PUBLIC HEALTH AND INTELLECTUAL PROPERTY RIGHTS: RECONCILING ACCESS TO MEDICINES WITH PATENT PROTECTION

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ABSTRACT

Intellectual Property Rights, particularly patents, form the foundation of the modern pharmaceutical innovation system. They grant exclusive rights for a limited period, enabling companies to recover high research and development costs. However, this exclusivity may also restrict affordable access to essential medicines, especially in developing nations. The present article examines the legal, ethical and policy conflict between patent protection and the right to health. It analyses international frameworks and TRIPS flexibilities, evaluates India's statutory provisions and landmark judicial decisions such as the compulsory licence for Nexavar, and reviews mechanisms like compulsory licensing, patent pools, voluntary licensing and tiered pricing. The study advocates a balanced approach that safeguards innovation while strengthening public health protections. The Indian experience demonstrates that statutory flexibility, judicial vigilance and creative licensing can uphold both innovation and access.

Keywords: Intellectual Property, Patents, Access to Medicines, Compulsory Licensing, TRIPS Flexibilities, Right to Health

Introduction & The Rationale for Pharmaceutical Patents

The pharmaceutical sector exists at a critical intersection of private innovation and public welfare. Patent systems reward inventors with exclusive rights for a limited period so that they may recover heavy investments involved in research and development. Without such protection, private firms might underinvest in new drug discovery. However, monopoly pricing often makes essential medicines unaffordable for many individuals and public health systems.

This inherent tension between the need to incentivize innovation and the responsibility to ensure affordable access to health care forms the central issue of this research.

This paper explores that issue through three dimensions. The first is the rationale behind patent protection in the pharmaceutical sector. The second is the human rights perspective which views access to medicines as part of the right to health. The third is the reconciliation of these interests within international and domestic legal frameworks, particularly in India.

Patents are granted in exchange for disclosure of inventions and grant exclusive rights for a limited time. The economic justification for patents lies in internalizing the heavy costs and risks associated with research and development in pharmaceuticals. Developing a new drug often requires more than ten years of research and an investment of several billion dollars.[1]

The disclosure function enriches public knowledge and enables further research once patent protection expires. However, exclusivity may also result in high prices and limited access, particularly in low and middle income countries. Policymakers must therefore maintain a delicate balance between rewarding innovation and ensuring the availability of affordable medicines.

Public Health and the Right to Health

Access to medicines is an integral part of the human right to health. The Constitution of the World Health Organization (1946) recognises that the highest attainable standard of health is a fundamental right of every human being.[2] Similarly, Article 12 of the International Covenant on Economic, Social and Cultural Rights (1966) obliges states to secure the right to physical and mental health.[3]

The UN Committee on Economic, Social and Cultural Rights, in General Comment No. 17

(2005), clarified that intellectual property regimes must not obstruct the realization of this right.[4] Therefore, every state has a positive duty to make essential medicines accessible, affordable and available without discrimination.

The International Legal Framework: TRIPS and Its Flexibilities

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) establishes minimum standards of intellectual property protection for all WTO members.[5] At the same time, TRIPS provides several flexibilities such as compulsory licensing and parallel importation. The 2001 Doha Declaration on TRIPS and Public Health reaffirmed that member states may use these flexibilities to protect public health and promote universal access to medicines.[6]

These provisions give nations legal space to reconcile intellectual property protection with health concerns. Yet, political pressure and trade negotiations have often restricted their effective implementation.

India's Statutory Framework and Judicial Response

The Indian Patents Act, 1970, as amended, incorporates TRIPS flexibilities through Sections 84 to 92 which allow compulsory licensing and government use of patents during public health emergencies.

The landmark case of **Bayer Corporation v. Union of India (2014)**[7] is a remarkable example. Bayer's patented cancer drug Nexavar was sold at about ₹2.8 lakh per month, making it unaffordable for most Indian patients. Natco Pharma applied for a compulsory licence to manufacture a generic version at ₹8,800 per month. The Intellectual Property Appellate Board and later the Bombay High Court upheld the licence. The Court held that the right to life under Article 21 of the Constitution includes access to affordable medicines, and that patent rights cannot override public welfare.

This judgment marked a major development in harmonising patent law with the constitutional mandate of social justice and health equity.

Practical Mechanisms for Reconciling Innovation and Access

Several mechanisms have been adopted globally and in India to maintain the balance between

innovation and access.

a) Compulsory Licensing

This permits production of a patented product without the consent of the patent holder, subject to payment of reasonable compensation. The Nexavar case in India stands as a successful illustration.

b) Patent Pools and Voluntary Licensing

The Medicines Patent Pool (MPP) works with patent holders to negotiate voluntary licences and sub-license them to generic manufacturers in developing countries.[8] This arrangement facilitates large scale access without abolishing incentives for innovation.

c) Tiered Pricing and Differential Procurement

Pharmaceutical companies may voluntarily adopt price structures that differ by region and income level. This approach encourages equity in access while allowing cost recovery.

d) Competition and Regulatory Tools

Competition authorities may intervene against abuse of dominant position. Regulatory bodies can expedite approval of generic drugs to increase competition and lower prices.

Emerging Challenges

Although these mechanisms exist, several challenges continue to obstruct effective implementation.

1. **Patent Evergreening** where companies file minor modifications to extend monopolies.
2. **Data Exclusivity and TRIPS Plus Clauses** that delay entry of generic medicines.
3. **Biologics and Complex Drugs** which require advanced manufacturing capacities.
4. **Pandemic Experience** which revealed serious inequities in global medicine distribution during COVID 19.

5. **Infrastructure and Procurement Barriers** that limit access even where legal provisions exist.

These issues demonstrate that reform must extend beyond law into policy and capacity building.

Reform and Policy Recommendations

1. Simplify compulsory licensing procedures and spread awareness among domestic manufacturers.

2. Strengthen patentability standards to prevent evergreening.

3. Promote patent pooling and voluntary licensing through public private partnerships.

4. Mandate transparency in drug pricing and R&D cost disclosures.

5. Encourage technology transfer by linking public research funding with access conditions.

6. Incorporate human rights impact assessments into all IP policy decisions.

7. Explore alternative R&D models such as prize funds and market commitments that separate innovation incentives from high drug prices.

Conclusion

The reconciliation of public health imperatives with intellectual property protection stands as one of the most pressing legal and ethical challenges of the twenty-first century. Intellectual Property Rights are essential tools to promote innovation, investment, and technological advancement. In the pharmaceutical sector, they provide the foundation upon which new drugs and therapies emerge. However, the same framework that rewards creativity can also generate exclusion, inequality, and human suffering when life-saving medicines remain beyond the reach of those who need them most.

The law, therefore, cannot treat patents as isolated economic privileges divorced from their social context. It must interpret and apply intellectual property norms in light of the higher

constitutional and human rights values that govern society. The experience of India, especially through the jurisprudence of cases such as *Bayer Corporation v. Union of India*, illustrates that the right to life and health occupies a superior position in the legal hierarchy. The judiciary has reaffirmed that the object of patent law is not to enrich private entities but to serve public welfare by ensuring that scientific progress benefits all.

True innovation cannot exist in a moral vacuum. A system that measures success solely in terms of profit overlooks the essential human purpose of law. The legal order must ensure that patents remain instruments of progress rather than barriers to human dignity. The challenge is to preserve the delicate equilibrium where inventors receive adequate reward for their ingenuity without allowing such reward to convert into a permanent monopoly over life itself.

In this context, global cooperation becomes indispensable. The COVID 19 pandemic has vividly demonstrated that health crises respect no borders. The refusal or delay in sharing technologies, vaccines, and know-how can prolong global suffering and deepen inequality between nations. Consequently, international law must evolve towards models of shared responsibility, transparency in drug pricing, open innovation, and technology transfer mechanisms that respect both intellectual property and human survival.

India's policy choices have shown that it is possible to strike a humane balance. Through its statutory provisions on compulsory licensing, its resistance to TRIPS-plus obligations, and its judicial insistence on access to medicines as a constitutional right, India has created a model that many developing countries can emulate. However, reform must not stop here. It requires consistent political will, global solidarity, and continuous dialogue between governments, pharmaceutical companies, and civil society.

Ultimately, the question is not whether patents should exist, but how they should operate within a framework of justice and humanity. Innovation must remain a means to an end rather than an end in itself. The end is human welfare. A society that celebrates discovery but denies its benefits to the suffering stands in contradiction to the very ideals of justice, equality, and compassion that law is meant to uphold.

Therefore, the future of global health depends on our collective ability to ensure that the fruits of science are distributed equitably and responsibly. The reconciliation between patent protection and access to medicines is not simply a technical legal exercise; it is a moral

imperative and a test of civilization's conscience. Only when innovation and compassion coexist can the promise of intellectual property truly serve the progress of humankind.

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