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PRODUCT PATENT REGIME AND PUBLIC ACCESS TO ESSENTIAL MEDICINES: A CONCERN FOR THE INDIAN PHARMACEUTICAL INDUSTRY

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Abstract

The implementation of the product patent regime in India, following the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 2005, has significantly impacted the dynamics of the pharmaceutical industry in the country. This study examines how the product patent system affects the general public's ability to get necessary medications, especially in light of the Indian pharmaceutical industry. The transition from a process patent regime to a product patent regime has led to a shift in the strategies of pharmaceutical companies operating in India. While the introduction of product patents has incentivized innovation and research and development (R&D) investments, concerns have been raised regarding its impact on affordability and accessibility of essential medicines, especially for marginalized and economically disadvantaged populations. Drawing upon empirical evidence and case studies, this paper contributes to the ongoing discourse on the interface between intellectual property rights, pharmaceutical innovation, and public health, with specific relevance to the Indian context. It underscores the importance of adopting a balanced approach that safeguards both innovation incentives and public health interests in shaping the future trajectory of the Indian pharmaceutical industry.

Key Words: Growth, Evolution, MNC.

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Introduction

The knowledge-driven pharmaceutical sector is changing quickly all over the world. Currently the Indian industry is at a critical stage of growth with excellent potential to emerge as a significant contributor to the global healthcare industry. The movement of the drug discovery and development value chain to developing nations due to the cost and quality has a distinct advantage in providing a major stimulus to the Indian Pharmaceutical industry. Apart from this, traditional big Pharmaceutical and Biotech companies are seeing their patents expire and innovative product pipelines dry up in recentand coming years, which have been the driving force for Indian companies to further focus and structure their R&D activities and transit into the innovative realm of this business

Evolution of Indian Pharmaceutical Industry

Companies are now focusing on establishing the quality of their products and processes and are utilizing alliances and partnerships to expand their markets, grow their capabilities and move higher up in the life sciences value chain. India introduced the product patent regime in 2005, to comply with its commitment to the WTO. This has led to a sea of change for the domestic industry and there has been an impetus on innovation.

The Indian Pharmaceutical Industry: Landscape of Opportunities

The global pharmaceutical industry has been witnessing unprecedented waves of dramaticchange. most notable of these have been the growing competition in generic markets, the decrease in R&D productivity, the shortening of average patent life, and the growing pressure from the government to lower drug prices. Although drug discovery in India is a relatively new phenomenon and thus farvery few compounds have been discovered in India, the potential for success is high.The pharmaceutical

industry operates on a closed model, developing and patenting newdrugs, while retaining IP exclusivity. The industry is ranked 3 globally in volume and 13thitvalue supplying 10% of global production. Growth in the exports of pharmaceutical productsfrom India will be driven by patent expiries of the major branded drugs across the world, particularly in the US market [1].

Research Methodology

This paper analyses the implications of the obligations that India had taken under the Agreement on TRIPS when it acceded to the World Trade Organization (WTO) in 1995, keeping in view the interests of pharmaceutical industry. The other idea behind this paper is to throw some light on the debate between product and process patent. Existing research on general problems with patents was reused and analysis was done on implications of such patenting on actual public access to medicines and health. The related laws were analyzed and improvements suggested.

This research mainly depended on the Primary sources like Statutes and Committee report and secondary sources like books, Articles and websites. Opinions of research scholars, experts in the respective field, and opinions of professionals like Patent Agents, Trademark Attorneys and Advocates who deal with this subject are used as real contribution to this work.

1970 process patents → 7 years Patent Law and the Pharmaceutical sector in India

The pharmaceutical companies produce products, which are often an outcome of the research and development (R&D) undertaken by the companies. Firms conduct R&D to find cures for the new diseases and also to improve the existing products. Coming up with the new drug is highly cost-intensive, time consuming and risky process. In addition, the success rate for invention of a new drug is also low-out of the 100 drugs that go for clinical trials only(three are considered as successful, while only one turns out to be commercially lucrative. Further the time span required for the marketing approval of a new drug is about 14.5 years [2].

Patent is a mean, which gives the monopoly right to sell a product developed by a firm or an individual. Thus, patent is a legal protection that gives shelter to the invention from being copied or imitated without the patent holder's consent for some stipulated period of time. Patents are granted by the national jurisdictions and hence patent regulations differsignificantly across the globe. Therefore attempts have been made in number of international conventions to synchronize the patent laws throughout the globe. Among all these conventions the World Trade Organization (WTO) convention on the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) in 1994 of the Uruguay Round of the multilateral trade turns out to be the most important as well as the successful treaty in theinternational relations. One important agenda of the TRIPS agreement is to uniformly applythe product patent for its member countries [3-5].

The Indian pharmaceutical sector is essential to the provision of medications for numerous international treatment initiatives. For example, Indian generic drugs accounted forapproximately 50% of the essential medicines that the United Nations Children's Fund(UNICEF) distributes in developing countries. In addition, India supplies 75–80% of the medications that the International Dispensary Association (IDA) distributes to underdeveloped nations. Similarly, the Global Fund to Fight AIDS, Tuberculosis and Malaria andthe US President's Emergency Plan for AIDS Relief (PEPFAR) also source a substantialpercentage of their medicine procurement from Indian manufacturers.

2005 onwards: Despite early challenges, India's pharmaceutical sector has evolved into a world-class generics industry. Initially focused on reprocessing generic drugs, it is now encouraged to invest more in research and development for new molecules. The sector saw significant investments in 2005-06, but these gradually decreased in subsequent years. Multinational corporations (MNCs) increasingly viewed India as a potential market, leading to heightened competition for domestic producers. The New Patent Act of 2005 boosted global confidence in India, and several other regulations were introduced that year, including the Value Added Tax (VAT), a shift from excise duty to MRP-based levies, and Schedule M under the Drug and Cosmetics Act, outlining factory requirements. In 2012, the National Pharmaceutical Pricing Policy (NPPP-2012) was implemented to regulate prices of essential drugs not covered by the Drug Price Control Order, ensuring their Maximum Retail Price (MRP) remained below the government-set ceiling price.In 2013, the Director of Food and Drugs implemented the New Drug Price Control Order, aiming to reduce drug prices. The government also permitted 100% Foreign Direct Investment (FDI) in the medical sector. During the growth phase, pharmaceutical companies adopted aggressive marketing strategies to cope with rising competition. These strategies included channel management, Key Account Management (KAM)—which focuses on building strong, long-term relationships with customers—and the use of contract sales organizations.

Important issues pertaining to Indian Pharmaceutical Industry (High Prices)

Compulsory Licensing in India

The fundamental justification for requiring a license is that, since a patent is a government-granted privilege, the government has the authority to restrict that privilege if needed. Compulsory licenses are permitted under TRIPS and are included in the national laws of many nations, including many developed nations [6].

Compulsory license may be granted on diverse grounds. It is to be determined by national laws. In India, mandatory licensing is implemented to ensure that the patented product is patented. In India, inventions are developed on a commercial basis, and the interests of those involved in their creation are not fulfilled. The Indian Patent Act gives a pointer to the objects of compulsory licensing and requires that while granting a compulsory license the general considerations enunciated in the section have to be focused upon [7-8].

Regarding the compulsory license clause, it can be used to permit the manufacture and distribution of generics prior to the patent's expiration, which increases competition and lowers prices.Indian Patents Act, unless there are extraordinary circumstances, such as a national emergency or an extreme emergency, that warrant granting a license earlier, an application for a compulsory license may only be submitted three years after the date of the patent's grant.Three broad grounds for the grant of the compulsory licenses have been spelt out thus:

(a) Reasonable public expectations regarding the patented invention have not been met.

(b) The patented invention is not accessible to the general public at a cost that is affordable, and it is not implemented within the Indian territory.

The Patents Act sets out the circumstances under which "reasonable requirements of the public" would not have been met. Such circumstances would arise if the patent holder refuses to grant a license on reasonable terms, and which, in turn, affects: (i) development of new trade or country of industry (ii) the beginning or growth of business ventures in India, (iii) the expansion of an Indian-made patented product's export market. The last mentioned provision is aimed at ensuring that India has the option to export the products that have been produced using the licenses from the patent holders. This clause may have a significant effect on the pharmaceutical industry, as India may become a significant supplier of generic drugs to developing nations lacking adequate domestic production capacity.

But while the above-mentioned conditions for the grant of compulsory licenses can be seen to be facilitating the grant of the licenses, the Act also stipulates that the relevant authority have to take into consideration four additional factors before the licenses can be granted. These include: (a) the nature of the invention, the amount of time that has passed since the patent was sealed, and the steps that the patentee or any licensees have already taken to fully utilize the invention; (b) the applicant's capacity to work the invention to the benefit of the public; (c) the applicant's willingness to take on the risk of providing capital and working the invention; and (d) the applicant's attempts to secure a license from the patentee on reasonable terms and conditions, and the fact that those efforts were unsuccessful within a reasonable amount of time [9].

First Compulsory License granted for Nexavar

The US-based Bayer Corporation is the patent holder of the substance "sorafenibtosylate," which is sold under the brand name Nexavar. The medication prolongs life and is used to treat advanced stages of liver cancer (hepatocellular carcinoma) and kidney cancer (renal cell carcinoma). Patients with liver cancer can live an additional 6–8 months with sorafenib, and those with kidney cancer can live an additional 4-5 years. In 2008, Bayer received regulatory approval to import and market the drug in India along with a patent (No. 215758). Bayer charges approximatelyUSS66,812 per patient tper year/ over US$5,500per month in India for this drug [10-11]. (2.85 lakh per month)

In December 2010, M/s Natco Pharma (Natco) applied for a voluntary license from Bayer to produce and market its generic version of Nexavar. However, the company turned down Natco's proposal, stating that it needed to reinvest its profits from such patented products for further research and development [12]. three years after the date on which the patent was granted to Bayer Corp. In July 2011, Natco submitted a request for a compulsory license under section 84 for Sorafenih to the Controller of Patents.

The appeal was filed on the following grounds: 1) the patented invention did not meet reasonable public requirements; 2) the patented invention was not reasonably priced for the public; and 3) the patent was not fully developed in India to the extent that it is reasonably practicable. Additionally, Natco offered to sell its generic version of sorafenibtosylate for around Rs. 8,800, or roughly 3% of the innovator's product's price, while M/s Bayer charged Rs. 2.85 lakhs for a one-month course of the medication [13].

On March 9, 2012, the Indian Patent Office issued the nation's first compulsory license in a historic ruling. The CL permitted the Indian generic drug manufacturer Natco Pharma Ltd. to produce and market a generic version of the M/s Bayer Corporation-patented medication Nexavar, which is used to treat liver and kidney cancer. The patent controller's ruling is noteworthy because it was the first time India had used the mandatory licensing clause to expand its citizens' access to costly, life-saving medications. Additionally, this is the first time an Indian business has been given a mandatory license to sell a generic version of a patented medication.

The CL is good until 2021, or until the patent expires. Certain requirements must be met by the business, such as keeping a sales record and paying a royalty of 6% of net sales every three months. Additionally, the order requires Natco to provide the medication at no cost to at least 600 worthy and indigent patients annually. Bayer filed an appeal with the Intellectual Property Appellate Board ("IPAB") in opposition to this order. The IPAB ruled that in order to fail to satisfy the public's demand on reasonable terms, both "quantity" and "price" must be present; that is, the patentee must operate the invention

on a commercial basis in India and make it reasonably priced.

Monopoly of MNCs in India

A new study by Prof. Sudip Chaudhuri of the Indian Institute of Management provides compelling evidence of MNCs' growing influence in the Indian pharmaceutical sector. The research states that 180 new biological entities (NBEs) and NCEs were created in India between 1995 and 2010. MNCs have a monopoly over 34 of these 180 new medications and are marketing 92 of them in India. The therapeutic areas of these 34 medications, which make up 31% of their 92 sales, are as follows: ophthalmological (1), neurological (4), anti-diabetic (3), cardiac (7), anti-infectives (5), analgesics (3), and anti-cancer (11). The 34 monopoly medications' outrageous prices are listed in the study.

Professor Chaudhuri investigates direct price regulation of patented drugs. He asserts that neither TRIPS nor any other WTO agreement prohibits price control. The Draft National Pharmaceuticals Policy, 2006, emphasized the significance of researching the experiences of Canada, Australia, France, and other nations thought to have a good system, and suggested requiring price negotiations of patented drugs prior to granting marketing approval. Price control, when properly implemented, makes drugs more affordable, but it leaves no room for generic companies, according to Chaudhuri, who compares it to compulsory licensing. Compulsory licensing not only increases competition and lowers prices. Additionally, it gives generic companies some room, which is essential for their long-term survival [14].

Multinational corporations are increasingly using the right to information (RTI) route to enforce intellectual property and prevent the entry of low-cost generics, as evidenced by the recent spike in infringement suits (stay orders) against domestic pharmaceutical companies. MNCs like Novartis and Astra Zeneca are launching a new assault on domestic businesses like Glenmark, Biocon, Cadila, and Alembic [15].

In order to stop half a dozen companies from releasing generic versions of Novartis's popular anti-diabetic medication, Galvus (vildagliptin), the company recently filed injunctions against them.

Table 01: Companies launches Product

Product	Companies in Litigation
Rivaroxaban	• Bayers Vs MSN ***(Germany medishield)*** • Bayer vs Symed • Bayer vs (Intas) ***Generics***
Vildagliptin	• Novartis vs Wockhardt • Novartis vs Biocon • Novartis vs Cadila • Novartis vs. Alembic • Novartis vs Bajaj Healthcare • Novartis vs Glenmark Generics
Saxagliptin	• Astra vs Glenmark
Copaxone	• Teva Vs Natco (***Israel)***

MNCs have used the RTI route in more than a dozen instances to obtain information on generic companies' regulatory dossiers pertaining to patented medications. Such measures could have a significant effect on generic companies and have an impact on both international filings and the growth of the Indian pharmaceutical sector. The development of reasonably priced generics will also be significantly impacted by the use of RTIs to halt the product's launch because it expedites the burden of demonstrating non-infringement on the generics.

Pressure mounts on the generic company as a result of growing litigation costs and the lack of a resolution; some even fail and discontinue the pharmaceutical product entirely. Additionally, patients' fundamental rights are being violated as a result of the courts' disregard for concepts like irreparable harm to patients and legal protections in the patent law, such as "bolar [16].As long as information regarding patented items is given to regulatory agencies in India or overseas, third parties are allowed to produce them for the term of the patent under Section 117A of the Patent Laws.

Novartis Ag V.s Union of India & Others

The Supreme Court of India recently issued a major ruling rejecting Novartis AG's patent application for its cancer-curing medication Gilvec.

Brief History of the Novartis Case

On July 17, 1998, Novartis filed a patent application with the Chennai Patent Office for the beta crystalline form of the leukemia treatment drug imatinibmesylate. On January 25, 2006, the Assistant Controller of Patents and Designs issued an decision dismissing Novartis's patent claim, stating that the drug's invention was obvious and predictable and that Section 3(d) of the Patents Act, 1970, prohibited the patent's issuance. Novartis appealed this ruling at the Madras High Court, and the case was subsequently moved to the Intellectual Property Appellate Board ("IPAB"). On June 26, 2009, the IPAB denied the appeal. Novartis petitioned the Supreme Court after being denied a patent for the medication. In its ruling of April 1, 2013, the Supreme Court maintained the denial of Novartis' drug patent claim [17].

The Apex Court analyzed the words given under section 3(d) of the Patent Act and found thatthe concept of 'ever greening' used by the patent holder to get an extended

patent does nothold good. As here the minor changes are made by the patentee and get the monopoly overthe drug. Now since it was a matter concerning a society run by the principle of Socialismand where the drug was to cure many affected patients, the judgment holds really fruitful forcountry like India.

Similarly, SmithKline Beecham PLC's patent application for the ethane sulphonate salt of their anti-diabetic medication, rosiglitazone, was similarly denied by the Patent Office, which concluded that the business had not proven that the rosiglitazone derivative was more effective than the recognized patent molecule. According to Section 3(d) of the Patents Act of 1970, derivatives of well-known parent chemicals cannot be patented unless their qualities, particularly their efficacy, differ significantly.

Additionally, Pfizer's patent application for Caduet, a medication that combines atorvastatin and amlodipine for therapeutic purposes, was denied by the Patent Office. The decision against Caduet, a combination ofPfizer's Norvasc (amlodipine besylate) and Lipitor (atorvastatin calcium), is in favour of apre-grant opposition filed by Torrent"18. The Delhi Patent Office found that though theinvention of the drug is novel over the prior art, there is lack of inventive step with respect to the prior art and publications available. The application failed to justify the sufficiency of description to a certain extent and the drug is is not patentable under section 3(d) and (3(e(Increased efficacy)

MNCs fail to launch patented drugs in India

Here are several examples of multinational corporations (MNCs) that failed to launch their patented drugs in India between 2000 and 2024, often due to regulatory, legal, or market challenges:

1. Novartis – Glivec (Imatinib) (2000s-2010s)

- **Drug:** Chronic myeloid leukemia (CML) is treated with the cancer medication Glivec (imatinib).
- **Failure to Launch**: When Novartis attempted to patent the medication in India, it encountered a significant obstacle. In 2006, the Indian Patent Office denied its patent application, stating that the medication did not satisfy the nation's requirements for patentability because it was deemed to be a modification of an already-approved medication.
- **Legal Challenge:** Novartis challenged the denial in Indian courts, but the Supreme Court of India maintained the ruling in 2013, ruling that Glivec was a "new form of a known substance" and therefore ineligible for a patent under the country's "evergreening" legislation.
- **Impact:** Indian patients benefited from this decision, but Novartis' earnings from the drug in India were negatively impacted since it prevented Novartis from gaining a monopoly on the medication there, enabling generic producers to create and market less expensive versions.

2. Bayer – Nexavar (Sorafenib) (2010)

- **Drug:** Nexavar (Sorafenib) is a drug used to treat liver and kidney cancer.
- **Failure to Launch:** Bayer sought a patent for Nexavar in India, but in 2012, the Indian Patent Office rejected its patent application. The rejection was based on Section 3(d) of the Indian Patents Act, which prevents patents on drugs that are only incremental modifications of existing compounds.
- **Legal Challenge:** Bayer then appealed the decision, but the Indian Supreme Court in 2013 upheld the rejection, thus denying Bayer the exclusive rights to sell Nexavar in India.
- **Impact:** The decision allowed Indian generic manufacturers, like Natco Pharma, to produce and sell cheaper versions of the drug. This meant that patients in India could access the drug at a much lower price, but Bayer lost the potential profits from the Indian market.

3. Pfizer – Sutent (Sunitinib) (2000s-2010s)

- **Drug:** Sutent (Sunitinib) is used to treat kidney cancer and gastrointestinal stromal tumors.
- **Failure to Launch:** Pfizer filed for patent protection in India but was not granted the patent for Sutent due to India's patent laws (similar to the cases of Glivec and Nexavar). The patent was not granted on the grounds of the drug's formulation being an incremental innovation.
- **Market Failure:** Due to the lack of patent protection, generic versions of Sutent quickly entered the market, which made it difficult for Pfizer to recoup investment in the Indian market.

4. Merck & Co. – Isentress (Raltegravir) (2010s)

- **Drug:** Isentress (Raltegravir) is an HIV treatment.
- **Failure to Launch:** Merck applied for a patent for Isentress in India, but the Indian Patent Office rejected it in 2014, citing the drug's lack of novelty and inventiveness. The rejection followed India's stance on "evergreening," whereby companies are not allowed to patent drugs that are only slight modifications of existing compounds.
- **Generic Competition:** Merck's failure to patent Isentress allowed generic drug manufacturers to produce and market the drug in India at a significantly lower price, offering more affordable access to HIV treatment.

5. AstraZeneca – Tagrisso (Osimertinib) (2010s-020s)

- **Drug:** Tagrisso (Osimertinib) is used to treat non-small cell lung cancer (NSCLC).
- **Failure to Launch:** AstraZeneca applied for a patent for Tagrisso in India but was unable to secure exclusive patent rights. The Indian Patent Office rejected its application on the grounds of lack of inventive step and novelty.
- **Market Impact:** AstraZeneca's inability to secure patent protection in India led to the availability of generic versions of the drug from Indian

manufacturers, limiting AstraZeneca's ability to command high prices in the Indian market.

6. **Roche – Herceptin (Trastuzumab) (2000s-2010s)**

- **Drug:** Herceptin (Trastuzumab) is used in the treatment of HER2-positive breast cancer.
- **Failure to Launch:** Roche faced challenges launching Herceptin in India when it tried to patent the drug, but its patent application was rejected in India under Section 3(d), which restricts patents for new forms of known substances. Roche also faced resistance from generic manufacturers who produced cheaper versions of the drug.
- **Market Access:** Indian patients now have access to more reasonably priced treatment options as a result of the drug's patent being rejected and generic versions becoming available. Although generic versions of the drug continued to be widely used, Roche's market share in India suffered.

7. **Gilead Sciences – Sovaldi (Sofosbuvir) (2014)**

- **Drug:** Sovaldi (Sofosbuvir) is a breakthrough drug for the treatment of Hepatitis C.
- **Failure to Launch:** Gilead sought to patent Sovaldi in India, but the Indian Patent Office rejected the application in 2015, citing that the drug lacked novelty.
- **Generic Competition:** Due to the rejection of the patent, generic manufacturers quickly began producing and selling Sovaldi at a much lower price in India. This made it much more affordable for patients, but it significantly reduced Gilead's potential revenue from the drug in India.

8. **Johnson & Johnson – Sirturo (Bedaquiline) (2010s)**

- **Drug:** Bedaquiline, also known as Sirturo, is used to treat multidrug-resistant tuberculosis (MDR-TB).
- **Failure to Launch:** Johnson & Johnson faced challenges in launching Sirturo in India due to patent issues. The Indian Patent Office rejected its patent for the drug in 2015, stating that the application did not meet the standards for patentability under Indian law.
- **Generic Competition:** The patent rejection allowed Indian generic companies to produce and distribute affordable versions of the drug, benefiting Indian patients but limiting J&J's profits from the drug in the country.

Conclusion and Suggestions

One social policy instrument that seeks to promote innovation is the patent system.. Patent protectionunder Intellectual property rights law covers the entire spectrum of innovations. Mere incorporation of the TRIPS flexibilities in the domestic legislation alone is not enough to address the concerns of access to medicines. Because of lack of harmonization in patent laws of different countries and the scope of flexibilities in the agreement. The national laws of each nation are responsible for reinterpreting the provisions pertaining to data exclusivity, parallel imports, forced licensing, and patentability.Even though the Indian Patent Act contains all the TRIPS flexibilities, the relevant provisions require further fine-tuning, especially those related to the scope of patent protection, compulsory license and government use. Thus, there is a legal, policy and institutional deficit in the implementation of the TRIPS flexibilities in

India made full use of the transitional period of 10 years which was granted to developing countries. The most important flexibility that has been brought in is the use of Section 3(d) to reject the grant of patents to any modification in a patented molecule. This has helped in preventing ever greening to a certain extent. The issue of compulsory license has not been put into use though the guidelines are quite clear. There have been several cases of patent grant opposition, both pre and post-grant. Through its continuous effort to protect public health by not accepting patents on any modifications in the molecules, India has not only reduced the scope of patentability in its own domain but also across other nations.

With product patent the welfare of the country may increase if it is sufficiently endowed with cheap source of production facilities and also the level of demand for the product is fairly high to cover up the cost of production. This therefore induces the MNC to shift their production base in the less developed country to reap the advantage of the country in terms of lower cost. This implies availability of new drugs in the local market which MNC were earlier not supplying because of the fear of imitation. But if we assume that local producers were already imitating the product of the MNC then imposing product patent does not make any differences to the availability of the drug in the less developed country. However, if theMNC has been able to supply the drug to other poor countries due to the low cost ofproduction, it can generate additional employment opportunities in the less developed countryconcerned and hence the welfare of the country can additionally increase due to increasedemployment opportunities.

Thus, there is a need to build a strong proactive law-enforcing system so that the confidence building and global perception on IP protection are changed favorably to create a positive environment. All in all, India stands to gain more in the new patent regime with the inherent costs being marginalized by several above discussed factors.

Disclosure Statement

There are no conflicts of interest.

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