INDIAN JOURNAL OF LEGAL REVIEW

VOLUME 6 AND ISSUE 6 OF 2026

INSTITUTE OF LEGAL EDUCATION

INDIAN JOURNAL OF LEGAL REVIEW

APIS – 3920 – 0001 | ISSN - 2583-2344

(Open Access Journal)

Journal's Home Page – https://ijlr.iledu.in/

Journal's Editorial Page - https://ijlr.iledu.in/editorial-board/

Volume 6 and Issue 6 of 2026 (Access Full Issue on - https://ijlr.iledu.in/volume-6-and-issue-6-of-2026/)

Publisher

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INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]

VOLUME 6 AND ISSUE 6 OF 2026

APIS – 3920 - 0001 *(and)* ISSN - 2583-2344

Published by

Institute of Legal Education

https://iledu.in

PATENT RIGHT AND ACCESS TO MEDICINES IN INDIA: RECONCILING INNOVATION WITH PUBLIC HEALTH IMPERATIVES

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BEST CITATION – ISHANI**,** PATENT RIGHT AND ACCESS TO MEDICINES IN INDIA: RECONCILING INNOVATION WITH PUBLIC HEALTH IMPERATIVES, *INDIAN JOURNAL OF LEGAL REVIEW (IJLR),* 6 (6) OF 2026, PG. 214-220, APIS – 3920 – 0001 & ISSN - 2583-2344.

I. Abstract

Protection of patents and availability of medications has been one of the most important legal and legislative issues in India. Patent laws protect pharmaceutical discoveries by giving innovators exclusive rights to a unique drug for some period of time and a financial incentive to pursue research and development. But this exclusivity leads to high pricing that renders vital treatments expensive to the vulnerable segments of the population. The fundamental problem in a developing country like India, where the need for cheap health care is still huge, is how to strike a fair balance between the protection of intellectual property and the interests of public health.

India has built a unique and balanced system under the Patents Act, 1970 as amended in 2005 to meet the commitment under the TRIPS Agreement. The law provides for product patent for pharmaceuticals and forbids the misuse of monopoly power. Subsection 3(d) forbids evergreening or patenting of trivial variations of existing medications unless they show increased clinical efficacy. Section 84 on compulsory licensing also permits the manufacture of patented drugs without the approval of the patent owners if the products are sold at excessive costs or are not available to the public in sufficient quantities. They represent India's wish to have patent law serve the cause of social progress, not only the private gains of business.

Judicial statements have also maintained the balance. In Novartis AG v Union of India, the Supreme Court ruled that only actual and substantial advances as envisaged under section 3(d) of the Patent Act are to be granted patent protection. India's first compulsory licence in Bayer Corporation v. Natco Pharma Ltd led to a substantial fall in the price of a key anti-cancer drug. In the rulings it is said that right to life under Article 21 of the Constitution cannot be separated from the right to access healthcare.

Keywords : Access to Medicines, Compulsory Licensing, Evergreening, Innovation, Patent Rights, Pharmaceutical Patents, Public Health, Section 3(d), TRIPS Agreement.

II. Introduction

It is widely accepted that the patent system is a fundamental tool to stimulate innovation and technological development. Patent rules provide innovators a limited exclusive right for a period of time to their innovations. This rewards inventors , draws commercial investment and promotes scientific development . Such protection allows for the recovery of research costs as well as reasonable earnings from inventions. Patents are particularly crucial in the pharmaceutical business since the creation of a new medication usually entails many years of scientific investigation, laboratory experiments, clinical trials, regulatory approval and a

significant financial outlay. Pharmaceutical companies often contend that without legal exclusivity incentives, investment in new drug discovery would be significantly diminished.[443]

But pharmaceutical patents are not like patents in many other industries as the medicines are strongly tied to human life and public welfare. Drugs are not luxuries, or any other commercial item. They are vital health products. Excessive pricing of patented drugs causes problems of access to treatment for large portions of society, particularly in low income and developing nations. The application of patent law in the health sector involves important ethical, social and economic questions.

India has a vital role to play in this global conversation. It is one of the largest generic pharmaceutical companies in the world and supplies low-cost medicinal products to many developing countries. Indian manufacturers have been essential to supplying life-saving drugs to Asia, Africa and other regions of the globe. At the same time, India, as a member of the World Trade Organization and the TRIPS Agreement, has an obligation under international law to grant patent protection to pharmaceuticals.

For India, the central issue has been how to balance incentives for real innovation against the risk that patent monopolies might restrict access to vital medicines. Its legal system tries to strike a balance between the promotion of research, trade commitments and the health concerns of the public.[444]

III. Concept Of Patent Rights In Pharmaceutical Industry

Intellectual property law covers patent rights . They give innovators exclusive legal rights to manufacture innovative, useful and imaginative patented products or techniques. The pharmaceutical industry relies heavily on patents that grant the patent holder exclusive rights for a period of time, usually twenty years from the date of filing a patent application, to develop, market, utilise and distribute a medicine. The objective is to foster the generation of new ideas and the flow of money for scientific research.

Research & Development is the key to the success of the pharmaceutical business as a whole. The development of a new pharmaceutical sometimes includes many months of extensive lab testing, pre-clinical research, human clinical trials, regulatory approval and a lot of money. The majority of medicines under investigation never get marketing authorisation. The inventions that don't work have to pay for the inventions that do. Entrepreneurs can use patent protection to pay their costs and generate an acceptable rate of return on their investment.[445]

Product patents are meant to protect the active therapeutic ingredient in the medicine. Process patents are concerned with the processes used to make medications. Formulation protection includes different patentable new dosage forms including tablets, capsules, syrups, injections and controlled release formulations. Combination Goods When two or more therapeutic compounds are combined in the same dosage form, they are patented as combination goods. Biotech patents might be for vaccines, biologics, synthetic proteins and genetic advancements.

Drugs are not simply commodities. Abuse of monopoly power can lead to price gouging and denial of care to patients. The problem is more serious in developing countries when most health expenses are paid for by people themselves. So the patent rights in the pharmaceutical sector have a legitimate function, but they have to be limited to the preservation of human life, public health and equal access to treatment. It's not that there are

[443] World Intellectual Property Organization, *Understanding Patents,* WIPO Publication No. 895€ (2020).
[444] Shamnad Basheer & K.M. Gopakumar, *The Indian Patent System and Public Health* 55–72 (Oxford Univ. Press 2009).
[445] World Intellectual Property Organization, *Patents and the Pharmaceutical Industry* (2020).

INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]
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APIS – 3920 - 0001 *(and)* ISSN - 2583-2344
Published by
Institute of Legal Education
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patents, it's how they have to operate with social responsibility.[446]

IV. Indian Patent Law: An Evolution Of Changing Times & Changing Laws

India's patent system has had diverse periods marked by colonisation, economic policies and public health considerations. The Patents and Designs Act was enacted in 1911 during the British colonial control, and this created a legal system based on the English law. In this way powerful monopoly rights were formed, mostly to the benefit of the multinational companies that dominated commerce and industry at the time. This resulted in a shortage of pharmaceuticals, which were too expensive for the average Indian to afford.

After independence in 1947, the national leaders pondered whether the colonial patent system was suitable for a developing country. The major concerns were public welfare, industrial independence and equal health care. The Government set up the Justice N. Rajagopala Ayyangar Committee which, in its report of 1959, advised decrease of monopolistic power in the pharmaceutical market and increase of indigenous manufacture.[447]

These notions formed the basis for the Patents Act passed in 1970. This legislation constituted a major turning point. Food, chemicals and pharmaceuticals were excluded from the list of product patents. The patent protection period has just shortened. It gave Indian companies the legal right to develop the same medicine, but they had to do it in a different way.

The result, in the end, was game-changing. Cipla, Dr. Reddy's Laboratories, Sun Pharmaceutical Industries, Aurobindo Pharma, Torrent pharmaceuticals, Alembic Pharmaceuticals Limited, Zydus Lifesciences and Lupin Limited are among the top manufacturers of generic medications and there is a growing number of local pharmaceutical companies. India is the "pharmacy of the developing world" as prices plunged.[448]

India's new beginning came in 1995. That was the year India became a member of the World Trade Organisation and accepted duties under the TRIPS Agreement. Under the TRIPS agreement, member nations are required to grant patent protection for medications. India modified its patent laws in 1999, 2002 and 2005.

The 2005 amendment reintroduced product patents for pharmaceuticals, but kept safeguards such as compulsory licensing, pre-grant opposition and Section 3(d) which prevents the granting of deceptive secondary patents. These elements were instances of India's effort to meet its international obligations and at the same time provide access to healthcare.

India's patent history reveals the intricate balancing act between inventiveness, industrial progress, international trade commitments and the economic wellbeing of its people.

V. Indian Patent And Pharmaceuticals Regulatory Framework.

The present legal environment on patent rights and pharmaceuticals in India is a cocktail of home-grown law, constitutional principles, judicial interpretation and international commitments. The principal Act is the Patents Act 1970 which has been revised on a number of occasions.

A) Health - A Fundamental Right

The right to health is not a fundamental right explicitly mentioned in the Constitution. Article 21 of the Constitution guarantees the right to life and personal liberty. The Supreme Court of India has been holding that the right to life includes the right to seek medical care, access to health care and to obtain conditions necessary for a decent existence. Availability of life saving

[446] United Nations Development Programme, *Using TRIPS Flexibilities to Improve Access to HIV Treatment* 12–19 (2010).
[447] N. Rajagopala Ayyangar, *Report on the Revision of the Patents Law* 12–25 (Gov't of India 1959).
[448] World Health Organization, *The World Medicines Situation: Access to Essential Medicines* 34–39 (2011)

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medications is a matter of constitutional importance.

The Directive Principles like Article 38, 39, 41 and 47 of the Constitution require the state to work for the improvement of public health and living conditions. They are not immediately put into practice but form the basis for legislation and policy.[449]

B) Patents Act, 1970

The Act specifies that patents shall be granted only for innovative innovations which include an inventive step and are capable of industrial application. But there are a number of safeguards for public welfare.

1.Section 3(d) -Under the Act, new forms of existing substances cannot be patented unless they are more effective. It prevents "evergreening" – the practice of making minor tweaks to extend monopolistic control.

2. Section 84. License, legal- In India, third parties may request for permission to make a patented pharmaceutical if the patent is not fully utilised, the costs are too high or public needs are not met.

3. Section 100 - Government Use , In emergencies or serious medical crises, the government is permitted to use copyrighted ideas to benefit the public.[450]

C. The Opposition Proceedings

Pre-grant and post-grant opposition actions are mechanisms to dispute patents that are flawed or not worthy of protection. This means we can be certain that only actual inventions are protected.

D.International obligations

India is a member of WTO and has to adhere to basic patent regulations as laid down in TRIPS. On the other hand, the Trade-Related Intellectual Property Rights (TRIPS) recognises a variety of flexibilities available to member states, including compulsory licensing, exclusions and parallel imports. The Doha Declaration on TRIPS and Public Health affirmed the right of WTO members to protect public health and to promote access to medicines for all people.

E. Regulation of Pharmaceutical Prices

The National Pharmaceutical Pricing Authority regulates and monitors the price of critical medicines as per national policy. This amendment in patent law stops the overselling of some products in some categories. Hence, the legislative framework in India focuses at pursuing two objectives: fostering innovation and providing healthcare that is accessible and cheap.

VI. MAJOR LEGAL AND REGULATORY CHANGES CONCERNING PATENT RIGHTS AND ACCESS TO DRUGS

In India there have been important legal and legislative developments which have emphasised the contradictions between private intellectual property rights and the public interest.

A) Novartis AG Vs. Union of India (2013)

The query is about the anti-cancer drug, Glivec. Novartis wants a patent on a new crystal form of an old chemical. According to the Supreme Court, Section 3(d) does not allow patenting of trivial modifications in physical properties of a product without improvement in medicinal efficacy. The decision has had an unparalleled impact globally, bolstering India's position on evergreening and ensuring that cancer sufferers would continue to have access to affordable generic medicines.[451]

B) Bayer AG v Natco Pharma UK, 2012

India has now given its first obligatory licence for Bayer's revolutionary cancer medication Nexavar. The first drug was very expensive and hard to get. So Natco was permitted to develop and sell a far cheaper alternative. The case revealed that patent rights are not absolute

[449] Constitution of India arts. 38, 39, 41, 47.
[450] Patents Act, No. 39 of 1970, §§ 2(1)(j), 2(1)(ja), 3(d), 84, 100, India Code (1970).
[451] Novartis AG v. Union of India; Patents Act, No. 39 of 1970, § 3(d), India Code (1970).

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and might be lost when urgent public necessity exists.[452]

C) HIV/AIDS medication provisions

Indian generic medication companies have substantially cut the cost of antiretroviral drugs for treating HIV/AIDS in Africa, Asia and Latin America. The drugs that used to be outrageously pricey are now substantially lower in price. It has been enormously influential in the humanitarian sector.[453]

D) COVID-19 Pandemic

The outbreak has renewed concerns over immunisation patents, intellectual property transfers and production capacity. India and South Africa had jointly proposed a temporary waiver for pandemic-related technologies under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) accord. The program showed India's continued commitment to providing equitable access to healthcare.[454]

India has allowed bulk purchase of medications and set up Jan Aushadhi outlets to sell generic medicines at inexpensive prices and carried out large scale immunisation efforts. They also help indirectly cut down on the potential negative impact of expensive brand name drugs.Taken together, these shifts suggest that patent law cannot be understood apart from socioeconomic realities.

VII. Striking The Right Balance Between Innovation And Public Health

Still, there are many challenges for the Indian pharmaceutical industry even after the legal protection given to them. This adds another layer of complexity to the debate about patent rights and public health.

A) Cost of Patent Medicines -The average family cannot afford many of today's medicines for cancer, autoimmune diseases, rare diseases and biologic therapies. In India, high personal health care costs mean economic hardship in the event of long-term treatment.

B) Ever greening practices;- Some companies attempt to extend their monopoly power by purchasing patents for minor modifications, such as changes in dosage, new formulations or drug delivery methods. Such practices are prohibited under section 3(d), but the ongoing litigation is a waste of time, money and administrative resources.[455]

C) The importance of incentivising innovation- Generic drug manufacturing has done fairly well in India, but original drug discovery is still at its infancy. Weak patent protection may discourage investment in high risk research, biotechnology and advanced therapeutic products.

D) Red Tape and Regulatory Delays- Long backlogs in patent examination, inconsistent decision making and lengthy dispute resolution processes create uncertainty for innovators and for generic manufacturers. Delays can be discouraging for investment and delay bringing medicines to market.[456]

E) No Public Health Infrastructure- Even when low prices are available, access is often limited by hospital shortages, poor insurance coverage and unequal health facilities. "Patent reform alone will not solve the systemic vulnerabilities of the health care system.[457]

F) Pressure from foreign trade- Developed nations and multinational companies have lobbied for tighter enforcement of intellectual property rights, frequently using trade talks and diplomatic means. India requires adequate policy space to protect its domestic healthcare interests.

G) Reliance on Foreign Technology- India still imports some specialised active pharmaceutical ingredients, biologic

[452] Bayer Corp. v. Natco Pharma Ltd.; Patents Act, No. 39 of 1970, § 84, India Code (1970).
[453] World Health Organization, *Scaling Up Antiretroviral Therapy in Resource-Limited Settings* (2010)
[454] World Trade Organization, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19,* IP/C/W/669 (2020).
[455] World Health Organization, *Medicines Reimbursement Policies in Europe* 12–20 (2018)
[456] World Bank, *Out-of-Pocket Health Expenditure Data: India* (2020).
[457] Controller General of Patents, Designs & Trade Marks, Annual Report 2021–22

technologies and advanced medical supplies. This dependence can impact prices, availability and the stability of supply.

H) Ethical issues and research priorities- In general they target profitable lifestyle diseases, not neglected tropical diseases or diseases of the poor. This is the point where market incentives and public health needs diverge.[458]

These issues underline the need for ongoing policy analysis, balanced regulation and a patient-centred approach to integration of innovation and access to health care.

VIII. Way Forward

Future India Outlook requires a forward looking and balanced policy for balancing patent protection and public health needs. That should be the aim of encouraging real pharmaceutical innovation, and ensuring that essential medicines are available and affordable for all.

The Government has simultaneously promoted domestic innovation through schemes such as Make in India, Production Linked Incentive Scheme, and biotechnology support programs encouraging research, vaccine development, and pharmaceutical manufacturing. These initiatives seek to reduce dependence on imports, strengthen active pharmaceutical ingredient production, and expand India's role as a global pharmaceutical hub.

India's pricing and healthcare access policies also remain important. The National Pharmaceutical Pricing Authority continues to regulate prices of essential medicines, while public schemes such as Ayushman Bharat aim to improve healthcare affordability for lower-income populations. Through these combined measures, India continues to demonstrate that intellectual property protection and access to medicines can coexist within a welfare-oriented legal system.

A) Growth of public research spending - Increased investment in universities, research institutions and public laboratories can help drive the development of medicines for neglected diseases, antimicrobial resistance and rare disorders that are too often underfunded by private investment.[459]

B) Driving Innovation from Home - Indian companies should be incentivised through tax benefits, grants and policy incentives to invest in original drug discovery, biotechnology, vaccines and advanced therapeutic products.[460]

C) Patent Administration in Practice - "More staff, special training and digital processing will mean a faster, clearer patent system. An early look at patent filings could reduce uncertainty for innovators and manufacturers.

D) Use of TRIPS flexibilities appropriately- Legal mechanisms such as compulsory licensing and parallel imports should be available in cases of real public interest, such as health emergencies and life-saving medicines that are too expensive to afford.

E) Extending health coverage - Better health insurance schemes and stronger public health care programmes lower out-of-pocket medical costs and increase patient access to treatment.

F) Increased Drug Price Regulation - Effective supervision of essential drugs can help to check excessive pricing of essential medicines and improve their affordability via the National Pharmaceutical Pricing Authority.

G) Encouraging voluntary licensing and transfer of technology - Patent holders should be encouraged to collaborate with local manufacturers to increase production and availability of essential drugs.

H) Dependence on imports India needs to improve its supply security through increased domestic production of active pharmaceutical ingredients, biologics and specialised medical inputs.

[458] NITI Aayog, *India Health System Review* (2021)

[459] World Health Organization, *Access to Medicines and Vaccines: Policy Framework* 5–12 (2021).

[460] Department for Promotion of Industry and Internal Trade, *National IPR Policy* (2016).

I) A Patient-Focused Policy Approach - Health care policy must be patient centred, not commercial. Medicines are closely linked with the right to life and dignity of the human person.[461]

IX.Conclusion

Patent rights stimulate science research, technology development and new medicine development. The patent system gives pharmaceutical companies a limited time of exclusivity to recoup the costs of research and develop future innovation. Even in an industry where developing drugs is a long, skilled and expensive process, legal protections are still a powerful incentive to push ahead.

Meanwhile , medicines are not just everyday commodities of commerce, they are essential for the protection of life and health and of human dignity. Patented medicines are expensive and this makes it difficult for many patients to access the treatment, especially in developing countries. Patent protection must respect boundaries informed by other public welfare concerns.

The Patents Act, 1970, the provisions on compulsory licensing, Section 3(d) and judicial supervision have been attempts made by India to strike a balance in the legal framework. These provisions are intended to deter the abuse of monopoly power while preserving incentives for real invention.

The challenge for the future is to increase domestic research, upgrade the health care infrastructure, ensure fair drug pricing and use international legal flexibilities effectively. A fair patent regime is one which rewards innovation but also makes sure that life saving medicines reach all sections of society. Progress is measured not only in discovery but in access and social benefit.

[461] NITI Aayog, *Health System for New India* (2021).

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ISSN 2583-2344