Patent regime and pharmaceutical industries

B Dhananjay[1], Dr. Santosh Kumar[2]
Law, Amity University Noida

Abstract -The abstract begins by outlining the fundamental role of patents in pharmaceutical innovation, highlighting their importance in providing incentives for research and development (R&D) and facilitating access to capital for drug discovery. It then explores recent trends in patenting activity within the pharmaceutical industry, including the rise of biologics, gene therapies, and personalized medicine, which present unique challenges in terms of patentability, regulatory approval, and market exclusivity.

Furthermore, the abstract discusses the impact of the patent regime on access to medicines, particularly in developing countries where affordability and availability of essential drugs are critical concerns. It examines issues such as compulsory licensing, patent pools, and technology transfer agreements, which have emerged as mechanisms to balance the interests of patent holders with public health priorities.

Moreover, the abstract addresses the implications of international trade agreements, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), on pharmaceutical patenting and access to medicines. It explores debates surrounding the flexibilities and limitations of TRIPS, particularly in the context of public health emergencies such as the COVID-19 pandemic.

1. INTRODUCTION

The exclusive property rights to intangible works of human creativity are represented by patents. They can only be enforced to the degree that an application has been submitted and a patent has been awarded covering the territory of a sovereign state. They only exist as specified by the laws of sovereign nations.

The typical worldwide patent rights period is 20 years from the date of application. However, this is not always the case. A novel product, article of manufacture, or method must be disclosed in a patent application if it has never been disclosed before worldwide and would not be apparent to someone with ordinary competence in the relevant field. The claims of the patent applicant are compared to the corpus of published literature in the subject, including previously granted patents, to determine if these standards have been satisfied. This procedure is called inspection, and it guarantees that no one may assert patent rights over intellectual property that already exists.

Different industries have different ways of using patents. Patents in the electronics sector are frequently pooled or cross-licensed across rival companies. Because a particular product frequently incorporates many patented technology, this sharing is required. In the pharmaceutical, chemical, and biotechnology sectors, on the other hand, patents often match the product and safeguard the substantial financial outlay necessary for the product's development and testing before to its release. When compared to other sectors, patent protection for chemical and pharmaceutical goods is particularly significant since the actual manufacturing process is frequently simple to duplicate and may be done for a fraction of the cost of research and clinical testing.

Due to the high expense of developing a new pharmaceutical product, the private sector has invested a disproportionate amount of money in pharmaceutical innovation to create products that meet the needs of patients in developed nations, especially the US, where there is free market competition and robust patent protection.

Many developing nations did not offer pharmaceutical product patent protection prior to the 1994 TRIPS Agreement. Furthermore, although WTO members have committed to provide this kind of protection, least developed nations are exempt from this need until 2016. In most developing nations, it is extremely difficult to start research-based enterprises since pharmaceutical goods are still not protected by patents. In these nations, public health facilities are the primary sites of medical research. The inability to patent these innovations and the ensuing inexperience in granting private sector licenses hinder the growth of businesses aimed at reducing the prevalence of diseases prevalent in developing nations.

A renewed interest in mandatory licensing for pharmaceutical items has come from the issue surrounding the accessibility of patented treatments

for the treatment of HIV illness. The TRIPS Agreement enables such forced licensing in health crises, even in circumstances where the licence is for an imported product, the WTO Council recently confirmed after two years of deliberation. Though the prospect of forced licensing has been used to pressure vendors into offering cheaper rates, no genuine compulsory licenses have been given as of yet.

Promising advancements are being made in nations like Brazil and India, who are starting to employ patents to grow their commercial pharmaceutical industry and create goods targeted at regional illnesses that are affordable for local people can afford. Such initiatives are supported by nonprofits and foundations including One World Health, Inc. and the Bill and Melinda Gates Foundation. These initiatives demonstrate that developing nations are capable of creating pharmaceutical firms with a strong research base that can make a profit given the local market's circumstances.

But in order for these regional sectors to establish themselves and flourish, there has to be strong patent protection accessible, encouragement for the commercialization of publicly financed research, and Minimum requirements for compulsory licensing must be met. Rich nations may support this process by directing programs of aid like the one recently suggested by President Bush, as well as by financing local markets for the purchase of medications through the Global Fund. Instead of trying to transfer the expense of medication development to others, consumers worldwide may fairly share the burden of research by purchasing medicine at a price that fits within their means.

2. THE WORLD INTELLECTUAL PROPERTY ORGANIZATION [WIPO]

WIPO is a specialized United Nations agency with its headquarters located in Geneva. It acts as the secretariat for the majority of international intellectual property treaties. It is the main venue for new patent treaty negotiations and the top supplier of providing developing nations with technical support in the area of intellectual property rights. The International Bureau for the Protection of Intellectual Property, which had been in operation since the 19th century, was replaced by WIPO in 1967. There are 179 member nations of WIPO now.

2.1 WORLD TRADE ORGANIZATION

The Uruguay Round of Trade Negotiations ended successfully, and in Marrakech, Morocco, the World Trade Organization was founded in 1994. The General Agreement on Tariffs and Trade (GATT) was the organization that preceded the WTO. The Agreement on Trade Related Aspects of Intellectual Property Rights, or TRIPS, which is incorporated as an appendix to the treaty creating the World Trade Organization, was a major revision of the Uruguay Round.

It is critical to understand that the goal of the TRIPS Agreement was to provide a more equal framework for global commerce. Rich nations committed to lowering tariffs on price-competitive goods from outside, while poor nations committed to up their markets to the industrialized countries' high-value added products. A disproportionate amount of the technology included in these high-value added exports is intangible, meaning that its full potential must be unlocked by robust intellectual property protection laws. One of the most significant subcategories of high-tech items is pharmaceuticals.

3.SPECIAL PROBLEMS FACED BY PHARAMACEUTICAL INDUSTRIES

One of the three technology-based sectors where the product and the patent are nearly identical is the pharmaceutical business. The two other sectors are the biotechnology and chemical industries, whose advances cover the range from cultivated plant cultivars to pharmacological treatments for humans. Compared to other patenting businesses like computers and electronics, these three industries are quite distinct. The computer and electronics sectors are known for filing a large number of patents, but they also frequently employ other methods to manage inventions, such as trade secrecy and pooling patents with rivals to meet industry and governmental technical standards.

Most crucially, pharmaceutical businesses' patented products can be readily and inexpensively manufactured, in contrast to other industries that generate goods needing costly and sophisticated production infrastructures. copiers may easily and affordably duplicate it with little initial outlay. The only practical means of protecting and profiting from the capital invested in laboratory research and clinical

trials—rather than the production of the finished product—in the pharmaceutical sector is through patent exclusivity.

One key feature that distinguishes the pharmaceutical business from other sectors that depend on patent protection is its uniqueness. It is feasible to keep inventions a secret until they are commercialized in many technology-based enterprises. This makes possible In order to take full advantage of the 20-year patent term that begins on the date the patent application is filed, inventors should postpone submitting patent applications until the very last minute. In contrast, the medical research culture places great emphasis on the early disclosure of inventions—typically well in advance of the product's ability to be commercialized.

This is because researchers in the field of human pathology have a duty to promptly disseminate their discoveries to their colleagues so that those colleagues will be able to gain from the fresh insights in their own investigations. Furthermore, government organizations strictly oversee the pharmaceutical business, in contrast to other industries like software and computers, in order to ensure the efficacy and safety of goods that are supplied to customers. This task is carried out in the US by the Food and Drug Administration. A significant portion of the money spent on novel medications goes on the clinical trials required to appease regulators of effectiveness and safety. Compared to other businesses, the pharmaceutical industry has a very low tolerance for the "buyer beware" mentality.

Compared to other patent-dependent businesses, pharmaceutical producers enjoy considerably shorter periods of patent exclusivity due to the protracted timeframe between filing for a patent and releasing a product into the market. This issue has been discussed in laws, both domestically and internationally, that allow a patent applicant to request an extension of the patent term in order to make up for the fact that safety and efficacy regulations prevent ideas from being commercialized. The time frames allowed for these extensions, however, do not match the amount of time lost in terms of marketing.

Although the patent-based pharmaceutical industry makes a significant contribution to the economy and the creation of jobs, pharmaceutical researchers' creations have an additional dimension that is hard to measure in terms of money: their influence on prolonging life and reducing the pain of people. There were 402 new cancer medications, 123 new heart and stroke therapies, 83 new AIDS treatments, and 176 novel medications for neurological illnesses in the pharmaceutical industry pipeline in 2001. These figures are especially alarming in the context of the ongoing discussion about the validity of patents for HIV medications. Not one of the 74 novel medications currently being developed

Without the patent incentive and the possibility of a return on investment it offered, medications that have already drastically reduced the number of AIDS-related fatalities in the United States would never have been developed.

When the patent system was used effectively in the 20th century, businesses were created that improved medical research beyond anything that had been achieved in previous eras.

While public support for scientific training and fundamental research significantly increased the comprehension of human pathophysiology As the century went on, patients received much-needed new medicines thanks to the economic motive that drove pharmaceutical companies, who were answerable to investor stockholders. Over 92% of all new medications were created by patent-dependent pharmaceutical corporations by the 1980s.

4.PROMISING DEVELOPMENT IN PHARMACUETICAL INDUSTRY AND IPR

Certain emerging nations are showing indications of progress. India is one such instance. A vigorous initiative has been launched by the Indian Council for Scientific and Industrial Research (CSIR) to market the research conducted by scientists employed by its labs. This program entails finding practical discoveries and patenting them in large markets like the US as well as in India. The United States Patent & Trademark Office granted six patents to CISR in 1991. The total number of US patents awarded to CISR increased to 145 in 2002.

Numerous patents pertain to medicinal goods developed via research grounded in traditional knowledge and the indigenous ecosystem of India. Among the best-performing instances is Asmon, a polyherbal medicine for the prevention of bronchial asthma by blocking the pathways of leukotrienes and lymphokines that trigger asthma. Asthma sufferers in

India may now get the medicine at a reasonable cost because it is now on the market there.14 Due to collaborations between CISR and private Indian pharmaceutical firms like Cadila Pharmaceuticals, Ltd., similar commercialization initiatives including novel treatments for leprosy, HIV, and cancer are being developed.

Biotechnology spin-off firms in Brazil are leveraging the vast genetic resources of the Amazon area to develop specialized goods. 16Additionally, funds are being provided by groups like the Global Malaria Initiative and the Gates Foundation to It is feasible to establish pharmaceutical firms in developing nations that can effectively tackle the illnesses prevalent in such regions. One World, Health, Inc. of San Francisco is one company that has made unique attempts to transfer technology and intellectual rights to other firms.

5. TECHNOLOGICIAL STRATEGIES OF INDIAN PHARMACUETICAL

Since the mid-1990s, there has been a significant shift in the kind and scope of innovative initiatives undertaken by companies in the pharmaceutical sector in India. Not only has The industry's R&D spending has grown significantly (Pradhan, 2003; Chaudhuri, 2007). The composition of Indian companies' R&D efforts has also shifted, moving from the creation of new processes to the modification of already-approved medications as well as the creation of novel formulations and compositions (Chaudhuri, 2007). Compared to the rate of growth of 3.88 percent in the pre-TRIPs period, R&D spending have climbed at a higher rate of 5.07 percent in the post-TRIPs period (Kiran and Mishra, 2009). The automotive sector is the other major innovator, although the industry has emerged as one of the top two.

The pharmaceutical industry's increased focus on innovation appears to have had a major role in the sector's explosive growth.

As of right now, the industry is ranked thirteenth in terms of value and fourth in terms of volume worldwide. Furthermore, a number of Indian firms are presently dominating the market along with many of the important therapeutic sectors, when previously the industry was dominated by multinational corporations. Several Indian pharmaceutical businesses, including Lupin, Ranbaxy Industries, Wockhardt, Cipla, Nicholas Piramal, and Dr. Reddy's Laboratories, have established a significant presence in developed markets like the US and Europe.

But when these creative endeavors are compared against other technological initiatives, it becomes clear that spending on technology acquisition, has risen in tandem with internal R&D, particularly from overseas sources; yet, between 2001 and 2008, the pace of increase in R&D intensity is only slightly more than that of foreign technology purchase intensity.

6. STRUCTURE, STRATEGY AND INNOVATION IN INDIAN PHARMASUETICAL INDUSTRY

India's pharmaceutical business ranks twelfth globally in terms of sales, but it is the fourth largest globally in terms of volume. With a 2005 valuation of US$5.3 billion, the Indian pharmaceutical sector accounts for little less than 1% of the global market. Nonetheless, as Fig. 4 demonstrates, India's pharmaceutical sector has experienced rapid expansion. Compared to 1970, when they provided just approximately 20% of the country's overall pharmaceutical market, Indian pharmaceutical businesses supplied 95% of it in 2006. There are several ways to gauge innovation performance in general and R&D success in particular. However, a study survey discovered that fewer than 10% of the businesses employed a single success metric. The most commonly used indicator of innovation is typically provided by patents, which do so through:

1. Offering impartial measurements
2. Drawing from reports, both internal and external
3. Clearly stating the importance of the research
4. Strongly correlated with indicators such as scholarly publications and the national

The legislative and institutional frameworks for innovation in the Indian pharmaceutical business were modified in response to political and legal concerns for higher societal returns. The British pharmaceutical firm ICI Pharmaceuticals created propranolol, the first beta blocker that lowers adrenaline and other fight-or-flight hormones, as a high blood pressure treatment in the 1960s. But the drug's high cost turned off many Indians. The CEO's son, Yusuf Hamied, the head of R&D at Cipla, an Indian business, began producing a less expensive version for the domestic market.

7. PHARMASUETICAL INDUSTRY ARISING WITH THE HELP OF PATENT REGIME

The pharmaceutical industry has been significantly influenced by the patent regime. The introduction of patent protection for pharmaceuticals has played a crucial role in incentivizing innovation in the sector. Before the implementation of patent laws specific to pharmaceuticals, there was limited incentive for companies to invest in the research and development of new drugs, as competitors could easily replicate and sell the same drugs without bearing the costs of research.

With the establishment of patent protection, pharmaceutical companies gained exclusive rights to manufacture and sell their drugs for a specified period, usually around 20 years. This provided them with the opportunity to recoup their investment in research and development through sales revenue, as well as to profit from their innovation. As a result, companies were motivated to invest in the discovery and development of new drugs, leading to a significant increase in the number of innovative treatments available to patients.

However, the patent regime in the pharmaceutical industry has also sparked debates and controversies. Critics argue that patent protection can lead to high drug prices, limiting access to essential medications for those who cannot afford them. Additionally, some argue that the patent system can be exploited by pharmaceutical companies to extend their monopolies on certain drugs beyond what is necessary for incentivizing innovation.

Overall, while the patent regime has undoubtedly played a central role in driving innovation in the pharmaceutical industry, policymakers continue to grapple with finding the right balance between incentivizing innovation and ensuring access to affordable medications for all.

8. SPECIAL PATENT REGIMES FOR PHARMA INDUSTRIES IN INDIA

India has implemented specific patent regimes tailored to the pharmaceutical industry, balancing the need for innovation with public health concerns and accessibility to medicines. Here are some key aspects of India's patent regime for pharmaceuticals:

1. Product Patents: India transitioned to a product patent regime for pharmaceuticals in 2005 as part of its obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO). This allowed for the patenting of new drugs and pharmaceutical formulations.
2. Section 3(d) of the Patents Act: This section is particularly significant in Indian patent law for pharmaceuticals. It specifies that mere discovery of a new form of a known substance which does not result in enhanced efficacy of the substance or the mere discovery of any new property or new use for a known substance does not constitute an invention unless the substance itself meets the criteria of novelty and inventive step. This provision aims to prevent evergreening, where pharmaceutical companies attempt to extend patent protection by making minor modifications to existing drugs.
3. Compulsory Licensing: India's patent law includes provisions for compulsory licensing, allowing the government to grant licenses to produce patented drugs without the consent of the patent holder under certain conditions, such as public health emergencies or when the patented drug is not available at an affordable price. This provision helps ensure access to essential medicines.
4. Government Use: The Indian Patents Act also includes provisions for the government to use patented inventions for public purposes, such as public health emergencies, national security, or in the interest of the public.
5. Pre-Grant and Post-Grant Opposition: The Indian patent system allows for pre-grant and post-grant opposition mechanisms, providing opportunities for interested parties to challenge the grant of a patent on various grounds, including lack of novelty, non-obviousness, and non-patentability under Section 3(d).

These aspects of India's patent regime for pharmaceuticals reflect a balance between promoting innovation and ensuring access to affordable medicines, particularly important for a country with a large population and diverse healthcare needs.

9. CASE STUDIES

There have been several notable patent cases in the pharmaceutical industry, both in India and globally, which have had significant implications for drug development, access to medicines, and intellectual property rights. Here are a few examples:

1. Novartis vs. Union of India (Glivec Case): This case garnered international attention and centered around Novartis' patent application for the cancer drug imatinib mesylate (sold under the brand name Glivec/Gleevec). The Indian Patent Office rejected Novartis' patent application based on Section 3(d) of the Indian Patents Act, which requires that new forms of known substances demonstrate enhanced efficacy. Novartis challenged this decision in the courts, arguing that India's patent law was overly restrictive. However, the Supreme Court of India upheld the decision, reinforcing the importance of Section 3(d) in preventing evergreening and promoting access to affordable medicines.
2. Bayer vs. Natco (Nexavar Case): This case involved Bayer's patent for the cancer drug sorafenib tosylate (sold under the brand name Nexavar). The Indian company Natco Pharma sought a compulsory license to produce and sell a generic version of Nexavar at a lower price. The Controller of Patents granted Natco Pharma the compulsory license, citing Bayer's failure to make the drug available at a reasonable price and meet the public health needs of the country. This case highlighted the use of compulsory licensing provisions to ensure access to essential medicines.
3. Merck vs. Glenmark (Sitagliptin Case): Merck, the manufacturer of the diabetes drug sitagliptin (sold under the brand name Januvia), filed a patent infringement lawsuit against Glenmark Pharmaceuticals, alleging that Glenmark's generic version of sitagliptin violated its patents. The case raised questions about the validity of Merck's patents and Glenmark's right to market a generic version of the drug. Ultimately, the Delhi High Court ruled in favor of Merck, temporarily restraining Glenmark from manufacturing and selling its generic version of sitagliptin.
4. AbbVie vs. Indian Generic Companies (Ritonavir Case): AbbVie, the manufacturer of the HIV/AIDS drug ritonavir (sold under the brand name Norvir), faced legal challenges from Indian generic drug companies seeking to produce generic versions of the drug. These companies argued that AbbVie's patents were invalid or not infringed. The case highlighted the tension between patent holders and generic manufacturers in the context of essential medicines for treating HIV/AIDS.

These cases illustrate the complex interactions between pharmaceutical patents, public health considerations, and access to medicines, shaping the landscape of drug development and affordability in India and beyond.

10.CONCLUSION

According to the study, the pharmaceutical industry in India, which operates as an oligopoly, faces numerous challenges in the future. These include increased spending on research and development, the patent expiration of several major drugs made in Ireland, growing competition in the global generic market, China's reliance on bulk drugs, an increase in mergers and acquisitions, growing costs associated with new drug discovery, and stricter safety and efficacy testing regulations. At a lower value chain, smaller businesses are probably going to serve as contract manufacturers for medium-sized and larger businesses. For the top pharmaceutical exporters, the Normalized Revealed Comparative Advantage (NRCA) index was computed. It was discovered that the IPI's NRCA index showed decline from 1996 to 2005, then improved starting in 2006, with the exception of 2009. The development of patent regimes in India, particularly in the pharmaceutical sector, has been marked by a balancing act between promoting innovation and ensuring access to essential medicines. Here are some key conclusions regarding the evolution of patent regimes in India:

1. Promotion of Innovation: India's transition to a product patent regime for pharmaceuticals in 2005 was a significant step toward aligning with international intellectual property standards, particularly under the TRIPS agreement. This change provided greater incentives for innovation by granting pharmaceutical companies exclusive rights to their inventions for a specified period.
2. Safeguarding Public Health: Despite strengthening patent protection, India has implemented safeguards to prevent abuses of patent rights and ensure access to affordable medicines. Provisions such as Section 3(d) of the Patents Act and compulsory licensing mechanisms have been instrumental in striking a balance between promoting innovation and safeguarding public health interests.
3. Preventing Evergreening: India's patent law includes provisions aimed at preventing evergreening, a practice where pharmaceutical companies seek to extend patent protection by making minor modifications to existing drugs. Section 3(d) and

rigorous examination standards help ensure that patents are granted only for genuine innovations that offer significant therapeutic benefits.

4. Access to Medicines: The Indian patent regime acknowledges the importance of access to medicines, particularly for a population with diverse healthcare needs and limited financial resources. Compulsory licensing provisions and judicial decisions have demonstrated a commitment to ensuring access to essential medicines, even in the face of patent barriers.

5. Balancing Competing Interests: The development of India's patent regime reflects a careful balancing of competing interests, including those of patent holders, generic manufacturers, public health advocates, and consumers. Courts and policymakers have played a crucial role in adjudicating disputes and shaping the legal framework to achieve a fair balance between these interests.

In conclusion, India's patent regime for pharmaceuticals has evolved to strike a delicate balance between fostering innovation and ensuring access to affordable medicines. While challenges remain, such as enforcing patent rights effectively and addressing concerns around access and affordability, India's experience provides valuable lessons for other countries grappling with similar issues at the intersection of intellectual property rights and public health.

REFFERENCE

1.https://users.wfu.edu/mcfallta/DIR0/pharma_patents.pdf

2. https://intapi.sciendo.com/pdf/10.2478/v10033-010-0018-z

3.https://www.emerald.com/insight/content/doi/10.1108/IJPHM-12-2016-0066/full/html

4.https://www.sciencedirect.com/science/article/abs/pii/S0040162511001351