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RESEARCH PAPER ON ABUSE[1] OF PHARMACEUTICAL PATENTS

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ABSTRACT

The abuse of pharmaceutical patents has become a growing concern in the global healthcare system. While patent protection is intended to promote innovation by granting temporary market exclusivity to drug developers, this system is often exploited to delay the entry of affordable generic medicines. Practices such as patent evergreening, strategic litigation, and the creation of patent thickets enable pharmaceutical companies to maintain monopolies far beyond the original intent of patent laws. This abuse not only inflates drug prices but also restricts access to life-saving treatments, particularly in developing and under-resourced regions. This explores the various forms of patent abuse, its impact on public health and healthcare systems, and the urgent need for policy reforms. Emphasizing the balance between rewarding innovation and ensuring equitable access to medicines, the study calls for stricter regulatory oversight and global collaboration to prevent the misuse of intellectual property rights in the pharmaceutical industry.

INTRODUCTION

Pharmaceutical patents are intended to protect and incentivize innovation by granting companies exclusive rights to produce and sell new drugs for a limited period. This system is designed to encourage investment in research and development, ultimately leading to medical breakthroughs that benefit society. However, in practice, this well-meaning framework is often manipulated by some pharmaceutical companies to maximize profits at the expense of public health. Through tactics such as extending patent life unnecessarily, blocking generic competition, and exploiting legal loopholes, these companies can maintain monopolies on essential medicines. As a result, access to affordable healthcare becomes a significant challenge, especially in low- and middle-income countries. international cooperation to ensure that the patent system serves both innovation and the broader public interest.

1. UNDERSTANDING PATENT ABUSE IN PHARMACEUTICAL IN INDIA AND GLOBALLY

Patent law in India has provisions for a more stringent bar and an extra test to determine whether or not drugs are patentable. Under the provisions of section 3(d) of the Patents Act, pharmaceutical patents are required to be subjected to a test in addition to originality and inventive step. According to the provisions of Section 3(d), "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance" is not eligible for patent protection under the Act. According to the explanation provided for the section, compounds such as salts, esters, and polymorphs are to be deemed to be the same drug unless there is a significant difference between them in terms of the efficacy that is known to be associated with the substance.

According to the explanation provided in section 3(d), there are numerous categories of substances, and the absence of an appropriate interpretation has frequently resulted in

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unfavorable outcomes for advances. The determination of what constitutes "a known substance" and what constitutes its "known efficacy" is sometimes inconsistent and left up to the examiner's interpretation, which is one of the primary issues. Additionally, primary patents are frequently made use of and exploited in accordance with Section 3(d).

There are numerous instances in which a single application contains more than six pre-grant oppositions. Grants are delayed unnecessarily as a result of these pre-grant oppositions, which can occasionally include oppositions with no name (sometimes known as "benami" oppositions). In the case of ***Dhaval Diyora v. Union of India and Others***, the Mumbai High Court expressed its strong disapproval of such benami oppositions and pointed out that the legislature had not granted the power to abuse the right under section 25(1) to any individual. During the time that it was in existence, the Intellectual Property Appellate Board (IPAB) took a strong stance against benami pre-grant oppositions. In order to prevent the filing of pre-grant oppositions by benami or fictitious applicants, the IPAB issued a directive that "any person" who filed a pre-grant opposition must present their valid Aadhar card, voter ID, passport, or driving licence in order to authenticate their identity.

The success of the pharmaceutical sector in the United States is dependent on striking a reasonable balance between access and innovation. Pharmaceutical businesses who are well-known for their success in finding and producing breakthrough treatments and cures that enhance the quality of life for all people are awarded for their efforts.

On the other hand, we are increasingly seeing evidence of how the patent system is being used to tip the scales and delay patient access to a point that is well beyond what Congress intended. A recent research by I-MAK found that the top 12 brand pharmaceuticals that were available on the market in the previous year were covered by a total of 848 patents, with 71 patents for each drug. This means that there was an average of 38 years without generic competition. Just a few samples taken from the report:

- The medication Humira, which is the most popular brand drug in the world, is used to treat arthritis and other chronic illnesses. There are 132 patents that have been on the market since 2002 and they prevent competition for up to 39 years. Revlimid, which is one of the most commonly prescribed cancer medicines, was granted approval by the FDA in the year 2005.
- Patients[2] with diabetes who rely on the insulin medication Lantus may not see a generic option for 37 years due to the 49 patents that have been issued. The patent thicket is comprised of 96 patents, which could provide a period of 40 years without competition. Nevertheless, patients are forced to pay higher dr[3]ug prices for a longer period of time as a consequence of the widespread exploitation of the patent system to construct barriers to competition from generic and biosimilar products.

2. FORMS OF PATENT ABUSE

Typical types of patent abuse includes the following:

During the first eight decades of the twentieth century, a variety of patent licensing practices led to court rulings that ruled that patents were being misused. The patentee was perceived to have overreached in each and every one of these cases. In the event that a patent is misused, the patent in question will become unenforceable until the misuse is remedied. This can be accomplished by releasing the contractual covenant that was violated and waiting for a period of time for the anticompetitive effects to fade away.

Misuse was a powerful defence since it could be invoked by anybody, not just the licensee who was bound by the restrictions itself. Plaintiffs in patent infringement lawsuits continue to seek discovery of licenses with other parties that are covered by the patent that is the subject of the

lawsuit. They do this in the hope that they may uncover a misuse provision in one of the licenses, which would provide the defendant, who is not familiar with the license, with a comprehensive defence against the patent. There is not a single instance of case law in this field that has been overruled directly. On the other hand, a significant portion of the abuse doctrine has been relegated to a rule of reason rather than a per se analysis as a result of an increasing emphasis on reasonableness and market power in statutory amendments (35 U.S.C.

§ 271(d)) and in court decisions. The patentee will only sell the patented product if the purchaser agrees to purchase another product or service in addition to the patented product. This is known as mandatory tying.

1. Licenses for patent A will only be granted to the licensee if the licensee also obtains a licence for patent B. This is referred to as mandatory package licensing.

2. An obligatory royalty base that is excessively broad where the patentee asks that royalties be determined based on products that are not covered by the patent. As an illustration, the patent covers painkiller XX, and the patentee is demanding a payment that is calculated as a percentage of the licensee's sales of all painkillers.

3. An agreement to refrain from dealing in non-patented items that are competitive. In most cases, patents do not cover all products that are of a comparable nature and quality. When a patent covers painkiller XX, it is a misuse to demand a covenant that the licensee will not sell any other painkillers throughout the period of the license. This is true even in an exclusive license with duties to make best efforts.

It is important to keep in mind that all of the aforementioned scenarios include coercion. When the licensee wants a package licence, wants to pay a reduced fee based on all goods of a certain category (all painkillers), wants to pay royalties out over a longer length of time than the patent term, or wants to pay royalties out for financial reasons, etc., there is no misuse of the patent.

3. LEGAL FRAMEWORK PREVENTING PATENT ABUSE IN INDIA AND GLOBALLY

Indian Scenario

During the time that the concept of intellectual property was initially conceived, India was governed by the British. Acts pertaining to copyright, trademarks, designs, and other concepts were also enacted during this time period. In 1856, the Patent Act was initially enacted, and five years later, in 1859, it was updated. The only laws that the Parliament of India is able to enact are those that pertain to patents, inventions, designs, copyrights, and trademarks.

European Union Scenario

There are two different patent systems that are now in use in Europe.

1. It is possible to get patents that cover up to 38 European countries, including the United Kingdom, according to the regulations that are established by the European Patent Organization. On October 7, 1977, the European Patent Organisation (EPO) was established, and the cornerstone for its establishment was the European Patent Convention, which had been agreed in Munich in 1973.

2. The European Patent Office (EPO) is comprised of two different organizations: the Administrative Council and the European Patent Office.

Within the European Patent Office, the Administrative Council is in charge of supervising the activities that take place within the office. European Patent Office is the executive division of the European Patent Organisation (EPO). Equal opportunities are available to both individual inventors and businesses that are interested in obtaining patent protection in any of the 38 European nations that are listed by the European Patent

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Office.

United States of America Scenario

It is true that the histories of patent law in both the United States and Europe have been fraught with controversy. In the United States, the very first Patent Act was only in effect for a span of three years, from 1790 to 1793. Almost immediately, it was superseded by a new Patent Act that included an examination procedure. This further prevented exploitation by ensuring that the product was inspected prior to the acquisition of the patent. Even though the United States patent system is not exactly the same as it was in 1790, the prerequisites for applying for a patent are, for the most part, the same as they were back then.

In 1836, a third Patent Act was passed in order to address the problems that were caused by the first two Patent Acts. This event marked the beginning of operations at the Patent Office. The Secretary of State was no longer in charge of issuing patents, despite the fact that the Department of State remained to have power over the process.

4. NOTABLE PATENT CASE STUDIES

On the one hand, the government of India is working hard to increase the number of pharmaceuticals that are available at low prices in order to make treatment more accessible to all groups of people. On the other hand, patent holders [4]are facing pressure to extend the duration of their patent rights and maintain their market monopoly. The effort that is being made by patent holders is motivated by a self-serving desire to keep royalty income from the commercial exploitation of the patents that they possess and to maintain exclusive rights over the production of the medications that are being marketed towards the market. This will allow them to continue to be the dominant force in the market for a few more decades.

The Novartis case: Indian judiciary's opposition to patent evergreening

The recent verdict by India's Supreme Court regarding the Novartis case has highlighted the issue of patent evergreening. Novartis, a Swiss pharmaceutical corporation, aimed to secure a patent for an enhanced formulation of its cancer medication Gleevec, asserting its superior efficacy in combating leukemia. India's patent legislation, particularly Section 3(d) of the Patents Act of 1970, forbids evergreening by disallowing the issuance of patents for trivial alterations of existing patents.

Novartis contested the legitimacy of Section 3(d) in court, asserting that it violated international treaties, including the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement and Article 14 of the Indian Constitution. The case traversed multiple stages, encompassing the Madras High Court and the Intellectual Property Appellate Board, before to arriving at the Supreme Court of India. The two-judge panel of the Supreme Court dismissed Novartis' appeal, asserting that their patent application lacked demonstrable novelty upon comprehensive comparison with the existing patent, hence precluding the issuance of a new patent to avert evergreening.

The Indian Supreme Court agreed with the IPAB's conclusion that Novartis did not establish "enhanced therapeutic efficacy" over the prior patented invention, hence failing to meet the conditions outlined in section 3(d). The subsequent concepts can be derived from the Novartis case to address the issues posed by section 3(d):

i. Assessing the novel formulation of the established invention and its effectiveness regarding pharmacological characteristics;

ii. Analysing the pharmacological properties [5]of the prior and novel formulations of the established compound;

iii. Incorporating comparative data on enhanced efficacy through affidavits or in the patent application process;

iv. Excluding physicochemical factors such as "superior flow characteristics," "enhanced thermodynamic stability," and

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"decreased hygroscopicity" when evaluating therapeutic efficacy;

v. The therapeutic efficacy of medications should be evaluated with strict precision.

vi. The application must explicitly claim and support through research findings a correlation between bioavailability and enhanced therapeutic efficacy;

vii. For patents pertaining to pharmaceuticals and chemicals, the innovator must demonstrate not only improved efficacy but also that the new substance constitutes a "invention" and involves a "inventive step."

Nevertheless, the Court did not elucidate the definition of "enhanced efficacy" in accordance with section 3(d), leaving it subject to interpretation. The alterations in patent legislation in India exerted considerable extraterritorial impact. The European Union and the United States both vehemently opposed India's initiative to overhaul and restructure patent regulations to curtail evergreening.

The Supreme Court's decision against patent evergreening is a crucial measure to curtail the exploitation of patent monopolies and foster authentic innovation within the pharmaceutical sector. It maintains the purpose of the Patent Law of 1970, which seeks to guarantee that patents are awarded solely for genuinely unique and non-obvious discoveries, rather than for trivial modifications to already protected products. This ruling has significant ramifications, since it preserves access to cheap medications for people in need, fosters authentic innovation, and protects the public interest in healthcare.[6]

AstraZeneca's patent on Losec™

Commentators addressing the "evergreening" issue in Australia frequently highlight AstraZeneca's patent on Losec™, a pharmaceutical utilised to diminish stomach acid, which contains the active element omeprazole.[i] The High Court of Australia confirmed the validity of the Losec patent, although the corresponding patent in the United Kingdom was deemed invalid. Upon examining the context surrounding the development of the Losec formulation, it becomes evident that the Australian High Court was warranted in affirming the patent's validity.

Despite the initial patent application for omeprazole being submitted in 1978, it was not until 1985 that AstraZeneca developed an appropriate commercial formulation for the effective delivery of the active compound to patients. A multitude of challenges needed to be surmounted to get this formulation. The initial issue was that omeprazole is acid-sensitive, indicating that it would decompose upon contact with gastric acid. A further issue affecting the bioavailability of omeprazole is its limited solubility in water. The enteric coating enables the formulation to traverse the stomach without exposing omeprazole to gastric acid. Upon traversing the stomach, the enteric coating and the water-soluble sub-coating disintegrate, facilitating the absorption of omeprazole in the proximal small intestine.

No evidence was offered at the trial indicating that omeprazole or its qualities constituted part of the common general knowledge in the field in Australia. One of Alphapharm's witnesses received information about omeprazole and its characteristics and was prompted by Alphapharm's solicitors to delineate the procedures he would undertake to create an appropriate formulation Despite receiving information regarding omeprazole and its characteristics, and being urged by Alphapharm's legal representatives, he failed to deduce the purportedly evident formulation asserted in the patent.

Abbott's patent for Norvir™

NorvirTM, an anti-HIV/AIDS medication marketed by AbbVie, is frequently referenced in discussions of "evergreening[7]" and contains the active ingredient ritonavir. The grievance against AbbVie, or more specifically Abbott, who initially marketed the medicine, seems to pertain to the quantity of patents submitted to safeguard the active ingredient and its mixtures

with other substances. Patients afflicted with Hepatitis C express great satisfaction that AbbVie continued its research on ritonavir and its combinations with other medicines, resulting in the recent approval of a novel antiviral combination using ritonavir for the treatment of Hepatitis

C. Reports indicate that this combination of antiviral medicines has attained a 97% cure rate for individuals afflicted with Hepatitis C.

The challenges in locating a stable form of ritonavir for pharmaceutical applications exemplify the significance of selecting a suitable form of an active ingredient for inclusion in a commercial pharmaceutical product. The initial variant of ritonavir, referred to as Form I, appeared suitable for inclusion in Abbott's Norvir product. At that time, this formulation of ritonavir exhibited adequate solubility and stability, with no evidence suggesting instability.

In 1998, an incident occurred at the US manufacturing site that resulted in the manufacture of a novel crystal form of ritonavir, designated as Form II.3 Due to the greater thermodynamic stability of Form II compared to Form I, Abbott soon encountered difficulties in producing ritonavir in its original form. Scientists from the US reportedly visited another manufacturing plant in Italy and poisoned the environment with crystals of the new Form II. Subsequently, Abbott was unable to produce ritonavir in its original formulation at the Italian manufacturing site. Ultimately, Abbott successfully identified a resolution[8] to the stability issue and introduced a new formulation of ritonavir that need refrigeration.

5. IMPACT OF PATENT ABUSE

In spite of the fact that there are several negative consequences that result from unethical corporate actions in patent law, these problems are broken down into a few distinct categories. In order to comprehend the reasons why it is even a problem, it is essential to investigate its repercussions. For the most part, developing countries [9]are the ones who suffer the negative consequences of patent law abuse. This is because they are less likely to pay attention to and care for medications that are seen to be less profitable than those that are aimed at wealthy countries.

Large pharmaceutical companies are primarily concerned with the production of pharmaceuticals that generate profits, which can have a significant negative impact on both innovation and the quality[10] of life for individuals. There is evidence that pharmaceutical corporations concentrate their research and development efforts on chronic diseases, which have a large number of clients who last a lifetime. The financial support of research and development initiatives is not interested in supporting anti-parasitic or antibiotic medication, despite the fact that these medications are prevalent in less developed nations population. It is interesting to note that developing nations, in comparison to developed nations, do not place a greater focus on possessing more stringent patent rules. This is due to the fact that the expenses of maintaining patents in a developing nation are too costly in the short term. Any earnings that are generated as a result of the technology investments are then reinvested in international corporations based in other countries.

6. MEASURES TO PREVENT PATENT ABUSE

Altering the major form of patent legislation that is employed and providing state governments with increased control over business practices that are carried out by third parties are two ways in which the application of patent law can be improved. When taken together, these factors have the potential to produce an atmosphere that inhibits immoral behavior on the part of companies in communities where the consequences would be significantly damaging. The aforementioned corporate social responsibility[11] (CSR) and social obligations, which comprise both the business and ethical perspectives of the patent law issue, should be taken into mind when these

proposals are taken into consideration.

In order to stop imitation while yet encouraging innovation, the type of patent legislation is quite important. Patent laws have the potential to protect individuals against others stealing their work or ideas; nevertheless, for the purpose of preventing pricing or information monopolies, these rules need to be controlled by the government. Despite the fact that the pharmaceutical business[12] in India invests only 1.6% of its sales into research and development, in comparison to the 15% that is invested in Research and Development in Western nations, these corporations have enhanced cost advantages and innovation. There is a direct correlation between the use of process patents and the aforementioned benefits. Product patents, on the other hand, have the potential to hinder innovation.

7. ETHICAL CONSIDERATIONS

The practice of evergreening pharmaceutical patents is a contentious tactic employed by pharmaceutical corporations to prolong their patent protection beyond the typical duration. This is frequently achieved by making slight alterations to existing medications, such variations in dosage forms, release mechanisms, or the introduction of new salt forms, which do not substantially improve therapeutic efficacy. Although patents are crucial for fostering innovation, evergreening is frequently condemned as a misuse of the system that favours profit over patient well-being.

- **Access to Fundamental Pharmaceuticals**

One of the most urgent ethical issues of evergreening is its impact on the pricing and accessibility of important medications. Pharmaceutical firms maintain artificially elevated medicine prices by postponing the introduction of generic alternatives, rendering life-saving treatments expensive for numerous patients, particularly in low-income nations. This practice intensifies healthcare inequity, as individuals who require these medications most frequently face accessibility issues due to financial constraints. Furthermore, evergreening extends the financial strain on healthcare systems by compelling governments and insurance companies to dedicate substantial resources on costly patented medications rather than investing in comprehensive public health efforts. In nations with government-funded healthcare systems, such as the National Health Service (NHS) in the UK or Medicaid in the U.S., extended patent protection leads to heightened expenses, thereby diminishing the resources allocated for other essential medical operations.

- **Exploitation of the Patent System**

Evergreening utilizes legal loopholes in the intellectual property framework to prolong monopoly rights beyond what is warranted by authentic innovation. Pharmaceutical corporations frequently implement slight alterations to current medications such as varying formulations, combinations, or delivery mechanisms that may not enhance clinical efficacy yet still meet the criteria for new patents. The ethical concern is that by issuing patents for insignificant modifications, regulatory bodies allow pharmaceutical companies to exploit the system to the detriment of patients and healthcare providers. In several jurisdictions, including India, legislation such as Section 3(d) of the Indian Patent Act seeks to mitigate this misuse by necessitating evidence of improved efficacy for patent prolongation.

- **Effects on Public Health Systems[13]**

The financial strain of evergreening transcends individual individuals, impacting entire public health systems. When vital medications are subject to prolonged patents, governments are compelled to allocate billions to branded pharmaceuticals rather than investing in preventive healthcare, infrastructure, or disease eradication initiatives. The misallocation of resources has enduring repercussions,

particularly in nations grappling with significant illness loads and constrained healthcare budgets. Another ethical dilemma pertains to the strong marketing strategies employed to promote evergreen pharmaceuticals. Pharmaceutical corporations frequently persuade physicians and healthcare professionals to prescribe costly, patented medications instead of similarly effective generics. This engenders a conflict of interest and prompts enquiries over the integrity of medical experts potentially influenced by corporate incentives.

- **Ethical Obligations of Pharmaceutical Corporations**

Pharmaceutical firms possess a corporate social responsibility (CSR) to reconcile profits with ethical duties to society. Evergreening undermines the ethical tenet of egalitarian healthcare by limiting access to affordable medications to prolong market exclusivity. Although corporations contend that extended patent protection facilitates additional research and development, evidence indicates that a significant portion of the profits derived by evergreening is allocated to marketing [14]and litigation rather than innovation. Ethical business practices must encompass enhanced openness in pharmaceutical pricing, patent filings, and research and development expenditures. Governments and regulatory authorities must guarantee that patent laws are not manipulated to the detriment of patient welfare. Companies ought to implement ethical pricing solutions to enhance the affordability of important medicines in low-income areas, utilizing either voluntary licensing agreements or price regulations.

CONCLUSION

The misuse of pharmaceutical patents poses a serious threat to global healthcare, as corporate profit often takes precedence over the well-being of the public. Although the original purpose of patents is to foster innovation by compensating pharmaceutical companies for their investment in research, unethical practices can result in extended market control, increased medication costs, and limited availability of essential drugs—particularly in developing nations. Strategies like evergreening, dense patent layering, and exploitation of legal gaps distort the true purpose of patent systems by favoring profit over patients needs. To tackle this problem effectively, a well-balanced strategy is necessary that safeguards true innovation while promoting fair access to affordable treatments. encouraging open drug pricing, and backing global initiatives that emphasize health over high profit margins.

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