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Case Study on Patent Issues in Indian Pharmaceutical Industry.

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ABSTRACT

Developments in Intellectual Property Rights have far reaching implications for the prosperity and the future of human race. Patent is a legal right granted to the inventor for the new creation of his mind. Invention relates to the creation of a new product or process which did not exist before. The Indian pharmaceutical industry is known for the production of quality generic drugs. This industry supplies generic off-patent drugs to third world countries at affordable prices and is known as 'pharmacy of the world'. The current study focus on the challenges and scope towards pharmaceutical industry, the scientific community and the public regarding the pros and cons , recent developments in the patent legislation in India.,

Keywords: Patent, Pharamacy, India, Product

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INTRODUCTION

It had been estimated that only about 7 per cent of the patients suffering from AIDS/HIV in India received the required therapy and some 5.7 million people suffered with the disease. The government has an enormous responsibility to take care of the health requirements of the people. The infrastructure facilities and the number of hospitals and doctors for treating the patients require substantial improvement, particularly the treatment of the poor. A peep into the government hospitals would only tell the realty in the health sector. The health insurance sector has not provided any remedy to the situation so far. It is hoped that the insurance sector reforms would help to improve the situation. The life-saving and critical drugs are expensive and not affordable to the common man. For example, the blood cancer drug, Glivec, sold by Novartis cost Rs.1 lakh per month for a patient. The same thing applied to the kidney cancer drug, Nexavar, supplied by Bayer Corporation. The drug cost Rs.2.80 lakhs per month for a patient. There were many instances such as these drugs, where the patented life-saving drugs cost many times more than the copycat or generic versions of the same drugs. The pharmaceutical companies in India have a bigger responsibility to share the health care concerns of the people and find out ways and means to supply drugs at affordable costs to the needy and the poor. Considering the importance of the health care related issues which affect billions of poor people in developed and developing economies, and the significance of innovations for new drug discoveries, the member countries agreed for a separate agreement on Trade Related Intellectual Property Rights (TRIPS) under the auspices of World Trade Organisation. TRIPS brought into effect some minimum standards of protection to the patent holders and flexibilities to the countries for the protection of their population.

Government of India in its earnestness to honour its commitment to the World Trade Organisation and to encourage innovation and to protect public health amended the Patents Act, 1970 in 2002 and 2005. These changes in the Patent law brought into force the product patent regime in India. A product patent gives exclusive right to the patent holder for a period of 20 years. Indian pharmaceutical industry which hitherto was manufacturing copycat drugs under the process patent framework could no longer manufacture a patented drug without the permission from the patent holder, in most of the cases, multi-national drug companies because of the admission of product patents for the pharmaceutical products. The present article studied the consequences of the changes in the patent law and the many challenges the Indian pharmaceutical industry faces due to these changes.

PATENTS AND HUMAN WELFARE

Developments in Intellectual Property Rights have far reaching implications for the prosperity and the future of human race. Intellectual Property Rights take various forms and the World Trade Organisation has recognised Patents, Trade Marks, Copy Rights, Industrial Designs, Geographical Indications, Layout Designs of Integrated Circuits and Undisclosed Information in TRIPS. They impact living standards, an economy's prosperity, global trade and even the culture in the long run. Hence, the modern society has understood the need for a proper mechanism to protect the interests of the innovators and put in place a regulatory mechanism for the intellectual property rights. This article analyses the patent rights' related issues of Indian pharmaceutical companies. Since the patent right gives the inventor an exclusive right over the invention, it facilitates investments across countries which help both the inventor and the recipient countries. At the same time, the patented invention comes into the public domain and the people and the industry are able to take note of the latest innovations in the concerned field. This further encourages new innovations. Without an incentive mechanism in the form of patents, the world would not have had the opportunity to be aware of most of the inventions, which helped further advancements in research [22]. Article 7 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) itself states its objective as "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technology and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

WHAT CAN BE PATENTED?

Patent is a legal right granted to the inventor for the new creation of his mind. Invention relates to the creation of a new product or process which did not exist before. Discovering something is not an invention as what is discovered exists already. The legal right is granted by the government under the patent law. The

legal right excludes others from using the invention without obtaining the permission from the patent holder. Normally the patent holder gives permission to others for usage of the invention on payment of royalty, which is mutually negotiated and agreed upon. Patent rights are given by the government in order to encourage commercial exploitation and not for shelving them as monopoly rights. The intention is that public shall derive benefit out of the invention and the inventor is adequately compensated for his invention.

An invention can be patented if it is new, involves inventive step and is capable of industrial application. Indian Patent law does not recognise the following as falling into the meaning of invention and hence not patentable [22] "(1) An invention that does not have value (2) an invention whose use would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or the environment (3) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living or non-living substance occurring in nature (4) 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 mere/new use for a known substance or of the mere use of a known process, machine or apparatus unless the known process results in a new product or employs at least one new reactant (5) a substance obtained by a mere admixture of the components or a process for producing such substance (6) the mere arrangement or rearrangement or duplication of known devices each functioning independently of one another in a known way (7) a method of agriculture or horticulture (8) any process for the medical, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings, animals or plants, biological processes for the production and propagation of plants and animals (9) a mathematical or business method or a computer programme per se or algorithms (10) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions (11) a mere scheme or rule or method of performing mental act or method of playing game (12) a presentation of information (13) topography of integrated circuit and (14) an invention which in effect is traditional knowledge or the aggregation or duplication of known properties of traditionally known component or components (15) inventions relating to atomic energy." For the reason of the absence of enhancement in the known efficacy of the substance, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance are considered to be the same substance. The Supreme Court of India has ruled during March, 2013 that Glivec, a blood cancer drug, produced by Novartis, a Swiss multinational, was not eligible to get the drug patented as it did not meet the requirements of invention and the product not proving any enhanced efficacy over the known substance of which it was a new form. Glivec is beta crystalline form of *imatinib mesylate*.

PATENT ISSUES IN INDIAN PHARMACEUTICAL INDUSTRY

Indian pharmaceutical industry is known for the production of quality generic drugs. This industry supplies generic off-patent drugs to third world countries at affordable prices and is known as 'pharmacy of the world'. Till the amendment of the patent law in 2005, the industry thrived with the production of drugs through reverse engineering. The amended patent law provided for the granting of product patents in addition to process patents for the manufacture of drugs. Hence the Indian pharmaceutical companies could no longer manufacture copycats. The multinational pharmaceutical companies who hold patents for life saving drugs charge, it is alleged, exorbitant prices for their drugs as they have exclusive right to manufacture and sell the patented drugs. Also, the multinational companies try to prolong the patent life of their drugs by making small modifications in the patented drugs and claim them as new patents, thus extending the life of the patent for the same drug, which is known as ever-greening of patents [5] The multinational pharmaceutical companies justify their stand of charging high prices for the reason that the life-saving drugs were invented after many years of research and after spending millions of dollars in research. Also, they claim that unless they recover their research expenditure through the sale of the drugs, future research and new drug discovery would be hampered. The current patent related issues for the pharmaceutical industry could be mentioned as under:

- Introduction of Section 3(d) to the Patents Act which unsettled the patent rights of many multinational pharmaceutical companies like Novartis
- Granting of Compulsory License to Natco Pharma, an Indian pharmaceutical company
- Provisions related to the post-grant opposition of patents which questions the patent right after the grant of such right

THE CASE OF NOVARTIS

Novartis holds patent rights for its blood cancer drug, Glivec in over 40 countries. The drug is used for the treatment of chronic myeloid leukemia. Glivec cost Rs.1 lakh a month, but the local version of the same drug is available for a cost of Rs.8,000 to Rs.10,000. Pre-grant oppositions were filed by many interested parties, including some domestic pharmaceutical companies when the Indian Patent Office started considering the patent application of Novartis, after the amended Patents Act, 2005 came into force. The oppositions mainly relied on the amended Section 3(d) of the Indian Patents Act. Section 3(d) of the Act has been expanded to discourage companies from indulging into the practice of ever-greening. The oppositions claimed that *imatinib mesylate* (brand name, Glivec) was a substance which already existed in the form of *imatinib* and that there was nothing 'new' and no inventive step involved. Also, they claimed that *imatinib mesylate* did not enhance the efficacy of the substance and hence not eligible for a patent. They argued that Novartis claimed patent only for the crystalline form of *imatinib*. The Patent Office rejected the application of Novartis accepting the arguments of the opposition. The Intellectual Property Appellate Board also rejected the claim of Novartis for the reason that data was not made available to show that beta crystalline form of *imatinib mesylate* enhanced the efficacy of the known substance. Before the apex court of the country, Novartis argued that 'efficacy' in Sec.3(d) has not been given any meaning by the law and that 'efficacy' can be in the form of 'therapeutic efficacy' or otherwise. Novartis argued that the crystalline form of *imitinib mesylate* improved the bio-availability and thermodynamic stability of the substance which reflected enhancement in the efficacy of the known substance and hence Glivec was eligible for a patent. Also the multinational argued that since clinical data was not available on the original substance, it was not possible to prove the enhanced therapeutic efficacy of the crystalline form of *imitinib mesylate*. The Supreme Court of India dismissed the claim of Novartis and stated that the crystalline form of *imitinib mesylate* did not satisfy the requirements of Section 3(d) of the Patents Act as all the pharmacological properties of the crystalline form of *imitinib mesylate* were equally possessed by *imitinib* in free base form and there was no enhanced efficacy in the crystalline form of the substance. The ruling in Novartis' case will surely set the precedent in the decision of the pending disputes. Various other patented drugs are in various stages of dispute in the country like Glivec. Some of the drugs whose patents were being disputed before patent authorities in the country were, Sutent, Sprycel, Baraclude, Nexavar and Januvia. In fact the Indian Patent Office had recently revoked the patent granted to Pfizer for its cancer drug, Sutent as being non-inventive [20] As is obvious, Novartis and other multinational drug companies were not happy with the interpretation of Section 3(d) of the Patents Act as it was detrimental to their business interests. It is estimated that patented drugs worth $150 billion would become off-patent between 2010 and 2017 and the multinationals are worried with the developments, the article discussed above [20].

COMPULSORY LICENSING OF PATENTS

Indian patent law provides for Compulsory Licensing of patents. Compulsory licensing is the grant of a licence by the Patent Office to a third party overlooking the existing patent rights of a patent holder. The system of granting compulsory licence is reported to be in use even as early as 1830s. Compulsory licensing was recognised by the Paris Convention of 1883. Provision for the grant of compulsory licence exists in the patent laws of many countries, developed and developing, such as Canada, UK, USA, Australia, Malaysia, Brazil and Thailand. It had been reported that about 100 nations practised some kind of compulsory licensing when the World Trade Organisation came into effect [13] Generally, the government resorts to compulsory licensing in case of health emergency and when the lifesaving drug is not available to the public at affordable prices. Some of the instances where compulsory licences were issued by Thailand were, *efavirenz* and *lopinavir/ritonavir* (HIV drugs) and *clopidogrel* (heart disease drug). Brazil had also resorted to the issue of many compulsory licences in the past. Compulsory licensing mechanism had been introduced into the patent law to ensure that the patent right granted to an inventor was used for the benefit of the society and not to withhold the invention as a monopoly right. The mechanism makes sure that the patent right granted for a product or process is exploited on a commercial basis for common good at an affordable price. The following grounds, under law, justify the Patent Controller to grant a compulsory patent:

"(1) that the reasonable requirements of the public with respect to the patent have not been satisfied (2) that the patented invention is not available to the public at a reasonably affordable price or (3) that the patented information is not worked in India". Anyone interested could approach the Patent Controller for the grant of the compulsory licence after 3 years of the grant of the original patent if the above conditions for the

grant of the compulsory licence were satisfied. Also the Patent Controller can grant a compulsory licence at the instance of the Government for reasons of national emergency, extreme urgency or public non-commercial use of the patent. For the first time since the introduction of the amended Patents Act in 2005, the Patents Controller, Mumbai had granted a compulsory licence in favour of Natco Pharma for the manufacture and marketing of Nexavar (*Sorafenib Tosylate*), a kidney and liver cancer drug patented by Bayer Corporation, USA. Nexavar is not a life-saving drug but life extending drug. It can extend the patient's life by about 4-5 years and 6-8 months in the case of kidney cancer and liver cancer respectively. Whereas Bayer Corporation sold the drug at a price of Rs.2.80 lakhs per month, the generic drug manufacturers could produce and sell the drug for a cost of Rs.8,800 for a month's treatment. The Patent Controller granted compulsory licence in favour of Natco Pharma because Bayer did not take any effort to manufacture the drug in the country and during the last three years it was only supplying the drug in India through imports. Also, the price of the drug was high and unaffordable for the public. However, the Patent Controller had allowed Bayer to compete with Natco Pharma as well as grant permission to any other domestic company to manufacture Nexavar in India. The important advantage of the compulsory licence is that Natco shall manufacture and supply the drug at a price of Rs.8,880 for a pack of 120 tablets against Bayer's price of Rs.2.80 lakhs. It was also reported that the Government of India was exploring, at the time of this study, to grant compulsory licences for the manufacture of three more cancer drugs, namely, *trastuzumab, ixabepilone and dasatinib* [11] The multinational pharmaceutical companies started lobbying for soft pedalling by the government.

POST-GRANT OPPOSITIONS

The amendment Act of 2005 made it possible for the interested parties to oppose a patent already granted. The grounds for post-grant opposition are the same as for the pre-grant opposition, namely, 1. the patent was wrongfully obtained 2. the invention was made public before the date of the claim 3. the patent was obvious and does not involve any inventive step 4. there was no invention within the meaning of the Patents Act

5. the patent did not fully describe the invention 6. patent application did not give full information or gave false information 7. origin of biological material used was wrongly mentioned or not mentioned. The post-grant patent shall be filed before the Patent Office before the expiry of 12 months from the date of grant of the patent. The country's first post-grant opposition had been filed by Sankalp, a non-government organization against the granting of patent to Roche for its Hepatitis C drug, *Pegilated interferon* [11]. The admission of post-grant opposition was one more hurdle for the patent holding drug companies in the enjoyment of their patent rights.

CHALLENGES BEFORE THE INDIAN PHARMACEUTICAL INDUSTRY

The pharmaceutical industry, the scientific community and the public have deliberated the pros and cons of the recent developments in the patent legislation in India. Part of the scientific community had expressed that the ruling and interpretation of the apex court in the interpretation of Section 3(d) was not pragmatic, ambiguous and would affect the interests of the pharmaceutical industry and the public in the long run [17]. Section 3(d) stated the requirement of improved enhancement in efficacy and that need not concern only therapeutic efficacy as interpreted by the apex court. Also, experts claimed that while other countries admitted incremental innovations, the Indian authorities had given too restrictive a meaning to Section 3(d) [14], [6] [19], stated that if the pharmaco-kinetic properties of a drug was unstable, even the most break-through compounds could fail. The same could hold true if the drug degraded in the human system or there was no shelf life for the drug. Hence she claimed that even very small changes in molecules could bring tremendous benefits to the patients. USA grants patents for incremental innovations. Over 70 per cent of the present day medicines were developed through small scale improvements in the already existing medicines. Hence, doubts had been raised whether the patent refusal to Novartis was in the right direction. However, [15] gave a different opinion that any enhancement other than the therapeutic enhancement in efficacy was not useful and did not satisfy the objective of the patent system. The industry had questioned the feasibility of future investments in research for the discovery of new drugs. Human beings not only require affordable medicines for the known diseases but also new medicines for the emerging and new diseases. Without big investments in research, invention of new medicines would not happen. Another challenge for the developing countries in general pertained to the quality of generic drugs or the patented drugs produced under the grant of compulsory licences. [13]and [5] reported that Global Fund withdrew its support of $133 million to

Government Pharmaceutical Organization of Thailand because of the GPO's failure to meet the World Health Organization's quality standards. Regarding compulsory licensing, some of the experts stated that the mechanism could be used only when there was national calamity or in situations of extreme urgency and importance and not routinely. Also, they stated that though prices could be brought down through the grant of compulsory licenses, the domestic industry was not competent enough to maintain the quality standard of the patented drugs and the patients may not really get the desired benefit. Also, the Controller of Patents, who has the authority to grant compulsory license has discretionary powers without proper safeguards and this could jeopardize the interests of the patent holder. As a result, many lifesaving drugs may not enter the country and not available to the patients.

RECOMMENDATIONS

Indian pharmaceutical industry was capable of only small scale innovation, as was observed by a committee chaired by Dr.Mashelkar, the architect of the Indian patent system. During 1996, marketing expenditure of top 15 global firms had been estimated at 30.5 per cent of sales by a pharmabiz study. Those companies had spent just 15.1 per cent in research and development [5]. The Government should endeavour to bring on board the drug manufacturers to deliberate the misgivings raised relating to research investment and the affordability for the patented and generic medicines. Controller of Patients has been given the authority to decide the terms and conditions of the grant of the compulsory license. He discharges his duty at the pleasure of the executive and therefore may not enjoy independence in his work. The government in its wisdom may work out detailed guidelines to the Controller in solving the issue. [3] ,[19] and [6] recommended that the government shall constitute a compulsory license tribunal whose members came from judiciary and from the related disciplines to hear matters of grievance. [16] and [18] suggested that academic institutions, industry and non-governmental organisations shall collaborate and carry out joint research. The government can think of promoting a medical prize to encourage research for drug discovery, as suggested by Professor Stiglitz, a Nobel Laureate. The reward could be big for critical medicines and small for other incremental innovations. The drugs thus discovered could then be offered to generic drug manufacturers for the manufacture of drugs at an affordable cost. The government could invest and modernise the public sector pharmaceutical industry and build capabilities to manufacture, in partnership with the multinationals and domestic industry, lifesaving and critical drugs at affordable prices [1] The government could launch massive health care programmes joining hands with the multinational and domestic drug firms for the treatment of the poor patients, by suitably rewarding them [9]. Medicines Patent Pool (MPP) is a non-governmental organisation which had devised a new mechanism wherein the patent holding drug companies contributed their HIV patents to the pool and the patents of the pool were made available to other companies for the manufacture of affordable medicines for supply to the poor countries. MPP pays reasonable royalty to the patent holder for its contribution of the patent to the pool. Already three Indian companies, Aurobindo Pharma, MedChem Labs and Emcure , had made use of the Medicines Patent Pool [4] Though there were initial glitches in the functioning of the Pool, the government could study the situation and initiate a suitable policy framework so that such new measures brought drugs at affordable costs without much litigation. Another option that was deliberated is that the government could negotiate the price of the drug before its entry into the country [8]. The merits and demerits of this move might be studied in conjunction with the consequences on the issue of compulsory licences and a decision could be taken by the government to avoid disputes in the sector. [12], have designed a model to analyse the impact of drug price control and compulsory licences on human welfare and concluded that those policy instruments complement each other in providing access of the drugs to the people. The government could think of softening its policy stance to accommodate any enhancement in the efficacy of a known substance and not necessarily the enhancement in therapeutic efficacy only which would allow better storage and beneficial flow properties, better thermodynamic stability, lower hygroscopicity, lower side effects and better delivery for qualifying as invention.

CONCLUSION

TRIPS and the Indian patent law recognise the value of the inventions and the mechanism for the protection of the interests of the inventor through the issue of patents. At the same time, the patent holder is expected to utilise the patent right for the common benefit and not for the enjoyment of the patent as a monopoly right. Thus the regulations aim for the balancing of the rights of the patent holder and the benefits to the common man. Challenges had arisen to the extended meaning given to Section 3(d) and the issue of compulsory licenses. Also, instances of post-grant oppositions to the patents already granted had arisen. While

the government is responsible for the welfare of the people and enforces the regulatory mechanism, the pharmaceutical industry laments as being affected. This review article had brought out many suggestions. In the interest of all concerned, it is imperative that the government, the industry, the non-governmental organisations and the experts join together and design methods to overcome the challenges.

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