International Journal of Engineering Applied Science and Management
ISSN (Online): 2582-6948
Vol. 2 Issue 8, October 2021

Striking a Balance: IPR and Patent law Access to Essential Medicines in Developing Countries

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Abstract: *Access to essential medicines remains a major hurdle in developing countries despite the UN recognizing the right to health. High costs of patented drugs create a barrier, as developed nations leverage TRIPS agreements to extend pharmaceutical monopolies. This sparks a debate between the right to health and intellectual property rights. While patents incentivize drug development, they can restrict access. The challenge lies in balancing innovation with affordability. Possible solutions include compulsory licensing for generic production and tiered pricing by pharmaceutical companies. Ultimately, a global approach is needed, with developed nations acknowledging the impact of TRIPS and developing countries striking a balance between innovation and affordability. Only through collaboration can everyone access the essential medicines they need.*

Keywords: *Human Rights, Right to Health, Intellectual Property Rights, Patents, Compulsory Licenses, Doha Declaration, Pharmaceutical Patents.*

1. Introduction

The Patents Act, 1970, established in India to protect inventors' interests, has undergone significant amendments. The 2005 amendment, allowing product patents for pharmaceuticals, ignited a debate on balancing the right to health with intellectual property rights. Prior to 2005, India dominated the generic medicine export market, offering a vast array of affordable drugs. However, the product patent amendment has triggered a decline in generic production. Limited technology transfer from patent holders hinders generic manufacturers' ability to replicate drugs. Additionally, the fear of trade sanctions discourages generic production, and even after product patents expire, non-infringing patents held by originators can restrict generic alternatives. This decline in affordable medicines directly impacts access to essential healthcare, particularly for critical medications like cancer treatments.

This situation highlights the conflict between the fundamental right to health, enshrined in the UN Declaration of Human Rights, and the individual-oriented rights granted by intellectual property rights. While intellectual property rights incentivize research and development, they can also create barriers to access. Finding a solution requires navigating this complex relationship. India must strike a balance between fostering domestic innovation and ensuring affordable healthcare for its citizens[1].

2. Balancing Innovation and Access to Medicine in India

India's Patents Act, established in 1970 to protect inventors, has been a point of contention. The 2005 amendment, allowing product patents for pharmaceuticals, ignited a debate on balancing the right to health with intellectual property rights. Prior to 2005, India dominated the generic medicine market, offering affordable drugs for diseases like tuberculosis, HIV/AIDS, and cancer. However, the product patent amendment has triggered a decline in generic production due to several factors. Limited technology transfer from patent holders hinders replication, and the fear of trade sanctions discourages generic production. Even after product patents expire, non-infringing patents held by originators can restrict generic alternatives. This decline directly impacts access to essential healthcare, particularly for critical medications. This situation highlights the conflict between the fundamental right to health, enshrined in the Indian Constitution, and intellectual property rights. While intellectual property rights incentivize research and development, they can also create barriers to access. Finding a solution requires navigating this complex

relationship. India must strike a balance between fostering domestic innovation and ensuring affordable healthcare for its citizens [2].

2.1 Human Rights and Intellectual Property: A Global Challenge

The concept of human rights in intellectual property (IP) rights is linked to international conventions. Understanding the legal frameworks for both rights, both nationally and internationally, is crucial. Intellectual property rights exist to protect the interests of inventors and creators, while human rights are inherent entitlements every person possesses. This raises questions about the impact of intellectual property on basic human rights, particularly the right to health. The World Trade Organization (WTO) and the World Health Organization (WHO) have recognized the link between the right to health and pharmaceutical patents. In India, the impact of pharmaceutical patents on access to essential medicines is stark. Millions suffer from diseases like HIV/AIDS, and high drug prices due to patent monopolies create a life-or-death situation for many.
The lack of access to lifesaving drugs disproportionately affects the poor in developing countries. While India is a growing economy, a significant portion of the population lives below the poverty line and cannot afford essential healthcare. This underscores the need for a detailed discussion on reconciling the right to health with intellectual property rights. The international community has acknowledged the right to health since 1945. However, discussions on intellectual property and the right to health gained traction only in the late 1970s. The WHO has played a significant role in promoting the right to health, and initiatives like the "Health for All" program aim to ensure access to essential healthcare for all. The challenge lies in finding solutions that promote innovation while safeguarding the fundamental right to health. Mechanisms like compulsory licensing, where governments can issue licenses for local production of patented drugs under specific circumstances, offer some promise. However, a global approach is needed, with developed nations acknowledging the impact of intellectual property rules on access to medicines in developing countries. Ultimately, collaboration is key to ensuring everyone, regardless of location, has access to the essential medicines they need[3].

2.2 Human Rights and Intellectual Property in the Context of Health

The concept of the right to health as a human right has seen a significant evolution over the past few decades. While international recognition of this right dates back to 1948 with the Universal Declaration of Human Rights, it wasn't until the 1970s that discussions on its connection to intellectual property (IP) rights gained traction. The World Health Organization (WHO) played a key role in propelling this discussion. The 1978 Alma-Ata Declaration emphasized the importance of primary healthcare, reflecting the right to health perspective. Similarly, the UN Committee on Economic, Social and Cultural Rights (CESCR) adopted General Comment No. 14 in 2000, defining access to medicine as a crucial component of the right to health. This General Comment established four key principles for access to medicine: availability, accessibility, acceptability, and quality. However, intellectual property rights, which grant inventors and creators exclusive rights over their creations, can create barriers to accessing essential medicines. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sparked debate due to concerns regarding its potential impact on access to medicines in developing countries. The tension lies in striking a balance between promoting innovation, incentivized by intellectual property rights, and ensuring access to affordable healthcare, a fundamental human right. The Doha Ministerial Conference Declaration on TRIPS and Public Health in 2001 acknowledged the importance of both aspects, but challenges remain in implementation[4].

2.3 The Indian Scenario and Judicial Responses

India exemplifies the complex interplay between intellectual property rights and the right to health. The 2005 amendment to the Patents Act, allowing product patents for pharmaceuticals, raised concerns about affordability of essential medicines. However, Indian courts have shown a willingness to prioritize the right to health. In the Novartis v Union of India case (2013), the Supreme Court upheld the importance of life-saving drugs over patent rights, demonstrating a commitment to balancing these competing interests.

2.4 A Collaborative Approach

The present situation highlights the need for a collaborative approach. Developing countries face challenges in accessing medicines due to factors like poverty and the influence of powerful pharmaceutical companies. Developed nations must acknowledge the potential impact of TRIPS on access to medicines. Finding solutions that promote innovation while safeguarding the right to health is crucial. Mechanisms like compulsory licensing, where governments can issue licenses for local production of patented drugs under specific circumstances, offer some promise. Ultimately, a global effort is necessary to ensure

that everyone, regardless of location, has access to the essential medicines they need. This requires both legal frameworks and international cooperation to ensure that intellectual property rights don't become a barrier to the fundamental right to health.

2.5 Balancing the Right to Health and Patent Rights in India

India's legal framework grapples with the tension between the right to health, a fundamental right enshrined in the Constitution, and the patent regime that incentivizes innovation. The right to health is interpreted as encompassing access to affordable medicines, as seen in landmark cases like State of Punjab v Mohinder Singh Chawla (1997) and Hoffmann-La Roche Ltd. v Cipla Ltd. (2008). These cases highlight the judiciary's willingness to prioritize public health considerations over patent monopolies. However, ensuring access to essential medicines remains a challenge. The Patents Act, 1970, grants pharmaceutical companies exclusive rights for 20 years, potentially leading to high drug prices. Compulsory licensing provisions, allowing the government to authorize generic production of patented drugs under specific circumstances, offer a potential solution. The Doha Declaration (2001) further affirmed flexibilities in TRIPS Agreement for public health needs.

Despite these provisions, India has granted only one compulsory license. Fear of trade sanctions from developed nations and complex procedures often deter applications. This limited use of compulsory licenses raises concerns about affordability of essential medicines, especially for diseases like cancer, HIV/AIDS, and tuberculosis. To bridge this gap, the Indian government has implemented various healthcare schemes like National Health Mission and Pradhan Mantri Jan Arogya Yojana. However, the effectiveness of these initiatives hinges on the availability of low-cost medicines, which can be facilitated by a more robust compulsory licensing regime. India's international obligations under human rights instruments like the Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights further emphasize the need to prioritize the right to health. Moving forward, India needs to find a balance by streamlining compulsory licensing procedures and taking a more proactive approach to ensure access to affordable medicines for its citizens[5].

3. Balancing Innovation and Access to Medicine in India

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994 significantly impacted India's intellectual property landscape. Coming into effect in 1995, TRIPS established minimum standards for intellectual property protection, including patents. While it provided member countries flexibility in implementation, the tension between patent rights and access to medicine emerged as a key concern. Articles 27 to 34 of TRIPS directly addressed patents and human rights. Notably, Article 31 allowed for compulsory licensing, permitting governments to authorize third-party production of patented drugs under specific circumstances. This offered a potential solution for access to essential medicines, especially in developing countries where affordability could be a barrier. However, concerns regarding the impact of TRIPS on public health persisted. Recognizing this, the World Trade Organization (WTO) addressed the issue at the 2001 Doha Ministerial Conference. The resulting Doha Declaration proved pivotal. Paragraphs 4, 5(b), and 6 reaffirmed the importance of public health and provided flexibilities regarding compulsory licensing. Paragraph 4 emphasized the primacy of public health rights over intellectual property rights, while Paragraph 5(b) recognized the right of countries to issue compulsory licenses.

Developed countries, led by the US, initially opposed extensive use of compulsory licenses, arguing limitations and advocating for solutions only in extreme public health emergencies. However, developing countries, particularly India and Brazil, countered this argument, highlighting the need for affordable medicines for their populations. Ultimately, Paragraph 6 acknowledged the right of WTO members lacking domestic pharmaceutical manufacturing capacity to utilize compulsory licensing for public health purposes. Despite these advancements, concerns remain regarding attempts to circumvent these provisions. Developed nations have advocated for "TRIPS-plus" standards in bilateral and multilateral trade agreements. These go beyond TRIPS, often imposing stricter intellectual property protection requirements than the minimum standards set by TRIPS. This approach can further restrict access to affordable medicines in developing countries.

The core issue lies in the tension between pharmaceutical companies' interests and the right to health. These companies invest heavily in research and development (R&D). Product patents grant them exclusive rights over their inventions, allowing them to recoup R&D costs and generate profits. However, this can lead to high drug prices, making them inaccessible to many people. Pharmaceutical companies often argue that compulsory licensing discourages R&D, as they wouldn't invest in new drugs without the prospect of exclusive profits. Additionally, they claim that competitors could use reverse engineering to replicate drugs, further undermining their

incentive to innovate. Finding a solution requires striking a balance. While protecting intellectual property incentivizes R&D, it shouldn't come at the cost of the fundamental right to health. India's efforts to utilize compulsory licensing provisions for essential medicines demonstrate a commitment to this balance. Further international collaboration and a focus on workable solutions are crucial to ensure that everyone, regardless of location, has access to essential medicines[6].

4. Developed Nations, Patents, and the Right to Health in India

Developed nations play a significant role in shaping the landscape of patents and access to medicine in India. While the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) offers some flexibilities, developed countries often push for stricter "TRIPS-plus" standards in bilateral trade agreements. These go beyond minimum TRIPS requirements, making it harder for developing countries like India to ensure affordable access to essential medicines. One key issue is compulsory licensing, a provision in TRIPS allowing governments to authorize generic production of patented drugs under specific circumstances. Developed nations, often backed by pharmaceutical companies, have opposed extensive use of compulsory licenses. They argue that this discourages research and development (R&D) due to concerns about reduced profits. However, developing countries counter that high patent prices restrict access to essential medicines, violating the fundamental right to health.

India's experiences illustrate these tensions. Despite having provisions for compulsory licensing, India has only granted one such license. This limited use raises questions about affordability of essential medicines, especially for diseases like cancer, HIV/AIDS, and tuberculosis. Additionally, pressure from developed nations through measures like the US "Special 301 Watch List" can discourage countries from using compulsory licenses. The debate boils down to balancing innovation with public health needs. While intellectual property rights incentivize R&D, they shouldn't come at the cost of basic health rights. Developed nations need to acknowledge the challenges faced by developing countries and work towards solutions that ensure access to affordable medicines for all. This might involve revising TRIPS-plus demands and fostering international collaboration in R&D focused on diseases prevalent in developing countries[7].

5. Conclusion

The Doha Declaration marked a significant step towards recognizing the right to health within the TRIPS framework. However, challenges remain in implementing these principles. While provisions like compulsory licensing offer potential for affordable medicines, their effectiveness depends largely on national policy decisions. The tension between intellectual property protection and public health access is evident. Developed nations' emphasis on stricter IP rights and pressure on developing countries like India to limit compulsory licensing creates a barrier to affordable medicines. This undermines the fundamental right to health enshrined in international conventions. The limited use of compulsory licenses in India exemplifies this challenge. Political pressure from developed countries, potentially influenced by pharmaceutical companies, can discourage their use. This highlights the need for a nuanced approach that balances innovation incentives for drug discovery with the human right to access essential medicines. Ultimately, a human rights approach to patents and public health requires a global commitment. By working together, the international community can ensure that intellectual property rights facilitate, rather than hinder, access to life-saving medicines for all.

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