

Changing Dimensions of Drug Patent Laws in India

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Abstract: The evolution of the pharmaceutical industry is from many years in India, and it was developing day by day. Patent rights are important rights given to the inventor for the protection of patent rights and there is patent law in India. The Patent Act 1970 provided that the pharmaceutical patent has process patenting in which there are huge manufacturers. But the Patent Act 2005 was enacted that allowed the process and product patent for pharmaceutical substances which entirely changed the concept of drug patents and it also brought major changes and modifications such as tenure of patent, no restriction for filing applications and other factors that are made for the protection of patent rights. The growth of patents may reflect the development of the nation. In the present world, the lack of knowledge on patent rights and awareness must be increased amongst Indian companies for the protection of patents worldwide. The trend of drug patent application in India is at a slow rate but the total patent application is rapidly increasing and there were certain reasons prescribed in the present paper. This article aims to analyse the trend and growth of drug patents in the Indian pharmaceutical industry. This article deals with the brief historical background of patent laws and changes made under the Patent Act 2005 and also provided the relation between the TRIPS agreement and India. This article mainly focused on the trend of drug patents in India and the changing dimensions of a drug patent in India and also focused on the reasons for the slow rate of development of drug patents in India this paper also provided certain recommendations for the growth of the trend of drug patents.

Keywords: *Drug Patent, Pharmaceutical Industry, TRIPS, Patent Act.*

1. Introduction

In the present society, the growth of socio-economic is increasing and it plays an important role to govern the nation. Intellectual property is a legal right provided to that of the creator or the inventor of any of the original creations with their intellect such as the technical,

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scientific, literary, designs, symbols, images, and names used in the commerce or the artistic creations. The intellectual property throughout provides a sense of security or protection to that of the inventor or the creator by providing the legal right over the invention made, the legal right conferred is provided exclusively to the creator or the assignee chosen by them.¹ In India, these major intellectual property rights were available.

A patent is a legal right granted by the sovereign authority of a country to the creator or the inventor of the invention made such as novel medicines, or vaccines etc., this right granted is an exclusive right of the inventor for a specific period accordingly to a limited term of monopoly over the inventions in the market which helps in recovering the costs of research and development. The patent could be accessed by anyone, but the ownership is granted to anyone who is an inventor, *i.e.*, considering for instance the airbag in the car is used for the purpose of reducing the life threat to that of the passengers in the accident, though is accessible or is used in almost all the cars nowadays was once an invention and the inventor being an independent American John W. Hetrick.² As observed serves the safety of every individual but is patented under the name of the inventor whose invention was helpful to people all around the world. The inventions made are a mixture of skills, technology, hard work etc.

In India, the patent is one of the major intellectual property rights used in the pharmaceutical sector and there are certain types of pharmaceutical patents such as drug compound, formulation, technology, synergistic combination, polymorph and process patents.³ After the Patent Act 2005, the product patented was allowed in India. Indian pharmaceutical industry was developing and the protection of patent rights there are various laws were amended, modified, and added certain concepts such as product patenting for flourished Indian pharmaceutical industry.

2. Patent Law in India

In India, the Indian Patents and Designs Act 1911 was enacted and the patent rights were mentioned under this Act. There were various amendments that took place and in 1957,

¹ Shruit, 'Changing Dimensions of Patent Laws in India' (*Legal Service India*) <<https://www.legalserviceindia.com/legal/article-5991-changing-dimensions-of-patent-laws-in-india.html>> accessed 25 August 2022

² Mastinu Giampiero & Ploechl Manfred, *Road and Off-Road Vehicle System Dynamics Handbook* (CRC Press 2014)

³ Vipin Mathur, 'Patenting of Pharmaceuticals: An Indian Perspective' (2012) 4(3) IJDDR 27

the Justice N. Rajagopal Ayyangar Committee was appointed by the Government of India to examine the questions of patent systems this committee made a certain recommendation for the process of patent with respect to drug and chemical inventions. In 1970, the Indian Government introduced a new statute that is Patents Act 1970 which was enforced in 1972.⁴ In India, the products of chemical reaction which actively prepared are non-patentable even though it exhibits synergistic properties and if there is a prohibition on mere admixtures that result in the aggregation of qualities in which the components do not exhibit any synergistic properties, severely restricts the items that can be patented. Moreover, the typical drug formulation in which the ingredients act as admixtures is not patentable and only the method of making the production process can be patented.⁵ This Act had been amended several times these are the Patent (Amendment) Act 1999, Patent (Amendment) Act 2002, and Patent (Amendment) Act 2005.

Many important changes were made in the Patent Act 2005 that the methods were patented and processes in all fields of technologies also can be patented.⁶ Indian can file a patent application anywhere and the restrictions mentioned in the Patents Act 1970 were removed.⁷ The list of products that didn't qualify as inventions were updated with the addition of Trade Related Intellectual Property Rights (TRIPS). Previously, any invention that resulted in unlawful conduct or went against public norms was not considered an invention, but they are now and can be patented.⁸ The major change was the tenure of the patent was changed to 20 years where earlier it was 14 years and the compulsory licensing with TRIPS was allotted where earlier it was only a right and was available to license.

3. TRIPS and Indian Patent Law

In the past two decades, changes have been made to regulations for the protection of intellectual property rights including patents. In 1994, the TRIPS agreement was signed by India that came into force on 1st January 1995 pharmaceutical patents were not granted

⁴ Vijay Pal Dalmia, 'Patents Law in India: Everything you must know' (*Mondaq*, 18 December 2017) <<https://www.mondaq.com/india/patent/656402/patents-law-in-india--everything-you-must-know>> accessed 25 August 2022

⁵ Nilesh Zacharias & Sandeep Farias, 'India: Patents and the Indian Pharmaceutical Industry' (*Mondaq*, 20 November 2019) <<https://www.mondaq.com/india/patent/865888/patents-and-the-indian-pharmaceutical-industry>> accessed 25 August 2022

⁶ Ridhi Mittal, 'Change dimensions of Patent Laws in India' (*Ipleaders*, 25 September 2021) <<https://blog.ipleaders.in/changing-dimensions-patent-laws-india/>> accessed 22 February 2022

⁷ Dalmia (n 4)

⁸ Zacharias (n 5)

before this and the agreement came into effect and was amended in 1995 in the Patent Act 1970.⁹ Article 65.2 of the TRIPS agreement states that – “a developing country Member is entitled to delay for a further period of four years the date of application, as defined in Paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5”.¹⁰ Under Article 65.4 of the TRIPS agreement – “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, as defined in Paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.”¹¹ Exclusive Marketing rights systems were introduced which operations during the transition period until TRIPS requirements were adopted by developing countries.¹²

India revised the Patent Act in 2005 to comply with all the agreements of the World Trade Organization (WTO), TRIPS which establishes the global standards for the protection of intellectual property.¹³ In India, the pharmaceutical industry has a prospect for growth with this agreement and the introduction of product patents for pharmaceuticals was made. The Bolar exemption provisions were adopted by India which allowed generic producers can enter before the patent expires, here the Bolar exemption means – “to create conditions so that the generic drug manufacturers can introduce their products immediately after the patent on drug lapses.”¹⁴ During the post-TRIPS period, the Indian pharmaceutical industry emerged as a global giant.

4. Evolution of Pharmaceutical Industry in India

Indian pharmaceutical companies mean – “the companies or individuals who create or develop new molecules or biological entities for treating medical conditions are known as innovator companies while those that enter the market with improved the process or

⁹ Mohammad Suleman Palwala, ‘Impact of Patent Law on Economic Growth of India: An Analysis’ (Mondaq, 18 July 2019) <<https://www.mondaq.com/india/patent/827016/impact-of-patent-law-on-economic-growth-of-india-an-analysis>> accessed 25 August 2022

¹⁰ Trade-Related Aspects of Intellectual property Rights Agreement 2004

¹¹ *Ibid*

¹² Manjul Vaidya *et. al.*, ‘Changing Dimension of Drug Patents of Indian Pharmaceutical Industry’ (2018) 28 JIPR 111

¹³ Atsuko Kamiike, ‘The TRIPS Agreement and the Pharmaceutical Industry in India’ (2020) 32 (1) JIE 95

¹⁴ Biswajit Dhar & KM Gopakumar, ‘Effect of product patents on the Indian Pharmaceutical Industry’ (2020) WTO Centre

modified dosage regimens once the product patent has expired are known as generic manufacturers.”¹⁵ The evolution of the Indian pharmaceutical sector is made into four stages that are in *first stage*, prior to 1970, the Indian market with a very less domestic market was dominated by international companies. The *second stage*, where many domestic companies operated and started participating in the markets was between the years 1970 to 1990. In the *third stage*, the exports and market operation were taking place it is from 1990 to 2010, in this duration, the Indian government enacted and amended the Patent Act 2005 in which a lot of changes and modifications took place such as the introduction of product patent which results to the component of India was launch operation in foreign countries. In the *fourth stage*, the Indian pharmaceutical industry which manufactures generic drugs became one of the largest industries in the world and to some sources, it is estimated that by 2030 the Indian pharmaceutical industry which is the major country manufacturing generic drugs will be the top 5 of pharma industry in the world.

5. Drug Patents of Indian Pharmaceutical Industry: Its Changes

The patents as observed are the rights provided to an invention made by a company or an individual in order to protect the invention made from being commercially exploited. Drug patents are exclusively made for medicines which restrict other companies from manufacturing or marketing the specific drug. In India, various amendments bring changes and modifications to extend the drug patent in the Indian pharmaceutical sector.¹⁶ There are two types of drug patents that are process patent and product patent which means the process patent means the method of manufacturing drugs only be patented and not the drug that leads to the generic medication. Product patent means the drug is patented and helps to prevent the manufacturing of the same drug from other companies. Before the introduction of product patents in India, multinational companies had an important impact on the Indian healthcare and pharmaceutical sector and after this, the Indian company's dominance in the market increased.¹⁷ Indian companies may focus on producing patented medications or drugs under license from international companies or on generating cash from generic drug production.

¹⁵ Pratibha Gokhale & Sudha Kannan, 'Patenting Trends in Indian Pharmaceutical industry' (2017) 64(4) ALIS 260

¹⁶ Athulya, 'How Do Drug Companies Purchase Patents?' (*Vakil Search*, 12 May 2020) <https://vakilsearch.com/advice/how-do-drug-companies-purchase-patents/> accessed 25 August 2022

¹⁷ Manjul Vaidya (n 12)

In India, the Patent Act 1970 introduced product patents that exclude the food, and pharmaceutical sectors. This was mainly incorporated for the protection of health, domestic industries, and food but it was changed when India signed the TRIPS agreement.¹⁸ As per the TRIPS agreement, India also implemented the agreement by excluding certain various chemical compounds such as salts, polymorphs, pure form, isomers, mixtures of isomers, complexes, combinations, esters, metabolites, and other drug combinations from patentability. These exclusions were made by focusing on the prevention of access to health care and the large pharmaceutical companies and other factors. Product patent that excluded food and drugs brought huge benefits to Indian pharmaceutical industry through the rise of reverse engineering. However, after obtaining the TRIPS agreement India amended the new law in 2005 which brought changes regarding the term of tenure and other factors mentioned above.

The conflict view within Indian pharmaceutical companies with regard to the transition into the product patent regime and some of the companies viewed that the product patents are the way for innovation. Indian pharmaceutical companies would be expanding the growth of research and developments and the protection of product patents encourage to development of the drugs as per the Indian disease list. Larger companies are already rising their total R&D spending as a percentage of sales, and they are beginning to shift their focus away from development research and toward novel chemical discovery. While some firms may fail to adapt, early indications suggest that a lot of Indian firms will do so successfully and emerge as more inventive.¹⁹ The absence of product patent protection affected India where there is very less investor from foreign companies.

6. Trend of Drug Patents in India

As mentioned above. the patents with respect to drugs or medicine and other certain chemicals have no patent was granted for only substances itself even that substance is new but only the method or process such manufacturing is patentable as the Patent Act 1970.²⁰ In the world, the Indian Pharmaceutical industry is one of the largest industries and many changes took place since 1970 presently, it was expanded its fields in many aspects such as

¹⁸ Gokhale (n 15)

¹⁹ Zacharias (n 5)

²⁰ 'Changes in India's Patent Law' (Joshi) <<https://www.joshiattorneys.com/articles-and-publications/cross-border-and-international-law-topics/changes-in-indias-patent-law/>> accessed 2 March 2022

manufacturing, research, and development of several branded and generic drugs.²¹ At the end of 2020, the Indian pharmaceutical industry is expected to grow by the US \$45 billion and attracts high FDI which is one of the elements for the progress of a nation.²² For the country's economic growth, this industry extracts enough revenue.

The trend of application of drug patents as total patent application percentage increased significantly up to 2004. After that, the drug patent applications had been reduced in percentage specifically after the implementation of the TRIPS agreement. In this agreement, it introduced the product patent basically stopping reverse engineering and replacing it with a process patent causing a huge fall in patent applications.²³ As per Compound Annual Growth Rate, the application of total patents was 8.39% and a pharmaceutical patent application was 3.27% this rate was from the financial year 1997-1998 to 2015-2016.²⁴ As per this, the total patent application increased trend post TRIPS agreement and the drug patent applications still remained slow in the last decade.

A study conducted by Yaeko Mitsumori on the new patent regime in 2005 established the two major issues that might aid to shrink the negative effect of the stringent patent system.²⁵ That is firstly, clause (d) of Section 3 of the Patent (Amendment) Act 2005 states that – “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 of 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. Explanation. - For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”²⁶ And secondly, the Indian pharmaceutical companies were embracing the transitioning business methods.

²¹ Annika Bergman, 'FDI and Spillover Effects in the Indian Pharmaceutical Industry' (2006) LUSEM

²² Vaidya (n 12)

²³ Teg Alam & Rupesh Rastgi, 'Trend Analysis of Cost Efficiency for the Pharmaceutical Industry: A DEA Approach' (2019) 9 Management Science Letters

²⁴ Mittal (n 6)

²⁵ Rory Horner, 'The Global Relevance of India's Pharmaceutical Patent Laws' (2013) 48(31) Economic and Political Weekly

²⁶ Patent (Amendment) Act 2005, s 3(d)

There can be other reasons for not increasing the drug patent applications such as policies of the government, for instance, the majority of Indians do not have health insurance and the government of India made efforts to issue some patents in past few years. Most patent cases are filed in India for the mode of deliveries, combination drugs, and formulation and India is significant for the production of generic drugs but it still lacking in drug patenting.

7. Conclusion

In the present society, people with their intellect are inventing many things related to different concepts. There are many intellectual property rights were provided in that patent is also a right available. It is one of the most important rights for new inventions and innovation. In India, patent law changes with time and there are various amends were taking place still now for the protection rights of inventors. The Patent Act 1970 focused on patenting the process of manufacturing but not on the substances and this act also introduced product patenting excluding food and drugs that affected the Indian pharmaceutical industry by no investor from the multinational companies. After that India signed TRIPS agreements and started operating and enacted new patent law that is the Patent Act 2005 which introduced product patents including drug and food sectors. There are certain conflicting views regarding the product patent regime in Indian drug companies. However, the product patent can encourage and increase the research and developments in accessing the drug.

The trend of drug patent applications is raised up to the year 2004 and after that, the rate of drug patent applications filed from India appeared to downtrend however it can be for a temporary period. As mentioned above, the reasons for this are Section 3 (d) of the Patent Act 2005 and the Indian pharmaceutical companies embracing the transitioning business methods and there can be other reasons such as government policies. As provided in the data, the total patent application was increasing but the drug patent applications were slow for the past few decades. However, the Indian pharmaceutical industry is one of the largest counties that provides manufacturing generic drugs in the world.

7.1. Recommendations

- The Government of India must form a committee the analyze and interpret the rate of the trend of drug patent applications in the Indian pharmaceutical industry.

- Pharmaceutical Industry of India is the largest manufacturer of generic drugs even though it lacks infrastructural facilities, lack of monetary, and research equipment are expensive and other factors that should be considered by the Government of India.
- The growth of research and development expenditure is correlated to the pharmaceutical industry, If the Indian pharmaceutical industry makes effort to bring growth in research and development then the drug patent industry also grow.