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A Critical Analysis of India Patent Law in the context of Pharmaceutical Patent Protection

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A Critical Analysis of India Patent Law in the context of Pharmaceutical Patent Protection

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Abstract
Patents are among the main kinds of Intellectual Property Rights (IPRs) utilized in the pharmaceutical sector. India's patent system underwent substantial modifications following its ratification of the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement in 1995. Patent law's main task is to strike a balance between access and innovation. Pharmaceutical patents are a major point of dispute between industrialized and developing nations. The pharmaceutical business claims its right to patent ownership, generating profits from elevated prices and research and development expenses. Developing nations demand lower prices for manufacturing and acquiring medications. India has been amending pharmaceutical patent laws to meet the country's health requirements, especially for individuals who are unable to buy costly medications. Technology has played a crucial role in the progress and development of civilization, and mandatory licensing in the TRIPS Agreement can assist in tackling health concerns. Indian pharmaceutical businesses play a significant role in distributing low-cost drugs, highlighting the need of pharmaceutical licensing for public health. Compulsory licensing in the TRIPS Agreement permits generic drug manufacturers to make patented pharmaceuticals, ensuring cost-effective availability of these medications for individuals requiring them. This study intends to examine Nature and scope of patent infringement in the pharmaceutical industry. The text explores the legal framework, which includes the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and later revisions to national patent laws.

Key Words: *Patent, Pharmaceutical industry, TRIPS*

1.1 Introduction

Conventions such as the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement are global regimes that deeply influence patent laws. TRIPS runs minimum standards of intellectual property protection that still need to be translated into members' own laws. Nevertheless, TRIPS also incorporates flexibilities that can be used to protect public health, including compulsory licensing and the exclusion of specific types of patents. While these safeguards exist, the actual usage of TRIPS flexibilities has been inconsistent, and patent evergreening often manipulates legal loopholes that bypass these protections.
India's intellectual property regime, established after committing to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), prioritizes creating mechanisms to ensure affordable access to medicines for its citizens. India stands out among developing countries due to its robust generic pharmaceutical industry, enabling the production of medications at highly competitive costs globally. The Patents Act enacted by India in 1970 deserves much credit for this progress. Two crucial provisions enabled this approach. The first change involved implementing a process patent system for chemicals, while the second change was reducing the duration of patents issued for pharmaceuticals. The requirements to enforce the Agreement on TRIPS altered the circumstances under which the Indian pharmaceutical industry had established itself. The main problem was the reinstatement of the product patent system and the restrictions it placed on the ability to develop technology through reverse engineering. The industry's future prospects were seen to depend significantly on the policymakers' capacity to utilize the flexibilities within the Agreement on TRIPS.

India needed to make three sets of adjustments to its Patents Act to fully fulfil the Agreement on TRIPS. Developing countries were given the opportunity to align their patent laws with TRIPS standards by January 1, 2000. However, countries like India, which had a process patent system for pharmaceuticals and agricultural chemicals, were granted an extended transition period until January 1, 2005, before they had to implement product patents.[1]

India's obligations under the TRIPS Agreement were first expected to primarily affect access to pharmaceuticals through amendments to the Patents Act, 1970. However, a recent development has altered this perception. Article 39.3 of the TRIPS Agreement mandates the protection of test and other data provided by pharmaceutical companies to regulators for marketing approval, creating uncertainty for the generic industry. The US and EU require that a firm seeking marketing approval for a product containing a new chemical entity must provide

[1] Biswajit Dhar and KM Gopakumar, "Effect of Product Patents on the Indian Pharmaceutical Industry".

data protection for a fixed period. During this time, generic producers are not allowed to obtain marketing approval for the same or a similar product. The US and the EU have requested fixed duration commercial exclusivity for the pioneer firm.

Pharmaceutical corporations invest billions of dollars in research. Out of every thousand prospective medications tested, approximately 4-5 advance to clinical trials, with only one ultimately authorized for sale. Pharmaceutical corporations patent their developed pharmaceuticals to get exclusive marketing rights. They recover research costs and income for shareholders by setting prices for patients who use the copyrighted drugs. Drug patents and exclusive marketing rights are granted internationally for a 20-year period, during which no other pharmaceutical company can produce or sell the same drug. Once the patent expires, other companies can produce and sell the drug under their own brand names, which are referred to as generic versions.

This paper examines the consequences of India's commitments under the Agreement on TRIPS upon joining the World Trade Organization (WTO) in 1995, with a focus on the pharmaceutical industry's interests.

In the pharmaceutical industry, research costs are measured in the billions of dollars. Out of every thousand possible treatments that are evaluated, it is believed that only four to five of them make it to clinical trials, and only one of them is really approved for commercialization. With the help of suitable pricing mechanisms, pharmaceutical companies are able to recover the expenses of research and the profits that are owed to shareholders from the patients who receive the patented pharmaceuticals.[2] Pharmaceutical businesses obtain exclusive marketing rights by patenting the drugs that they produce.
On a global scale, medication patents and the exclusive marketing rights that are associated with them are granted for a duration of twenty years. During this time period, no other pharmaceutical company is permitted to manufacture or market the same drug. Following the expiration of the patent, other businesses are granted permission to manufacture and sell the medication; the brands that they produce are referred to as generic versions.

At the beginning of the 1970s, the government of Indira Gandhi enacted the Indian Patents Act in order to make it possible for the less fortunate people in the country to have easier access to medications at more affordable prices. According to the Act, patents on processes would be recognised, but patents on products would not be recognised. To put it another way, India would not grant patents to

[2] Chittaranjan Andrade, Nilesh Shah, et.al., "The New Patent Regime: Implications for Patients in India" 1 Indian Journal of Psychiatry 56-59 (2007).

specific medications but rather to the manufacturing process that was used to produce the individual medication. On account of this, Indian pharmaceutical companies were able to produce the same medicine by employing different manufacturing procedures (this is often referred to as reverse engineering). In light of the fact that Indian corporations spent very little money on the research and development of new medications, it became feasible to make new medications accessible to the nation at prices that were within their financial means.

The Patents Act 1970

On April 20, 1972, the Indian Patents and Designs Act 1911 was replaced by the Patents Act 1970 and the Patents Rules 1972. The recommendations of the report of the Ayyangar Committee, which was led by Justice N. Rajagopala Ayyangar, formed the bulk of the Patents Act. One of the suggestions was to only permit process patents for inventions pertaining to chemistry, pharmaceuticals, and other life sciences.

Later, India signed on to a number of international agreements in an effort to enhance its patent system and catch up to the rest of the world. Joining the Trade Related Intellectual Property Rights (TRIPS) system was one of the important stages towards accomplishing this goal. Significantly, India also became signatory of the Paris Convention and the Patent Cooperation Treaty on 7th December 1998[3] and thereafter signed the Budapest Treaty on 17th December 2001.[4]

The present Indian position in respect of patent law is governed by the provisions of the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005 (hereinafter referred to as the Act) and Patents Acts Rules, 2006 (hereinafter referred to as the Rules). [5]

Patent Law in India

Liberalization and globalization are characteristics of the modern world. As a result, several nations, including India, which must compete with other nations on the global market, have enacted economic reforms. A nation's development is greatly influenced by patent legislation. More so now that India must compete with wealthy nations like the United States in the World Trade Organization.

A patent is a legally binding document granted by the government to the inventor, granting them the sole authority to sell, produce, utilize, and import the invention for a specified duration after the concept is published. Patents are legally mandated to protect innovators by imposing restrictions on the individuals authorized to market their products on their behalf. The origins of the term

[3] Patent Cooperation Treaty on 7th December 1998

[4] Budapest Treaty on 17th December 2001

[5] "Jaya Bhatnagar and Vidisha Garg,India,Patent Law in India,publishing date- 13 December 2007,https://www.mondaq.com/india/patent/54494/patent-law-in-india,"

"patent" can be traced back to ancient French, Latin, and English. The term "patentem" and "patente" originated in the late 13th century, denoting the concept of an open letter. The phrase acquired its present connotation during the 1580s when it was elucidated as a governmental authorization for the production and commercialization of a certain commodity.

The law governing patents is essential because it fosters the development of new technologies. It does this by protecting the rights of those who introduce new ideas, which in turn encourages scientific research and advancement. Patent law is responsible for providing regularization as well as assistance with all aspects of patent registration. Patent law was developed with the primary purpose of ensuring that creativity is unlimited and encouraging people to continue innovating by providing protection for their works. This was the major driver behind the formation of patent law. As a consequence of this, patent law is essential since it functions to protect the rights of innovators. There is widespread recognition of the importance of patents on a global scale.

One of the primary objectives of patents was to encourage the development of new technologies, breakthrough scientific discoveries, and industrial advancements. The law about patents grants the inventor a monopoly on the use of their patented products, but it also allows others to use such products with the inventor's permission and for a price.

Features of Patent Act: [6]

Not only Product but also "Process can be patented under act:

- Invention shall be useful, novel and something which is not obvious.
- Shall be capable of getting used in Industry, if not then it may amounts to revocation of patent.
- Invention shall be new and shall not form part of Section 3 and 4, which provide for exceptions of ideas which cannot be patented.
- Term of patent – 20 years (can be renewed) (in some case it may also be upto 7 years)
- Patent Examination can be conducted on request.
- Both pre-grant and post-grant opposition is enabled.
- Fast track mechanism shall prevail for disposal of appeals if any disparity exists.[7]
- Values to protect integrity of Indian Constitution's various clause such as Article 51-A of fundamental Duties is also taken into consideration by nurturing and keeping nature and rich heritage of culture in mind. Hence Provision for protection of bio-diversity and traditional knowledge is specified in act.

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[6] "Sonu Arvind Chaturvedi,Patent Law – Salient Features and Upgradation-Justice India ,Patent Law - Salient Features and Upgradation - E-Justice India (ejusticeindia.com)"

[7] "Patent Law in India, https://www.mondaq.com/india/patent/54494/patent-law-in-india, Last visited 9th April."

- Publication of applications after Eighteen months with facility for early publication enable getting patented rights as if it was registered from day if reasonableness of time is observed".

Concept of Patent Evergreening

Evergreening is the process of filing additional patents that are linked to the initial invention. This gives patent holders the ability to prolong the duration of their ideas and safeguard them from their competitors for an extended length of time. Usually, the process consists of submitting several follow-up patents that are based on the original patent. This is done to provide the innovation further protection. The objective is often to make sure that there are no loopholes that rivals can exploit to get around the original invention and produce a product or service that competes with it without violating the patent.

In India, patents are granted for a period of 20 years once the annual fees have been paid. When the patent period for an invention expires, it becomes part of the public domain. This means that any individual, company, or organisation is free to manufacture, sell, or import the invention. However, there are times when the patent holders, who are typically pharmaceutical companies, attempt to maintain their monopoly on the invention even after the patent has expired. They accomplish this by submitting a new patent for small changes made to the original invention, which prevents any other company from producing or selling the invention.

Impact of Patent Evergreening

Pharmaceutical companies spend billions of dollars on research. It is estimated that, of every thousand potential drugs screened, only 4-5 reach clinical trials and only one is actually approved for marketing. Pharmaceutical companies patent the drugs that they develop and thereby obtain exclusive marketing rights; the costs of research and the profits due to the shareholders are recovered through appropriate pricing mechanisms from the patients who receive the patented drugs. Internationally, drug patents and the exclusive marketing rights associated therewith are awarded for a period of 20 years; during this time, no other drug company is allowed to manufacture or market the same drug. After the patent expires, other companies are permitted to manufacture and market the drug; their brands are known as generic versions.

In the early 1970s, the Indian Patents Act was passed under the Indira Gandhi government to permit greater access of medicines at lower rates to the poor in the country. According to the Act, process patents but not product patents would be recognized. Expressed otherwise, India would award patents not to individual drugs but to the process whereby the drug was manufactured. This allowed Indian drug companies to manufacture the same drug using other processes (this is otherwise known as reverse engineering). As the Indian companies incurred little

expenditure on research and development of new drugs, it became possible to make new drugs available to the country at affordable rates.
As India sought to improve its presence in the global market, it became clear that it could no longer protect domestic consumers in its patent policy. India is a member of the World Trade Organization. India therefore requires a new patent law to fulfil its obligations under the trade-related aspects of intellectual property rights (TRIPS). India became a member of the Paris convention and signed the Patent cooperation treaty with effect from December 7, 1998. Since then, amendments to the Patent Act were enacted in April 1999 and May 2002. The third amendment became due. The necessary bill to make the Indian Patents Act TRIPS-compliant was supposed to have been tabled during the 2004 winter session of Parliament; instead, an ordinance was passed on December 26, 2004, which came into effect on January 1, 2005. This ordinance modified the Indian Patents Act. This ordinance was itself modified and the Patents (Amendment) Bill was passed by the Lok Sabha and Rajya Sabha on March 22 and March 23, 2005, respectively. The President signed the bill on April 5, 2005, making it an Act of Parliament[8].

An example of a drug subject to evergreening is trastuzumab for breast cancer. Trastuzumab is an immunotherapeutic medicine that is used in treatments for patients with HER2+ early and metastatic breast cancer. Trastuzumab was first registered as Herceptin® by Roche in 2000 as an intravenously administered drug. In 2013, Roche received authorization for a newly patented subcutaneous administration form of trastuzumab, the evergreening version. This was just several months before the patent on the intravenous administration form expired in 2014. In 2018, the first intravenous administration form of biosimilars received authorization to enter the market, the competitive version. Trastuzumab is not the only drug for which a pharmaceutical company introduced a subcutaneous administration form near patent expiry[9].

Challenges in Generic Pharma Industries

The domestic pharmaceutical business is mostly a "branded generics" market, where pharmaceutical companies sell off-patented pharmaceuticals under their own brand names, and the prices of these drugs differ from one rival to another. Branding and marketing efforts are still vital to pharmaceutical businesses' sales strategies, especially since the quality and testing standards in the pharmaceutical industry are not as strict as those in other regulated markets, such as the United States. Pharmaceutical businesses in India have large sales teams that reach out to doctors, who are the main decision-makers in a situation where insurance coverage is poor.

[8] https://pmc.ncbi.nlm.nih.gov/articles/PMC2900001/
[9] https://www.eur.nl/en/media/2023-07-2023001-kirshner-et-al-trastuzumabescherworking-paper

Most of the biggest pharmaceutical businesses in India have better credit profiles since they are present in the domestic pharmaceutical industry. This is due to the fact that they have a healthy long-term growth potential, sufficient profitability, and the advantage of diversification. Indian pharmaceutical companies will be negatively impacted by a significant decrease in the market share of branded generics, as the average prices will drop significantly and will outweigh any potential gains from lower marketing expenditures. That so, we believe that the new criteria will not likely cause a quick transition away from branded generic[10]s. The implementation will face practical hurdles since the less strict drug quality standards in India could result in differences in drug quality and effectiveness among different producers. The requirement could change the decision-making process for the selection of a drug manufacturer from doctors to chemists, who may not have the necessary qualifications or may not prioritise the safety and effectiveness of the medication for patients. The government has already received a request from a national association of Indian physicians to postpone the new standards. The association has cited the difficulties that the new rules will create for clinicians in their efforts to ensure that patients receive safe and effective care.

A) Novartis v. Union of India (2013) 6 SCC[11]

Pharmaceutical patents are at the center of the historic intellectual property lawsuit "Novartis AG and Ors. v/s Natco Pharma Limited" in India. Under the Indian Patents Act, the international pharmaceutical corporation Novartis AG applied for a patent for the anti-cancer medication imatinib mesylate. Natco Pharma Limited, however, objected to Novartis' patent application in a pre-grant objection, arguing that it lacked inventive step and novelty.

The case attracted a lot of interest because of its potential effects on the availability of inexpensive medications, especially in developing nations like India. The interpretation of Section 3(d) of the Indian Patents Act, which addresses the requirements for patentability for novel forms of well-known compounds, was the main legal dispute.

The 2013 verdict of the Supreme Court of India maintained the denial of Novartis' patent application, stating that the medication lacked sufficient evidence of improved efficacy to support patent protection under Section 3(d). This ruling had a significant impact on the clarification of India's patentability requirements, especially with regard to pharmaceuticals. It has also had a global impact on debates over intellectual property rights and public health.

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[10] https://www.epw.in/engage/article/pharmaceutical-patents-public-health-and-pandemic

[11] Case Name: Novartis AG v. Union of India
"Citation: (2013) 6 SCC 1 Document Link: http://www.scconline.com.eu1.proxy.openathens.net/DocumentLink/GSw0hHTj"

B) Glenmark Pharmaceuticals Ltd. &Anr. v. Symed Labs Limited[12]

Process patent infringement in the pharmaceutical business has received more attention as a result of the Delhi High Court's decision in the Glenmark Pharmaceuticals Ltd. case [FAO (OS) No. 60 of 2015]. The Delhi High Court's division bench reversed the decision made by the court's sole judge. Section 48 of the Act grants the patentee exclusive rights to forbid third parties from using the patented technique without permission and from using, offering for sale, importing, or using the product created in India using the patented process directly. On the other hand, a product patentee has the right to prohibit anyone from developing, using, offering for sale, selling, or importing the patented goods into India.

Process patent infringement is relevant to Section 104 A of the Act. This clause states that the burden of proof in an infringement lawsuit transfers to the defendant if the patentee can show that the product made using the patented process and the product made by the defendant are identical. The defendant is then required to prove that the process they used to make their product differs from the one outlined in the patent.If the product generated by the defendant is the same as the one produced by the patented technique, then the defendant must demonstrate that they did not employ the patented process.

Sugggestions

- Altering the focus from one that is directed towards exporting to one that is focused on global marketing is necessary. In order to accomplish this, strategic marketing alliances will need to be established in developed countries. These alliances will allow Indian pharmaceutical businesses to function as profit sharing partners and would offer access to distribution networks. In addition to this, it is necessary to implement vertical integration in a strategic manner into the distribution and utilisation chain, beginning with developing markets and progressing all the way up to developed markets.

- Research and development that is both cost-effective and efficient for the development of low-cost bulk pharmaceuticals, formulation and discovery research, and clinical studies for the global market are all things that need to be carried out. Discovery research on a therapeutic segment for a single molecule costs between Rs 150 and Rs 200 crore in India, whereas in developed countries it costs between US $ 650 and US $ 800 million. This research is expected to be carried out over a period of 8 to 10 years.

[12] "Case Name: Symed Labs Ltd. v. Glenmark Pharmaceuticals Ltd.
Citation: 2015 SCC online Del 6745 or (2015) 61 PTC 485 Document Link: http://www.scconline.com.eu1.proxy.openathens.net/DocumentLink/53TbOnjT"

- **Streamline the Patent Examination Process:** Improve the effectiveness and openness of the patent examination process in order to guarantee the timely granting of patents for real inventions while also preventing the granting of patents that are either frivolous or evergreening, which hamper generic competition.

- **Encourage the Implementation of Compulsory Licencing Mechanisms:** In order to promote the timely issue of licences for critical medications, you should strengthen the implementation of compulsory licencing regulations.

Conclusion

The pharmaceutical industry is widely recognised as a sector that is very "knowledge driven" and is characterised by extreme levels of competition. Research in the pharmaceutical industry is extremely expensive and frequently unpredictable in nature. Therefore, it is of the utmost importance for pharmaceutical businesses to secure a patent monopoly on any novel, imaginative, and helpful product that may emerge as a result of years of dedicated research labour.

In the past few decades, the pharmaceutical industry in India has seen substantial modifications, mostly as a result of the development of a robust generic industry. The passage of the Patents Act in 1970 was the primary impetus behind the growth of the industry as well as its final centralization. A couple of significant elements of the Patents Act of 1970 were crucial in facilitating the development of the generic industry in India. In the beginning, the only entities that were allowed to get process patents were chemical entities, which included pharmaceuticals. As a consequence of this, the length of time that pharmaceutical patents are protected at the patent level was shortened.

Since the advent of the process patent system, generic manufacturers have been able to acquire alternative procedures for products that were previously available on the market much more easily. Although there were some critiques, the practices of the generic companies that involved reverse engineering were judged to be akin to counterfeiting. On the other hand, the multinational corporations, whose products they were reverse engineering, were not able to compete with any of the generic manufacturers. Following the implementation of India's responsibilities under the World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), the Patents Act of 1970 brought about a reform to the patents system. This alteration was brought about as a result of the enforcement of India's obligations. The TRIPS-compliant patent system raised uncertainties for generic manufacturers over their power to reverse engineer items, which would greatly constrain their ability to do so. In addition, India is confronted with the necessity of implementing data exclusivity, a move

that has the potential to dramatically influence the chances that generic manufacturers will have in the future.

It would appear that the influence of the TRIPS Agreement on intellectual property rights (IPI) is rather minimal in the short term. To be more specific, the Trade Related Intellectual Property Rights (TRIPS) does not permit the retroactive patenting of pharmaceuticals in India that are already on the market or that are covered by patent applications that are already being processed in other countries. After that, however, there will be a gradual increase in price pressure as a result of the launch of fresh compounds by multinational corporations (MNCs) as the patents on previous medicines expire.It is expected that generic competition will continue to exercise its influence on the remaining 85 percent of the market. A number of worries regarding the high cost of patented pharmaceuticals have been resolved as a result of the government's aim to limit the prices of these medications to the lowest international cost.

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