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The Present Scenario of Intellectual Property Rights and the Indian Pharmaceutical Sector

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Abstract

Intellectual property rights (IPRs) play a crucial role in fostering growth and sustainable development of the pharmaceutical industry by providing adequate protection to research, investment in research and technology. India has made a significant stride towards being an indispensable pharmaceutical producer for the world, most notably in the field of generics and the industry has been working under an equitable IP system ensuring medication availability and innovation. TRIPS Agreement is a historic shift in India's patent regime. Here is a bird's eye view of IPR in India's pharmaceutical industry, looking at IPR, compulsory licensing, challenges, opportunities and trends in pharmaceutical innovation and healthcare.

Keywords: Intellectual Property Rights, pharmaceutical industry, patents, TRIPS, compulsory licensing, India

Introduction

The Indian intellectual property and pharma innovation ecosystem is a well-governed regime. Called the "pharmacy of the developing world", India fulfills two roles, as the largest provider of low-cost, generics, and an emerging innovation powerhouse, driving drug discovery and development services through contract research. This requires balancing the protection of the private monopoly rights for investment into the R & D pipeline with protecting the health of the millions in LMIC who access life-saving medicines on the back of cheap Indian generics.

The reform in the pharmaceutical regime began with India's accession to the WTO, which mandated compliance with the TRIPS agreement in 2005. Prior to TRIPs, the Indian patent

regime had only process patent protection, allowing companies to develop medicines by reverse-engineering proprietary drug molecules developed abroad and therefore sell at significantly cheaper prices globally, than their international competitors. India's transition to a product patent regime prompted fears of disruption of the generic medicine supply but the legislature proactively built in robust public health safeguards (TRIPs flexibilities) in the 2005 patent legislation.[1]

Economic Ripples of the Post-TRIPS Regime: R&D, FDI, and Patent Trends

the TRIPS agreement coerced Indian corporations from the realm of copying into a globally significant journey up the value chain. For businesses, both local and international, this represented a watershed. As research by The Organization for Economic Co-Operation and Development (OECD) suggested, post TRIPS, there had been a surge in investment by India's pharmaceutical companies into R&D, particularly with an emphasis on biosimilars, novel drug delivery systems (NDDS) and research into new drugs.

In order to maintain competitiveness, Indian companies had actively pursued CRAMS as MNCs became eager to use this outsourcing business as their principal agent.

The strengthened IP rights (IPR) offered better security for cross-border acquisitions and Foreign Direct Investment (FDI). Product protection guaranteed by new legislations allowed MNCs to set foot on Indian soil again. With recent government policy initiatives like the "Make in India" scheme and Production-Linked Incentives (PLIs) to inject an estimated $3 billion into the pharmaceutical sector and make India more reliant on manufacturing high value biologics rather than importing expensive Active Pharmaceutical ingredients (APIs) from China, India now attracted large sums of investment in the pharmaceutical industry.2 Such innovations and drive is amply reflected by the patent filing figures recorded by the Indian Patent Office (IPO). In FY 2024-25, for instance, the IPO had a total filing of 110,375 applications.

However, foreign applications accounted for only 61.79% of the filings, and the IPO granted only 30.3% of the patents applied.

This shows there might be increase in number of filings, yet turning the applications into commercially viable patent remains difficult[3].

Comparison between pre and post TRIPS era

Economic/IP Indicator	Pre-TRIPS Era (Pre-2005)	Post-TRIPS Era
Patent Regime	Process patents only for pharmaceuticals.	Product and process patents (20-year term).
R&D Focus	Reverse engineering, process efficiency.	Novel drug discovery, NDDS, CRAMS, biosimilars.
IPO Grant Share	Dominated by foreign applicants.	Domestic filings comprise 61.79% (2024-25).
Supply Chain Role	Independent generic formulation.	Global CDMO integration, reliance on imported APIs.

Section 3 (d): Patent Eligibility and the Bar on Evergreening

A clampdown on "evergreening"- Perhaps the biggest current debate regarding the Patents Act revolves around Section 3(d) to prevent the 'evergreening' of medicines where pharmaceutical companies introduce trivial changes to an existing medicine in order to maintain their 20-year exclusive rights. The section states that a salt, ester, polymorph or other derivative is not a different substance unless it offers a "significantly improved therapeutic effect".

Landmark Precedents: Novartis and Roche v. Cipla

The case law defining Section 3(d) arose when Novartis AG filed a patent application in India for the beta crystalline salt form of their leukemia drug Glivec (Novartis AG v. Union of India, 2013). But the application was rejected when the Indian Supreme Court held that the meaning of "efficacy" in this section of the law refers only to "therapeutic efficacy"-that is, the actual effectiveness of the drug in curing a disease or ailment.

Simply possessing improved physical attributes such as thermodynamic stability was insufficient to satisfy the Section 3(d) criteria, unless the derivative could show better therapeutic effect.[4] Similar principles are illustrated by the Delhi High Court's decision in Roche v.

Cipla concerning their lung cancer drug Tarceva. The court found that Section 3(d) functions as an eligibility standard of patenting by "deeming fiction"-i.e., that a derivative which fails the efficacy criteria defined in the section is deemed to be equivalent to the original compound. The court therefore found that Cipla's production of the Polymorph B derivative infringed Roche's first base patent.[5]

Contemporary Application: Bedaquiline Rejections

The significance of Section 3(d) came to light once again in March 2023 and July 2024 when the Indian Patent Office rejected the secondary patent applications for the fumarate salt of Bedaquiline (essential treatment against multidrug-resistant tuberculosis, or MDR-TB) in March 2023 and its pediatric formulation in July 2024, filed by Johnson & Johnson. Pre-grant oppositions raised concerns over whether the new forms of the existing base compound offered any new and significant therapeutic benefits.[6] These rejections dismantled crucial impediments to access a significantly cheaper Bedaquiline treatment by Indian manufacturers.

Compulsory Licensing (CL): Safeguarding Public Health

CL functions as an emergency brake for patented inventions so that they are compliant with national public health goals. In accordance with Section 84 of the Act, a CL may be issued three

years after the grant of the patent if the needs of the public are not satisfied, if the cost of the drug is unaffordable for the general public, or if the patent has not been put to use in India.

The Bayer v. Natco Case and Evidentiary Thresholds

As early as 2012, India had issued its first compulsory license (CL) to Natco Pharma for the cancer drug Sorafenib (Nexavar) by Bayer. This drug was priced at nearly $5,500 a month for most patients and "would meet only a tiny fraction of a given country's patient demand" [Bayer] … Indian courts have ruled that a reasonably affordable price is defined as "a price that patients can afford … since Bayer had not been able to market sufficiently to the needs of the population[7,] the compulsory license was appropriate [India Supreme Court]. [This] CL to allow Natco to produce a low-cost generic version of Sorafenib to treat liver cancer and thyroid cancer, which paid a 7 percent royalty to Bayer" (National Organization for Rare Disorders) .

But let it not be said that Indian authorities readily grant these CLs: In 2013, a CL to BDR Pharmaceuticals was denied on the grounds that they failed to engage in voluntary negotiations in good faith.

Also in 2015, the CL attempt of Lee Pharma for Saxagliptin failed[8] when the firm did not "make sufficient showing of a lack of market affordability" of a drug already on market with alternatives[9.] When COVID19 threatened India in 2020, there was talk of CLs, but none were issued since voluntary licensing was available… Indeed, in April 2020 Gilead provided non-exclusive, royalty-free voluntary licenses to several Indian generic manufacturers for its Remdesivir that allowed Indian firms "to accelerate production and increase access to this promising medicine" in 127 high- and middle-income countries.

Defending Against TRIPS-Plus: Patent Linkage and Data Exclusivity

India strongly resists "TRIPS-plus" such as the clauses of Data Exclusivity and Patent Linkage found in many free trade agreements (FTAs). Patent linkage associates a drug's patent status with its market authorization. A recent case clearly demonstrates how the Delhi High Court dismissed the notion of patent linkage in Bayer Corporation v Union of India (2009) "the two

arms – Patent Office (which granted monopoly) and Drugs Controller General of India (who assessed quality, safety and efficacy) – operate in distinct legal fields."

The Drugs Controller General's office could approve a generic drug without this affecting its ability to do so; the patent holder could still go to civil courts.

India has no provision for data exclusivity, which enables generic firms to access and use innovative clinical trial data when seeking approval for generic medicines, bringing forward early generic access to drugs as soon as patents expire. Despite considerable lobbying in EU-India FTA negotiations, the health community was successful in resisting it - as a global health advocacy group explains, this position ensures "India provides 92% of the world's supply of antiretroviral for people with HIV"[10].

The Bolar Exemption and Process Patents in Biologics

In anticipation of the entry of generics as soon as a patent is due to expire, Section 107A of the Patents Act provides a "Bolar Exemption" to safeguard third parties against charges of infringement when the patented product is used to create and obtain the necessary data. In 2019, the Delhi High Court clarified that exporting patented APIs are protected under the exemption as long as the export of the API bears some reasonable nexus to the requirement for foreign regulatory approval.[11]

This section can become increasingly significant as industries transition towards a greater number of complex biologics and biosimilars where there are numerous ongoing litigation proceedings over process patents. Section 104A changes the balance in that it places the onus of proof on the defendant to prove non-infringement in the case of "identical" process products to the patented process. In the July 2024 Delhi High Court case of Roche v Zydus with respect to the biologic Pertuzumab, the Court definitively stated that for the purpose of Section 104A, biosimilars need to be "identical" and not functionally similar to the patented product[12]. This can offer some protection to the defendants from invasive trade-secret mining exercises.

Biopiracy, Traditional Knowledge, and the 2024 WIPO GRATK Treaty

There is a huge repository of Traditional Knowledge (TK) in India and unfortunately a lot of it has become subject to 'biopiracy'. In the face of glaring instances such as invalidation of false foreign patents on Neem, turmeric and Basmati rice, India's Traditional Knowledge Digital Library (TKDL) a prior art database was established and it has proved successful in preventing many cases of misappropriation.[13]

In May 2024 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (GRATK) was negotiated, mandating patent applicants to disclose the source of genetic resources and TK.14 This treaty however has huge lacunae which could compromise developing countries. Article 3.3, for example states that an applicant may state that they are not aware without making reasonable inquiries, and this article does not provide for revocation of a patent merely on the grounds of lack of disclosure.14 A treaty on TK without stringent Access and Benefit Sharing (ABS) mechanisms will most likely be nothing other than a loophole that allows "ignorance as a guise"[14].

Artificial Intelligence in Drug Discovery

The field of molecular generation and predictive modeling is experiencing the dawn of an AI era.

The only drawback?

This era is already running into a serious roadblock within the human-centric framework of the Indian Patent Act. The Indian Patent Office declined to grant a patent that identified an autonomous AI (DABUS) as the sole inventor in April 2026.

"Only a 'natural person' can be considered an inventor", according to the Office. However, the question of how a company can tie a creative process that was developed in a vacuum by AI into a human inventor comes into play, which brings up a wide host of questions surrounding patentability, the exclusions under Section 3(k) in the Indian Patent Act related to algorithms, and the meaning of a "Person Skilled in the Art".[15]

Conclusion

This case study demonstrates a rich interaction of law and practice that characterizes the intellectual property ecosystem of the Indian pharmaceutical industry. The legal architecture, comprising the traditional product patent system coupled with robust public health safeguards (such as Section 3(d), Compulsory Licensing, and Bolar exemption) has facilitated robust domestic R&D and confounded critics who predicted the demise of Indian drug manufacturing industry. The dense legal structure demonstrates the balance between the right to exclude others and the governmental responsibility for ensuring affordable access to medicines.

Moving forward, the Indian pharmaceutical industry faces several challenges in Navigating through biologics, resisting TRIPS plus and its ilk, understanding the deficiencies of the WIPO GRATK Treaty, formulating rules and regulations around artificial intelligence in drug discovery, among others.

For India to sustain its moniker as the "pharmacy of the world", its dynamic IP ecosystem has to continually adapt and evolve, maintaining a tight defence of the right to innovative medicines and affordable access.

References

1. *Article on IPR.docx (Uploaded document on Intellectual Property Rights and the Indian Pharmaceutical Industry).*
2. *Chauhan, S. (2024). Paper 3 - Post-TRIPS R&D intensity FDI Indian pharmaceutical industry empirical studies.*
3. *Office of the Controller General of Patents, Designs, Trademarks and Geographical Indications (CGPDTM). (2025). Annual Report 2024-25.*
4. *Novartis AG v. Union of India, (2013) 6 SCC 1 (Supreme Court of India).*
5. *F. Hoffmann-La Roche Ltd. v. Cipla Ltd., (2015) (Delhi High Court).*
6. *Indian Patent Office. (2023). Order on Bedaquiline pre-grant opposition (Johnson & Johnson).*
7. *Bayer Corporation v. Natco Pharma Ltd., (2012) (Intellectual Property Appellate Board).*

8. *Lee Pharma v. AstraZeneca, (2015) (Controller of Patents).*
9. *Gilead Sciences. (2021). Voluntary Licensing Agreements for Remdesivir.*
10. *Cyril Amarchand Mangaldas. (2024). Linking Patents to Pills: Unravelling the Patent Linkage Framework.*
11. *Bayer Corporation v. Union of India & Ors. (LPA No 359/2017) (Delhi High Court).*
12. *F. Hoffmann-La Roche AG v. Zydus Lifesciences, (2024) (Delhi High Court).*
13. *Legacy IAS. (2026). Biopiracy: Neem, Turmeric, Basmati Case Studies.*
14. *Spicy IP. (2024). WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge: Concerns of India.*
15. *Global Law Experts. (2026). AI Inventor Patent India 2026: DABUS Rejection.*

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