PHARMACEUTICAL PATENTS AND PUBLIC HEALTH: INDIAN APPROACH TO INTELLECTUAL PROPERTY AND MEDICAL INNOVATION

Mr. Vikas Gupta, Research Scholar, School of Law and Governance, Central University of South Bihar, Gaya[1]

Dr. Deo Narayan Singh, Assistant Professor (Senior Scale), School of Law and Governance, Central University of South Bihar, Gaya [2]

ABSTRACT

This paper analyse the close relationship between intellectual property (IP) and medical innovation in India, focusing on the legal frameworks, ethical considerations, and public health impacts that shape the development and accessibility of healthcare pharmaceuticals and technologies. It elucidates the dualistic role of pharmaceutical patents as both facilitators and impediments to innovation. On one hand, it incentivizes research and investment by granting exclusivity and commercial value to medical discoveries; on the other, it can hinder affordability and limit access due to monopolistic practices like evergreening and patent thickets.

India's legal approach, anchored by the Patents Act of 1970 and amended to align with TRIPS, emphasizes a balance between rewarding genuine innovation and safeguarding public welfare. Key provisions such as Sections 3(d), 3(i), and 107A reflect India's cautious stance on medical patents, while mechanisms like compulsory licensing and government use provisions ensure equitable access. Judicial decisions and government initiatives, including ICMR's 'Medical Innovations Patent Mitra', further strengthen this dual objective of innovation and inclusion.

The study emphasizes the importance of developing dynamic IP policies that adapt to emerging global health challenges and technologies. It reaffirms India's commitment to being a leader in medical innovation while safeguarding public health equity.

Keywords: Intellectual Property, Patent, TRIPS Agreement, Generic drugs

[1] Research Scholar, School of Law and Governance, Central University of South Bihar, Gaya
[2] Assistant Professor (Senior Scale), School of Law and Governance, Central University of South Bihar, Gaya

I. Introduction

Today, medical innovation is closely linked with Intellectual Property (IP) laws, regulatory systems, and ethical standards. These elements collectively influence how new medical technologies are developed, how accessible they are to the public, and what kind of impact they have on society. Intellectual Property encompasses legal rights that safeguard imaginative creations, including inventions, names, images, designs, symbols, and literary or artistic works utilized in commerce.[3] In the medical field, IP laws, particularly patent law, play a vital role in shaping the development, protection, and availability of medical discoveries to the public. The importance of intellectual property in medicine lies in its ability to stimulate research, development and its utility. By providing exclusive rights to inventors through patents, IP encourages pharmaceutical companies and researchers to invest their resources and time into developing new drugs, treatments, and medical technologies.[4] This exclusivity gives them the opportunity to recoup their intellectual and financial investments, ultimately leading to advancements that can save lives.[5] However IP protections can also introducing barriers to access.

In the context of India's rapidly growing pharmaceutical and biotechnology sectors, intellectual property protection presents windows of growth and barriers both.

On the one hand, strong intellectual property laws encourage pharmaceutical companies to invest in research and development by protecting their inventions from unfair competition. On the other hand, strict patent protection can lead to monopolies that drive up drug prices and limit access to medicines for those who need medical care the most. The Indian legal system has handled this complexity by implementing reforms and formulating policies aimed at balancing innovation with public welfare.

The connection between IP and medical innovation is complex and nuanced. On the one hand, IP rights are essential for transforming scientific discoveries into market-ready solutions and for encouraging long-term investment in health research & development. On the

[3] *Available at:* https://www.wipo.int/en/web/about-ip (last visited on May 19, 2025)
[4] Sarah McGraw, "The Double-Edged Sword of Medical Patents: How Monopolies on Healthcare Products Disparately Impact Certain American Populations" 5 *The University of Cincinnati Intellectual Property and Computer Law Journal* 5 (2021). A*vailable at:* https://scholarship.law.uc.edu/ipclj/vol5/iss1/3 (last visited on May 22, 2025)
[5] *Id.* at 9.

other hand, the exclusivity provided by IP can hinder access, particularly for vulnerable populations. Effective IP management and policy frameworks are needed to foster innovation while ensuring that new medical technologies and treatments reach those who need them most.[6]

So a balance must be struck between encouraging medical innovation, ensuring public safety and promoting equitable access. Failure to do so can hinder innovation or lead to health inequities. Medical innovation should not happen in a vacuum, it should be regulated, protected and scrutinized from a legal and ethical perspective.

II. IPR as a Catalyst and Constraint for Medical Innovation

Intellectual Property serves a dual role in the field of medical innovation it acts as a catalyst that drives the creation of new treatments and technologies, but it can also serve as a constraint by potentially limiting access to these innovations, especially in under-served populations.

As a Catalyst for Innovation

1. **Encouraging Investment and Research & Development:-** Developing a new drug typically costs in billion of dollar and it takes so much time and efforts, with high failure rates.[7] Without patent protection, competing companies could copy successful treatments at a fraction of the cost, eliminating the financial incentive for original research.[8] Intellectual property rights, especially patents, confer exclusive rights to inventors and corporations for their inventions for a finite duration, generally for 20 years.[9] This exclusivity incentivizes investment in research and development by ensuring that pharmaceutical companies recoup the high costs of drug development, their investments and potentially profit from their work.[10]

2. **Supports venture funding:-** Patent portfolios act as tangible assets that attract investment because they indicate commercial viability and potential returns. For

[6] Gokce Izgi and Merve Altinay, "The interplay between intellectual property and healthcare innovation: the role of trade secrets, compulsory licensing and patent law" *International Bar Association* (February 11, 2025). *Available at:* https://www.ibanet.org/intellectual-property-healthcare-innovation (last visited on June 9, 2025)
[7] Sarah McGraw, *Supra* Note 4 at 7.
[8] Why do competitors get to make a drug, without having to contribute to the research and development, after a drug's patent protection expires? (March 21, 2025). Available at: https://synapse.patsnap.com/article/why-do-competitors-get-to-make-a-drug-without-having-to-contribute-to-the-research-and-development-after-a-drugs-patent-protection-expires (last visited on June 2, 2025)
[9] Sarah McGraw, *Supra* Note 4 at 10.
[10] Sarah McGraw, *Supra* Note 4 at 1

startups and small and medium-sized enterprises (SMEs) in the healthtech and biotech sectors, strong IP protection is crucial for attracting investors. Strong IP protection attracts venture capital, private equity, and pharmaceutical company investment into medical research. Investors need assurances that successful innovations will yield profits sufficient to compensate for the risk of failure. Patents signal commercial viability and protect innovations from being copied, thereby increasing investor confidence.[11]

3. **Facilitating Collaboration and Licensing:-** IP frameworks enable companies, universities, and research institutions to collaborate by licensing technologies and sharing expertise.[12] With protected IP, companies and institutions freely share knowledge through licensing, allowing further discoveries while still recognizing inventors.[13] Licensee companies, through patent licensing arrangements, gain access to novel technology that they have not independently invented or that would be too costly to produce internally. Access to innovative technologies enables these companies to introduce new products more efficiently. Additionally, licensee companies can maximize the return on their research and development investments by incorporating licensed technologies into their innovation strategy.[14]

4. **Driving Economic Growth:-** The healthcare sector benefits from job creation, industry growth, and vendor contributions, all of which are supported by robust IP protection.[15]

5. **Promoting Competition:** Patent provides temporary exclusivity to incentivize research and development, they eventually expire, allowing generic manufacturers to enter the market. This process fosters competition, lowers prices, and increases patient

[11] Paul Omondi, "Unlocking the power of intellectual property in medical technology" Wipo Magazine (February 3, 2025). *Available at:* https://www.wipo.int/web/wipo-magazine/articles/unlocking-the-power-of-intellectual-property-in-medical-technology-71322 (last visited on June 2, 2025)
[12] Dan Leonard, "10 Reasons Biopharma Innovation Needs Strong IP Protections" *We Work For Health* (August 6, 2024). *Available at:* https://www.weworkforhealth.org/post/10-reasons-biopharma-innovation-needs-strong-ip-protections (last visited on June 9, 2025)
[13] Eva Biswal, Gabriela de Obarrio Carles *et. al*., "Driving Health Innovation Using Intellectual Property" *WIPO. Available at:* https://www.wipo.int/en/web/global-health/w/blogs/driving-health-innovation-using-intellectual-property (last visited on 9 June 2025)
[14] Thomas J. Chemmanur and Xi Chen et. al., "The Economics of Patent Licensing: An Empirical Analysis of the Determinants and Consequences of Patent Licensing Transactions" 33 (July, 2024). *Available at:* https://afajof.org/management/viewp.php?n=133532 (last visited on 29 June 2025)
[15] Eva Biswal, *Supra* Note 13

access to affordable treatments. By ensuring that no single company maintains a permanent monopoly, the system promotes both innovation and long-term public benefit.[16]

6. **Knowledge Disclosure:-** Patent systems require detailed disclosure of inventions in exchange for protection. This creates a public knowledge base that other researchers can build upon, accelerating cumulative innovation.[17]

7. **Advancing Global Health:-** Strong intellectual property protection encourages the invention of new medicines which is an urgent need in today's world. They empower researchers and bio-pharmaceutical companies to respond swiftly and efficiently to global health threats, such as pandemics and rare conditions.[18]

As a Constraint for Innovation

1. **Exclusivity and Market Monopoly:-** Exclusive rights prevent generic manufacturers from producing cheaper alternatives until patents expire, delaying widespread availability. This exclusivity can restrict access to life-saving medications, especially during public health emergencies.[19]

2. **High prices and limit affordability:-** Patented medicines are often more expensive than non-patented alternatives, making them less accessible to ordinary people, especially in low and middle-income countries. Monopolies let patent-holders set steep prices - especially in areas like rare diseases. High prices driven by patent protection limit access to essential drug treatments.[20] Similarly, in the case of medical devices, large manufacturers benefit from price hikes on patented products. Patents on even small improvements can restrict market entry for new competitors, potentially

[16] Eva Biswal, *Supra* Note 13
[17] Anatole Krattiger, "Promoting access to medical innovation", *WIPO Magazine* (September 23, 2013). *Available at:*https://www.wipo.int/web/wipo-magazine/articles/promoting-access-to-medical-innovation-38584(last visited on July 6, 2025)
[18] Dan Leonard, *Supra* Note 12
[19] Eva Biswal, *Supra* Note 13
[20] Ellen 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules For Access To Medicines* 4 (Health Action International, The Netherland, 2016). *Available at:* https://haiweb.org/storage/2016/07/Private-Patents-Public-Health.pdf (last visited on June 28, 2025)

limiting innovation and affordability.[21]

3. **Patent "evergreening":-** To maintain market exclusivity, companies often engage in strategic patenting, making minor tweaks to existing drugs, devices, or vaccines (e.g., tablet coatings, extended-release formats) just before the original patent expires. These changes, while requiring minimal additional research, can qualify for new patents and effectively extend exclusivity. This is called Patent "evergreening". This practice can limit generic competition even after the original innovation is off-patent and giving the original patent-holder a de-facto monopoly over an extended period.[22]

4. **Overlapping patent can restrict follow-on innovation and competition:-** While the expiration of drug patents is meant to open the market to generics and lower prices, overlapping patents on delivery systems, formulations, or minor modifications can delay this competition.[23] Companies often patent different aspects of the same drug to maintain their market dominance and prevent competition. This dense web of patents is particularly prevalent in industries such as the pharmaceutical industry. Broad or overlapping patents can create "patent thickets". These patent thickets create legal and financial risks that potentially hinder innovation and slow down research and development. As a result, new entrants face high costs and legal challenges, which discourage innovation and reduce competition in the market.[24]

5. **Patent of basic research method and technique can impede the scientific research:-** Patents on foundational research methods, genetic sequences, or laboratory techniques can create significant obstacles for scientific research. When these essential tools are patented, researchers and institutions often need to obtain licenses to use them, which can involve expensive fees or complicated negotiations. This financial burden can be especially prohibitive for academic labs or smaller companies,

[21] E. Richard Gold, Warren Kaplan et. al. "Are Patents Impeding Medical Care and Innovation?" 2 *PLoS Med 7(1): e1000208* (2009). *Available at:* doi:10.1371/journal.pmed.1000208 (last visited on July 6, 2025)
[22] Id.
[23] Sarah McGraw, *Supra* Note 4 at 15.
[24] "Untangling Patent Thickets: The Hidden Barriers Stifling Innovation " *TT Consultants* (June 26, 2024). *Available at:* https://ttconsultants.com/untangling-patent-thickets-the-hidden-barriers-stifling-innovation/ (last visited on June 17, 2025)

potentially slowing the pace of innovation and discouraging further research.[25]

III. Patentable and Non Patentable Medical Inventions in India

Not every invention is eligible for a patent. To be considered patentable, an invention must fulfill certain requirements known as 'patentability conditions'. These conditions are explicitly mentioned in the Indian Patents Act, 1970. To qualify for patent protection, an innovation has to meet three essential criteria: novelty, inventive step and industrial applicability.[26] However, it must not be classified as a non-patentable invention.[27] The discovery of a new form of a known substance that does not improve the known effectiveness of that substance is not patentable. Additionally, the discovery of a new property or a new use for a known substance, as well as the use of a known process, machine, or apparatus, is not patentable unless the known process results in a new product or involves at least one new reactant. Also substances like salts, esters, metabolites, polymorphs, pure forms, particle sizes isomers, or other variations of a known substance are typically regarded as the same. However, they can be patentable only if they significantly differ in efficacy.[28] In addition, any process related to the medicinal, curative, therapeutic, diagnostic, surgical, prophylactic or similar treatment of human beings, as well as any process intended to cure diseases of animals or to increase the economic value of them or their products, is not patentable.[29]

Thus it draws a clear distinction between what is patentable and what is not patentable. Here's classification of patentable and non-patentable medical inventions:-

Patentable Medical Subject Matter

Medical instruments, devices, kits, and pharmaceutical compounds can be patented as a product if they meet the core criteria of novelty, inventive step, and industrial applicability. For example, a new drug molecule, a novel surgical instrument, or a unique medical device can be patented as a product.[30] New compositions or formulations of drugs may be patentable,

[25] Youbin Chen, Shakila Yacob, *et.al.* (eds.), *Proceedings of the 2023 2nd International Conference on Public Culture and Social Services* 338 (Atlantis Press, 2023). *Available at:* https://doi.org/10.2991/978-2-38476-130-2_41 (last visited on July 1, 2025)
[26] The Patents Act, 1970 (Act 39 of 1970), s. 2(1)(j).
[27] The Patents Act, 1970 (Act 39 of 1970), ss. 3,4.
[28] The Patents Act, 1970 (Act 39 of 1970), s. 3(d).
[29] The Patents Act, 1970 (Act 39 of 1970), s. 3(i).
[30] Siddhesh Birajdar, Patentability of Medical, Diagnostic and Therapeutic Methods, *Mondaq* (April 22, 2021). *Available at:* https://www.mondaq.com/india/patent/1060438/patentability-of-medical-diagnostic-and-therapeutic-methods (last visited on July 3, 2025)

provided they are not mere admixtures or obvious combinations and show enhanced efficacy.[31]

Non-Patentable Medical Subject Matter

1. **Methods of treatment:-** A patent cannot be granted for any process relating to medical, therapeutic, diagnostic, surgical, curative, preventive or other treatments for humans or animals. This includes methods for diagnosing, treating or preventing diseases in both humans and animals, whether performed in vitro (outside the body) or in vivo (inside the body).[32]

2. **Diagnostic methods:-** Diagnostic techniques, both in vitro and in vivo, that directly detect diseases for treatment purposes are excluded from patentability.[33]

3. **Second medical use:-** Only discovery of a new use for a known substance or a new form of a known substance (unless it results in enhanced efficacy) is not patentable.[34]

4. **Other exclusions:-** An invention that is trivial in nature or that make claims that are in conflict with accepted natural laws cannot be patented. This prohibits the patenting of inventions that have no real value or are not practical, especially those that contradict established scientific theories.[35]

IV. India's Perspective on the Role of Patents in the Evolution of Medical Innovation

India's perspective on the role of patents in the development of medical innovation is shaped by a careful effort to balance the encouragement of research and development with the need to ensure affordable healthcare for its large and diverse population. The country's stance on patenting medical innovations is cautious and focused on public health.[36] India supports

[31] Saipriya Balasubramanian, Patenting 'Second Medical Use' Inventions in India, *Zacco*. Available at: https://www.zacco.com/articles/patenting-second-medical-use-inventions-in-india/ (last visited on July 4, 2025)
[32] Swarup Kumar, Understanding the Patentability of Diagnostic Methods under Section 3(i) of the Indian Patent Law: A Comparative Perspective, *FICPI* (September 18, 2024). *Available at:* https://ficpi.org/blog/understanding-patentability-diagnostic-methods-indian-patent-law (last visited on July 3, 2025)
[33] Id.
[34] The Patents Act, 1970 (Act 39 of 1970), s. 3(d).
[35] The Patents Act, 1970 (Act 39 of 1970), s. 3(a).
[36] AKSH IP ASSOCIATES, Striking a Balance between IPR and Public Health: Exploring India's Innovative Approach to the Pharmaceutical Industry, *Linkdin* (May 24,2024). *Available at:* https://www.linkedin.com/pulse/striking-balance-between-ipr-public-health-exploring-mrrvc (last visited on July 28, 2025)

patenting medical innovations that are genuinely novel and useful, but also imposes strict safeguards to prevent misuse of the patent system.

India offers patent protection for new medical products, processes and technologies that meet the criteria of novelty, non-obviousness and industrial applicability.[37] India recognize that patents play an important role in promoting medical innovation by granting exclusive rights and financial returns to inventors and research-focused companies. To foster research and development, it is important to provide temporary monopolies, particularly for private pharmaceutical firms. However, India's policy is heavily focused on public health, ensuring that life-saving medications remain affordable. Considering that a significant portion of the population lives below the poverty threshold and often bear the brunt of health care costs directly, the country emphasizes that patent protections should not create barriers to access to affordable medicines.[38] India's approach has always been to maintain a balance between medical innovation and public welfare. The Indian Patent Act, 1970 contains several provisions that balance medical innovation with public welfare; some significant provisions are as follows:

1. Prevent "Evergreening":- For a drug to be eligible for a patent, modifications to existing drugs must show improved therapeutic efficacy.[39] This prevent the "evergreening" of patents, where minor changes to existing drugs are used to prevent monopolies and to ensure that only truly innovative products receive patent protection.

In the landmark case of **Novartis Ag vs. Union of India & others**[40] the Supreme Court of India rejected a patent for cancer drug Glivec because the beta crystalline form didn't show significantly enhanced efficacy over the known compound. The Court stated that the product is merely a different version of an existing substance and not a new one. To qualify for a patent under Section 3(d) of the Patent Act, 1970, the new version must demonstrate improved "known efficacy," defined as therapeutic effectiveness. Section 3(d) aims to prevent "evergreening," where companies extend patents through minor modifications. If the invention fails the Section 3(d) test, it cannot be patented. This reflects India's view that patents should reward genuine innovation rather than allow companies to extend monopolies on existing

[37] The Patents Act, 1970 (Act 39 of 1970), s.2(1)(j)
[38] AKSH IP ASSOCIATES, *Supra* Note 36
[39] The Patents Act, 1970 (Act 39 of 1970), s. 3(d).
[40] AIR 2013 SC 1311. available at: https://indiankanoon.org/doc/165776436/ (last visited on July 14, 2025)

medicines.

2. Keeping treatment methods out of patent:- Any process for medicinal, therapeutic, diagnostic, curative, prophylactic or surgical treatment of humans or animals is exempt from patent. This protects public access to essential medical practices by ensuring that methods of treatment and diagnosis cannot be monopolized.[41]

3. Government use of patented drugs:- Any drug or medicine patented in India may be imported by the Government for its own use or for distribution to the Government or specified medical institutions.[42] This ensures that the government can intervene to protect the public interest and ensure access to essential medicines.

4. Revocation of patent in public interest:- Central Government can revoke any patents if it finds that the invention or its associated processes are harmful to the State or public interest after hearing the patentee, by declaring it in the Official Gazette.[43] This empowers the central government to promote the public interest while safeguarding public health.

5. Promoting Public Interest:- Patents should support technology transfer, public health, and economic welfare. Patents should not impede government actions for public health, prevent abuse of rights or unfair trade practices, and ensure that patented inventions are available to the public at affordable prices.[44] It emphasizes the goal of striking a balance between the need for innovation and the needs of public health.

6. Compulsory Licensing:- If the patented drug is not made available to the public at an affordable price, is not domestically produced in India, or fails to meet public health needs, the government may authorize third parties to produce patented drugs through compulsory licensing.[45] Furthermore the government can also issue compulsory licenses during national emergencies or public health crises, such as epidemics.[46] In addition, the government or its authorized agents utilize any patented invention for public purposes, including health emergencies, even before a patent is officially granted.[47]

[41] The Patents Act, 1970 (Act 39 of 1970), s. 3(i).
[42] The Patents Act, 1970 (Act 39 of 1970), s. 47.
[43] The Patents Act, 1970 (Act 39 of 1970), s. 66.
[44] The Patents Act, 1970 (Act 39 of 1970), s. 83.
[45] The Patents Act, 1970 (Act 39 of 1970), s. 84.
[46] The Patents Act, 1970 (Act 39 of 1970), s. 92.
[47] The Patents Act, 1970 (Act 39 of 1970), s. 100.

7. Defense in Patent Infringement Cases:- Individuals who are legally authorized to produce, sell or market patented drugs and medicine are allowed (under some conditions) to manufacture, use or import these products without infringing the patent.[48]

8. Defense against Patent Infringement for Development:- Most generic companies base their drugs on patented ones, which are protected for 20 years under the Indian Patents Act of 1970. During this period, the patent holder has exclusive rights to their product.[49] If a person makes, uses, sells or imports a patented invention only to develop and provide information required by law, it is not considered patent infringement. Additionally, if a person imports a patented product from someone who is legally allowed to make and sell it in another country, it is also not considered patent infringement.[50] This provision is commonly called the Bolar provision under which the problem of delay in entry of generic medicines due to patent restrictions was resolved. This provision is commonly called the Bolar provision under which the problem of delay in entry of generic medicines due to patent restrictions was resolved. This provision serves as a defensive mechanism for generic manufacturers, by allowing them to start research and regulatory procedures prior to the patent expiring and then enter the market right away, thereby avoiding a de facto extension of the patent holder's monopoly.[51]

In an important case of **Bayer Corporation vs. Union Of India & Ors.**,[52] the Delhi High Court division bench had to decide two appeals. The first was from the decision of a learned single judge in writ petition W.P.(C) No. 1971/2014, filed by the appellant Bayer against the respondent “Natco” and the second appeal concerned a suit resolved in CS (OS) (Comm) 1592/2016, which the appellant Bayer filed against “Alembic Chemicals Ltd.” In this case, the Delhi High Court needed to decide whether the term "sell" under section 107(A) also includes "export" and whether exporting a patented drug to another country for regulatory approval constitutes patent infringement.

In this case, Bayer Corporation, holder of a patent for Sorafenib Tosylate (used for

[48] The Patents Act, 1970 (Act 39 of 1970), s. 107.
[49] Aayush Sharma, Bolar Exemption in India, *Mondaq* (April 12, 2018). Available at: https://www.mondaq.com/india/patent/691036/bolar-exemption-in-india (last visited on July 15, 2025)
[50] The Patents Act, 1970 (Act 39 of 1970), s. 107 (A).
[51] Anuja Saraswat, Bolar Provision: An Exemption to Patent Exclusivity, *Global Patent Filing*, (March 24, 2022). Available at: https://www.globalpatentfiling.com/blog/bolar-provision-exemption-patent-exclusivity (last visited on July 31, 2025)
[52] AIRONLINE 2019 DEL 1712. Available at: https://indiankanoon.org/doc/85364944/ (last visited on July 15, 2025)

treating cancer), challenged Natco Pharma's export of the drug. While the suit was ongoing, Natco secured a compulsory license to manufacture and sell the drug in India and requested permission to export 1000 kg of active pharmaceutical ingredient (API) to China for clinical studies. Bayer opposed the export, claiming it violated Section 107A as a commercial transaction. Additionally, Bayer filed a suit to prevent Alembic from selling and exporting the drug Rivaroxaban in India, as well as to the European Union and the United States.

Bayer argued that Section 107A should be interpreted as an exception to the patentee's rights under Section 48, and that it does not mention "export" and should be restricted to sales within India.

In contrast, Natco and Alembic contended that Section 107A permits the sale of patented product for regulatory purposes in other countries, highlighting that the language of section 107(A) does not limit sales to India.

The Delhi High Court division bench dismissed Bayer's appeal, confirming that Section 107A permits the sale and export of patented drugs for regulatory approval and research. Bayer's patents cannot obstruct the export of these drugs for regulatory purposes.

Furthermore, as a member of the World Trade Organization (WTO), India has brought its intellectual property laws into conformity with the requirements of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. The Government of India has strategically amended the Patent Act of 1970 in 1999, 2002 and 2005 to incorporate the flexibilities permitted under the TRIPS Agreement. In 1999, the Patents Act of 1970 was amended to allow product patent applications and introduced Exclusive Marketing Rights under. A second amendment in 2002 aligned the Act with TRIPS Agreement provisions, except for product patents, and addressed patentable subject matter, extended patent duration to 20 years, and modified compulsory licensing. The third amendment on January 1, 2005, established a product patent regime for areas like pharmaceuticals that previously had only process patents.[53] These amendments aim to balance intellectual property rights with public health priorities, particularly ensuring access to essential medicines for the population. Changes in intellectual property rules in compliance with the TRIPS agreement have made India the

[53] Saurabh Chandra, "Impact of TRIPS over Indian Patent Regime vis a vis Indian Pharmaceutical Industry" 1 *Galgotias Journal of Legal Studies* 51 (2013). Available at: https://www.galgotiasuniversity.edu.in/pdfs/issue4.pdf (last visited on July 18, 2025)

largest supplier of generic drugs worldwide. Addressing the 70th Indian Pharmaceutical Congress in 2018, then Vice President M. Venkaiah Naidu pointed out that India became one of the top five emerging pharmaceutical markets in the world, Indian generic drugs accounted for 20% of global exports. He cited India's key role in supplying affordable antiretroviral drugs globally, bringing down the cost of HIV treatment from $12,000 per year to $400 per year.[54] India provides about 40% of generic medicines to the US and about 33% of generic medicines to the UK, and also supplies generic pharmaceutical products to low and middle-income countries such as sub-Saharan Africa.[55] All this was possible because simplified patent norms played a key role in accelerating development.

Except the above the Government of India promotes indigenous medical innovation through public and private medical research institutions especially for vaccines, diagnostics, and affordable health technology. Patents from these bodies aim to stimulate local research but are also aligned with public interest, often involving non-exclusive or socially responsible licensing.[56] Recent initiatives, such as the 'Medical Innovations Patent Mitra' launched by ICMR, aim to strengthen the medical innovation ecosystem by providing comprehensive support for patent filings, technology transfer, and the commercialization of biomedical innovations. This programme is designed to boost the translation of research into practical solutions and increase the number of life sciences patents filed in India.[57] This highlights the increasing acknowledgment that strong patent support is essential for developing a self-sufficient innovation ecosystem, particularly in the domains of behavioural research and medical technology.

V. Conclusion

The interrelationship of intellectual property (IP) and medical innovation in India reflects a dynamic balance between encouraging technological advancement and protecting public health. The patent regulations of India, play a key role in shaping the development,

[54] Make India the international capital for Generic Medicines: Vice President, Press Information Bureau Government of India Vice President's Secretariat (2018). Available at: https://www.pib.gov.in/newsite/PrintRelease.aspx?relid=186696 (last visited at July 28,2025)
[55] Ero Partsakoulaki, India’s drugs industry: how one country took over the global medicine market, *The Bureau of Investigative Journalism*, (April 16 2025). Available at: https://www.thebureauinvestigates.com/stories/2025-04-16/indias-drugs-industry-global-medicine-market (last visited on July 28, 2025)
[56] S&T brings Health for All. Available at: https://dst.gov.in/st-brings-health-all (last visited on July 27, 2025)
[57] ICMR launches 'Medical Innovations Patent Mitra' to support biomedical innovation (March 9, 2025). Available at: https://health.economictimes.indiatimes.com/news/industry/icmr-launches-medical-innovations-patent-mitra-to-support-biomedical-innovations/118814226 (last visited on July 27, 2025)

protection, and availability of medical discoveries to the public. India's approach is both strategic and socially conscious. Through carefully tailored provisions in the Patent Act, such as preventing evergreening, promoting compulsory licensing, and excluding treatment methods from patentability, India strives to ensure that innovation doesn't come at the cost of affordability and accessibility. It aligns its IP framework with global standards while keeping the public interest in mind, making it a unique model of striking a balance between exclusivity and equity. India's nuanced legal approach focuses on creating a middle path, encouraging genuine innovation, and ensuring that the fruits of benefits of this progress are not limited to a privileged few. As healthcare needs continue to evolve, India's legal framework must remain inclusive, equitable, and sensitive to societal needs.

India, in compliance with its obligations under the TRIPS Agreement, made several significant amendments to the Patents Act of 1970, the keystone of its IP regime. These changes brought India's laws into line with international standards, while preserving mechanisms such as compulsory licensing. Such provisions enable generic drug manufacturers to produce patented drugs under specific circumstances, especially during public health emergencies, thereby reducing the negative impact of exclusivity.

As India continues to strengthen its biomedical ecosystem, programs like the 'Medical Innovations Patent Mitra' highlight an increasing emphasis on responsible innovation and support for indigenous research. Ultimately, medical progress in India is guided not just by legal rights but by ethical duty and inclusive policy also.

India's strategic intellectual property direction has made India a global leader in supplying generic medicines to the world. India has gained prominence as a major exporter of affordable generic medicines not only to low and middle-income countries but also to developed countries. Referred to as the "pharmacy of the world,[58]" India's dynamic generic drug sector is flourishing under a relatively flexible intellectual property regime that prioritizes public health imperatives over stringent patent enforcement.

[58] Santosh Kumar, Ritu Kataria, et. al., India: The Pharmacy of the World, *PIB Research Unit* (2024). Available at:https://static.pib.gov.in/WriteReadData/specificdocs/documents/2024/aug/doc2024822379301.pdf#:~:text=India%27s%20pharmaceutical%20industry%20has%20gained%20international%20recognition%20as,medical%20supplies%20during%20the%20COVID-19%20pandemic%20and%20beyond. (last visited on July 28, 2025)