PATENTING OF PHARMACEUTICALS IN INDIA: A STUDY ON THE NOVARTIS AG VS. UNION OF INDIA CASE

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ABSTRACT

Patent is one of the major forms of Intellectual Property Rights (IPRs) used in the pharmaceutical industry. The Patent Act, 1970 is considered an exemplary piece of legislation in India to protect the Intellectual property holder from patenting its invention without his permission by any unauthorised person. The government of India is moving towards establishing a new patent regime in India that is at par with the new technological advancement as well as global commitments. In the era of highly competitive market, the pharmaceutical Industry of India is considered as one of the knowledge driven sector. The Indian pharmaceutical industry has been flourishing with the invention of life saving drugs. The patenting of Pharmaceutical product is only a new recognition in India like many developing countries across the world. In the age of globalization and industrialization, the pharmaceutical sector has been considered as one of the preferred for the policy makers for the developed as well as developing countries to give protection to drugs from being patented. In the landmark judgment of Novartis case, the Supreme court of India refused to grant patenting right to the Novartis, a foreign company by stating that just making some minor changes in a known product will not increase its efficiency and make it an invention .Through this paper, an endeavour is made to give an outlook of the growth of patent law in India and its effectiveness in the pharmaceutical regime of India. An attempt is also made to analyse the effect of the landmark Novartis case in regard to pharmaceutical product in India.

***Keywords*:** Patent, Pharmaceuticals, Novartis, Intellectual property, Globalization, Industrialization.

INTRODUCTION

The pharmaceutical industry has benefited a lot due to the advancement in technology. Every day, new life-saving drugs are being introduced in the market. Intellectual property rights in the pharmaceuticals sector is regulated by the law of patents. India has its own patent laws, and it is also a party to GATT. This has helped the law of patents to become more efficient.[i]

It has been recognized by industry, academia, and policy makers alike that innovation is pivotal to value creation, competitive advantage, and sustainable economic growth. As knowledge economy became the basis for globalization, innovation opportunities have been incessantly emerging around the world for value-added products, processes, and services to meet the ever-growing needs, wants, challenges, and opportunities of the world. As a result, today we find many individuals, companies, communities, and nations working relentlessly on innovation. Thus, policy makers, both nationally and internationally, have recognized that innovation either flourishes or suffers depending upon the innovation ecosystem. However, the innovation ecosystem of a nation depends upon three primary factors, namely, technology environment, business environment, and policy environment. Consequently, academia, industries, and governments around the world have been focused on strengthening and promoting the innovation ecosystem in order to meet the national priorities, as well as achieve competitive advantage, sustainable economic growth, and creation of employment in the global economy. In this regard, it is important to note that the vision and strategies of a country's patent regime play a crucial role in (a) advancing the goals of its innovation ecosystem (indigenously or as part of international agreements), (b) protecting its social and economic interests, and (c) safeguarding the legitimate business interests of competition. Indeed, it is in this light that the historical evolution of the Indian patent regime and its impact on innovation in the Indian pharmaceutical industry must be analysed and understood.[ii]

PATENT: IT'S MEANING

Patents are granted for protection of the inventions made by a person using his own intellectuals. Since, Patent is an exclusive right and therefore it is granted to the person who has applied for the same to protect his inventions. An application for patent can be made by the inventor of a particular creation or any person on his behalf who has assigned by the inventor

to do the same. The right of patent excludes others from unauthorized using, making, offering to sale, selling or importing the invention of any person. Patent is a negative right that means patent is not a right to make, use or sell the invention, rather it is a right which empowers the patentee (patent owner) to prevent or stop the use of his/ her invention by any third parties without his/ her permission. Patent includes right to license others for the purpose of making, using or selling the patented invention. Thus, patenting provides a strategy for protecting particular inventions without keeping the invention secret.[iii]

Patent provides technical solution to a technical problem. Patent is granted only to those inventions which fulfils certain criteria as prescribed to protect a particular invention known as criteria of patentability. Any legal action for the infringement or violation of the patent rights of an invention can be brought only when it has protected by the law of patent. For getting patent protection in different countries, patentee or the owner of an invention have to be applied in each of the countries. Patent Cooperation Treaty (PCT) provides a route to file an international patent application through with patentee can file patent for his invention in a large number of countries through a single patent application. However, after filing the Patent Cooperation Treaty (PCT) application, grant of patent to the applicant remains under the discretion of the individual patent office of the concerned country in which he has applied for patent.[iv]

DEVELOPMENT OF PATENT LAW AND INDIAN PHARMACEUTICAL INDUSTRY

In the developed as well as the developing countries including India, pharmaceutical sector has been the considered as most preferred one for the policy makers due to sensitive needs of the pharmaceutical products for the health safety of the masses as well as for increasing strategic benefits in the knowledge-based economy of a particular country.

The growth of pharmaceutical industry in the developing countries is mostly confined to a few countries like India, China, Singapore, Korea, Czech Republic, Brazil and Argentina. The Indian pharmaceutical industry, which had little technological capabilities to manufacture

modern drugs locally in the 1950s, has emerged technologically as the most dynamic manufacturing division in the Indian economy in the 1990s.

The history of patent law of India can be understood by analyzing various patent laws in India before 2005 when provisions of Trade related Aspects of Intellectual property rights were implemented by the government of India and made changes in their own patent law to give effect to the TRIPS. History of Patents Act in India is more than 150 years old. The First Patent Act was enacted in the year 1856 as "Act VI of 1856 on Prevention of Inventions." The Act of 1856 was based on the British Patent Law of 1852. The objective of "Act VI of 1856 on Prevention of Inventions" was to give encouragement for inventions of new and useful manufactures and to bring out secret of inventions**.** However, the Act of 1856 was subsequently repealed by Act IX of 1857 as it was enacted without the consent of British Crown. Fresh legislation was introduced for the purpose of granting 'exclusive privileges' to the owner of particular invention in 1859, in the form of an "Act XV of 1859.

In 1872, the Act of 1859 was amended to provide protection to the designs as well and was renamed as 'The Patents and Designs Protection Act' under Act XIII of 1872. This Act was further amended in 1883 and was named as 'The Protection of Inventions Act 1883' under Act XVI of 1883. It introduced the provision of protecting novelty of the invention. This Act was further amended as 'Invention & Designs Act' in 1888.After the Independence of India, the Indian parliament drafted a new Patents Bill in 1965,which reintroduced in 1967 after a considerable debate in the Parliament of India and same is finally resulting into The Patents Act, 1970.

The pharmaceutical industry in India was under the dominance of MNCs up to 1970, which imported most of the bulk drugs from abroad and sold in India. At that time MNCs were sold nearly 85% of antibiotic and other medicines in India. However, with the introduction of the Patens Act of 1970, pharmaceuticals products patents were excluded by the Act of 1970 from its ambit. In the area of chemicals, pharmaceuticals, agro-chemicals and foods, the patenting of products were discontinued and patenting of process was introduced with a restricted life of seven years or five years from the date of sealing the patent, whichever period was shorter,.9 This has been led to the rapid growth pharmaceutical industry of India that entitled to protection for copying the original R&D patented products of MNCs by making some cosmetic changes in the process. The lack of protection for products in pharmaceutical and agro-chemical sector

resulted in the development of a considerable expertise in reverse engineering of drugs that were patentable as products throughout the industrialized world, but unprotected in India. This resulted in a rapid growth of the Indian pharmaceutical industry whereby cheaper versions of a number of drugs were produced in respect of drugs patented for the domestic market.[v]

ADVENT OF NEW INTERNATIONAL IP REGIME AND ITS RAMIFICATIONS ON INDIAN PHARMACEUTICALS INDUSTRY

The establishment of the World Trade Organization (WTO) marked the beginning of a new era in the field of intellectual property. International standards for the protection of intellectual property paved their way in the form of TRIPS Agreement. The Trips agreement obliged the Member States of it to provide exclusive protection to various categories of intellectual property covered under the Agreement, which include copyrights, patents, trademarks, geographical indications, designs, etc. The developing countries, including India required incorporating major amendments in the product patents in pharmaceuticals including chemicals and food products as to give effect to the provisions of the Trips agreement as a signatory of it.

Patents First Amendment

The 1st amendment to the Patent Act, 1970 was made in the year 1999 as The Patents (Amendment) Act, 1999 that was made effective retrospectively from 1st January 1995. This amendment introduced the 'Mail -Box'17 system under Section 5(2) of the Patent (Amendment) of 1999 Act as similar to the one required under Article 65.4 of TRIPS Agreement,[vi] in order to provide a means by which applications for product patent could be filed in the areas of drugs, pharmaceuticals and agro- chemicals.

The 1st Amendment to the Patents Act, 1970 was introduced after the United States lodged complaint before the dispute settlement body of the WTO in 1996. The issue was whether the Indian Patents Act, 1970 included a mechanism that adequately preserved novelty and priority of product patent applications in the field of pharmaceuticals and agro chemicals. The panel of World Trade Organization established that under the Patents Act of 1970, substances classified such as "food(s), medicine(s) or drugs(s)" were entitled only to process patents and that the

product patents in these fields were not granted. Thus, the WTO panel concluded that India was in breach of Article 70.8 (a) of TRIPS for not providing mailbox provision and had violated its obligation under Article 70.9 of the TRIPS by failing to provide Exclusive Marketing Rights (EMR) during the transition period.

Patents Second Amendment

The second amendment to the Patents Act of 1970 was made in order to brining the Patents Act in conformity with all the substantive provisions of the TRIPS, barring those related to the introduction of the product patents. The key issues in second amendment of Patents Act,1970 were:

- Redefining of patentable subject matter;
- Enlargement of the period of patent term from 14 years to 20 years from the date of filing of complete specifications of the patentable subject matter;
- Strengthened of section 84 which is dealing with compulsory licenses by amending compulsory licenses system**;**[vii]

The 2002 Amendment to the Patents Act of 1970, besides limiting the exclusive right of the patent holder by issuing the compulsory license after a period of three years on account of violation of Section 84 of the Act, also made various provisions to meet the circumstances arising out of the crisis in the Public health sector, or the cases of national emergency or extreme urgency or in case of public non-commercial use of the patented article. It is one of the flexibilities on patent protection that have in the TRIPS Agreement.[viii]

Patents third Amendment

The second barrier imposed by the TRIPS Agreement viz. introduction of product patents in The Patent Act was crossed by 1 January 2005 by introducing product patents in the Third Amendment Act, 2005. This led to the beginning of new Patent regime in India.

The third amendment to the patents Act of 1970 aims at providing product patent protection in various fields of technology and expected to have far reaching implicate on the pharmaceutical industry. Thus from Jan 1,2005 the Patent Amendment Act of 2005 prohibited pharmaceutical companies (producing generic versions of drug by using different process) from manufacturing or marketing them in case drug-patent which has been obtained elsewhere. This Act also

provides protection for product as well as process patents in all technical fields. Thus product patents can now be obtained for drugs, pharmaceuticals, chemicals, etc., which were earlier prohibited under Section 5 (1) (i) of the Patents Act, 1970.The Patents (Amendment) Act of 2005, however, provides certain exceptions to Section 3 under the heading of Inventions not deemed to be inventions. The amended to Section 3 (d) became a cause of concern as it excludes patentability for derivates of known substances; unless it is proved that the efficiency is significantly greater than the original substance. This amendment of Section 3 (d) was carried out to control 'evergreening'[ix] and attempts to obtain product patent protection for Pre-1995 molecules in India, which otherwise do not qualify for product patent in India. Amended to Section 3 (d) resulted in rejection of the product patent application which led Novartis to file a Writ Petition challenging the validity of Section 3 (d) amendment in the case of Novartis AG v. Union of India and others[x] before the Hon'ble High Court of Madras.

The most controversial change that has been brought to the patents regime in India is the introduction of the product patenting in the field of pharmaceuticals, agrochemicals, etc., besides the other changes made in order to bring the patent laws in India in compliance with the TRIPS Agreement. This change as to the patenting of the products gave a chance to the proponents of the earlier view to implicate an increase in the prices of drugs which were earlier not the subject matter of patenting. However, the Act of 2005 contains a number of safeguards to ensure that the production of existing generic versions of drugs is not jeopardized. It contains various provisions to ensure affordable access to new drugs in India.[xi]

THE NOVARTIS AG VS. UNION OF INDIA AND ORS [xii] CASE STUDY

In recent decades, many nationals and international organizations have made a concentrated effort to homogenize the laws governing intellectual property. The attempt at standardization, however, has not been free of dissention, particularly with regard to the laws pertaining to pharmaceutical patents. This is due to the continuing tension that exists between large, multinational pharmaceutical companies (MNCs), and developing nations that lack both the infrastructure and capital to establish their own self-subsisting pharmaceutical industries.

In 2005, because of its obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) as signatory to it, India was compelled to amend its laws to provide product patent protection to pharmaceuticals. In an attempt to meet the competing demands for inexpensive drugs and effective intellectual property protection, the government of India created a law that afforded protection to pharmaceuticals only if they constituted brand new chemical substances or enhanced the therapeutic "efficacy" of known substance. This law, which is codified under section 3(d) of the Patents (Amendment) Act of 2005, has not set well with some multinational pharmaceutical companies (MNCs), including the Swiss company Novartis.[xiii]

Novartis a Swiss pharmaceutical company struggles with the Indian patent regime began in 1993, when it filed patents application around the world for its synthesis of the molecule imatinib. According to Novartis, however, the molecule can only be administered to cancer patients as imatinib mesylate. The resulting drug is currently patented in forty countries as Glivec. Following the formation of the World Trade organization and passage of TRIPS in 1995, Novartis filed a patent application for Glivec (imatinib mesylate) in India in accordance with the "mail box" requirement. The Madras Patent Office rejected the patent application, citing that imatinib mesylate was a known compound (a pre 1990s molecule) and the beta crystalline form was merely a derivative of imatinib mesylate. Pursuant to section 3(d) of the 2005 Act, the Patent Office concluded that Glivec failed to show "novelty and inventiveness," as well as increased efficacy as required by the law. Novartis then appealed the Madras Patent Office's decision to the Intellectual Property Appellate Board (IPAB).IPAB modified the decision of the Patent Office stating that ingredients for grant of patent novelty and non-obviousness may be present in the application but rejected the application on the ground that the drug is not a new substance but an amended version of a known compound. Novartis mounted a separate and concurrent litigation before the Madras High Court arguing that Section 3(d) has violated Article 14 of the Indian Constitution because the definition of "enhanced efficacy" was too vague and was in violation of India's obligations under the TRIPs Agreement. The High Court ruled that the law was not vague and that the law complied with TRIPS. In upholding the constitutionality of Section 3(d), the Madras High Court noted that: "India, being welfare and a developing country, which is predominantly occupied by people below poverty line, has a constitutional duty to provide good health care to its citizens by giving them easy access to life saving drugs.[xiv] In so doing, the Union of India would be right, it is

argued, to take into account the various factual aspects prevailing in this big country and prevent 'ever greening' by allowing generic medicine to be available in the market." Thus, it was evident that Novartis could not back up its claim of "enhanced efficacy" for imatinib mesylate over the parent molecule, according to the patentability standards laid down by Section 3(d).

Next, Novartis appealed IPAB's decision to the Supreme Court of India. However, the Indian Supreme Court agreed with the IPAB ruling that Novartis had not established the "enhanced therapeutic efficacy" over the parent compound, and thus failed to meet the requirements laid down by Section 3(d). In addition, the Indian Supreme Court opined that the constitutional validity of Section 3(d) was as per the flexibilities offered by TRIPS framework.[xv] Thus, the Novartis vs. Union of India case makes clear that India will not permit the ever-greening of patents, risking its social and economic goals. Indian patent regime also sends a strong message to the world that an extended monopoly to salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of a known substance will not be possible unless they exhibit demonstrably high therapeutic efficacy over the known substance.

THE NOVARTIS DECISION AND PUBLIC HEALTH CONCERNS

A significant reason why the Novartis case got considerable attention from the global community was the impact of the decision on the availability of generic drugs in the developing world. Many proponents of affordable healthcare feared that decision of the court in favor of Novartis would be a "death sentence" for patients struggling to pay for treatment. The challenge of providing affordable pharmaceuticals is especially pronounced in countries like India, where there is no developed insurance system.

The concern over affordable drugs in India and elsewhere was an important factor in the Intellectual property Appellate Boards decision to reaffirm the patent office's denial of the Glivec patent application. Section 3(b) of the Patents (Amendment) Act of 2005 holds that "patents cannot be granted to an invention, the primary or intended use or commercial exploitation of which could be contrary to public order, or morality, or which causes serious

prejudices to human, animal or plant life or health or to the environment." Following this provision, the Intellectual property Appellate Boards (IPAB) concluded that the Glivec patent failed not only due to the drug's lack of enhanced efficacy pursuant to section 3(d), but also because its exorbitant price was seen as placing the drug "beyond the reach of the common man." The Supreme Court similarly expressed "bewilderment" over the excessive price of Glivec.[xvi]Indeed, the justice even complained to Novartis about the drug's cost prior to rendering their decision. Novartis, however, has attempted to stave off these complaints by drawing public attention to the fact that 90% of Indian patients diagnosed with the form of leukaemia that Glivec is designed to combat receive the drug for free through Novartis's donation program. But not everyone is convinced; as one commentator bemoaned, "health policy cannot be hostage to corporate charity.

The decision of the Supreme Court in Novartis case is landmark for Indian Pharmaceutical Industry. The Indian Pharmaceuticals industry achieved a new height in the field of patent regime in pursuance to the decision of the Famous Novartis case. The decision of the court in Novartis case sends a message to the world pharmaceutical community as to how multinational pharmaceutical companies could business in India in the future as well as role of India as the Pharmacy of the developing world. The Novartis case sets an important precedent for access to medicines by putting the Pharmaceutical industry on the reach of patent law.

CONCLUSION

The Indian Pharmaceutical Industry is by far one of the most diverse, knowledge driven, technology intensive growth area, where fast track advancements can surely generate significant resources. When Trade related Aspects on Intellectual Property Rights (TRIPS) was signed, it was apprehended that it would be hindrance for the growth of pharmaceutical industry of India. But as a result of Trips agreement India is increasing its pharmaceutical industry by encouraging big foreign companies to invest in India. If the patent act of any country doesn't provide enough support for patenting of things which are patentable under the patent law of a particular country, it will never invest in that country.

The concern for securing access to affordable drugs is a real one, and there are strong moral arguments for why increasing patent protection for the products of powerful MNCs works only to hurt the common man. The reality, however, is that the protection of intellectual property rights provides these corporations with the needed incentive to invent and manufacture the drugs on which patients around the world rely, whether branded or generic. In theory, India could continue down its current path where its generics industry simply reverse-engineers the pharmaceuticals that are researched and developed elsewhere. But if India desires to grow into its role as a major scientific and technological powerhouse, then it must work to protect intellectual property rights, as opposed to doing the bare minimum to ensure compliance with TRIPS. It is no mystery why Indian pharmaceutical patent law has developed the way it has, but India has also changed significantly since it enacted its first patent laws. The Novartis case was, in many ways, a missed opportunity for India to redefine its place in the international debate over intellectual property rights. The decision may serve the immediate interests of India's generics industry and supporters of inexpensive pharmaceuticals, but may ultimately hinder the growth of research and development, both at home and abroad.[xvii]

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[iv] *Ibid.*

[v] Dr. Nandeep Kaur Sasan, "Trips and its implications on Indian Pharmaceutical industry", 2.1 *IJLPP* 36 (2015)

[vi] Article 65.4 TRIPS Agreement provides: "to the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, ……."

[vii] Section 84 provides that the compulsory license can be granted after the expiry of three years from the grant of the patent on the ground that reasonable requirements of the public have not been satisfied or patented invention is not available to the public at a reasonably affordable price; or that the patented invention is not worked in the territory of India.

[viii] *Supra* note 5 at 41

[ix]Ever-greening is basically a strategy adopted by the companies by which they bring some minor changes in such as adding new mixtures of isomers, using same molecular formula but with different structure.

[x] *Novartis AG v. Union of India* (2007) 4 MLJ 1153

[xi] *Supra* note 5 at 42

[xii] *Novartis AG v. Union of India* (2007) 4 MLJ 1153

[xiii]William J. Bennett, "Indian Pharmaceutical Patent Law and the Effects of Novartis Ag Indian Pharmaceutical Patent Law and the Effects of Novartis Ag vs. Union of India", 13 *WUGSLR* 536 (2014)

[xiv] *Supra* note 1 at 287

[xv] *Ibid*

[xvi] *Supra* note 13 at 550

[xvii] *Supra* note 13 at 557