered, if the owner does not use it for the period prescribed under the Act, the doctrine of non-use will apply and applicant can, on this basis seek to remove the registration from the register. This doctrine however, cannot be applied if the registration is a defensive registration of the trademark. This doctrine applies even to very well known trademarks.

In order to determine whether a trademark is well known the Registrar will consider the knowledge or recognition of that trademark in the relevant section of the public including knowledge in India obtained as a result of promotion of the trade mark. The Registrar will also consider the duration, extent and geographical area of any use, promotion and publication of the trademark and the record of successful enforcement of the rights in that trademark. This amendment for well-known trademarks also has international impacts.

CONCLUSION

The following facts are noteworthy to gauge the impact of the introduction of pharmaceutical patents in India: 1) Consistent growth rate of the Indian economy, 2) Rising income levels, 3) Increasing penetration of insurance on all fronts, especially after allowing entry of private players, 4) For the 60% of the "poor" in India, who currently do not have access to pharmaceuticals, price rise and demand sensitivity due to patent introduction is irrelevant. Thus only a small part of the market will be affected by the new regime, 5) India is governed by a government which relies more on populist politics for survival and this would ensure that the best interests of the population is kept in mind without buckling too much under international pressures. All in all, India stands to gain more in the new patent regime with the inherent costs being marginalized by several factors.

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