

Patent Regime In India – Challenges And Proposal For Reform

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Abstract. Patents represent one of the most powerful Intellectual property rights. The purpose of the law of patents is to protect inventive ideas by giving the inventor exclusive rights over the invention for a period of time. The procedure for granting patent, the requirements placed on the patentee and the extent of exclusive rights vary between countries according to the national laws and international agreements. The protection provided by patents is more useful in some industries than in others. For example, chemical and pharmaceutical firms are large users of the patent system partly because innovations within these industries tend to be relatively cheap to imitate. Companies within these industries see patent registration as an important part of maintaining competitive advantage. The paper explains about the effects of the legislative provisions with respect to patent rights and procedure in India and the compliance of international treaties and conventions concerning patents. In this paper we present the legal effect of the amendments introduced by the Patents (Amendment) Act, 2005 and the problems relating to it. The domain of Pharmaceutical products were considered in this paper to identify the harmful effects of the amended patent provisions which infringes the rights of the patentee and an initial approach to propose a reformation to be done safeguarding the interests of the patent holders.

Keywords: Product patents, infringement, TRIPS.

1. Introduction

In all areas of intellectual property there is trade-off between the creator's right to commercially exploit his or her novel idea and the community's right to benefit from those creations. Intellectual property rights are regarded as personal property and can be bought, sold and licensed like other forms of property. The term patent originated from the Latin term 'litterae patentes' (letters patent) which means 'open letters'. The origin of patent law in India can be traced back to the law and practice on patents in the United Kingdom. The Indian Patents Act of 1970 was modelled on the British Patents Act of 1949 as amended. However there exists a stark difference between the Indian Patents Act of 1970 and the British Patents Act of 1949 in the sense that the Indian Act granted product patents for food, medicines and chemicals only from January 1st 2005 unlike the British Act which provided such patents under the 1949 Act and continue to do so. The main aim of this research is to work out and propose a legal framework concerning the procedure of product patents and to overcome the difficulties existing in the present system, through which the rights of the patentees can well be protected absolutely. The paper is organized as follows: In the next section, we give a background on the concept of patents and its essentials for protection, Section 2 gives an introduction to Pharmaceutical product patents in India, and Section 3 explains international protection afforded for patents which includes TRIPS obligations for member countries to comply with. The legislative effects of the amended provisions of the patents Act is described in Section 4.

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Section 5 explains the legal battle between the Indian government and a famous pharma company and finally the proposed work is concluded in Section 6.

2. Background

Salient features of Indian Patent law:

The Patent law of India has the following salient features that decide whether a patent will be granted or not:

(a) The Object: The object of patent law is to encourage scientific research, new technology and industrial progress. The price of the grant of the monopoly is the disclosure of the invention at the Patent Office, which, after the expiry of the fixed period of the monopoly, passes into the public domain. (b) Inventive step: The fundamental principle of Patent law is that a patent is granted only for an invention which must have novelty and utility. It is essential for the validity of a patent that it must be the inventor's own discovery as opposed to mere verification of what was, already known before the date of the patent. (c) Useful: The previous Act, i.e. Act of 1911, does not specify the requirement of being, useful, in the definition of invention, but courts have always taken the view that a patentable invention, apart from being a new manufacture, must also be useful. (d) Improvement: In order to be patentable, an improvement on something known before or a combination of different matters already known, should be something more than a mere workshop improvement, and must independently satisfy the test of invention or an inventive step. It must produce a new result, or a new article or a better or cheaper article than before. The new subject matter must involve "invention" over what is old. Mere collocation of more than one, integers or things, not involving the exercise of any inventive faculty does not qualify for the grant of a patent. (e) The guiding tests: To decide whether an alleged invention involves novelty and an inventive step, certain broad criteria can be indicated. Firstly if the "manner of manufacture" patented, was publicly known, used or practised in the country before or at the date of the patent, it will negative novelty or 'subject matter'. Prior public knowledge of the alleged invention can be by word of mouth or by publication through books or other media. Secondly, the alleged discovery must not be the obvious or natural suggestion of what was previously known [1].

In short, the invention must involve an inventive step and the same must be capable of industrial application. It must be supplemented by the concept of non-obviousness. Patent system encourages the disclosure of information instead of it being kept confidential as a trade secret. Hence it contributes to the prior art in the particular field and enhances scientific knowledge by using the information contained in the published patent documents. They help in identifying the uncovered areas and initiate R&D in such areas [2]. Hence the patent system helps in ascertaining global technological trends in specific areas of interest. Lastly, the patent system helps in identifying the possible competitors and their strength in particular areas of interest.

3. Pharma patents

The Indian Pharmaceutical industry is one of the largest in the developing world and is ranked as the fourth largest in terms of production and 13th largest in terms of domestic consumption value. Over the past 30 years Indian drug industry has emerged from almost non-existent to a world leader in the production of generic drugs. With the changes brought about by the Patents Act of 1970, Indian drug manufactures became experts in the field of reverse engineering and increased its supply of less expensive copies of the world's best-selling patent protected drugs. This could only be possible because there was no product patents system for drugs and medicines. While the Patent Act of 1970 in its original form does provide a distinction between product patents and process patents, the exception provided in section 5 of the act of 1970 (which has been omitted by the amendment of 2005) offered only a process patent for food, medicine or drug substances and specifically excluded product patents for the same. Thus India was able to copy foreign patented drugs without paying a license fee and was able to make it

available to the masses at one-tenth of the original price. Moreover the Drug Price control Order, 1970 put a cap on the maximum price that could be charged and ensured that the life saving drugs are available at reasonable prices. The Act of 1970 could be considered to be one of the most progressive statutes which safeguards both the interest of the inventor and the consumer in a balanced manner. The Act has been promulgated keeping Directive Principles of State Policy contained in Article 39 of the Constitution in mind.

Hence with a regulatory system focusing on process patents and being in the grip of a rigid price control framework, the Indian pharmaceutical industry has emerged from a import dependent industry to in the 1950's to having achieved world wide recognition as a low cost producer of high quality pharmaceutical products with an annual export turnover of more than \$ 1.5 billion dollars [3].

4. International protection

A key international convention relating to patents is the Paris convention for the protection of industrial property, initially signed in 1883.

TRIPS Agreement: The WTO was established through the agreements known as 'MARKKESH' agreement establishing the WTO. Intellectual property was not a part of WTO until the Uruguay round. It was introduced in the Uruguay round especially by the developed countries to be a part of WTO and it got the status in the WTO in the form of an agreement which is known as Trade Related aspect of Intellectual Property rights (TRIPS). Intellectual property was opposed by some developing countries to be a part of WTO as they argued that "it is a tool used by the developed countries for exploiting the developing countries and colonizing them". However their opposition failed and TRIPS agreements was finally signed on 15th April 1994 by nearly 125 member countries. However it came into effect on 1st January 1995.

The TRIPS consistent Indian patent law addressed three important issues relating to patent of products: i) Adoption of definition of "pharmaceutical substance"; ii) Exclusion of "mere discovery of a new form of known substance" and "new use for a known substance"; and iii) Protecting the interests of those who are already producing the products which may be granted patent protection in the new regime. The patent regime adopted in TRIPS by the developed countries is somehow of the capitalists nature and it prioritizes the profit motive over the social responsibilities. In continuation to these discrepancies, TRIPS also rule out any discrimination between the technological sectors and advocates the same protection for all the technological inventions fulfilling the criteria.

Even after the acceptance of the TRIPS agreement, the following five major areas still controversial for both the parties to the trips: 1) IPRs and access to medicines, 2) IPRs, community property rights and indigenous knowledge, 3) IPRs and biodiversity, 4) IPRs, biotechnology and agriculture, 5) IPR policy and trade. There is no doubt that "product patent regime" have spurred the R&D for diseases- notably, those with the lucrative potential market in the industrialized world. However, TRIPS has failed and will continue to fail to stimulate sufficient R&D for diseases that primarily affect poor countries. TRIPS had forced all the developing countries to switch over to product patent regime from process patent regime and hence, restrict the access of the cost effective essential medicines to their people.

5. Legal effects of the amended Patent provisions

The amendments introduced by the Patents (Amendment) Act, 2005 and the problems relating to it are as follows:

The definition of the term "Pharmaceutical substances" as given under the new act is too broad and ambiguous. The amendment describes "Pharmaceutical substances" as "any new entity involving one or more inventive steps". The term "chemical" should have been added so as to read as "any chemical entity". The term "inventive step" has been modified under section 2(f) of the Patents (amendment) Act, 2005. This definition

broadens the existing provision to the benefit of the patent holders and it provides for two criteria for meeting an inventive step and hence is quite ambiguous. As the new amendment stands now, for meeting the criteria of an inventive step the patentee will have to show that the invention includes a “technical advance” or has economic significance or both. The provision should have required the applicant to comply with both the requirements for meeting the inventive step requirement. Otherwise it leads to the dilution of the inventive step requirement by the fact that a patent could be granted on economic significance alone.

Section 3(d) of the Patents Act, 1970 has been amended under the new Act to read as follows - “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 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”. The phrase “does not result in the enhancement of the known efficacy” is too broad and ambiguous and can lead to ever greening of patents as it may lead to new forms of existing substances to become patented [4].

The Indian Patents (Amendment) Act, 2005 introduced product Patents in India and marked the beginning of a new patent regime aimed at protecting the Intellectual property rights of patent holders. The Act was in fulfilment of India’s Commitment to World Trade Organization (WTO) on matters relating to Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement).

6. Challenges faced by Indian Patent regime – Novartis sues Union of India

The Gleevec challenge is the latest controversy facing India since its January 1, 2005, implementation of substantially enhanced patent protection for pharmaceuticals [5].

In August and September 2006, patients with cancer, lawyers for patient advocacy groups, and representatives of nongovernmental organizations (NGOs) converged on the offices of Novartis in Mumbai, India, to protest the company's efforts to obtain an Indian patent on Gleevec, the company's brand-name version of imatinib mesylate. Gleevec (spelled Glivec outside the United States) is used to treat chronic myeloid leukemia, and Novartis has patented the drug in 35 countries. The protesters also decried the drug's high price: Novartis sells it in India (where only 5% of people have private health insurance) for \$26,000 per year; generic-drug manufacturers offer the drug at less than one tenth that price. India's membership in the World Trade Organization (WTO) means that for the first time in 35 years, drug products (the pharmaceutical compositions themselves, rather than merely the processes for making them) must be considered potentially patentable in India. The letter and spirit in which India transitioned into the new patent regime has been put to litmus test by Novartis which sued India with the institution of a writ Petition before the High Court of Judicature at Madras [6].

Several countries praised India’s contribution to life saving drugs and requested Novartis not to challenge. However, Novartis filed its case with Indian court at Chennai and sought patentability of its product Gleevec filed under EMR provisions on the grounds alleging: (i) illegality in procedure adopted and also the text of 3(d) of The Act which was in violation of Article 27(1) and 27(2) of TRIPS Agreement; (ii) arbitrariness by the Controller General of Patents & Designs, Chennai and ignoring rationality underlying Articles 253 and 51(c) of the Indian Constitution whereby national laws are required to be harmonized with International treaties; (iii) Provision relating to discovery of “new form” contained in 3(d) is illogical and against the concept of patents which encourages innovation and Intervention by rewarding the person associated with such acts beneficial for society; (iv) Deliberate incorporation after approval of its product Gleevec under the earlier prevailing EMR provisions resulted in disturbing the level playing field laid under the Act in compliance with conditionality under TRIPS Agreement. Novartis has asked the Chennai High Court to strike down this section as inconsistent with the WTO's Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). TRIPS requires that patentable inventions be new and involve an "inventive step." Novartis contends that TRIPS gives WTO members the option of

providing patent rights more generous than these basic criteria would mandate but does not allow members to go in the opposite direction by implementing stricter requirements for obtaining a patent. The counterargument is that TRIPS does not define "inventive step." It permits (but does not require) WTO members to equate this criterion with the "nonobviousness" requirement of U.S. patent law — and thus gives member countries the flexibility to fine-tune their inventive-step criteria to reflect national socioeconomic conditions.

Moreover, Section 3(d) of India's patent law does not necessarily impose stricter requirements than are used elsewhere; it may be seen as simply creating a general presumption of non patentability for modifications of known chemical compositions — and shifting to patent applicants the burden of rebutting this presumption in each particular case. For example, the U.S. Patent and Trademark Office may reject a claimed drug as "prima facie obvious" on the basis of its structural similarity to existing chemical compositions. A classic way to overcome the rejection is to demonstrate the drug's unexpectedly good results. India's new efficacy test might well operate in a similar fashion. The Chennai High Court considered these issues of sufficient importance to merit referral to a two-judge panel. By late January 2007, the panel had not issued a decision. NGOs were disappointed by the court's refusal to dismiss Novartis's challenge outright. But the Indian judiciary must analyze and rule on the viability and uncertain contours of the new patentability test. Until it does so, the patent office retains virtually complete discretion in its application of Section 3(d). The court must also determine whether the patent office followed correct administrative procedures in rejecting Novartis's application. The company contends that among other errors, patent examiners ignored data demonstrating that Gleevec has greater manufacturing stability than does the imatinib free-base form, as well as 30% greater bioavailability [7]. But after a court case and four months of deliberation, two High Court judges concluded that the Indian courts have no jurisdiction to decide whether the national law is compliant with this international treaty. They also rejected an additional charge that Indian patent law was unconstitutional, vague and arbitrary.

7. Conclusion and Future Work

The new patent regime in India concerning Pharma patents has raised several contentious issues relating to right to health of the people, which is in conflict with the economic right of patent holders. In this paper, we have briefly analyzed the legal battle of Novartis seeking appropriate remedies for the infringements of their patent rights since amended provisions were incorporated under the new Act of patents. The paper briefly explains the role of fulfilment of India's Commitment to World Trade Organization (WTO) on matters relating to Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) and its legislative impact. It is proposed that judiciary must intervene in certain circumstances to strike out those clauses which are unconstitutional which affects the rights of the patentee through judicial reformation and at the same time taking into consideration the public interest. As the main objective of law is to promote economic prosperity, protect individual liberty and to provide social justice, judicial interpretation is must to protect patentee's interest which might encourage research and invention. Current work is in very early stage; this research work is further likely to be strengthened carrying out a detailed investigations with respect to reformation required for the current legal regime concerning product patents which might protect both the patentee's interest and also public interest. Based on the investigations and its analysis, it is intended to draft a legal framework which might reform the existing law concerning product patents which will be more useful for Indian Parliamentary counsel to consider while carrying out a statutory law reform in this area.

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