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Product Patent vs. Process Patent, Protection of right to Ipr and right to life in India (pharmaceutical industry)

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Abstract

Among all the assets found under intellectual property rights, patents tend to be extensively sought by inventors and industries. This is because it gives them the right to prevent others from using, manufacturing, or even making a product by a similar technique. The patent right has been given the first position in the most developed countries, benefiting the pharmaceutical industry. For instance, their patent regime in India has been significant for the generic drug industry's development, enhancing the availability and production of critical drugs at affordable prices. A product patent is intended to protect an investor's product. This is facilitated by providing a safeguard to the original innovator to ease competition toward a similar product. Whereas, a process patent is primarily used to protect the procedures via which one produces the product and not the product itself. This kind of protection helps in reducing the monopoly element within the market. Therefore, as India practices intellectual property rights laws, all its members must change their patent to product from the patent process.

The point remains to find out what is unique about a product patent that is not within a process patent. Under the product patent, exclusive rights are provided to the original innovator of the product. Its attributes include; the provision of monopoly rights to the product's creator. They are termed to be at a high level of protection compared to process patents, where its grant depicts that no person apart from the innovator has the mandate to manufacture a similar product by utilizing a similar process. Unlike in process patents, where the process regime is offered to only a specific process but not the final product. It differs from the product patent because another manufacturer can create a similar product using a different process, it provides a lower range of investor protection, and a single product can have multiple process patents.

Therefore, the development of the pharmaceutical industry has emerged due to a regime connected to patents that have positively impacted India. The country acts as the leading medicine supplier to developing countries, making it known as a doctor with no borders. Earlier Indian pharmaceutical industries were using process patents where different industries would produce generic drugs on massive levels, facilitating access to developing and underdeveloped countries. Thus, introducing product patent laws meant that Indian

pharmaceutical industries would not manufacture medicines through reverse engineering until the patent became in use. This study aims to add to the existing knowledge on the difference between product and process patents. And so,, to achieve the aim of the study, secondary research was carried out by reviewing existing literature from journals, articles, and even scholarly works to provide evidence. Inclusion and exclusion criteria were adopted to decide what articles to include in the study.

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Objectives

1. To find the difference between product patents and process patents
2. To investigate the importance of product patents and process patents to an individual's creation or invention.
3. To examine how patent regimes have benefited pharmaceutical industries in India.
4. To find out between product patents and process patents, which Indian investors most prefer.
5. To examine the nature of pharmaceutical industries in India under Product and Process patents.

Product Patent vs Process Patent

A patent is a legally binding document that functions to protect an invention. In order to mitigate the occurrence of imitative actions, the legal framework provides considerable safeguards to the initial creator. Product patents are designed to protect the final product, whereas process patents are intended to safeguard the specific methods or steps involved in the creation of said product. This mitigates the monopolistic characteristics of the market, including elevated pricing, suboptimal medication sales volumes, exploitative business strategies, and unpredictable scheduling. Two additional characteristics are compulsory licencing and limited growth in projected pharmaceutical revenues.

A product patent status

According to this arrangement, the patent is awarded to the individual who initially conceived the idea. Several characteristics serve to delineate a Product Patent: Once a patent is granted for a specific product, exclusive production rights are bestowed upon the inventor, granting them legal authority to manufacture the product using either the patented method or any alternative method. The individual who holds the patent for an invention enjoys a state of exclusive market control, commonly referred to as a "True Monopoly." Product patents are commonly perceived as being more secure in comparison to process patents.

A process patent is awarded specifically for a distinct methodology rather than the outcome, as implied by its nomenclature. We assign a limited parental rating to the safeguarding measures. This is due to the theoretical possibility of another manufacturer or innovator being able to produce a similar product using an alternative approach (Chaudhry, 2011). A process patent affords the inventor a restricted degree of protection. Hence, it is probable that competing firms will endeavour to comprehend the functionality of the product by examining its source code. A single product has the potential to be protected by multiple method patents.

If businesses were granted exclusive monopoly rights through patents in the present day, as is commonly posited in the field of economics, it is anticipated that prescription prices would increase and the number of medications available in the market would be suboptimal. In order to address this inefficiency, patents are designed with the purpose of providing incentives for additional research and development (Chaudhry, 2011). The protests are a manifestation of concerns regarding the implications of a textbook product patent system. This system grants foreign innovating firms exclusive rights, while domestic infringing firms are excluded from the market for the duration of the patent. Consequently, essential drugs experience substantial price hikes. As a result, numerous activists and policymakers have voiced their criticism of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

There exists a widely held belief that TRIPS, the Agreement on Trade-Related Aspects of Intellectual Property Rights, triggered an increase in patent protection in developing countries. However, it is important to note that this is merely an illustration of the potential for varying interpretations and adaptability inherent in TRIPS and similar international agreements. Compulsory licencing, formal price controls, and the provision for domestic firms to pay a royalty and maintain commercial operations after producing newly patented molecules are all illustrative instances of regulatory measures encompassed within patent reform (Chaudhry, 2011). In certain instances, proactive businesses may proactively modify their operational practises prior to the imposition of legal mandates. The mere presence of these supplementary regulatory safeguards diminishes the potential for exorbitant price escalations, even in the absence of their actual implementation.

According to Albutt (2013), the timing of patent decisions exhibits considerable variability. Based on this observation, it is estimated that the average price increase for patented chemicals falls within the range of 3-6%. Notably, more recently developed compounds and those exclusively manufactured by a single entity at the initiation of the patent system tend to experience even higher price increases. Nevertheless, the findings did not yield a statistically significant impact on either the sales volume or the presence of pharmaceutical enterprises within the market.

The relatively small magnitude of the projected consequences presents both positive and negative implications. It appears that in the near future, the implementation of enhanced intellectual property protection is unlikely to result in substantial static inefficiencies. Given India's prominent position as a major exporter of pharmaceutical products, particularly to developing countries, the significance of this matter is further underscored (Albutt, 2013). In 2010, the total value of pharmaceutical products exported from India amounted to approximately $17.2 billion. Vaccines and antiretroviral drugs utilised for the treatment of HIV are illustrative instances of essential commodities that heavily depend on exports to meet the substantial demand within the African, Asian, and Latin American markets.However, drug companies may only notice a little increase in expected revenues due to the absence of a substantial pricing impact. The failure of patents to generate substantial improvements in profits is crucial to any analysis of how companies allocate resources toward developing new products. This research demonstrates that new compounds were not introduced any faster after India adopted a patent regime that complied with TRIPS. This might be the outcome of creative endeavors failing to adapt to variations in projected income. The data strongly demonstrate that the absence of an inventive reaction is most

often driven by slight changes in expected profitability. Thus, the projected small rises in price once the patent expires should not be seen as totally positive.

What may be Patented?

According to subsection (j) of section 2 of the Patent Act, an invention is a novel product with the potential for industrial use. A patent will not be issued for an idea or product that has been utilized or sold by any third party, either in or outside of India. The application for a patent will be invalidated and the invention will not be deemed exclusive if it is already known to someone else (Albutt, 2013). It is imperative to maintain the confidentiality of the innovation until the patent application has been officially filed. The phrase "new" about a product may be used everywhere around the globe. So if there is any document or record which reveals that the innovation has previously been disclosed, utilized, or patented by any other person, a patent for the product will not be awarded in India. Nevertheless, there are some sorts of advances that do not fit within the category of inventions.

Patent Law in India

The pharmaceutical industry in India has been steadily growing as a successful high technology-based industry since the enactment of the Patents Act in 1970, especially in the last three decades. The regulations that were integrated into the Act came from the Paris Convention for the Protection of Industrial Property in 1883 and the Patent Cooperation Treaty in 1970, both of which India was a signatory.

Due to the unavoidable nature of medicine and pharmaceutical products, great skill has developed in the field of drug reverse engineering. Certain pharmaceutical goods are typically able to get patents in industrialised countries, whereas patent applications can be made in India.

As a direct consequence of this, the pharmaceutical industry in India is swiftly creating and distributing a far more cost-effective version of a number of medications that are patented as a result of the Patents Act of 1970. They are also making a concerted effort to establish a strong presence on the foreign market with generic versions of medications whose patents in that country are about to run out.

How does Indian law coordinate with international law to oversee pharmaceutical patents?

The World Trade Organisation (WTO) established trade-related intellectual property rights (TRIPS), and on April 15, 1994, India joined the General Agreement on Tariffs and Trade (GATT), which required adherence to its standards.

The Patents Act of 1970 stipulates that the protection duration must be a minimum of twenty years. The regulatory authority considers the merits of each individual patent application before deciding whether or not to

give a compulsory license, they do this regardless of whether the product in question was made locally or elsewhere. India is therefore required by the TRIPS Agreement to maintain the minimal standards controlling pharmaceutical industry patents.

India is in the process of formulating the Exclusive Marketing Rights (EMR) policy and implementing a mailbox system as part of its efforts to adhere to the commitments outlined in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The aforementioned task will be carried out for a duration of five years or until the outcome of the application is disseminated, contingent upon whichever event occurs earlier, namely acceptance or rejection.

The Patents (Amendment) Act of 1999 incorporated a clause known as "pipeline protection," which confers the applicant with Exclusive Marketing Rights (EMR) if the application is filed on or after January 1, 1995, in any of the countries that are signatories to the Paris Convention. The aforementioned provision was rendered feasible as a result of the enactment of the Patents (Amendment) Act of 1999. If the applicant satisfies the stipulated criteria, the grant of an EMR (Exclusive Marketing Rights) will be facilitated under the provisions of the Patents Law of India. The duration of this grant will span five years, or until the application is either rejected or approved, whichever event occurs earlier.

Because of this amendment, it is now required that the patent application be filed either in India or outside of India, regardless of where the applicant is located. However, the latter calls for prior authorization from the relevant government.

What is the impact of the lack of product patent protection on the pharmaceutical industry?

Given the absence of product patent protection for pharmaceuticals, it is conceivable that multinational corporations may limit their portfolios once their existing patents expire.. As a consequence of this, the company's market share may drop as a result of the introduction of less technologically advanced medications made by local producers who use the method of reverse engineering.

A royalty is collected from the overseas companies that produce medications, and in the meantime, Indian manufacturers are reformulating the most up-to-date molecules from all over the world so that they can offer them on the Indian market. Because of this absence, the patent rights for pharmaceutical goods in India are being systematically weakened, which has resulted in the departure of a number of foreign research-based pharmaceutical companies.

Patent infringement is a concern for a number of large pharmaceutical companies, despite the fact that these companies have stated interest in growing their operations in the Indian market. Because of this risk,

pharmaceutical companies have been forced to proceed with caution when introducing new products until their patents are sufficiently protected to thwart infringement.

The formulation-focused pharmaceutical sector in India is being greatly impacted by the obligations that were brought about by the TRIPS Agreement. Consequently, businesses who want to compete with international corporations have to put their attention on developing new drugs and manufacturing their own proprietary products. Generic medicine production is where most of the money is made for Indian companies, therefore they should focus on that rather than trying to compete with global pharmaceutical giants by developing their own proprietary products.

Current Status of the Pharmaceutical Industry in India

In 2022, the pharmaceutical sector in India has shifted from producing volume to providing value. Covid was a significant obstacle for the pharmaceutical business. Recognizing the condition and then devising a treatment for it was the largest obstacle for Indian and international pharmaceutical companies. Yet, the Indian pharmaceutical sector accepted the challenge and created vaccinations that saved millions of lives. Indian pharmaceuticals have already wowed world leaders with their promise to decrease barriers to drug affordability and accessibility. In 2020, the pharmaceutical business was largely concerned with covid medicines, but by 2022, it had moved its attention to other serious ailments, such as anaemia and cancer.

In addition, the Indian pharmaceutical sector valued research and development highly. By growing its R&D ecosystem and increasing exports of pharmaceuticals, India has become a worldwide medical powerhouse by 2022. The pandemic caused by COVID-19 has impacted the public's opinion of pharmaceutical research. It has highlighted the importance of discovering novel therapeutic modalities, undertaking complex clinical investigations, and building specialised knowledge and skills to traverse the drug development process.

This year, there was a greater degree of collaboration between the government and industry, with each playing a significant role in assisting the sector expand its position on the global market. As a result of COVID-19, the pharmaceutical business has undergone a paradigm shift, and the government and industry have been increasingly united, resulting in a growing feeling of partnership.

In recent years, the pharmaceutical business has experienced great growth, and the view for 2023 remains optimistic.It is projected that the industry's value will surpass $1 trillion within the upcoming year. Currently, a significant number of compounds are undergoing advanced clinical testing, with the expectation that numerous new medications will receive approval in 2023 and subsequent years. The current accumulation of pharmaceutical products is unparalleled and has not been witnessed in more than ten years.

According to projections, the pharmaceutical industry in India is anticipated to reach a valuation of $65 billion by 2024 and $130 billion by 2030.

The current valuation of India's pharmaceutical industry is estimated to be $50 billion.

India's pharmaceutical exports currently cater to a substantial number of nations, surpassing the count of 200. This signifies India's significant role as a prominent participant in the global pharmaceutical export market. India currently fulfils approximately 50% of Africa's demand for generic medications, as well as approximately 40% of the United States' demand for generics and around 25% of the total medicine requirement in the United Kingdom.

Moreover, India plays a significant role in meeting more than sixty percent of the global demand for vaccines, serving as a major supplier of DPT, BCG, and measles vaccines. As per the essential immunisation schedule, India serves as the primary provider of seventy percent of the vaccinations administered by the World Health Organisation.

In the fiscal year 2021-22, the average Index of Industrial Production of Manufacture of medicines, medicinal chemicals, and botanical goods is 221.6, representing a 1.3% increase over the previous year.

When compared to the figure of $24.44 billion for the year of 2020-21, the value of the export of pharmaceutical products and pharmaceuticals reached $24.6 billion during the period of 2021-22. During the period of 2014-22, the pharmaceutical business in India had exponential growth of 103%, going from $11.6 billion to $24.6 billion in revenue.

Conclusion

Although the pharmaceutical industry submits many patent applications, there is very little clinical translation. Logically, the generic market currently dominates the Indian pharmaceutical sector, and invention plays a very small role in its growth. The primary causes of this appear to be soiled work in each field, a lack of appropriate interdisciplinary collaboration between preclinical and clinical scientists, inadequate funding, diverse interests of the relevant sectors, a lack of systematic workforce training, and a lack of visionaries. Collaboration between business and academia and the creation of quality control organizations can be helpful in this approach.

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