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Conundrums in Administration of IPR in Pharmaceutical Industry in India

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Abstract

With time, there are numerous developments in the pharmaceutical industry which came with certain problems concerning getting the particular drug & medicine to be patented following the *Patents Act 1970* which laid down the criteria and conditions under which the patent can be granted to the inventor in the field of the pharmaceutical sector to achieve new drugs and medicine as a result following the laid down criteria in the patents act benefiting the public due to the manufacturing of drugs which are effective and cost-efficient.

This paper will enlighten the concepts of Patent Rights granted under the patent laws in the pharmaceutical industry and what are the major problems associated with the process of patenting a drug or medicine and it's further licensing to other manufacturers. It will highlight the problems in getting patent rights and licenses by other manufacturers from the patentee to manufacture the drugs at an easy and affordable price with the help of compulsory licensing. Further, this paper will highlight the new measures and steps taken by the government to improve the current situation of Intellectual property in the pharmaceutical industry in India.

Keywords: *Evolution of patent system, Problems, Compulsory Licensing, reforms.*

I.) Introduction

"For any country, drugs and medicines are the most vital resources which safeguard the health of the people of every country".

In the growing years, there has been an ample amount of development that took place in the pharmaceutical industry curing severe diseases which were earlier seems to be not possible at all to be cured. With the increase in technological advancement by pieces of machinery, the drugs & medicine produced by the pharmaceutical industry have been on a constantly rising graph by producing drugs that are very effective as well as very economical and affordable by the general public. Since there is an ample number of pharmaceutical companies which are present in the market, there is also head-to-head competition between the manufacturers for launching their medicines & drugs in the market with exclusive rights by getting their drugs patented and earning good profits out of it. Today, the international pharmaceutical industry is dominated by a small number of MNCs. As per the patent laws, every inventor has the right to get their product patented and can enjoy the exclusive rights of his newly developed product thus manufacturers of new drugs and medicine has all the rights to get their product discrimination, applies to every person of the country without any discrimination but the earlier patent system was creating difficulty for the low-income countries of creating new drugs due to the strict patent mechanisms to deliver new drugs to their people.

Further, if we look into the process and procedure of getting a patent of any product, it focuses on some principles which should be followed & to be present in the product to get it registered as a patent and to grant the exclusive rights to the inventor for their product which includes *"it should be a novel product or procedure that involves creative step and can be used in industry qualifies as an invention and is eligible for patent protection. But it can't fit within the categories of innovations that sections 3 and 4 of the patent Act 1970 which specifies what cannot be patented."* After a

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thorough analysis of all the principles laid down above, the product is set to be competent for getting the patent and all its exclusive rights to the inventor of the product by the Controller General after verifying all the documentation and fulling the criteria and eligibility for registering the product as a patent.

II.) History of patent laws in the pharmaceutical industry in India

Over the last three decades, Indian pharmaceutical has grown significantly with the help of technological advancements in the particular industry[2064]. Indian companies have grasped a notable share of the domestic pharmaceutical market due to promising government policies and low competition from overseas. The Indian pharmaceutical sector is an ideal example of an industry that has grown over these years and to reconsider its long-term goals and business models as India opens its markets to global commerce. [2065] Aspects such as intellectual property protection are becoming more vital as more people recognize the need for securing significant investments in research and development (R&D). Efforts are being undertaken in India to address the problems of the insufficient enforceability of existing intellectual property legislation, The Indian government is working to develop a patent regime that is favorable to technological advancement and in line with its worldwide obligations.

Intellectual Property Rights were initially introduced in India in 1856, and the Patent Act 1970 ("the Patents Act") was passed in 1970, abolishing all earlier legislation. India has also signed the 1883 Paris Convention for the Protection of Industrial Property and the 1970 Patent Cooperation Treaty. According to the Patents Act, any invention that fulfills the requirements of newness, non-obviousness, and utility can be the subject of a patent. Techniques of agriculture or horticulture, processes for the medicinal, surgical, curative, prophylactic, or other treatment of human beings, animals, or plants, or substances obtained by a simple admixture, resulting only in the accumulation of the structural characteristics, are types of non- inventions under the Patents Act.

In the case of the pharmaceutical sector, patents are allocated only for the processes of manufacturing such substances, not for the substances themselves, in the case of substances intended for use or capable of being used as food, medications, medicines, or compounds created by chemical processes. As a result, pharmaceutical items do not presently have patent protection under Indian law. The Patents and Designs Act 1911 defined a product patent regime for all inventions in India. Moreover, in 1970 the government legislated the new Patents Act, which barred medicines and agrochemicals from acquiring patents. . This exclusion was introduced to reduce India's reliance on imports for bulk pharmaceuticals and formulations and to allow for the establishment of self-dependent pharmaceutical industries in India.

According to the present patent laws in India, molecules, which are byproducts of chemical processes, are not patentable. This restriction, along with the prohibition on simple admixtures resulting in the aggregation of qualities in which the components display no synergistic action, significantly limits the things that may be patented in India. Even if they have functional qualities, "actives" created through chemical synthesis are not patentable in India. Similarly, standard medicine formulations in which the constituents act as simple admixtures are not patentable in India. Only *"the process can be patented"* i.e., the process of making the final product will be patented to remove monopoly on the particular product. The abolition of patents on the final products resulted in the development of new drugs at a more affordable rate contributing to the general well-being of the people of the country throughout the industrialized world but unprotectable in

[2064] Available at – http://articles.economictimes.indiatimes.com/2010-06-08/news/28423319_1_salaryhikes-manufacturing-sector-survey.
[2065] Available at - Official website of Intellectual Property India (2019), "https://ipindia.gov.in/history-of-indian-patent-system.htm".

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India. [2066] As a result, it adds to the prior art in the subject and advances scientific understanding by utilizing the information included in published patent filings. They aid in discovering unexplored regions and initiating R&D in such areas. [2067]

The Indian government is pushing towards setting a patent regime that is cooperating with technological advances and in keeping with its global commitments. The cost of manufacturing and doing the research and development in developing a new drug is very costly but manufacturing the product and providing it to the general public at a cheaper version than before is truly innovative.

III.) Problems in the development of new drugs and medicines in the Pharmaceutical Industry

For medicines, Indian patent law imposes a higher standard and an extra test of patentable subject matter. Drug patents must be evaluated under section 3(d) of the Patents Act in addition to originality and inventive step. Section 3(d) of the Act states that "the simple discovery of a novel form of a known substance that does not increase that substance's recognized effectiveness" is not patentable. According to the section's explanation, compounds such as salts, esters, and polymorphs are regarded as the same substance unless they differ considerably in terms of the drug's recognized effectiveness. Section 3(d) specifies many distinct sorts of material, and a lack of accurate interpretation has frequently resulted in a poor conclusion for inventions. One of the major difficulties is that determining what is "a recognized drug" and what is its "known effectiveness" is sometimes inconsistent and left to the examiner's discretion. Section 3(d) is frequently utilized and misused in the context of main patents. It is important to emphasize that the Act does not exclude the protection of incremental inventions, but only requires that they pass the extra section 3 criteria (d). Opponents frequently utilize this clause to openly dispute patents that do not correctly apply to the claimed innovation. Further, opponents have regularly filed frivolous & baseless serial pre-grant oppositions in pharmaceutical patents owing to a lack of clarity under the Act.

Furthermore, there are an alarmingly high number of pre-grant oppositions being filed. For example, the yearly Ip Rights Office Report indicates that, although almost 400 plus pre-grant oppositions were lodged in 2018-19, this number climbed dramatically in 2019-2020, while the number of applications lodged remained constant. The majority of objections were made against medicinal innovation. Pre-grant oppositions are sometimes submitted in a single application. These pre-grant oppositions (which may contain no name ("Benami") oppositions) cause awards to be delayed needlessly.

The Mumbai High Court strongly chastised such Benami oppositions in *Dhaval Diyora v. Union of India and Ors*[2068], saying that no one had been given the authority to abuse the privileges under section 25(1) by the law. The Intellectual Property Appellate Board (IPAB) (during its existence) also took a tough stance against such Benami pre-grant objections and even went so far as to state explicitly that "any person" filing a pre-grant opposition must submit their valid Aadhar card, voter ID, passport, or driving license to prove their authenticity in order preventing Benami or completely fictional applicants from doing so.

IV.) Compulsory Licensing and its usage in Pharmaceutical Industry

Compulsory License or involuntary license refers to the grant of the patent rights to other parties for the production of the patented product for a certain payment (royalty) or under any emergency i.e., during the period pandemic (allowing the manufacturers to produce the drugs without the consent and permission of the inventor due to emergency). Compulsory

[2066] Available at – *TRIPs and Pharmaceuticals: Implications for India"*, https://www.nishithdesai.com/fileadmin/user_upload/pdfs/Patents_and_the_Indian_Pharmaceutical_Industry.pdf

[2067] Available at Dr.B.L.Wadhera, Law Relating to Intellectual Property http://www.patentoffice.nic.in/ipr/patent/patent_2005.pdf

[2068] Dhaval Diyora v Union of India and Ors , 1 2005 3 SCC 265

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Licensing is mentioned under section 84 of the Patents Act 1970, and it is granted by the controller general to other parties if it fulfills some requirements such as if the requirement of the public has not been satisfied or if the drug is not available at an affordable price or if the patent is non- working in India.

The First case of an Indian Patent was *Natco Pharma v Bayer Corporation*[2069] held on March 09, 2012. In this case, it was decided by the Controller general that the drug produced by the Bayne corporation for the treatment of Liver and Kidney cancer was very expensive and non-affordable by the general public and the particular patent invention was also non-working in the Indian Territory. The price of the drugs produced by the Bayne Corporation per dose was around 280000/ per month treatment course which was further developed by Natco at an affordable price of 8800/ per month course. In this landmark judgment, it was, Natco was granted the compulsory license and it was stated that the compulsory license was granted for the interest of the general public as it is contributing towards the social welfare of the people and maintains the right to dignity and access to medicine to the people of the country or if the efforts made by the person by the patentee but the inventor denied the other party for Compulsory license. This was the only case held in India for granting of compulsory license till now and after that there no compulsory license was granted in India.

A compulsory License in Pharmaceutical Industry is granted to generate new drugs and medicines with the use of novelty and innovation. The main purpose and objective of granting a compulsory license are to develop medicines at an affordable rate that should be easily accessible to the general public. Some provisions safeguard the interest and rights of the inventors to maintain their exclusive rights of the patent being vested with them under the patents act 1970 however, it does not mean creating a monopoly in the market or the accumulation of wealth only one hand. The main purpose of the patents act is to protect the rights of the inventor as well it should be useful for the people of the country and should serve the welfare of the public.

In 2001 at Doha Ministerial Conference, a significant portion of this was resolved. The WTO member nations emphasized the need to execute and interpretation of the TRIPS Agreement in a way that improves public health by fostering both accessibilities to already available medications and the development of novel medications in the major Doha Ministerial Declaration of November 14, 2001. As a result, in 2001, WTO participants adopted a unique Declaration on TRIPS and Public Health. It asserts that taking actions to preserve the public's health is not prohibited under the TRIPS Agreement and should not be prohibited. It highlighted TRIPS's flexibility concerning exhaustion and compulsory licensing, and it also laid the groundwork for prolonging the least developed nations' transitional time in the pharmaceutical industry.[2070]

Everyone has the right to a compulsory license under section 5(6) of the DOHA declaration 2001. As per Doha declaration paragraph 6, it states if a country has no laboratories and pharmaceutical labs to make medicines, then another country can export the medicines from another country which got the patent from the patentee country. This transaction is also known as the "***parallel import"*** between two countries.

V.) Major Impact of the IPR upon WTO regarding Pharmaceutical Patents

The formation of the World Trade Organization has led to a significant structural change in global trade. WTO agreement is one of the most vital agreements on trade-related aspects of Intellectual property.The agreement on Trade-Related (Aspects of) Intellectual Property Rights (TRIPS) was managed to negotiate during the General Agreement on Tariffs and Trade (GATT) Uruguay round trade arrangements, and "one of the major reasons for introducing intellectual

[2069] Natco Pharma v Bayne Corporation, 2014 (60) PTC 277 (Bombay)

[2070] Available at- https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

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property issues into the GATT structure was the pharmaceutical industry." India joined the GATT on April 15, 1994, making compliance with GATT regulations, including the TRIPS agreement compulsory and mandatory. India must thus adhere to the minimum requirements outlined in the TRIPS Agreement concerning patents and the pharmaceutical sector. The validity of patents for both pharmaceutical items and process discoveries needs to be addressed under India's patent laws. For each innovation of a pharmaceutical product or technique that meets certain requirements, patents must be awarded for at least 20 years.

VI.) Suggestions and new measures for the protection of IPR in the Pharmaceutical Industry

The Indian government has taken several initiatives and indicators to support, promote, and motivate Indian pharmaceutical companies, including i) allowing 100% Foreign Direct Investment (FDI) for the production of drugs and pharmaceuticals as long as the activity does not require a compulsory license and does not use recombinant DNA technologies or specific cell- or tissue-targeted formulations (ii) tax benefits under the Income Tax Act of 1961 for internal research and development (iii) exempting life-saving vaccines from excise duty (iv) exempting clinical trials of new drugs from service tax to make India a favored location for drug testing; (v) exempting anti-AIDS medications and life-saving vaccines from excise duty to motivate businesses like Cipla, and (vi) requiring customs to clear all drugs and equipment used in clinical trials.

VII.) Conclusion

Considering all the factors and the patent regime being followed in India, there have been problems regarding the development of drugs and medicines due to certain sections and provisions of the Patents Act 1970. However, there has been significant changes and development in the patent laws in these recent years which aided the Pharmaceutical Industry in developing new drugs and medicine which are more efficient and effective than the previous versions available at affordable prices and are easily accessible to the general public. Despite the aforementioned concerns, recent developments in pharmaceutical patent enforcement and litigation have indeed been positive. The judgments of the courts and the former IPAB have been not just well-reasoned, but also fast. Some of these rulings defined the law on numerous significant issues of Indian patent law, such as the Benami parties' oppositions, the conditions for filing divisional applications, the extent of claim revisions, and cross-examinations in oppositions.

The Indian courts operated virtually for the majority of 2020, before progressively transitioning to in-person sessions in 2021. Despite the obstacles posed by the epidemic, they proceeded to enforce patents. A significant development in the last year has also been the IPAB's abolition in April 2021, followed by the establishment of a specialized Intellectual Property Division (IPD) by the Delhi High Court (within three months) to fill the void. In early 2022, the Delhi High Court announced two rules - the IPD Rules and the Rules regulating Patent cases - that provide clarification on several issues concerning intellectual property rights before the Delhi High Court. The recent analysis of India's intellectual property rights legislation by the Parliamentary Standing Committee on Commerce proposed that such specialized benches be established in all High Courts. The recent analysis of India's intellectual property rights legislation by the Parliamentary Standing Committee on Commerce proposed that such specialized benches be established in all High Courts. Thus, despite variations in the Indian pharmaceutical patent system, Indian patent law is changing, with increased litigation and government operations at all levels contributing to forming the jurisprudence to improve the current scenario in the Intellectual Property rights in the pharmaceutical industry.

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