INDIA'S STRATEGIC POSITION IN GLOBAL IP NEGOTIATIONS: BETWEEN INNOVATION AND PUBLIC INTEREST

Abhishek Kumar, LLM, Hidayatullah National Law University, Raipur[1]

ABSTRACT

India's strategic position in global Intellectual Property (IP) negotiations is defined by a critical policy paradox: the imperative to retain its legacy as the "pharmacy of the world" (prioritizing public interest and access) while simultaneously striving to become a global innovation hub that attracts high-value foreign direct investment (FDI). This paper analyses how India navigates this tightrope walk by expertly leveraging the flexibilities enshrined in the TRIPS Agreement and its robust domestic instruments. The analysis identifies **Section 3(d)** of the Patents Act, which prevents 'evergreening,' and the strategic deployment of **Compulsory Licensing (CL)** (as demonstrated in the *Bayer v. Natco* case) as the primary pillars of India's public interest defense.

However, India's innovation pivot is now supported by empirical success, including a significant surge in R&D expenditure and the milestone achievement of domestic patent applications surpassing foreign filings for the first time in 2022-23. This maturation is rigorously tested in bilateral trade negotiations, where demands for **TRIPS-plus provisions**—such as Data Exclusivity and Patent Term Extensions—threaten to erode India's policy space, restrict its generic industry's market access, and incur substantial fiscal costs.

The paper concludes that India's diplomatic leverage hinges on its policy dissension—its unique ability to integrate public welfare principles into its IP architecture. Sustainable governance requires strategic judicial reform (establishing specialized IP courts) and proactively reframing IP in FTAs as a tool for mandatory technology transfer aligned with developmental goals, rather than merely a defensive concession. The strategic imperative is to integrate the primacy of public welfare into the burgeoning innovation agenda, ensuring developmental justice is not sacrificed for global compliance.

[1] LLM, Hidayatullah National Law University, Raipur

I. Introduction: The Policy Paradox in India's IP Strategy

India's contemporary intellectual property (IP) regime is defined by a deep and evolving policy paradox. For decades, India cultivated an identity as the "pharmacy of the world," a critical global supplier of affordable, high-quality generic medicines. This role was predicated on legislative foresight, specifically strong public health safeguards embedded within its domestic patent law.[2] Simultaneously, driven by aspirations to transition into a developed economy and a global innovation hub, India has aggressively pivoted toward strengthening its IP ecosystem to attract Foreign Direct Investment (FDI) and foster indigenous Research and Development (R&D).[3]

This dual identity places India at a critical juncture in global IP negotiations. The central strategic challenge lies in reconciling the need to retain maximum policy space—essential for upholding its generic manufacturing leadership and safeguarding public interest—with the requirement to attract high-value R&D investments, which often demands a degree of international IP compliance that exceeds existing multilateral agreements, frequently referred to as TRIPS-plus standards.[4]

The core thesis of this analysis posits that India's strategic position in global IP negotiations is defined by this inherent, difficult-to-reconcile paradox: the retention of maximum policy space (Public Interest) is essential for upholding its generic manufacturing leadership, yet its ambition to attract FDI and foster indigenous R&D (Innovation) necessitates a degree of international IP compliance often exceeding existing multilateral agreements. This tightrope walk requires continuous, nuanced policy intervention.

Historical Context: The Shift from Common Heritage to Compliance

The roots of India's current strategy lie in its legislative history. The Patents Act of 1970 deliberately excluded product patents for food, medicine, and chemicals, focusing instead on granting process patents. This legislative framework institutionalized a 'common heritage' approach, prioritizing widespread access and allowing domestic firms to engage in process

[2] U.S. Trade Representative, *2019 Special 301 Report* 3, 5 (2019); *Intellectual Property Rights and Food TRIPS*, *Economic and Political Weekly* (Feb. 15, 2020).[1]
[3] The Nat'l Bureau of Asian Research, *India's Intellectual Property Rights Regime: An Assessment and Scenarios for Continued Advancement* 5, 12 (2015). [2]
[4] Médecins Sans Frontières, *Patents, Power and the Public Interest: Why IP Barriers to Essential Medicines and Vaccines Must be Addressed in the Pandemic Preparedness and Response (PPR) Accord* 2, 4 (2023).

innovation to create affordable alternatives to patented products.[5] The tectonic shift occurred with India's accession to the World Trade Organization (WTO) and the subsequent ratification of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS mandated minimum IP standards, forcing India to amend its Patents Act, culminating in the 2005 amendments that introduced product patents in the pharmaceutical sector. While this move represented alignment with international trade norms, India strategically utilized TRIPS flexibilities, successfully embedding legal provisions designed to maintain policy space for public health interventions. This strategic maneuver ensured that while India complied with the letter of the TRIPS law, it retained critical tools to address market failures and protect public welfare.[6]

The initial defense of public interest was a necessity born of weak domestic R&D capacity and the need for access to essential technologies. As domestic R&D capacity has strengthened, [7]the public interest argument has strategically evolved. It is no longer solely about protecting consumers *from* foreign monopoly pricing, but increasingly about protecting the substantial *Indian generic industry's market access* against regulatory burdens, such as those imposed by TRIPS-plus demands, which could stifle competition and reverse the gains made in the post-TRIPS era. India's strategic leverage in negotiations relies fundamentally on the global recognition of its role in providing low-cost medicines, [8]a leverage that must be vigilantly protected against attempts to dilute it through excessive alignment with developed world IP standards.

II. The Foundational Pillars of Public Interest: Maximum Use of TRIPS Flexibilities

India's ability to defend its public interest mandate in global fora rests upon its expert utilization of the flexibility afforded by the TRIPS Agreement and its domestic legislative instruments. These mechanisms form the strategic shield against external pressure.

The Multilateral Mandate: Doha Declaration and Developmental Space

The TRIPS Agreement itself provides the foundational rationale for developmental policy

[5] *supra* note 1 (discussing the shift from the "common heritage" framework).
[6] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299 (entered into force Jan. 1, 1995).
[7] Deloitte India Press Release, *Blueprint to boost India's R&D sector* (Aug. 10, 2022); Office of the Controller Gen. of Patents, Designs & Trade Marks, *Annual Report 2022-23 (English)* 4 (2023). [3]
[8] *Ensuring Access to Vaccines: The COVID-19 Pandemic and the TRIPS Waiver*, 13 *PMC, Nat'l Libr. Med.* 328 (2022).

space. Articles 7 and 8 outline the objectives of IP protection, stating that the enforcement of IP rights should contribute to the promotion of technological innovation and dissemination, ultimately serving social and economic welfare and achieving a balance of rights and obligations.[9]

Building on this, the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO Ministerial Conference in 2001, was a crucial diplomatic victory. It formally confirmed the right of WTO members to utilize TRIPS flexibilities, explicitly highlighting compulsory licensing (CL) as a legitimate tool to ensure access to medicines for all.[10] The Doha Declaration is the indispensable legal and diplomatic backbone of India's defensive strategy, strengthening the ability of governments to intervene when patents create barriers to accessing medical products.[11]

The Strategic Shield of Domestic Legislation: Section 3(d)

The most potent and controversial domestic legislative instrument is Section 3(d) of the Patents Act, 1970 (as amended). This provision explicitly prevents the patenting of known substances unless they demonstrate significantly enhanced efficacy. Its purpose is to curtail 'evergreening'—the practice by innovator firms of seeking new patents for minor modifications (such as new forms, uses, or combinations) of existing, known drugs, thereby extending market monopolies beyond the stipulated patent term.

Section 3(d) has proven to be far more than a technical legal clause; it functions as a dynamic policy instrument.[12] By setting a high bar for patentability, it actively shapes R&D decisions in global boardrooms, forcing pharmaceutical corporations seeking market access in India to focus on genuine, inventive breakthroughs rather than merely incremental innovations.[13]This clause serves as a powerful testament to India's sovereign commitment to prioritizing public health and economic competition over patent monopolies for non-essential improvements.

Unsurprisingly, this provision has been a continuous source of geopolitical friction. The United

[9] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 7 (1995); *TRIPS Agreement, Flexibility and Environmental Technologies*, *J. Emerging Tech. & Innovative Rsch.* 15 (2025). [4]
[10] Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001).
[11] *Id*.
[12] *See Indian Pharmaceutical Patent Prosecution: The Changing Role of Section 3(d)*, Drug Patent Watch Blog (Dec. 12, 2018).[5]
[13] *Id*.

States Trade Representative (USTR) has historically placed India on its "priority watch list" in annual reports, citing inadequacies in IP protection and enforcement, specifically targeting provisions like Section 3(d). These external pressures highlight the direct trade-off India accepts: maintaining robust domestic public interest protection at the expense of international trade harmony.[14]

Operationalizing Policy: The Compulsory Licensing Experience

India's Patents Act sets out clear criteria for granting compulsory licenses, which allow the government or a designated third party to manufacture a patented product without the consent of the patent holder, subject to adequate remuneration. A compulsory license may be granted if three primary conditions are met: the reasonable requirements of the public regarding the patented invention are not satisfied; the invention is not available to the public at a reasonably affordable price; and/or the patented invention is not worked in the territory of India.[15]

The landmark case of *Bayer Corp. v. Natco Pharma* in 2012 demonstrated the functional efficacy of this mechanism. Natco Pharma was granted India's first-ever compulsory license for the generic production of Bayer Corporation's kidney and liver cancer drug, Nexavar. The ruling was based on the finding that Bayer had failed the two critical tests of public interest.[16]

First, regarding affordability, Bayer sold the drug at an exorbitant rate, costing approximately Rs 2.8 Lakh for one month's dosage. Second, regarding the availability and working requirement, the Controller estimated that Bayer supplied only 593 boxes, which fulfilled the needs of less than 200 patients, representing only about 2% of the total estimated patient requirement.[17]The judgment established that affordability (high price) is often intrinsically linked to the 'non-working' criterion, as an unaffordable drug cannot satisfy the reasonable requirements of the public.

Compulsory licensing serves two paramount strategic purposes. Firstly, it ensures crucial access and affordability during public health crises or market failures. Secondly, it functions as an implicit industrial policy lever. By invoking the 'working in India' requirement, CL incentivizes foreign companies to actively manufacture locally, or license their technology to

[14] U.S. Trade Representative, *supra* note 1.
[15] *Judicial Cases Relating to Compulsory Licensing in India*, IPR Studio (2018).[6]
[16] *Bayer Corp. v. Natco Pharma*, Compulsory License Order (Mar. 9, 2012).
[17] *Id*

local partners. This pressures foreign IP holders to engage in technology transfer and local capacity building, linking public health protection directly to the promotion of domestic manufacturing, thereby maximizing the socio-economic benefits derived from the patent system.[18]

Mechanism/Provision	**Policy Objective**	**Legal Justification/Rationale**	**Example of Application**
Section 3(d) of Patents Act	Prevents Evergreening	Ensures new patents demonstrate enhanced efficacy, adhering to TRIPS Articles 7 & 8	Denial of patent for minor modifications of existing drugs[19]
Compulsory Licensing (CL)	Ensures Affordability and Availability	Authorizes production if invention is not worked or is unreasonably priced	Granted to Natco Pharma for Nexavar due to inadequate supply (2%) and high cost[20]
Doha Declaration Flexibilities	Confirms Sovereign Policy Space	Affirms the right to prioritize public health and utilize TRIPS safeguards	Defense against TRIPS-plus demands in bilateral talks[21]

III. The Innovation Imperative: Transitioning to a Global IP Producer

While India has rigorously defended its public interest model, governmental policy in the last decade has signaled a decisive shift towards fostering a robust, competitive, and globally compliant IP generation ecosystem. This pivot recognizes that long-term economic prosperity requires moving beyond mere imitation and establishing India as a source of novel intellectual

[18] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 7 (1995).
[19] *Indian Pharmaceutical Patent Prosecution: The Changing Role of Section 3(d)*, *supra* note 11.
[20] *Bayer Corp. v. Natco Pharma*, *supra* note 15.
[21] Doha Declaration on the TRIPS Agreement and Public Health, *supra* note 9.

property.[22]

The National IPR Policy and Strategic Vision

The current strategic vision, encapsulated in the National IPR Policy, emphasizes the urgency of creating a stable and predictable IP ecosystem that can attract high-tech FDI and bolster global competitiveness.[23]The government's efforts, spearheaded by the Office of the Controller General of Patents, Designs & Trade Marks (CGPDTM), focus on concrete steps toward effective implementation of the policy, streamlining administrative processes, increasing IP awareness, and promoting the commercialization of patented innovations.[24]

These initiatives aim to leverage India's vast, skilled workforce to strengthen the country's R&D ecosystem.[25] Measures taken include the launch of initiatives such as NIPAM 2.0 (National Intellectual Property Awareness Mission), which sensitized millions of students and faculty members about IP, alongside open house discussions and continuous process improvements to make the IP system more transparent and user-friendly.[26]

Empirical Evidence of Maturation: The Statistical Inflection Point

The strategic investment in innovation is yielding measurable results, suggesting a maturation of India's R&D capacity. A fundamental indicator is the substantial surge in Gross Expenditure on R&D (GERD). Over a decade, GERD increased significantly, rising from INR 60,196.75 crore in 2010–11 to INR 1,27,380.96 crore in 2020–21.[27]This sustained commitment of financial resources underscores a determined policy effort to fuel indigenous research.

Perhaps the most significant evidence of this pivot is the changing landscape of patent filing. During the reporting year 2022-23, India reached a pivotal statistical inflection point: domestic patent applications surpassed foreign filings for the first time.[28]A total of 82,811 patent applications were filed during 2022–23. Domestic filing increased to 43,301, accounting for 52.29% of the total, a significant increase from the 44.41% share recorded in the previous year

[22] The Nat'l Bureau of Asian Research, *supra* note 2.
[23] *Id*.
[24] Office of the Controller Gen. of Patents, Designs & Trade Marks, *supra* note 6, at 4.
[25] Deloitte India Press Release, *supra* note 6.
[26] Office of the Controller Gen. of Patents, Designs & Trade Marks, *supra* note 6, at 4–5.
[27] Deloitte India Press Release, *supra* note 6 (reporting Gross Expenditure on R&D rising from INR 60,196.75 crore in 2010–11 to INR 1,27,380.96 crore in 2020–21).
[28] Office of the Controller Gen. of Patents, Designs & Trade Marks, *supra* note 6, at 1.

(2021–22).[29] This shift, where indigenous inventors drive the majority of patent applications, is a robust indicator of burgeoning domestic innovation capability.

Furthermore, administrative efficiency gains have supported this momentum. The streamlining of internal processes led to a substantial reduction in the pendency of IP applications and an overall increase in patents granted, which saw a 13.5% increase compared to the previous year. This improved transparency and reduced transaction time encourages local inventors to formalize their IP, further fueling the growth in indigenous patent filing.[30]

Metric	**2021-2022 Data**	**2022-2023 Data**	**Percentage Change**	**Policy Implication**
Total Patent Applications Filed	66,440	80,211	+24.64%	Reflects growing inventive output[31]
Domestic Share of Patent Filings	44.41%	52.29% (43,301 filings)	Significant Increase	Domestically-driven innovation pivot[32]
Gross R&D Expenditure (GERD)	INR 60,196.75 Cr (2010-11)	INR 1,27,380.96 Cr (2020–21)	~112% increase over 10 years	Sustained governmental commitment to R&D[33]

Policy Tools to Foster Domestic Innovation

To reinforce the innovation imperative, India is actively considering and implementing policies aimed at attracting high-quality R&D investment. Suggestions include establishing innovation zones that offer preferential tax rates and incentives to Multinational Corporations (MNCs).[34]Crucially, these incentives are often tied to the requirement of "substantial IP development" within India, a direct method of countering historical criticisms that foreign entities merely use India as a market or low-cost manufacturing platform without meaningful

[29] I*d*. at 4 (noting 43,301 domestic filings).
[30] *Id*. at 5 (noting a 13.5% increase in patents granted).
[31]*Id*. at 4 (reporting a 24.64% increase in patent application filing).
[32] *Id*. at 4 (reporting domestic share at 52.29%).
[33] Deloitte India Press Release, *supra* note 6
[34] *Id*. (suggesting innovation zones with preferential tax rates).

technological contribution.[35] This policy, which seeks to incentivize foreign IP holders to *voluntarily* invest locally, represents an attempt to manage the inherent tension with the involuntary mechanism of compulsory licensing. By linking FDI to local R&D, the government seeks to foster technology transfer proactively, potentially bypassing the need to resort to the CL threat, which is costly in diplomatic capital.

Furthermore, strengthening the enforcement infrastructure is seen as vital for global IP acceptance. Policy recommendations call for establishing special IP courts staffed with trained human resources. Improving judicial efficiency and consistency in the application of IP law would serve to improve the acceptability of India's robust IPR regime internationally, which is a prerequisite for sustained investment and global economic cooperation.[36]

IV. Navigating the Geopolitical IP Minefield: The Threat of TRIPS-Plus Provisions

India's strategic position in global IP negotiations is most rigorously tested in the arena of bilateral and regional Free Trade Agreements (FTAs), where powerful trading blocs frequently attempt to impose standards that restrict India's policy space—a maneuver known as "TRIPS-plus."

Multilateral Failure and Crisis Management

The persistent dominance of innovator interests in multilateral discussions was starkly exposed during the COVID-19 pandemic. Despite extensive negotiations among WTO members for a global IP waiver, the final decision reached at the 12th WTO Ministerial Conference (MC12) in June 2022 proved inadequate.[37]The outcome had severe limitations: it failed to allow members to waive IP protection completely, applied solely to vaccines, and critically excluded COVID therapeutics and diagnostics.[38]

This failure demonstrated that the existing multilateral framework is incapable of delivering meaningful IP reform during global public health crises. Consequently, the battles over intellectual property rights have increasingly been pushed into bilateral and regional trade

[35] *Id*.
[36] The Nat'l Bureau of Asian Research, *supra* note 2, at 10 (recommending establishing special IP courts).
[37] Médecins Sans Frontières, *supra* note 3, at 1.
[38] *Id*. at 2

negotiations, where negotiating power is often uneven, allowing developed countries to demand stricter IP standards beyond the TRIPS minimums.[39]

The Assault on Policy Space: TRIPS-Plus Demands in FTAs

TRIPS-plus provisions refer to IP protection standards that are additional to, or longer than, the minimum requirements set out in the TRIPS Agreement. These provisions, often introduced through FTAs and Bilateral Investment Treaties, disproportionately favor multinational pharmaceutical corporations by strengthening their monopolistic positions.[40]

In India's ongoing bilateral negotiations, particularly with the European Union (EU) and the United Kingdom (UK), several damaging TRIPS-plus provisions are routinely proposed.[41]

1. **Data Exclusivity:** This provision requires regulatory bodies to protect the clinical trial data submitted by innovator companies for a fixed period (often 5 to 10 years). During this period, generic manufacturers are restricted from using that data to obtain marketing authorization, even if the patent has expired or was never granted. This acts as an effective, market-based extension of the monopoly, regardless of the efficacy bar set by Section 3(d), posing a direct threat to the generic industry's speed-to-market advantage. [42]

2. **Patent Term Extensions (PTEs):** These provisions seek to extend the 20-year patent term to compensate innovators for delays encountered during the regulatory approval process. PTEs would delay generic entry into the market, directly diluting the public benefit derived from the expiration of intellectual property protection.

If implemented, these TRIPS-plus provisions would restrict Indian generic manufacturers from supplying essential medical products globally. [43]These mechanisms allow innovator companies to control who manufactures the product, where it is produced, and at what price it is sold, severely constraining India's ability to utilize its generic manufacturing capacity for global public health.[44]

[39] *Id*. at 4 (discussing the use of FTAs for TRIPS-plus demands).
[40] *Id*.
[41] *Id*. at 4 n.20, 21 (naming the UK and the EU).
[42] *Id*. at 4
[43] *Id*.
[44] *Id*. at 4.

The Policy Space Erosion: A Critical Friction Point

The divergence over IP standards remains a critical friction point in major negotiations. In the context of the EU-India FTA, the EU envoy noted that recent rounds presented a "missed opportunity" due to divergence in sensitive areas, including intellectual property.[45]

India's reluctance stems from a fierce commitment to retaining its policy space. It has been argued by some commentators that India exhibits an "obsession with the policy space," sometimes acquiring more flexibility than it actively puts to use.[46]However, this "obsession" can be understood as strategic necessity. Policy space represents a critical, latent power—a strategic asset to be deployed instantaneously when future public health crises or market failures mandate state intervention, as evidenced by the inadequacy of the limited COVID waiver.[47]

Furthermore, compliance with TRIPS-plus demands carries severe socio-economic costs. FTAs generally require deep tariff cuts, leading to substantial fiscal consequences. An analysis of potential tariff revenue loss from a deep tariff cut scenario suggests a mammoth EUR 1.86 billion loss for India, significantly higher than the estimated loss for the EU (EUR 0.91 billion).[48]This loss of fiscal capacity directly reduces the state's ability to fund crucial social development initiatives and meet its Sustainable Development Goals (SDGs).[49]

The strategic challenge for India is that it is being pressured to dismantle its public interest defense mechanisms (Section 3(d), CL) at the exact moment its domestic industry is demonstrating global competitiveness.[50] Trading IP flexibility for market access in other sectors, such as automobiles or agricultural products,[51] would fundamentally undermine the generic sector, eroding public health access and losing India its most significant diplomatic leverage.

The risks are substantiated by comparative examples. The Jordanian pharmaceutical industry,

[45] Herve Delphin, *EU envoy: Latest round of FTA talks with India 'missed opportunity' to make breakthrough*, PTI News Report (Sept. 29, 2024).
[46] Richard E. Feinberg, *Can Geopolitical Alignment Seal the India-EU FTA?*, Carnegie Endowment for Int'l Peace (Mar. 18, 2025).
[47] Médecins Sans Frontières, *supra* note 3.
[48] Heinrich Böll Found., *The Proposed EU-India FTA: Key Concerns and the Way Forward* 3 (2023).[7]
[49] I*d*
[50] Office of the Controller Gen. of Patents, Designs & Trade Marks, *supra* note 6.
[51] Herve Delphin, *supra* note 44.

for instance, experienced severe conditions after its accession to the WTO in 2000, which required it to introduce TRIPS-plus provisions into its national laws. This premature adherence, coupled with a lack of appropriate policy infrastructure, hampered innovation and growth in its pharmaceutical sector.[52] This demonstrates that retaining the policy space allows India to control the pace and conditions of IP liberalization, ensuring that the innovation push serves developmental goals rather than undermining established public interest safeguards.

Dimension	**Innovation Agenda (Pro-IP) Driver**	**Public Interest Defense (Anti-TRIPS-Plus) Risk**	**Strategic Tension**
Objective	Attract FDI and protect emerging domestic IP holders	Maintain policy space for generic production and price control	Balancing global integration with developmental autonomy[53]
FTA Demand Examples	Data Exclusivity; Patent Term Extension	Erosion of Section 3(d) and CL effectiveness	Increased monopolistic power vs. reduced affordability[54]
Socio-Economic Cost	Short-term market access gains in non-IP sectors	Loss of fiscal capacity (tariff revenue) and constraint on SDGs[55]	

[52] Mohamed Salama, *The Impact of the TRIPS Agreement on the Pharmaceutical Industry in Developing Countries: A Comparative Analysis of India, China, and Brazil*, 13 *PMC, Nat'l Libr. Med.* 328 (2022) (discussing the Jordanian experience post-WTO accession).[8]
[53] The Nat'l Bureau of Asian Research, *supra* note 2, at 5; Richard E. Feinberg, *supra* note 45.
[54] Médecins Sans Frontières, *supra* note 3, at 4.
[55] Heinrich Böll Found., *supra* note 47, at 3.

V. Beyond Pharma: IP in Biodiversity, Agriculture, and Knowledge Dissemination

India's strategic framework extends the principle of balancing private rights and public interest beyond the pharmaceutical sector to encompass essential public goods such as food security, agricultural technology, and biodiversity conservation.

The Interplay of IP and Food Security

In the agriculture sector, India faces a demanding balance between protecting the rights of plant variety innovators, primarily through its legislation such as the Protection of Plant Varieties and Farmers' Rights Act, and upholding the universal right to food security for its massive population.[56] The strategic goal is to ensure that IP regimes do not become barriers to accessing seeds, agricultural inputs, and essential technologies necessary for maintaining food security and sustaining rural livelihoods.[57]The debate in this sector mirrors the struggle in pharmaceuticals: proprietary control must not supersede the collective welfare required for survival.

Biodiversity and Traditional Knowledge: The Nagoya Protocol

As one of the world's most biodiversity-rich nations, India plays a critical role in the implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS), which is an agreement under the Convention on Biological Diversity (CBD).[58]

India's strategic position mandates that it enforces mechanisms to ensure that benefits derived from genetic resources and associated traditional knowledge used in R&D are shared equitably. This places a unique onus on India to enforce disclosure requirements for the source and origin of biological resources when patent applications are filed. This stance positions India as a key steward for the concerns of the Global South, demanding fairness in the global proprietary system when resources originate from developing nations. The principle underpinning the Nagoya Protocol aligns thematically with the pharmaceutical IP defense: the collective right to

[56] *See Intellectual Property Rights and Food TRIPS*, *supra* note 1.
[57] *Id.*
[58] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, Oct. 29, 2010, T.I.A.S. No. 13-1029.

shared natural resources must be safeguarded against privatization without corresponding community benefit.

IP and Technology Transfer for Environmental Goals

The global drive toward sustainability has placed IP at the center of technology transfer discussions, particularly concerning environmental or 'green' technologies. TRIPS Article 7 explicitly links IP protection to the promotion of technology transfer and dissemination for mutual advantage and social welfare.[59]For developing countries like India, the challenge lies not only in the high cost of advanced environmental technologies protected by IP but also in the limited local capacity and infrastructure required for their adoption and assimilation.[60] India's strategic position in global climate and technology negotiations requires it to link the discussion of IP to technology transfer mechanisms.

The national strategy must leverage public funding for research as a policy tool. Where research receives public financing, the government must mandate that the resulting IP be licensed and shared, including through patent pools, to promote rapid technology transfer and enable broad access to innovations.[61] This ensures that government investment aligns with the public interest and prevents the creation of publicly funded monopolies, demonstrating a commitment to developmental use of IP in line with the objectives of TRIPS Article 7.[62]

VI. Conclusion: Reconciling the Innovation/Public Interest Dialectic

India’s strategic position in global IP negotiations represents a high-stakes act of developmental diplomacy. The current IP strategy is defined by simultaneous acceleration of its innovation ecosystem (evidenced by the surge in R&D expenditure and the milestone of domestic patent filings surpassing foreign applications[63] and a staunch, unwavering defense of its public interest policy space (manifested primarily in Section 3(d) and resistance to TRIPS-plus demands).[64]

The synthesis of this strategic paradox is challenging but critical. India's global influence is derived fundamentally from its policy dissension—its unique ability to define innovation in

[59] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 7 (1995).
[60] *TRIPS Agreement, Flexibility and Environmental Technologies*, *supra* note 8, at 15.
[61] *Ensuring Access to Vaccines: The COVID-19 Pandemic and the TRIPS Waiver*, *supra* note 7, at 328.
[62] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 7 (1995).
[63] Office of the Controller Gen. of Patents, Designs & Trade Marks, *supra* note 6, at 4.
[64] Médecins Sans Frontières, *supra* note 3, at 4; *Indian Pharmaceutical Patent Prosecution: The Changing Role of Section 3(d)*, *supra* note 11.

developmental terms and its success in upholding public health flexibilities.[65] India's domestic legislative framework has consequences far beyond its borders, particularly for the global supply of low-cost medicines.[66]

The primary imperative remains the retention of policy space. While the domestic drive for innovation requires a robust IP framework, this framework must not be established by sacrificing hard-won public health safeguards. The argument that policy space is an "obsession"[67] overlooks the fact that this flexibility is crucial insurance against future crises. Conceding to TRIPS-plus demands, such as data exclusivity or patent term extensions, would fundamentally cripple the competitiveness of the generic sector—the core of India's current economic and diplomatic leverage.[68] Therefore, the path forward requires leveraging the economic success and geopolitical credibility derived from the generic sector to fund and protect the nascent innovation ecosystem.

Policy Recommendations for Sustainable IP Governance

To navigate the conflicting demands of innovation and public interest sustainably, India must solidify its domestic mechanisms and proactively reframe its strategy in international fora.

1. Strategic Investment in IP Enforcement Infrastructure

The focus must move beyond legislative protection to effective and efficient enforcement. While India has been criticized for poor enforcement,[69] solving this requires institutional specialization, not merely stricter adherence to foreign standards. There is an urgent need to establish specialized, dedicated IP courts with legally trained personnel.[70] This institutional reform would ensure the consistent and expert application of the Patents Act, including the nuanced interpretation of Section 3(d) and compulsory licensing provisions. Such a measure would significantly improve global confidence in India's IP regime, reducing its appearance on foreign watch lists[71] without requiring the sacrifice of critical public interest clauses.

[65] Doha Declaration on the TRIPS Agreement and Public Health
[66] *Ensuring Access to Vaccines: The COVID-19 Pandemic and the TRIPS Waiver*, *supra* note 7, at 328.
[67] Richard E. Feinberg, *supra* note 45.
[68] Médecins Sans Frontières, *supra* note 3, at 4.
[69] U.S. Trade Representative, *supra* note 1.
[70] The Nat'l Bureau of Asian Research, *supra* note 2, at 10.
[71] U.S. Trade Representative, *supra* note 1.

2. Reframing IP in Bilateral Negotiations

India must cease treating IP solely as a defensive concession in FTA negotiations. Instead, IP cooperation should be proactively framed as a tool for sustainable development and technology sharing, consistent with its commitments under the Nagoya Protocol[72] and TRIPS Article 7.[73] India should demand mandatory IP licensing (or patent pooling) for technologies deemed critical for climate resilience or public health, particularly those originating from partner nations where government funding was involved.[74] This reframing ensures that any IP provisions included in FTAs actively contribute to India's developmental goals, rather than merely imposing compliance burdens.

3. Localizing IP Incentives and R&D

To maximize the benefits of the domestic innovation push and attract quality FDI, India must fully implement proposals that link corporate incentives directly to substantial, measurable IP development and commercial working within India.[75] Preferential tax rates and incentives should be contingent on criteria that reinforce the principle underlying the compulsory licensing mechanism—that the innovation must be locally "worked" to satisfy the public requirements. Encouraging state-level innovation regimes, with locally tailored incentives and intellectual property protection policies, could further augur well for improvements in regional investment and R&D capacity.[76]

In conclusion, India's strategic position is unique: it is simultaneously the world's most aggressive defender of IP flexibilities and a rapidly emerging innovation power. Failure to manage this paradox will lead to unsustainable outcomes. If India acquiesces to TRIPS-plus demands, it risks undermining the generic sector, eroding public health access, and losing its diplomatic credibility. If it fails to build a robust, globally respected IP enforcement system, it risks stifling the very domestic R&D growth that will define its economic future. The strategic imperative for the coming decade is to integrate the principles of Section 3(d) and the Doha Declaration—namely, the primacy of public welfare—into the heart of its burgeoning

[72] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, *supra* note 57.
[73] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 7 (1995).
[74] *Ensuring Access to Vaccines: The COVID-19 Pandemic and the TRIPS Waiver*, *supra* note 7, at 328
[75] Deloitte India Press Release, *supra* note 6.
[76] The Nat'l Bureau of Asian Research, *supra* note 2, at 12.

innovation agenda, ensuring that the new IP architecture serves, rather than contradicts, India's foundational commitment to developmental justice.

References

I. Treaties and Agreements

Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 (entered into force Jan. 1, 1995).

Doha Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference, WT/MIN(01)/DEC/2 (Nov. 14, 2001).

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, Oct. 29, 2010, T.I.A.S. No. 13-1029 (entered into force Oct. 12, 2014).

II. Judicial and Administrative Decisions

Bayer Corp. v. Natco Pharma, Compulsory License Order (Mar. 9, 2012).

III. Government and Organizational Reports

Deloitte India Press Release, *Blueprint to boost India's R&D sector* (Aug. 10, 2022).

Heinrich Böll Foundation, *The Proposed EU-India FTA: Key Concerns and the Way Forward* (2023).[7]

Médecins Sans Frontières, *Patents, Power and the Public Interest: Why IP Barriers to Essential Medicines and Vaccines Must be Addressed in the Pandemic Preparedness and Response (PPR) Accord* (2023).

Office of the Controller General of Patents, Designs & Trade Marks, *Annual Report 2022-23 (English)* (2023).[3]

The National Bureau of Asian Research, *India's Intellectual Property Rights Regime: An Assessment and Scenarios for Continued Advancement* (2015).[2]

U.S. Trade Representative, *2019 Special 301 Report* (2019).

IV. Secondary Sources and Articles

Ensuring Access to Vaccines: The COVID-19 Pandemic and the TRIPS Waiver, 13 *PMC, Nat'l Libr. Med.* 328 (2022).[9]

Feinberg, Richard E., *Can Geopolitical Alignment Seal the India-EU FTA?*, Carnegie Endowment for Int'l Peace (Mar. 18, 2025).

Indian Pharmaceutical Patent Prosecution: The Changing Role of Section 3(d), Drug Patent Watch Blog (Dec. 12, 2018).[5]

Intellectual Property Rights and Food TRIPS, *Economic and Political Weekly* (Feb. 15, 2020).[1]

Judicial Cases Relating to Compulsory Licensing in India, IPR Studio (2018).[6]

Mohamed Salama, *The Impact of the TRIPS Agreement on the Pharmaceutical Industry in Developing Countries: A Comparative Analysis of India, China, and Brazil*, 13 *PMC, Nat'l Libr. Med.* 328 (2022).[8]

TRIPS Agreement, Flexibility and Environmental Technologies, *J. Emerging Tech. & Innovative Rsch.* 15 (2025).[4]

Delphin, Herve, *EU envoy: Latest round of FTA talks with India 'missed opportunity' to make breakthrough*, PTI News Report (Sept. 29, 2024).