Intellectual property rights in the pharmaceutical industry: Access to medicine vs Patent protection

Abstract:

This article delves into the intricate relationship between Intellectual Property Rights (IPR) and access to medicine within the pharmaceutical industry. It grapples with the challenge of harmonizing robust patent protection with the imperative of providing broad access to vital medicines, especially in economically constrained and developing regions. By analyzing pivotal legal cases and international agreements, the article advocates for a nuanced approach that strikes a balance between incentivizing innovation and safeguarding public health imperatives. This paper will deal with morals and socialism regarding the supply of medicine. It will examine what should be the stand of any developing country while patenting important medicines/drugs for the human race.

Introduction:

Patent laws are one of the important domains of Intellectual property laws. It protects innovations and inventions which is unique and has industrial applicability. A patent grants inventors exclusive rights to their inventions, giving them a temporary market monopoly in exchange for publicly disclosing their work. Patents boost a nation's economy by facilitating inventions. The pharmaceutical industry, which is at the forefront of medical advancements, faces a challenge in balancing the protection of intellectual property rights (IPR) with the equitable distribution of life-saving medications. This dilemma revolves around the concept of patents, which are essential for encouraging innovation. Patent system has undoubtedly driven pharmaceutical innovation, but it also raises important questions about access to medicine, particularly in light of global health disparities.

Examining the foundations of patent law reveals that its underlying aim is to strike a delicate balance. By granting inventors a temporary monopoly, patents aim to stimulate investment in research and development, leading to advancements that benefit society as a whole. However, in the field of pharmaceuticals, where the outcomes of innovation can mean the difference between life and death, this balance is challenged by the urgent need to ensure widespread access to essential medications.

India, with its thriving pharmaceutical industry and dedication to public health, plays a crucial role in this discussion. The Indian Patents Act, 1970 with its flexibilities and safeguards, attempts to navigate the delicate balance between incentivizing innovation and protecting public health. This paper lays the groundwork for an exploration of the evolving relationship between intellectual property rights, particularly patents, and the imperative of ensuring access to medications within the dynamic landscape of the pharmaceutical industry in India and beyond.

Intellectual property rights in the pharmaceutical industry: Access to medicine vs Patent protection

IPR in Pharmaceutical Industry:

The pharmaceutical industry, a vital component of global healthcare, operates on a delicate balance between innovation, competition, and the preservation of intellectual property rights (IPR). IPR encompasses patents, trademarks, copyrights, and trade secrets, but it is the patent system that holds the most sway in the pharmaceutical realm. Patents grant exclusive rights to inventors for a limited period, acting as a powerful incentive for companies to invest in the high-risk, high-reward world of medicines and drugs.

The underlying logic behind pharmaceutical patents is to strike a balance between encouraging innovation and providing a mechanism for companies to recover their substantial research and development investments. This exclusivity empowers pharmaceutical companies to bring new and often groundbreaking medications to market, fostering a competitive environment that drives continuous advancements in medical science. However, this balance is not without its challenges, and this is nowhere more evident than in the tension between the need for robust patent protection and the imperative of ensuring access to essential medicines. The high costs associated with pharmaceutical research, clinical trials, and regulatory approvals often translate into inflated drug prices, creating barriers to access, especially in economically disadvantaged regions.

The global pharmaceutical landscape operates within the framework of international agreements, with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement being a cornerstone. TRIPS establishes minimum standards for the protection of intellectual property, including patents, on a global scale. This agreement, while providing a unified approach to IPR, also allows flexibility for countries to implement measures that safeguard public health, such as compulsory licensing and the promotion of generic drug production.

In India Patents are regulated by The Patent Act, 1970. It has undergone significant amendments, balancing the interests of innovators with the imperative to make innovations affordable and accessible. The introduction of product patents for pharmaceuticals in 2005 marked a crucial turning point, aligning India with global patent norms while retaining certain flexibilities to

protect public health. The new provision (Section 92A) relates to compulsory licence for export of patented pharmaceutical products to such countries, that have inadequate production capacities.[1]

As we delve into the complexities of IPR in the pharmaceutical industry, it becomes clear that the landscape is constantly evolving. Legal battles, policy changes, and ethical considerations continually shape the discourse, prompting a nuanced exploration of how the delicate equilibrium between innovation and accessibility can be maintained in the face of global health challenges. This exploration serves as the foundation for a comprehensive understanding of the multifaceted interplay between intellectual property rights and the quest for equitable access to medicines in the pharmaceutical sector.

TRIPS Agreement and Its Impact:

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement is a key pillar of the World Trade Organization (WTO). It establishes minimum standards for the protection of intellectual property rights, including patents, trademarks, and copyrights. Enforced in 1995, TRIPS has had a significant impact on the pharmaceutical industry, where the balance between innovation and public health is a constant challenge. TRIPS requires member countries to adopt and enforce measures to protect intellectual property rights. In the pharmaceutical context, this means that member nations must grant a minimum 20-year patent protection period for new pharmaceutical inventions. This standardized approach has both positive and negative implications for global healthcare dynamics.

TRIPS includes certain flexibilities that allow member countries to implement measures to safeguard public health. For example, TRIPS allows countries to grant compulsory licenses, which permit the production and sale of generic versions of patented drugs without the consent of the patent holder. This can help to lower drug prices and improve access to essential medicines for people in need.

[2]Overall, the TRIPS agreement plays a complex role in the pharmaceutical industry. It has helped to stimulate innovation, but it has also raised concerns about access to essential medicines.

[1] The Patents Act, 1970, § 92A, (India).
[2] Jayashree Watal, Implementing the TRIPS Agreement: Policy Options Open to India, 32 Economic and Political Weekly 2461 (1997).

Intellectual property rights in the pharmaceutical industry: Access to medicine vs Patent protection

Important cases in India:

- *Novartis AG Vs. Union of India (UOI) and Ors.*[3]

In 1998, Novartis applied for a patent in India for its cancer drug Glivec. The Madras Patent Office rejected the application on the grounds that the drug was not novel or non-obvious and did not exhibit any major changes in therapeutic efficacy over its pre-existing form. Novartis appealed the decision to the Intellectual Property Appellate Board (IPAB), which also dismissed the appeal. Novartis then filed a Special Leave Petition (SLP) with the Supreme Court of India.

The Supreme Court rejected Novartis's appeal in April 2013. The Court held that the beta crystalline form of Imatinib Mesylate is a new form of a known substance, Imatinib Mesylate, and that the efficacy of Imatinib Mesylate was already well known. The Court also held that an increase in bioavailability does not necessarily qualify as an increase in therapeutic efficacy. Finally, the Court held that Novartis failed to prove that the therapeutic efficacy of the beta crystalline form of Imatinib Mesylate is more than that of Imatinib Mesylate.

The Supreme Court's decision is a significant victory for public health. It will help to prevent ever-greening of patents, which is the practice of obtaining new patents for minor changes to existing drugs. This will make it easier for generic drug manufacturers to produce and sell affordable versions of important medications.

- *Bayer Corporation vs. Union of India*[4]

Natco Pharma Ltd. ("Natco") applied to the Controller General of Patents, Designs and Trademarks ("Controller") for a compulsory license to manufacture and sell a generic version of Bayer's patented drug. The Controller granted the compulsory license, and Bayer appealed to the Intellectual Property Appellate Board and the Bombay High Court. Both the Appellate Board and the High Court upheld the decision of the Controller.

The courts found that Natco had made reasonable efforts to obtain a voluntary license from Bayer, but that Bayer had refused to grant one. The courts also found that the patented drug was

[3] Novartis AG Vs. Union of India (UOI) and Ors., MANU/SC/0281/2013.

[4]*Bayer Corporation vs. Union of India*, MANU/MH/0986/2014.

not available to the general public at a reasonably affordable price. Finally, the courts found that Bayer had not worked the patent in India, and therefore, there was no reason to adjourn the consideration of Natco's application for a compulsory license.

The Supreme Court of India dismissed Bayer's appeal, upholding the decision of the Bombay High Court. The Court noted that the aim of the Patents Act is to increase the availability of patented articles at reasonable prices. The Court also highlighted the need for a balanced approach to patent law that considers both the interests of patent holders and the public interest in promoting access to essential medicines.

- *Hoffmann-La Roche Ltd. and Ors. Vs. Cipla Limited* [5]

In the case of Hoffman-La Roche and Pfizer versus Cipla, the central dispute revolved around the patented cancer drug Erlotinib. The Plaintiffs alleged patent infringement by Cipla, seeking a permanent injunction and damages. Key issues included the validity of the Plaintiffs' patent, the enforceability by Hoffman-La Roche despite Pfizer being the patentee through a licensing agreement, and whether infringement occurred. The Plaintiffs contended a valid patent, emphasizing their role in meeting market demand.

The Single Judge initially rejected the Plaintiffs' interim injunction, citing public interest due to the drug's life-saving nature and accessibility concerns. The trial favored Cipla, emphasizing the anti-evergreening provision in Section 3(d) of the Patents Act. However, the Division Bench partially reversed the decision, employing the "Markmen Test" to assess infringement by comparing patent claims and the alleged infringing product.

The Division Bench found in favor of the Plaintiffs, determining that Cipla's product infringed the patent, and awarded damages. This case, one of the first post-2005 amendments to the Patents Act, clarified the application of the "anti-evergreening" provision and established standards for measuring patent infringement.

[5]F. Hoffmann-La Roche Ltd. and Ors. vs. Cipla Limited, MANU/DE/0517/2008.

Intellectual property rights in the pharmaceutical industry: Access to medicine vs Patent protection

Challenges in the COVID-19 Era:

The global response to the COVID-19 pandemic has spotlighted the intricate interplay between intellectual property rights and public health imperatives. The rapid development of vaccines, while a monumental achievement, has sparked debates around equitable access due to patent protection. A significant proposal at the World Trade Organization suggests a temporary waiver of TRIPS agreement provisions by India and South Africa, aiming to broaden access to COVID-19 technologies, particularly in low-income countries. Compulsory licensing has been explored as a means to address supply constraints, while debates on the waiver continue, with proponents emphasizing the urgency of global health over intellectual property concerns. Technology transfer and capacity building are also emerging as crucial elements in the discourse, highlighting the importance of collaboration and knowledge-sharing. As the legal landscape evolves, striking a balance between innovation incentives and global health equity remains a dynamic and complex challenge in the ongoing fight against the pandemic.[6]

Conclusion:

This paper delves into the intricate relationship between Intellectual Property Rights (IPR) and access to medicine in the pharmaceutical industry. Advocating for a nuanced approach, it highlights the delicate balance needed to harmonize robust patent protection with the imperative of providing broad access to vital medications.

Examining India's role, particularly through the Indian Patents Act and subsequent amendments, the study navigates the tension between incentivizing innovation and protecting public health.

Key legal cases in India, such as Novartis vs. Union of India and Bayer Corporation vs. Union of India, demonstrate the delicate balance between patent protection and public interest.

In conclusion, the dynamic interplay between intellectual property rights and global health, underscored by the challenges posed by the COVID-19 pandemic, demands a multifaceted and collaborative approach. Only through collaborative efforts and adaptive legal frameworks can we hope to overcome not only the immediate challenges posed by the pandemic but also to fortify the global community against future health crises.

[6] Emmanuel Kolawole Oke, Access to COVID-19 Vaccines, Patent Rights, and the TRIPS Agreement, 36 MD. J. INT'l L. 7 (2021).

Intellectual property rights in the pharmaceutical industry: Access to medicine vs Patent protection

AUTHOR-ADVOCATE VIKAS AWALE

CO-AUTHOR-ADVOCATE YASH LOTLIKAR