Pre-Launch Injunctions: Reshaping India's Public Health Vs. Patent Debate

Arshpreet Kaur

Advocate under Punjab and Haryana High Court

ABSTRACT

With the intersection of science and human welfare, the conflict between affordable public access to essential medicines and incentives for pharmaceutical innovation becomes evident. This conflict is a defining feature of global health policy, but it is nowhere more pronounced than in India because of its constitutional commitment to the right to health and its status as a global producer of generic and biosimilar drugs. India serves as a pivotal arena where this delicate balance is continually tested and redefined.

In 2026, the Indian government shifted its focus towards ease of doing business and "trust-based regulatory reforms." There is a need to examine what impact this shift has on the patent system, particularly in reference to the right to health.

A recent judgment from the Delhi High Court in E.R. Squibb & Sons LLC v. Zydus Lifesciences Limited represents the most significant judicial recalibration of India's patent-health balance in a decade (14). It effectively created a new enforcement paradigm that prioritizes patent certainty over immediate generic competition.

This article analyzes the judgment within India's complex legal and economic framework and examines the structural conflict between economic incentives and constitutional rights. It argues that alternative innovation models may offer a sustainable solution to balance these competing interests.

Keywords: Patent, public health, licensing, constitutional rights

Introduction

Patent protection and the right to affordable healthcare are frequently seen as competing interests. The Indian Patents Act attempts to balance these competing goals, while international human rights instruments recognize the right to health as a fundamental human right (3).

The Indian Constitution guarantees the right to life, and the Supreme Court has interpreted this right expansively to include the right to health as an integral component of Article 21. In Bandhua Mukti Morcha v. Union of India, the Court recognized the right to health as part of the constitutional guarantee of life and dignity (1). Similarly, in State of Punjab v. Mohinder Singh Chawla and Consumer Education & Research Centre v. Union of India, the Supreme Court reaffirmed that the right to health and medical care forms an essential component of the right to life under Article 21 (2).

Internationally, Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) recognizes the right to the highest attainable standard of physical and mental health (3). Furthermore, Article 15(1)(c) of the ICESCR protects authors' rights, including intellectual property rights, but places them within a broader framework of human rights obligations (4).

The Committee on Economic, Social and Cultural Rights, in General Comment No. 14, clarified that access to affordable medicines forms a core obligation of states under the right to health (5).

In the field of international trade law, the Doha Declaration on TRIPS and Public Health reaffirmed the sovereign right of WTO member states to utilize TRIPS flexibilities such as compulsory licensing and strict patentability standards to protect public health and promote access to medicines (6). These flexibilities are embedded within the TRIPS Agreement, which establishes a minimum twenty-year patent protection term but allows member states policy space to safeguard public health (7).

Indian courts have often relied on these principles to justify provisions like Section 3(d) of the Patents Act, which seeks to prevent patent evergreening and protect access to affordable medicines (7).

The tension between innovation incentives and public health access is particularly visible in the pharmaceutical sector through the practice of evergreening, whereby pharmaceutical companies attempt to extend market exclusivity by securing additional patents on minor modifications of existing drugs (8).

Over the years, Indian jurisprudence has increasingly emphasized the need to strike a balance between protecting innovation and ensuring affordable treatment for life-threatening diseases such as cancer and HIV/AIDS.

Methodology

This study adopts a doctrinal legal research methodology, examining statutory provisions, judicial precedents, and international legal instruments. The analysis focuses on how Indian courts have interpreted patent law in light of constitutional commitments to public health.

1 India's Patent Framework

The Indian Patents Act, 1970 incorporates a set of safeguards designed to balance patent protection with public interest. These mechanisms aim to encourage innovation while ensuring access to affordable medicines.

1.1 Preventing Evergreening (Section 3(d))

Section 3(d) creates a legislative barrier against patent evergreening. The landmark case Novartis AG v. Union of India upheld the constitutional validity of this provision and rejected the patent application for the beta-crystalline form of Imatinib Mesylate (9).

The Court held that improved bioavailability alone does not necessarily amount to enhanced therapeutic efficacy, thereby preventing pharmaceutical companies from extending monopoly rights through minor modifications.

1.2 Compulsory Licensing (Sections 84–92)

Compulsory licensing allows the government to permit third parties to manufacture patented products without the consent of the patent holder in situations where public needs are not adequately met.

A landmark example was the compulsory license granted for Bayer's anti-cancer drug Nexavar, allowing generic production to improve accessibility (11).

Subsequent cases such as Lee Pharma Ltd v AstraZeneca clarified that compulsory licensing is not an automatic remedy and must satisfy strict statutory requirements (9).

Similarly, BDR Pharmaceuticals v Bristol-Myers Squibb emphasized that applicants must demonstrate genuine efforts to obtain voluntary licenses before seeking compulsory licensing (10).

1.3 The Bolar Exemption (Section 107A(a))

The Bolar exemption allows generic manufacturers to use patented inventions during the patent term for regulatory approval purposes.

The Delhi High Court in Bayer Corporation v Union of India recognized that exports for regulatory testing are permissible under this exemption (11). The court adopted a functional interpretation of the term "sale" to include exports intended for regulatory approval processes.

Further clarity was provided in Bayer Intellectual Property GmbH v Alembic Pharmaceuticals Ltd, where the court reaffirmed the scope of the Bolar exemption in facilitating generic entry after patent expiry (12).

1.4 Parallel Importation (Section 107A(b))

Parallel importation allows patented products sold abroad to be imported into India based on the doctrine of international exhaustion.

In Sotefin SA v Indraprastha Cancer Society, the Delhi High Court clarified that foreign patents cannot be used to bypass Indian patent rights due to the territorial nature of patent protection (13).

2 The New Precedent: E.R. Squibb & Sons LLC v Zydus Lifesciences Limited

In Zydus Lifesciences Ltd v E.R. Squibb & Sons LLC, the Delhi High Court addressed a dispute concerning the biosimilar version of Nivolumab, an immunotherapy drug used to treat various cancers (14).

The patentee sought a pre-launch injunction, arguing that Zydus intended to commercially launch its biosimilar before the expiry of the patent.

The court granted an interim injunction restraining Zydus from manufacturing or stockpiling the drug prior to patent expiry, reasoning that a biosimilar must necessarily replicate the patented amino acid sequences of the reference biologic.

2.1 Analysis: Shift in the Balance of Power

The ruling strengthened the position of patent holders by allowing anticipatory enforcement through pre-launch injunctions.

While this enhances patent certainty and protects innovation investments, it also raises concerns regarding delayed access to affordable biosimilars.

The pharmaceutical sector is uniquely sensitive to patent enforcement due to the high costs and risks associated with drug development. Studies indicate that developing a new drug often requires over a decade of research and substantial financial investment (17).

2.2 Division Bench Ruling

The Division Bench subsequently vacated the interim injunction and emphasized the importance of public interest when life-saving medicines are involved (14).

The court held that injunctions should not be granted based on assumptions and must be supported by clear evidence of infringement.

Conclusion

The evolving jurisprudence surrounding pharmaceutical patents in India reflects an ongoing effort to reconcile innovation incentives with public health needs.

While strong patent protection may encourage research and development, excessive enforcement may delay access to affordable medicines.

India's legal framework continues to rely on a combination of statutory safeguards, judicial interpretation, and international legal principles to maintain this delicate balance.

Suggestions

To address the structural tension between patent rights and public health, alternative innovation models must be explored.

Initiatives such as the Medicines Patent Pool encourage voluntary licensing arrangements that allow generic manufacturers to produce patented medicines while ensuring royalties for patent holders (15).

Similarly, global initiatives like the COVID-19 Technology Access Pool (C-TAP) aim to facilitate collaborative research and technology sharing (16).

Another promising approach is the use of innovation prize funds, which reward successful drug development while placing the resulting intellectual property in the public domain (17).

Greater transparency in pharmaceutical markets has also been encouraged through international initiatives such as World Health Assembly Resolution 72.8, which promotes transparency in drug pricing and R&D costs (18).

Developing countries must also continue to preserve TRIPS flexibilities in order to protect access to medicines and resist pressure for TRIPS-plus obligations in trade agreements (19, 22).

Ultimately, achieving a sustainable balance requires a collaborative framework in which governments, pharmaceutical companies, and international organizations work together to ensure that medical innovation serves its ultimate purpose—the preservation of human life (21).

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