



INTRODUCTION OF PHARMACEUTICAL PATENTS IN INDIA: A BOON OR A CURSE?

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ABSTRACT

With the rapid advancement in technology, the pharmaceutical industry has benefited a lot. Every day, new life-saving drugs are being introduced in the market. Intellectual property rights in the pharmaceutical sector is regulated by the law of patents. India has its own patent laws, and it is also a party to General Agreement on Tariffs and Trade. This has helped the law of patents to become more efficient in India. With the introduction of the Patents Act in India in the year in 1970, pharmaceutical companies were allowed to patent their process of manufacturing drugs. The patents were valid for seven years. With the introduction of GATT, due to India becoming a signatory to it in 1994 many changes occurred in the Indian Market. It was now mandatory to comply with GATT as well as the Trade Related Aspects of Intellectual Property Rights Agreement. Not complying with these standards meant that the defaulting party would no longer be a member of the World Trade Organization. The pharmaceutical industry also had to meet the minimum standards which were provided under TRIPS. Hence, not only process patent, but product patent was also introduced, and the period of patents was increased from 7 years to 20 years. India got some extension to introduce these new measures as it got the benefit of being a developing country. The introduction of product patent has bought a broad aspect of pharmaceutical products which can be patented in India. The domestic

pharmaceutical industry has laid a strong foundation stone to the Indian economy. During the last three decades, the Indian Pharmaceutical industry has a high rate of growth and today India has emerged as one of the leading drug producing country globally. Many countries were in a fear that the patent protection in the pharmaceutical field will limit the spread of knowledge and thus curtail the scientific innovations that were needed for the public interest. Most of the developing countries concerns was that once a product is patented, the same product cannot be produced by any other method or process during the time of protection. However, if only the process alone is protected, i.e. the process patent, then an alternative method which is mostly invented could be used to produce a similar product because of the reason that a product can be produced by more than one method in pharmaceuticals. This article focuses on the pharmaceutical patents in India and the accessibility of drugs.

INTRODUCTION

India being a developing nation, there has been a rapid advancement in the field of science and technology. The Indian Patent Act, 1970 was amended and it implemented some of the provisions of Trade Related Aspects of Intellectual Property Rights (TRIPS) and it came into force on January 1, 2005. It was only applicable in the case of patentability of pharmaceutical substances to new chemical entities. Section 3(d) of the Patent Act, 1970 conveys that a mere discovery of a new form of a known substance, mere discovery of a new property or a mere use of a known substance or mere use of a known process, machine or apparatus which does not increases the efficiency



cannot be patented¹. Despite of having strong opposition from the pharmaceutical sectors, this provision still exists in the patent regime of the country. The recent patent law decisions including that of the Supreme Court in the Novartis case², indicates that India continues to put the best on public health with regard to pharmaceutical patent law decisions.

PATENT LAW IN INDIA

In 1856, patent rights were first introduced in India. In the year 1970, Indian Patent Act, 1970 was passed. It repealed all the prior legislations relating to patents. India is a signatory to Patent Cooperation Treaty, 1970 and also a signatory to the Paris Convention for the Protection of Industrial Property, 1883. According to Patent Act, 1970, an invention which satisfies the criteria of novelty, usefulness, and non-obviousness can be considered as subject matter of a patent.³ Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or animals to render them free of disease or to increase their economic value or that of their product, any method of agriculture or horticulture etc. cannot be treated as inventions.⁴ Patents can only be granted for the process of manufacture and not for the substances themselves with regard to pharmaceuticals, food items, medicines or drugs and substance produced by chemical process. Thus, in the pharmaceutical sectors, only process patent were granted and there was no product patent on drugs. For all

inventions, India had a patent regime under the Patent and Designs Act, 1911. However, the government brought in the new Patents Act in the year 1970 which denied agrochemical products and pharmaceuticals from patent eligibility. This expulsion was introduced to stop India's reliance on imports from other countries for drugs and to make advancements in the country by developing an independent indigenous pharmaceutical industry.⁵ Thus, in our existing patent regime, molecules which are products of a chemical reactions as such are non-patentable. This restriction on patentability was supplemented with the restriction on mere ad mixtures which results in aggregation of properties in which the components do not show any collegial behavior, limiting the items that can be patented. Even if the 'Actives' show functional properties which are produced by chemical synthesis, cannot be patented in India. Ingredients behaving as mere admixtures in standard drug formulations do not qualify to be granted patents in India. In such similar cases the patent can be granted only for the process, i.e. the process of manufacturing the product is patentable. As no protection for the product patent in agrochemicals and pharmaceuticals was granted, it had a huge impact on the pharmaceutical sectors. Thus it resulted in the advancement of ample skills in reverse engineering of drugs which are product patentable all over the global and industrialized world but is unprotected in

¹ Section 3(d) in The Patents Act, 1970

² Patralekha Chatterjee, *Five Years After The Indian Supreme Court's Novartis Verdict* :available at: <https://www.ip-watch.org/2018/05/20/five-years-indian-supreme-courts-novartis-verdict/> (Accessed on 10-09-2020)

³ Supranote1

⁴ *ibid*

⁵ Juan He, *Indian Patent Law and Its Impact on the Pharmaceutical Industry: What Can China Learn from India?*: available at: https://link.springer.com/chapter/10.1007/978-981-13-8102-7_11 (Accessed on 12-09-2020)



India.⁶ After this, the pharmaceutical industry in India had an immense growth as it developed cheaper version of many drugs patented for domestic market and then gradually moved into the global market with the generic drugs. Also, in order to give better access to drugs and to prevent misuse of patent rights, the Patents Act provides a number of preventive measures. In the case of processes or methods of manufacture of a substance proposed to be used or competent of being used as a medicine or drug and as food items, the term of patents is for a period of seven years from the date of filing or five years from the date of sealing the patent, whichever is less.⁷ All other patentable inventions have given a period of fourteen years from the date of filing unless it is shown to be invalid. Compulsory licensing is a provision provided under the Patents Act⁸. Any person interested in functioning the patented invention may apply for a compulsory license with regard to the invention on the completion of three years from the date of sealing the patent.

The patent holder may be directed by the Controller of patents to grants such license based on the terms as it may deem fit only if he or she is fully pleased that the equitable requirements of the public with regard to the patented invention have not been met or that the invention isn't accessible at a fair price to the public at large. Apart from the provision of compulsory licensing, Patent Act also includes a provision for 'licenses of right' that in certain circumstances, even after the

expiration of three years from the date of sealing of the patent, the central government can apply for an order that the patent may be certified with the words 'licenses of right' on the basis that reasonable requirements of the public with regard to the patented invention have not been fulfilled or it is not accessible to the public at a reasonable price.⁹ Those substances that are not food items and medicines or drugs but are able to be used as food items and medicines or drugs that are patented is deemed to be certified with the words 'license of right' from the date of completion of three years from the date of sealing of the patent. The effect of promoting a patent with the word 'license of right' is that a person who is engrossed in functioning of the patent invention in India may request the patentee to allow the grant of license. If a person is already a license holder under the patent, the grant of license would be on the conditions that have been mutually agreed upon. They can apply to the Controller of Patents to arrive at the settlement of conditions if the parties are not able to agree to the conditions provided under the license. The most significant contributions of the TRIPS agreement is the introduction of product patent in India and thus the Patent Act, 1970 has also played a significant role in leading India into a global patent field.¹⁰

THE NATIONAL PHARMACEUTICAL PRICING POLICY, 2012

Nowadays, the central issue of concern is access to essential drugs. The cabinet approved the National Pharmaceutical Policy

⁶ Chandra Nath Saha, *Intellectual property rights: An overview and implications in pharmaceutical industry* :available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/> (Accessed on 12-09-2020)

⁷ *ibid*

⁸ V. K. Ahuja, "*Law Relating to Intellectual Property Rights*", Lexis Nexis, 3rd ed

⁹ Suchi Rai, *India: License Of Rights In Patents* :available at:

<https://www.mondaq.com/india/patent/690290/licenses-of-rights-in-patents> (Accessed on 14-09-2020)

¹⁰ *ibid*



and notified in it in the year 2012. Consequently an order of New Drugs Price Control was notified in the year 2013. As a result of this, several essential drugs will come under the domain of the price control under the national list of essential medicines. The prohibition of patented drugs in the said policy for a short-term period i.e. five years. This might have been done to give more opportunity for creation and innovation to the pharmaceutical sectors. But the problem is that it will have an adverse effect on a constitutional guaranteed right i.e. right to health.¹¹ In *All India Drug Action Network v. Union of India*¹², the Supreme Court of India propounded that in order to provide access to the life-saving medicines, the government of India must make every efforts for the full realization of human rights. To implement the provisions of the TRIPS agreement which includes the product patent for pharmaceuticals, chemicals and food product, the Patent Act, 1970 has been revised three times in the year 1999, 2002 and 2005.¹³ The three articles of the TRIPS agreements which resulted in the amendment of Indian Patent Act ensures policy guidelines and flexibility to the member countries of WTO framework. Section 83, 84, 91, 92 and 92A of the Indian Patent Act provides general and special provisions for the grant of compulsory license on patents. After DOHA declaration, it confirms that the member states of WTO can interpret their TRIPS provisions in such a way that they contribute the working of their health policies.

The DOHA declaration fails to address the question of whether the introduction of product and process patent in developing countries is generally suitable with the measures that state must take to enhance the right to health of its citizens. The DOHA declaration also fails to answer more practical questions, that forbidding on a developing country like India compulsory licensing a drug mainly to export it to other countries that do not have the capacity to make drugs for their own use. If the exports are not allowed, most Saharan African countries would not be able to take benefits of alternative sources of medicines. If the manufacturing capacity of developing countries like India were reduced to a great extent, it will have a huge impact not only in India but also on several other countries which do not have the capacity to produce drugs by themselves and thus will have to depend on other developed nations. The DOHA declaration is not adequate so far as it only extends the chances of granting compulsory licenses and it does not amend the TRIPS agreement. The TRIPS agreement needs to be amended to include the concept favoring access to drugs in the main provisions of the TRIPS agreement rather than keeping them as exceptions.¹⁴

The Supreme Court of India has opined that the objective of patent law is to enhance new technology, scientific research and industrial progress. The product patents on drugs and pharmaceuticals would result in the increase in cost of life saving drugs and when the

¹¹ Dipika Jain, *Is the National Pharmaceutical Policy, 2012 Really Cheering The Pharma?* :available at: <http://www.ijlt.in/archive/volume9/Dipika%20Jain> (Accessed on 14-09-2020)

¹²(2011) 14 SCC 479

¹³Vipin Mathur, *Patenting of Pharmaceuticals: An Indian Perspective* :available at: <https://www.ijddr.in/drug-development/patenting-of-pharmaceuticals-an-indian-perspective.php?aid=4994> (Accessed on 15-09-2020)

¹⁴ibid



lifesaving drugs will become essential and when it cannot be accessed, the people in the developing countries would suffer the most. These people are not in a position to spent huge amount of money on their health care. In this context, the TRIPS obligations implemented by the developing countries, more particularly countries like India, it is clear that there arises an issue between a welfare and health care of the society and the economic rights of an individual patent holder if product patents are allowed.¹⁵

PHARMACEUTICAL INDUSTRY IN INDIA

The Indian pharmaceutical industry significantly contributes to the global pharmaceutical sector. It is the third largest pharmaceutical industry in the world comprising largely of generic pharmaceutical companies. India changed its Patent Act and it excluded product patents in 1971 in pharmaceutical and food sectors. It was mainly incorporated to boost the industries protect health and to satisfy the need of the population. India exclude certain types of chemical entities such as polymorphs when India signed the TRIPS agreement. These exclusions were introduced by keeping in mind the access to health care and cost of the drugs in the country and pharmaceutical companies which make drugs difficult to access to the general population who don't even have the financial strength to meet their health care needs¹⁶.

EFFECT OF THE CHANGES IN THE PATENT ACT ON PHARMACEUTICAL INDUSTRY

After the amendments made in Indian Patent Act, a need to balance the protection of patents and the rivalry between the pharmaceutical companies arose. The establishment of new product patent which has been implemented in India in 2005 may lead to situation of domination. Generic companies gave a lot of competition to the foremost companies before the introduction of the concept of product patenting. The major companies were forced to sell their product at least price if they wanted to endure in the market because of the reason that the generic companies produced the drugs at low cost.¹⁷

Then, the introduction of product patent on India has brought new changes. In such situation, in order to avoid dominance, the competition law will also play an important role in the market. The Competition Act, 2002 attempts to prevent domination in all field. In the pharmaceutical sector, there can be mainly three types of competition issues in the form of mergers, collusion, mergers and acquisition, mergers and misuse of a strong market position. Because of this there can be an increase in the cost of medicines which makes difficult to the poor people to buy medicines for their needs. So, in order to cope up this, it is very important to maintain a

¹⁵Samira Guennif and N Lalitha, *TRIPS Plus Agreements and issues in Access to medicines in Developing Countries* :available at: <http://nopr.niscair.res.in/bitstream/123456789/271/1/JIPR%2012%285%29%20%282007%29%20471-479%20.pdf> (Accessed on 18-09-2020)

¹⁶ibid

¹⁷ George T. Haley and Usha C.V. Haley, *The effects of patent-law changes on innovation: The case of India's pharmaceutical industry* :available at: https://www.researchgate.net/publication/263368673_The_Effects_of_Patent-Law_Changes_on_Innovation_The_Case_of_India's_Pharmaceutical_Industry (Accessed on 18-09-2020)



balance between protection of intellectual property and competition between the companies for the welfare of the society.

TYPES OF PHARMACEUTICAL PATENTS IN INDIA

Indian pharmaceutical industry is playing a major role globally and it has a strong generic base. The pharmaceutical companies of India are well known for their generic medicines or drugs and the pharmaceutical patenting has a significant position with respect to the present issues related to public health as they are supplying low cost pharmaceutical products in the form of generic drugs. Thus, Indian pharmaceutical industry has achieved global recognition that providing high quality pharmaceutical products with least price.¹⁸ In today's competitive market, it is very important for the pharmaceutical companies to protect their own inventions from any other illicit commercial use by gaining patent rights over their invented process or product. In India, pharmaceutical patents can be classified under the following categories which is based on the pharma patents list provided by the Indian Patent office.

differently. Same active ingredient may be presented in different dosage forms which in turn can be formulated using different pharmaceutically acceptable excipients. Composition claims cover active ingredients and pharmaceutically acceptable carriers or excipients such as fillers, lubricants, binders and disinfectant.¹⁹

Drug Compound Patents

These patent claims are commonly known as Markush type claims. It is a claim with multiple 'functionally equivalent' chemical entities allowed in one or more parts of the drug compound. This claim may include an enormous number of possible compounds. The acceptance of Markush claims generate rights over a particular wide-ranging set of compounds without prior experiment or testing. Drug compound patent allege a drug compound by its chemical structure by itself. Also, these patents provide feasible protection to the company's product, while other pharmaceutical companies are not allowed to make such drug by any means of synthesis or to produce or sell any formulation consisting this drug before the expiry of these patent.²⁰

i) Formulation and Composition Patents

This patent has claim of specific formulation technology or a class of drugs that applies to many drugs. The patents that are granted exclusively on the basis of formulation or composition do not protect the active ingredients i.e., if the information with regard to a particular active ingredient is already in the public realm, generic companies may market the same drug that is formulated

Synergistic Combination

When two or more drugs interact with each other in such a way that it enhances one or more effects of those drugs, there occurs the patent drug synergy. Patents can be obtained on new synergistic combination of the drugs. Combination products contain two or more prior known active ingredients. In certain countries, if there is no evidence to show the

¹⁸Srividhya, *India: Pharmacy to the World* :available at: <https://www.investindia.gov.in/siru/india-pharmacy-world> (Accessed on 18-09-2020)

¹⁹*Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals* :available at:

http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf (Accessed on 23-09-2020)

²⁰ ibid



combination product that has to establish a 'new and non-obvious' synergistic effect, patents on combination product will not be accepted.²¹

iv) Technology Patents

These patents are based on techniques. It is used to solve specific technology related issues like increase of solubility, stabilization etc.²²

v) Polymorph Patents

Polymorphs may exist in different physical forms such as amorphous solid and/or in different crystalline forms. Also, they may have different properties more or less importance. Polymorphs are not invented or created; they are discovered normally as part of usual testing related to drug formulation. Polymorphs claims are accepted in many countries. These are generally prepared to shrink impurities or increase stability of the compounds.²³

vi) Biotechnology Patents

Biotechnology is the science which involves the application of living organisms and processes in the preparation of materials used in the pharmaceutical products. These patents cover a broad range of therapeutic, diagnostic and immunological products.²⁴

vii) Process Patents

These patent covers an innovative and inventive process to produce an exact product. It does not claim the products as such.²⁵

According to Indian Patent Act, an application for grant of compulsory license can be made only after three years from the date of grant of patents unless exceptional situation like national emergency or extreme emergency can be used to justify the grant of a license on an earlier date. At any time after the expiry of three years from the date of grant of patent, any person interested may make an application to the Controller alleging that reasonable requirements of public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at reasonable price and also the reason that the patented invention is not worked in the territory of India.²⁶ The applicant may seek the grant of a compulsory license to work the patented invention. Compulsory licensing will boost the public interest while still maintaining the incentive to develop new inventions, it is important to keep in mind that compulsory licensing be allowed only where it is necessary to promote public interest, not significantly reducing the incentive to develop a new drug.²⁷

CONCLUSION

Indian pharmaceutical industry is one of the world's largest industry comprising of generic pharmaceutical industries. The Indian pharmaceutical industry accord significantly to the global pharmaceutical sector. The Patent Law in India is an exceptional piece of legislation which balances the interest of both the inventor and the society at large. Patenting drugs generally

COMPULSORY LICENSING IN INDIA

²¹ ibid

²² ibid

²³ ibid

²⁴ ibid

²⁵ ibid

²⁶Rahul Chaudhry, *Dealing with compulsory licensing in India* :available at: <https://www.iam->

[media.com/dealing-compulsory-licensing-india](https://www.iam-media.com/dealing-compulsory-licensing-india) (Accessed on 24-09-2020)

²⁷Surabhi Shekhawat, *Compulsory Licensing of Pharmaceutical Patents*, 5 Madras Law Journal 36 (2014).



provides an incentive for the advancement of pharmaceutical industry. Industrial representatives contend that pharmaceutical industry spends a heavy amount than any industry on the research and development and that development of a new drug is an expensive process and is relatively easy to imitate an already existing drug. Thus, the patent system allows the industries to levy a price much higher than the cost of production and distribution. The price of the drug will only come down when patent protection for the drugs expires. Even after the repeated requests for patent protection on drugs by pharmaceutical industries, a number of developing countries have still barred pharmaceutical patents on public policy grounds.

