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Evolution of Patent Law in the Pharmaceutical Industry

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A patent is one of the important forms of Intellectual property rights (IPRs) in India. While Copyrights and Related Rights, Trade Marks, Industrial Designs, and Geographical Indications are the various other forms of the IPR. The Patent Act, 1970¹ caused the biggest revolution in the pharmaceutical industry, where the generic manufactures faced a striking increase in their market. This is mainly due to the Act led both process patenting and product patenting which gave way for Reverse Engineering. However, after the amendment of the Patent Act in obligations with the TRIPS Agreement,² the pharmaceutical industry faced overall steady growth in India. In this article, we will learn more about the evolution of patents in the pharmaceutical industry in India and the various types of pharmaceutical patents which are currently accepted in India.

Keywords: *patents, TRIPS agreement, patents act, intellectual property rights.*

INTRODUCTION

Intellectual property (IP)³ is a type of intangible property created through the effort of the human mind or intellect. Intellectual property rights (IPR) are the rights derived from the

¹ Patents Act 1970

² TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 UNTS 299, 33 ILM 1197 (1994)

³ Vipin Mathur, 'Patenting of Pharmaceuticals: An Indian Perspective' (2012) 4(3) Int J Drug Dev & Res 27-34

creation of intellectual property. These rights are important rights to prevent the creation of an individual. Because of which it gives confidence to people as their inventions are protected. Among the various industries, the pharmaceutical industry is one such sector that is at a big risk of being copied by a third party.⁴ When a company successfully acquired a drug, there are many chances of them being copied by other companies through reverse Engineering. This is where a patent plays its role of protecting the rights of the inventor and invention. Even if the companies disobey its regulations, then they are vulnerable to face legal consequences.⁵ The Patent Act 1970⁶ was the first milestone related to IP rights after independence. This Act was created by replacing the Colonial Patents and Designs Act of 1911.⁷ There were two main specialisations of The Patent Act 1970, which largely supported the domestic entrepreneurs in their growth in the pharmaceutical industry. Firstly, it introduced a process patent regime, which gave rise to the local generic industry resulting in a thriving increase in the Indian pharmaceutical industry. Second, it reduced the period of the patent as shorter as possible to 5 years, where it was 14 years in another field of technology.⁸

But with time, international competition accumulated enormously, and there was a requirement to amend laws. With the formation of the World Trade Organization (WTO) and the important introduction of the Trade-Related Intellectual Property Rights (TRIPS) Agreement in 1995, all member countries were needed to follow journeys Agreement laws. The responsibility of the Asian nation to execute this agreement checked all the advantages enjoyed by the native pharmaceutical sector. The important issue on this agreement is that the introduction of the merchandise patent regime restricted the local firms to figure on proprietary processes, and it additionally increased the number of patents to 20 years. These laws highly affected the longer term of Indian pharmaceutical industries.

⁴ *Ibid*

⁵ *Ibid*

⁶ Patents (n 1)

⁷ Colonial Patents and Designs Act 1911

⁸ Manjul Vaidya & Others, 'Changing Dimensions of Drug Patents of Indian Pharmaceutical Industry' (*Manupatra*, May 2018) <<http://docs.manupatra.in/newslines/articles/Upload/DD69613C-5427-48D7-8AAD-EA1F323AA788.pdf>> accessed 23 July 2021

To make India wholly consistent with this TRIPS agreement, two significant amendments were required. First,⁹ the modification of the patentable subject material by permitting patenting of microorganisms and “essentially non-biological processes” and increasing the term of patents to twenty years from the date of application.¹⁰ The second amendment was the institution of product patenting within the field of pharmaceuticals. These two amendments had to be introduced on first Jan 2000, but the second was introduced solely on 1st January 2005.¹¹

TRIPS, PHARMACEUTICAL PATENTS AND SECTION 3(D)¹²

Intellectual property protection wasn't a district of the General Agreement on Tariffs and Trade's (GATT) objectives. But with the idea of the World Trade Organisation (WTO) within the Uruguay spherical and its agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) prescribed all the countries to follow pharmaceutical patents aside from the 'Least Developed Countries' even if therefore, international organisation member countries failed to enable the pharmaceutical patents in the starting of 1995, with the TRIPS agreement in result all the country started doing so from 2005. throughout the transition period, from 1995 till the date that a rustic created pharmaceuticals patentable, journeys needed members to receive and hold applications in a very “mailbox.” Thus, if in given country pharmaceutical patents were to become offered as of 1999, from 1995 to 1999, the country would settle for applications within the mailbox, and these would be examined as of 1999, in conjunction with alternative applications received from that date onwards.¹³ The Republic of India was one of the numerous countries that disagreed with the journeys agreement most throughout the Uruguay spherical in the early 90s and late 80s. It had been all against the incorporation of laws on a country's material possession practices in international trade. And once the TRIPS negotiations commenced, the Republic of India was stubborn in opposing the patenting of pharmaceutical

⁹ B Dhar & R K Joseph, 'The Challenges, Opportunities and Performance of the Indian Pharmaceutical Industry Post-TRIPS' (*Springer Link*, 7 September 2019) <https://link.springer.com/chapter/10.1007/978-981-13-8102-7_13#Fn5> accessed 23 July 2021

¹⁰ *Ibid*

¹¹ Vaidya (n 8)

¹² *Ibid*

¹³ Dhar (n 9)

industries altogether countries.¹⁴ As product patent was tabu in India and method patent was solely followed, it extremely boosted the generic trade that even created the Indian pharmaceutical industry mutually of the biggest within the world. This TRIPS agreement was unsafe to the country. Before totally yielding with drug patent, there was given a transition amount of five years to execute all the journeys provisions. Under Article 65.4¹⁵ of TRIPS extra five years was given to the countries which failed to even follow product patent protection in any of their sectors throughout the imposition of the TRIPS agreement. The law in the Republic of India was amended in numerous years (1999, 2002, and 2005) for pertaining all the necessities of TRIPS and to form specific changes that the country integrated within the new patent law. Throughout the transition amount, a system of Exclusive selling Rights (EMRs) was introduced and remained in operation till all the requirements of TRIPS were adopted.¹⁶ In fact, India dragged the patentable of the pharmaceutical product until 2005 that was the most period permitted. Adding to it, India was the sole country on victimization the whole transition amount and delayed until 2005. As on reluctant compliance to the new international obligations of the country, the Republic of India began to receive applications within the mailbox from 1999 as they're to be examined as of 2005 once the merchandise legal system was in process.

When the final amendments of the Patent act were in progress in 2005 to introduce pharmaceutical patenting, India introduced Section 3(d)¹⁷ which highly restricted the secondary patents. Section 3(d) portrays that most of the secondary patents are not eligible for patenting as most of them are not considered innovations. They were patented only if individuals display that they have greater efficacy. An explanation given by this section is as follows:

The following are not inventions within the meaning of this Act... 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 the mere use of a known process, machine or apparatus unless such known process results in a

¹⁴ *Ibid*

¹⁵ TRIPS (n 2), art 65.4

¹⁶ Dhar (n 9)

¹⁷ Patents Act 1970, s 3(d)

new product or employs at least one new reactant. For the purposes of this clause, 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.¹⁸

Section 3(d) was enforced expressly to handle considerations that further patents on existing substances can be wont to extend market exclusivity and delay generic competition. Even if several scientists prohibited the completion of the secondary patent approach, the developers of section 3(d) took a middle stand on permitting secondary patents, given that there are notable modifications of the present drug.¹⁹

During the deliberation withinside the Uruguay Round, which brought about the popularity of the TRIPS agreement,²⁰ there has been a controversy on growing the duration of the patent because the patent duration turned into too quick of five to 7 years. The groups ought to get back once more on speculating in Research and Development (R&D). Henceforth they demanded brand new rules and a degree of intellectual property protection, additionally the extension of the duration of the patent. This, the committee counseled that the duration extension can manifestly encourage the R&D activities to provide extra new molecules. These arguments had been accordant to the phrases of Douglass North, who stated that "development of a patent system and other laws protecting intellectual property ... encouraged the growth of innovation". This infers that a longer duration of a patent can handiest be beneficial whilst creators create new products and processes in place of mild adjustments of a current product. In different phrases, it is able to be claimed that granting 20years of patentable duration for a product that is changed from a current one could be referred to as anti-innovation.

The benefit of section 3(d),²¹ is that it provides effective fortification against the 'evergreening' patent. The term 'evergreening patent' is nothing, but when a company wants to reduce its

¹⁸ 'Indian pharmaceutical patent prosecution: Changing role of Section 3(d)' (NCBI) <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5880378/>> accessed 26 July 2021

¹⁹ Act (n 17)

²⁰ TRIPS (n 2)

²¹ Act (n 17)

financial interest, it comes up with this kind of strategy; these evergreening companies use the same molecular formula but different structure to an existing product, like adding a new product to a drug without changing its effect and seek 'full' term of a patent to that product with the minor modification and replicate the same process as long as possible. This plan of action works well for these evergreen companies as they continue to remain in the market by blocking the way for new sectors even if their original drug patent expires. This concern was underlined by the Mashelkar Committee, also known as the technical committee, which was designated by the Government of India to provide guidance on the Patent Act whether to permit patent only for those pharmaceutical drugs which include new chemical substances. The technical committee commended that providing patents for 'evergreening companies' must be restricted, which is achieved by implementing slight changes to the existing patented drugs.

The legal sustainability of segment 3(d)²² was examined in a case that emerged while Novartis petitioned in opposition to the competition of the patent claim. This drug employer had implemented a patent in India for blood most cancers drug Glivec in 1998. This utility changed into rejected via way of means of Indian Patent workplace because it changed into already forecasted via way of means of the previous book and it changed into in opposition to the segment 3(d) requirements. Novartis, in addition, implemented a petition withinside the High Court of Madras in opposition to the selection of the Patent workplace on its patent utility. As the Intellectual Property Appellate Board (IPAB) has become practical from 2007, Novartis filed a petition in IPAB for its patent utility which disapproved its claim. At last, Novartis filed his enchantment withinside the Supreme Court of India. He petitioned in opposition to the ruling of the Patent Office withinside the High Court of Madras in two points.

(i) Section 3(d) of the Patents Act, 1970, changed into inconsistent with Articles 1(1) and 27 of the TRIPS Agreement.

(ii) Section 3(d) changed into unconstitutional being vague, arbitrary, and violative of Article 14 of the Constitution of India, which ensures equality before the law.

²² *Ibid*

The Supreme Court of India declared that it did now no longer have the authority to offer judgment at the specs of the worldwide treaty, and as a result, it rejected the plea with the aid of using refusing to touch upon the Novartis allegation at Section 3(d) violation. However High courtroom of India made a critical statement at the elements of India's change to its Patents Act withinside the duty to the TRIPS settlement. ²³ The Court argued that Article 7 of the TRIPS Agreement²⁴ “provides enough elbow room to a member country” to conform with its responsibilities beneath the Agreement “with the aid of using bringing a regulation in a way conducive to social and monetary welfare and to a stability of rights and responsibilities” and brought that Article 1 of the TRIPS Agreement.²⁵ “allows a member country free to decide the proper technique of enforcing the provisions of this settlement inside their personal prison gadget and practice.” According to the second factor at the Novartis plea that Section 3(d) changed into unconstitutional as it's far vague, arbitrary, and violative of Article 14 of the Constitution of India, the High Court observed that phase 3(d) has extraordinarily laid down the policies that the patent claimant can obtain his patent only: "if a discovery is crafted from a recognized substance, an obligation is solid upon the patent applicant to expose that the invention had resulted withinside the enhancement of a recognized efficacy of that substance and in identifying whether or not to furnish a Patent or now no longer on such new discovery." The courtroom adjudicated that the provisions of phase 3(d) changed now no longer in opposition to Article 14 of the Indian Constitution. Indeed, it changed the Court's belief that the Government of India had amended the Patents Act with the intention "to save you evergreening; to offer smooth get right of entry to the residents of this us of a to existence saving capsules and to discharge their Constitutional duty of presenting right fitness care to its residents." Certainly, the discussions at the third amendment of the Patents Act withinside the Parliament portrays that “welfare of the humans of the country changed into withinside the thoughts of the Parliamentarians." And therefore, the High Court of Madras disapproved the Novartis plea proclaiming that Section 3(d) changed into unconstitutional and violative of Article 14 of the

²³ *Ibid*

²⁴ TRIPS (n 2), art 7

²⁵ TRIPS (n 2), art 1

Indian Constitution²⁶. The High Court observation on the Article 1 and 7 of the TRIPS Agreement that was provided in all World Trade Organisation (WTO) member states was that the agreement executed the number of resilience to the Country's Government as they can adapt on its own creative way to protect their public interest.

Looking on the explanation of the IPAB's rejection on the appeal of Novartis was as follows: "a requirement of the higher standard of inventive step by introducing the amended section 3(d) of the Act, what is patentable in other countries will not be patentable in India. The object of amended section 3(d) of the Act is nothing but a requirement of a higher standard of inventive step in the law particularly for the drug/pharmaceutical substances". And the Supreme Court of India investigated the petition of Novartis in light of the steps put forward in India's Patent Act, in Article 2(1)(j)²⁷ and Article 2(1) (a)²⁸. The court also examined if the drug created by the company is a 'new product' that is advanced from the existing one and made the creation 'not obvious to a people skilled in the art.' The court examined on the ground of section 3(d) and noticed that this section "clearly sets up the second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds." And then finally, the supreme court gave the judgement as to the drug which Novartis claimed for patent is rejected as it failed to meet the policies of section 3(d) and it did not meet the test of novelty and inventive.

COMPULSORY LICENSING SYSTEM

The most important motive for this system of licensing is followed on the grounds of public opinion in India. Those patented agencies, in the event that they cause a dispute to the general public, then this system may be used. The patent Act imposed this provision of licensing, and it is able to be authorised best after the 3years from the date of furnish of patent, and in first-rate instances, the license may be issued best in unexpected conditions like countrywide emergency

²⁶ Constitution of India, art 14

²⁷ Patents Act 1970, s 2(1)(j)

²⁸ Patents Act 1970, s 2(1)(j)(a)

or different intense urgency. Section 84 of the patent act²⁹ states the grounds on which the obligatory licensing may be furnished that are as follows:

- affordable necessities of the general public with recognize to the patented invention have now no longer be satisfied;
- the patented invention isn't always to be had to the general public at a fairly low-cost price;
- the patented invention isn't always labored withinside the territory of India, yet the compulsory licensing can only be provided if the patent holder pays enough reimbursement taking into consideration the economic value of the authorisation.

The Doha Declaration on TRIPS Agreement made it out clean that the Compulsory Licensing System (CL) is constant with the TRIPS Agreement. The ministers of WTO, withinside the Doha Declaration, which turned into followed in 2001, said that "TRIPS Agreement does now no longer and ought to now no longer save you, participants, from taking measures to defend public fitness." Additionally, the ministers quoted that "Agreement can and ought to be interpreted and carried out in a way supportive of WTO participants' proper to defend public fitness and, in particular, to sell get admission to drugs for all." And finally, this Doha Declaration promised that "Each Member has the proper to supply obligatory licenses and the liberty to decide the grounds upon which such licenses are granted."

In India, using this Compulsory Licensing machine turned into distinctly Judgemental. In the Post TRIPS process, the obligatory primary license turned into accepted withinside the Bayer v. Naco³⁰ case held in 2012. This case turned into at the Bayer Corporation, the American subordinate of the German organization, which adhered patent at the Anticancer Drug and offered it on an unreasonable fee and did now no longer make the product to be had in sufficient portions through import. The defendant Natco Pharma Ltd, the generic firm, got here ahead on generating this drug on the lowest fee of Rs.8000 for the month's delivery that is 1/2 of the part of Bayer's Corporation of Rs.2,80,000 and carried out for the supply of CL. On commenting the

²⁹ Patents Act 1970, s 84

³⁰ *Bayer v Natco* (2012) 7 SCC 729

Natco's application, the Controller of Patents declared that Bayer's Corporation failed to make the drug be had to the general public at an affordable fee and consequently granted a non-exclusive CL to the applicant. Also, the Office prescribed Natco Pharma Ltd to pay Bayer AG 6% of the internet income of the medication as nobility.

TYPES OF PHARMACEUTICAL PATENT

There are two types of pharmaceutical patents available to the newly discovered drug:

1. Active Ingredient Patent
2. Formulation Patent

1. Active Ingredient Patent

An Active aspect patent or Active pharmaceutical aspect patent (API) is used for protecting the newly created drug, and it's far one of the most powerful types of patent. This patent enables in protecting the molecular components of the drug, and it applies to any shape of the drug-like cream, liquid, tablet or tablet, etc. If a patented molecule is carried out in a drug, then the patent applies for that too. This is a rigid shape of a patent that restricts the competitor from promoting the accepted model of the patented drug in a shape if and handiest if the patent has expired. This patent may be carried out to a Markush Structure, wherein the non-compulsory shape connected with the middle molecular shape to supply little variations however functionally equal and as a result forming multiple shapes. The Active Ingredient Patent is likewise recognized for the combination of matter patent, compound patent, and product patent or even at instances interchangeably used.

2. Formulation Patent

It is usual for the pharmaceutical sector to establish a new form of the drug from a long-known compound. The typical purpose of this patent is that it restructures a chemical molecule or

combines with another ingredient in order to have different effects with still providing benefits. This is a useful patent in giving life to an aging but popular product.³¹

For instance, the drug amphetamine turned into determined via way of means of a Romanian chemist one hundred thirty years ago, in 1887. Its apparent stimulant outcomes made it a famous overall performance enhancer, and it turned into additionally advertised for a number of different uses, inclusive of nasal congestion.³² However, many a long time later, pharmaceutical groups have been nonetheless locating new approaches to reformulate it and alter its behavior so as to tweak its outcomes and create new applications.

In 1996, Richwood Pharmaceuticals started out promoting the highly a success ADHD drug Adderall, which turned into a formula that includes four otherwise established amphetamine salts. Despite being primarily based totally on a drug that turned into greater than a century old – the amphetamine salts in query have been additionally lengthy on account that withinside the public domain – however, due to the fact Adderall consisted of a unique formula, it turned into eligible for formula patent protection. A few years later, a brand new formula of the drug, Adderall XR, which bogged down the fee at which the drug turned into metabolized, turned into additionally granted a brand new formula patent no matter being nearly the same as the authentic Adderall formula.

EFFECTS OF CHANGES ON PATENT LAW

After the revolution of the patent in the pharmaceutical industry, there has been a want to stabilize the competition among the pharmaceutical sectors and the safety of patients. There can be a state of affairs of monopoly withinside the marketplace after the creation of a recent patent method that has been started due to the fact 2005. As earlier than the implementation of this new patent regime, there existed process patent manner which led the local manufactures to compete with a lot of large sectors via way of means of promoting low-value drug treatments which made the large groups lessen the fee so one can live energetic withinside the marketplace. But

³¹ Michael O'Brien, 'Types of pharmaceutical patents' (*O'Brien patent solution*, 13 March 2017) <<https://www.obrienpatents.com/types-pharmaceutical-patents/>> accessed 26 July 2021

³² *Ibid*

the creation of this new product patent method modified the complete scene of the marketplace. In order to keep away from the monopoly withinside the marketplace, competition law additionally performs a key role. This competition law of 2002 prevents the monopoly withinside the marketplace.³³ Three sorts of opposition troubles can stand up withinside the pharmaceutical sector. They may be withinside the shape of mergers and acquisitions and mergers, collusion, and misuse of a sturdy marketplace position. These can boom the fee of drugs to a completely excessive stage in which it becomes very tough for the poor patients to shop for drugs. Therefore, for the welfare of society, it's far very important that stability is maintained among the safety of intellectual property and opposition among the companies.³⁴

CONCLUSION

Indian pharmaceutical industry is one of the greatest exporters of drugs. It is also observed that post TRIPS era, the effectiveness of Research and Development(R&D) and export intensity had a high positive impact on the pharmaceutical field. The presence of the local generic industry played a huge role in this sector. The growth of these companies is linked with the Patents Act, which was enacted in 1970.³⁵ The main characteristic of this Act is that it allowed only for process patent and not product patent which favored the generic firms to remain in the market by selling the patented drugs at the lowest cost. Another characteristic is that it reduced the period of the patent to 5years. India's obligation to follow the TRIPS agreement amended these two main features by changing it to product patent and increased the period of a patent by 20years. This greatly affected the local generic companies. But the Government of India utilized the flexibilities offered by the TRIPS agreement and enforced two features in order to make the generic companies remain in the market. First, it introduced section 3(d), which restricted providing patents to the drugs that are minor modifications of the existing product. The main reason for this section is to eliminate the 'evergreening of the patent.' This section made sure that local companies remain in the market and avoids monopolies. The second feature is that it introduced a compulsory licensing system for the companies that are not in India and also for

³³ Competition Act 2002

³⁴ *Ibid*

³⁵ Patents Act 1970

the companies that takes advantage of their patent by selling the drugs at an unaffordable price. These provisions made India be the 3rd largest pharmaceutical sector in terms of volume today.