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Life After the Patent Cliff: TRIPS Flexibilities and Constitutional Imperatives in India's Post-COVID Access to Medicines Framework

Abstract

The global discussions on the equilibrium between intellectual property rights and fair access to essential medications have been revitalised after COVID-19. As blockbuster drug patents expire, the resulting cliff creates difficulties and openings. While original companies may experience declines in revenue, there is an opportunity for generic manufacturers to improve accessibility. In this scenario, India's strategy for leveraging patent subject matter flexibilities outlined in the TRIPS Agreement has gained increased importance. The Indian Patents Act of 1970, primarily through aspects like Section 3(d), compulsory licensing, and the Bolar exception, illustrates a conscious legislative approach to prevent evergreening and promote early entry of generics. This strategy adheres to the allowable flexibilities under TRIPS and is significantly influenced by India's constitutional principles, particularly the right to health as articulated in Article 21. This paper investigates the convergence of these three pivotal aspects: the economic consequences of the patent cliff, the legal frameworks India utilises under TRIPS to reconcile innovation with cost-effectiveness, and the constitutional values that underpin India's pharmaceutical patent policy. The argument presented is that the Indian model is a distinct, rights-centred approach to patent legislation that emphasises public health while still acknowledging the need for innovation incentives. Utilising case studies from the post-COVID era, judicial decisions, and international legal frameworks, this article examines how India's patent system could function as a viable model for other developing countries. It concludes by offering policy suggestions to strengthen this balance amid changing global dynamics, industry resistance, and evolving international trade and health governance standards.

Introduction

The COVID-19 pandemic significantly evaluated global healthcare systems, highlighting longstanding disparities in accessing essential medications. As case numbers rose and deaths

increased, there was a noticeable effort by major pharmaceutical companies to secure patent monopolies, often favouring profit over fair access to vital treatments and vaccines.[1] These firms utilised intellectual property rights to dominate markets, creating unnecessary scarcity and escalating prices, especially in lower and middle-income nations. This situation starkly contradicted the ethical standards expected during a global health crisis.

India, known as the "pharmacy of the developing world," became a crucial player during the pandemic by providing low-cost generic medications and vaccines to countries worldwide.[2] Its national pharmaceutical sector, shaped by years of supportive health policies, encountered renewed challenges as global patent standards became stricter following TRIPS (Trade-Related Aspects of Intellectual Property Rights). The Patents (Amendment) Act, 2005, introduced product patent protection to comply with TRIPS, significantly altering India's patent landscape and reigniting discussions on the balance between encouraging innovation and ensuring public health access.[3]

In this shifting legal environment, India's constitutional framework, particularly the judicial interpretation of Article 21, which guarantees the right to life and personal liberty, surfaced as a vital counterbalance to the global intellectual property framework.[4] The Indian Supreme Court consistently asserts that the right to health is an integral part of the right to life, establishing a constitutional duty for the state to provide access to affordable healthcare. Significant cases like Paschim Banga Khet Mazdoor Samity v. State of West Bengal and Consumer Education and Research Centre v. Union of India confirm that obtaining medical treatment is a privilege and a fundamental right.[5]

Looking ahead to the post-pandemic period, as India approaches the so-called "patent cliff" where many blockbuster drugs' patents expire, the challenge is to utilise the legal flexibilities permitted under TRIPS to ensure the continued supply of affordable medicines without breaching international commitments. Provisions such as compulsory licensing and the limited

[1] Akhil Gupta, 'Misuse of Pharmaceutical Industries during COVID-19' (iPleaders, 11 October 2022) <https://blog.ipleaders.in/misuse-of-pharmaceutical-industries-during-covid-19/> Accessed 27 July 2025
[2] Prateek Jindal, 'Pharmaceutical Drugs and Patent Protection about COVID-19' (iPleaders, 25 September 2020) <https://blog.ipleaders.in/pharmaceutical-drugs-patent-protection-reference-covid-19/> Accessed 27 July 2025
[3] Jaya Vats, 'Patents and the Right to Healthcare in India' (iPleaders, 31 January 2021) <https://blog.ipleaders.in/patent-right-healthcare-india/> Accessed 27 July 2025
[4] The Constitution of India, art 21
[5] Paschim Banga Khet Mazdoor Samity v. State of West Bengal & Anr, 1996 SCC (4) 37: Consumer Education and Research Centre v. Union of India, 1995 SCC (3) 42

Section 3(d) against evergreening are essential tools in this scenario.[6] The Doha Declaration on the TRIPS Agreement and Public Health (2001) further affirms the rights of WTO member countries to protect public health through legislative and administrative actions.[7]

Against this backdrop, India's framework for access to medicines in the post-COVID context should be analysed in terms of international trade requirements and constitutional law and human rights. The convergence of TRIPS provisions and constitutional obligations creates a legal and ethical responsibility to prioritise public health over monopolistic business interests.[8]

The Patent Cliff and Its Aftermath

The phrase "patent cliff" has gained notable attention recently, especially in the pharmaceutical industry. It describes the timeframe when the patents on numerous high-earning, blockbuster medications expire simultaneously, resulting in a sudden loss of exclusivity for the original manufacturers. Once these patents expire, generic producers can legally enter the market, which leads to heightened competition, falling drug prices, and a significant decrease in market share and revenue for the companies holding the patents.[9] While this phase negatively impacts the profits of innovator firms, it represents a crucial turning point for public health policy and worldwide access to medications, facilitating the availability of more affordable generic versions of lifesaving drugs.

The expiration of patents in the pharmaceutical sector carries significant economic and legal ramifications. The immediate outcome is decreased prices, which significantly benefits consumers, particularly those in low- and middle-income nations where the high cost of medications poses a considerable barrier to healthcare access. From a legal perspective, the expiration of patents eliminates obstacles that previously hindered generic production and opens avenues for increased competition and widespread distribution. This shift also helps

[6] The Patents Act, 1970 s 3(d)
[7] Mohammad Saleem and Karun Sanjaya, 'Patentability of Life Saving Drugs: A Constitutional Perspective' (ResearchGate, September 2023) <https://www.researchgate.net/publication/373659436_Patentability_of_Life-Saving_Drugs_A_Constitutional_Perspective> Accessed 27 July 2025
[8] Akshay Anurag, 'Pharmaceutical Patents and Healthcare: A Legal Conundrum' (SCC Times, 3 September 2019) <https://www.scconline.com/blog/post/2019/09/03/pharmaceutical-patents-and-healthcare-a-legal-conundrum/> Accessed 27 July 2025
[9] Karun Sanjaya, 'Utilising Patent Subject Matter Flexibilities under TRIPS-The Indian Approach' (2021) 8(25) LDIJL<https://www.researchgate.net/publication/351902512_Utilizing_Patent_Subject_Matter_Flexibilities_Under_TRIPS_-_The_Indian_Approach > Accessed 28 July 2025

alleviate the financial strain on healthcare systems caused by costly patented drugs, making treatment accessible to broader population segments.

With its strong generic pharmaceutical sector, India is particularly well-positioned to capitalise on the chances created by the patent cliff. Frequently referred to as the "pharmacy of the developing world," India excels in producing affordable generics. Given that the TRIPS-compliant framework limits compulsory licensing to specific exceptional cases, Indian companies strategically time their entrance into markets post-patent expiration, thus enhancing both domestic and international access to crucial medications. This capability to produce and sell economical drugs following the expiry of patents is further bolstered by India's adept implementation of TRIPS flexibilities, including compulsory licensing and the public interest exception specified in Section 92A of the Patents Act, 1970.[10]

Historically, before India fully complied with the TRIPS Agreement in 2005, the country's patent laws were structured to prioritise public health over private commercial interests.[11] Process patents instead of product patents were provided, enabling Indian companies to reverse-engineer medications and create less expensive alternatives without infringing on patent laws. This legal framework facilitated broad access to essential medicines. However, the post-TRIPS environment disrupted this balance. The introduction of product patents pushed many crucial medications out of reach financially for many people in India. Drugs that were once affordable as generics became costly due to patent protections, negatively affecting healthcare affordability in a nation where a large portion of the populace cannot afford private medical treatment.

Even so, the period following a drug's patent expiration signals a return to greater accessibility. After the monopoly period concludes, Indian manufacturers can produce and sell affordable generics, assisting millions in obtaining necessary treatments. This opportunity serves domestic consumers and enables India to meet a global obligation by providing lifesaving medications to developing countries through mechanisms like compulsory licensing for export.

Significantly, the phase after patent expiration represents a chance to balance two conflicting goals: promoting pharmaceutical innovation while ensuring public access to vital medicines.

[10] n 8, s 84-92A
[11] Ishita Tiwari and Dr Vijay Srivastava, 'Impact of Pharmaceutical Patents on Public Health in India' (2019) 6(1) IJRAR<https://www.ijrar.org/papers/IJRAR19H1169.pdf> Accessed 28 July 2025

The challenge lies in sustaining a patent regime that rewards research and development without creating overwhelming barriers to healthcare. The patent cliff, therefore, creates a legal and economic context in which this balance can be actively sought, allowing states, particularly developing countries like India, to broaden access without compromising international legal commitments.

TRIPS Agreement: Flexibilities and Their Legal Landscape

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), a fundamental element of the World Trade Organisation (WTO), established binding international benchmarks for protecting intellectual property, including patents. This represented a crucial transition for developing nations like India, as they were obligated to revise their intellectual property systems to align with global standards.[12] Although the Agreement requires adherence to minimum intellectual property standards, it also includes a series of legal flexibilities designed to protect the public interest, especially in developing countries grappling with public health issues. It is vital to understand these flexibilities to assess how nations like India manage the complex interplay between patent protection and access to medicines.

India's approach to TRIPS exemplifies strategic legal adaptation. The country utilised the transition periods stipulated in Articles 65 and 66 to postpone the implementation of product patents in essential sectors, including pharmaceuticals and agriculture. During this transitional phase, India set up a "mailbox" system under Article 70.8, accepting applications for pharmaceutical product patents while deferring their examination until necessary legislative changes were enacted. Observations indicate that India's capacity to comply with TRIPS while adapting domestic law to safeguard public health highlights the inherent versatility within the Agreement.

Legal scholars further support this perspective by arguing that the TRIPS Agreement was not designed to enforce a uniform standard of intellectual property protection across varied legal frameworks.[13] Instead, it incorporates intrinsic flexibility through Articles 7 and 8, which stress

[12] Jayashree Watal, 'Implementing the TRIPS Agreement: Policy Options open to India' (1997) 32(39) EPW <https://www.jstor.org/stable/4405898?seq=5> Accessed July 28 2025
[13] Carlos Correa, 'Interpreting the Flexibilities under the TRIPS Agreement' (ResearchGate, October 2021) <https://www.researchgate.net/publication/367808799_Interpreting_the_Flexibilities_Under_the_TRIPS_Agreement> Accessed 28 July 2025

the importance of balancing the encouragement of technological innovation with public interest, particularly concerning health and nutrition. Furthermore, Article 1.1 permits WTO Members to establish the most suitable method for implementing the Agreement within their respective legal frameworks and practices.[14] These interpretative elements empower countries like India to develop national patent systems that embody constitutional principles and public health priorities while fully adhering to TRIPS obligations.

One of the most potent tools in India's legal framework post-TRIPS is compulsory licensing, permitted under Article 31 of the Agreement. This article allows member states to authorise third-party utilisation of a patented invention without the patent holder's permission, under specific conditions such as national emergencies, public non-commercial use, or actions against competition. India codified this mechanism in Sections 84 to 92 of the Patents Act, 1970, enabling the issuance of compulsory licenses in situations where patented medicines are either unaffordable or inadequately supplied. Moreover, it is noteworthy that Article 31 imposes "no restrictions on the grounds" for granting such licenses, thus providing countries with considerable leeway to act in the public interest.

In addition to compulsory licensing, Section 3(d) of the Indian Patents Act protects against "evergreening," a strategy in which pharmaceutical companies secure multiple patents for slight modifications of existing drugs to prolong their monopolies. This section denies patents for new forms or derivatives of known substances unless they significantly improve therapeutic effectiveness.[15] The Supreme Court of India, in the case Novartis AG v. Union of India, upheld the constitutionality and public interest justification of Section 3(d), denying a patent for the beta-crystalline form of imatinib mesylate. This ruling reaffirmed India's authority to interpret patentability in a manner consistent with TRIPS and its constitutional duties to ensure health access.[16]

The Doha Declaration on the TRIPS Agreement and Public Health (2001) articulated a significant international endorsement of these rights. It clearly states that "TRIPS does not and should not hinder Members from implementing measures to protect public health" and

[14] Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, Art 1.1
[15] Javier Esparza, Indian Patent Law: Working within the TRIPS Agreement Flexibilities to Provide Pharmaceutical P vide Pharmaceutical Patent Protection While Protecting Public Health (2015) 24(1) FSUJTLP <https://ir.law.fsu.edu/jtlp/vol24/iss1/6/> Accessed 28 July 2025
[16] Novartis AG v. Union of India, 2013 (6) SCC 1

reaffirms "the right of WTO Members to fully utilise the provisions in the TRIPS Agreement, which provide flexibility." This proclamation gave political credibility to India's interpretation of TRIPS and allowed poor nations to create public health-sensitive patent regimes without fear of WTO reprisal.[17] Taken together, India's strategy indicates how TRIPS flexibilities, when properly construed, may be potent tools for public benefit. Rather than considering intellectual property law as a barrier to health access, India has worked within TRIPS to create a patent system that promotes innovation while adhering to its constitutional and humanitarian obligations.

Indian Patent Law and TRIPS Compliance

India's adjustment of its patent system in line with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has been a significant legal and political change. This alignment culminated in the passage of the Patents (Amendment) Act, 2005, which established product patent protection in vital areas such as pharmaceuticals and agriculture. This change marked a notable shift from India's previous legal framework, which had long nurtured the growth of its generic pharmaceutical sector by restricting patents to processes instead of products. The nation had taken advantage of the transitional provisions in TRIPS (Article 65.4) to delay this requirement until 1 January 2005, thereby maintaining its ability to produce affordable generic medicines during that period.[18] The amendments were carried out over three legislative stages, i.e., 1999, 2002, and 2005. The 1999 amendment introduced the "mailbox" provision under Article 70.8 of TRIPS and established exclusive marketing rights (EMRs). The subsequent amendments in 2002 and 2005 clarified India's patentability standards, introduced strong pre- and post-grant opposition processes, and improved the framework for compulsory licensing. The 2005 amendment eventually provided complete product patent protection while including crucial safeguards, particularly a clause preventing the patenting of known substances unless they show enhanced therapeutic efficacy. This clause has become fundamental in India's strategy to combat "evergreening," prolonging patent duration through slight, non-therapeutic modifications. It disallows patentability for simple alterations of known

[17] WTO Ministerial Declaration on the TRIPS Agreement and Public Health (14 November 2001) WT/MIN (01)/DEC/2, Para 4
[18] Shamnad Basheer, 'India's Tryst with TRIPS: The Patents (Amendment) Act, 2005' (2005) 1(1) IJLT <https://repository.nls.ac.in/ijlt/vol1/iss1/2/> Accessed July 28, 2025

substances unless those changes result in a considerable improvement in efficacy.[19] This provision illustrates India's effort to reconcile TRIPS commitments with the constitutional duty to guarantee access to affordable medicines. Its legal basis is supported by Articles 7 and 8 of the TRIPS Agreement, which allow member states to implement public interest protections. Although this clause has been criticised for allegedly violating Article 27 of TRIPS, which requires non-discriminatory patentability standards, international legal interpretations affirm that WTO members have the authority to define their patentability criteria.[20] Legal analyses validate that TRIPS permits national legislatures to include public health protections, as long as the essential conditions: novelty, inventive step, and industrial applicability are satisfied. The validity of India's strategy was upheld in a 2013 Supreme Court ruling, which determined that incremental innovations lacking enhanced therapeutic efficacy do not qualify for patent protection. This ruling emphasised that any alteration of a known substance must exhibit measurable therapeutic improvement to be considered a patentable invention under Indian law.[21]

India's progression towards TRIPS compliance was marked by political and academic debate. An expert committee, appointed by the government to assess whether limiting patentability to new chemical entities and excluding microorganisms would breach TRIPS, initially concluded that such restrictions were incompatible with India's commitments. However, this report was later retracted amid procedural controversies and claims of a lack of originality. The ensuing debate shifted focus from the fundamental legal questions, leaving critical interpretive issues regarding TRIPS unresolved. Despite these controversies, India has instituted various TRIPS-compliant flexibilities, compulsory licensing, patent opposition procedures, and stringent revocation processes that collectively promote innovation and public health goals. These strategies have allowed India to customise its patent system to meet its developmental requirements while staying within the limits of its international commitments. The constitutional foundation for this system, particularly under Articles 21 and 39 of the Indian

[19] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, arts 7, 8
[20] Id, arts 1.1, 27.1
[21] Rajnish Rai, 'Patentable subject matter requirements: An evaluation of proposed exclusions to India's patent law in light of India's obligations under the TRIPS Agreement and options for India' (ResearchGate, January 2008) <https://www.researchgate.net/publication/266684923_Patentable_subject_matter_requirements_An_evaluation_of_proposed_exclusions_to_India's_patent_law_in_light_of_India's_obligations_under_the_TRIPS_Agreement_and_options_for_India> Accessed 28 July 2025

Constitution, strengthens its validity.[22] By curbing undue monopolies, the legislation promotes equitable access to essential medications and aligns with broader distributive justice and public welfare aims.

COVID-19 and the Global Access to Medicines Debate

India's participation in the global discourse on access to medicines, particularly during the COVID-19 crisis, received renewed attention through its collaborative proposal at the WTO to waive specific provisions under the TRIPS Agreement. This proposal, which was initially presented in October 2020, symbolised a significant effort by developing nations to ensure unhindered availability of vaccines, diagnostics, and therapies by suspending intellectual property obligations that might obstruct manufacturing and distribution endeavours across the Global South.[23] The waiver initiative was motivated by the recognition that, despite permitting some flexibilities, the TRIPS Agreement fell short of supporting rapid and equitable access in a worldwide emergency. Specifically, although mechanisms like compulsory licensing are available under Articles 31 and 31bis of the TRIPS Agreement, they frequently face hurdles such as procedural delays, bilateral pressures, and restrictions that diminish their effectiveness during urgent health crises. Additionally, these flexibilities are tailored to address specific national needs, rendering them inadequate for the widespread and cross-border challenges posed by pandemics.

With support from South Africa and over 100 WTO members, India contended that only a complete waiver, not limited to vaccines but also covering diagnostics and treatments, could eliminate intellectual property obstacles throughout the supply chain. However, discussions remained contentious, particularly due to opposition from a coalition of high-income nations and pharmaceutical interests, who argued for preserving the existing intellectual property framework to encourage innovation. These dynamics highlighted that while TRIPS flexibilities are legally available, they face significant political constraints. This was further complicated by enforcement practices, especially injunctions, which Indian courts have increasingly granted without fully considering the implications for public interest. A thorough case study demonstrates that, in evaluating injunctive relief in pharmaceutical patent disputes, Indian

[22] n 6, art 39
[23] Muhammad Zaheer Abbas, 'Twenty Years After Doha: An Analysis of the Use of the TRIPS Agreement's Public Health Flexibilities in India' (2023) SSRN <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4525016> Accessed 28 July 2025

courts often give precedence to exclusive rights over constitutional and human rights concerns. This trend deviates from the spirit of TRIPS flexibilities, particularly those reaffirmed in the Doha Declaration on Public Health, which stresses access rather than exclusion.[24]

Injunctions are a powerful form of temporary relief in intellectual property conflicts. Still, they may hinder public access to medicine, particularly when issued against generic manufacturers providing affordable alternatives. Courts utilise a three-factor assessment, a prima facie case, a balance of convenience, and irreparable harm, yet the predominance of the prima facie factor, generally inferred simply from patent registration, has eclipsed a more thorough evaluation of public interest and the impact on access rights. These issues become even more pronounced during pandemics. The COVID-19 experience highlighted that injunctive relief can postpone the entry of generics, disrupt supply chains, and exacerbate inequities in access to crucial health technologies. Additionally, the strategic misapplication of interim injunctions to extend market exclusivity without prompt adjudication essentially undermines the intent of TRIPS-compliant protections. Courts may grant such injunctions without sufficiently determining whether the challenged patents are actively being utilised in India or whether the relief sought is proportionate to the implications for public health.

From a broader perspective under international law, any such interference must also align with the standards established in Article 4 of the ICESCR, which requires that limitations on rights such as the right to health be legal, necessary, and proportionate to the promotion of general welfare. Mechanically granted injunctions in pharmaceutical cases risk breaching these criteria, especially when they obstruct access to life-saving drugs.[25] India's involvement in the TRIPS waiver conversation and the judicial handling of injunctions during COVID-19 reflect the gap between legal options and practical implementation. While the TRIPS framework provides a range of flexibilities, their successful execution relies on political commitment, judicial judgement, and prioritisation of public interest. Moving forward, India's position as a global supplier of pharmaceuticals necessitates a coherent synergy between its international advocacy for access and the domestic enforcement of patent regulations.

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[24] Shirin Syed, Implementation of TRIPS Flexibilities and Injunctions: A Case Study of India (South Centre Research Paper No 194, February 2024) <https://www.southcentre.int/wp-content/uploads/2024/02/RP194_Implementation-of-TRIPS-Flexibilities-and-Injunctions-A-Case-Study-of-India_EN.pdf> Accessed 28 July 2025

[25] International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR), art 4

Constitutional Imperatives and the Right to Health in India

The relationship between intellectual property rights and the fundamental right to health in India has gained importance, particularly amid global patent norms and socio-economic conditions. Article 21 of the Indian Constitution assures the right to life and personal liberty, which the Supreme Court has broadly interpreted to include the right to health. This judicial interpretation has elevated access to essential medicines from a mere policy goal to a constitutional necessity.[26] In India, the right to health is firmly grounded in Article 21, which declares that "no person shall be deprived of his life or personal liberty except according to procedure established by law." Through significant judicial rulings, this provision has come to encompass the right to live with dignity, which intrinsically includes the right to health and, consequently, access to life-saving medications. In the case of Paschim Banga Khet Mazdoor Samity, the Supreme Court explicitly stated that a government hospital's failure to provide timely medical treatment to a patient violated Article 21. Furthermore, the Directive Principles of State Policy, especially Article 47, reinforce this mandate by requiring the state to enhance public health and nutrition as vital governance responsibilities.[27]

The connection between patent law and the right to health has become particularly pressing following India's commitment to comply with the TRIPS Agreement. The 2005 Amendment to the Patents Act signalled the completion of this alignment, bringing in product patent protection in the pharmaceutical domain. However, this amendment also incorporated public health safeguards such as compulsory licensing, opposition mechanisms, and working requirements that echo constitutional obligations to equitable healthcare.[28] The Supreme Court's interpretations of these provisions have continually upheld the significance of public health over private patent rights. Despite its international commitments, India has utilised TRIPS flexibilities in a manner that aligns with constitutional principles. For instance, compulsory licensing under Section 84 permits third parties to produce patented medications when pressing public health needs are met. This provision was confirmed and put into practice in a landmark case concerning Bayer's cancer medication, which was regarded as unaffordable by Indian

[26] Darpan, 'Right to Life Saving Drugs – A Study in Context to Indian Patent Law' (2025) 3(6) IJMR <https://theacademic.in/wp-content/uploads/2025/07/131.pdf> Accessed 29 July 2025
[27] n 24, art 47
[28] Rahul Vicky, 'Right to Health vis-à-vis Patent Protection: The Indian Scenario' (Academike, 13 May 2015 <https://www.lawctopus.com/academike/right-health-vis-vis-patent-protection-indian-scenario/> Accessed 29 July 2025

standards. The controller issued a license to a generic manufacturer, referencing the patent holder's inability to make the drug reasonably accessible to the public.[29] Similarly, the Doha Declaration on TRIPS and Public Health reaffirmed the rights of WTO members to implement measures that safeguard public health, underscoring that TRIPS should not obstruct access to essential medications.[30]

Research on the socio-legal effects of patent protection reveals that TRIPS-compliant frameworks can and should align with constitutional imperatives like the right to health. The challenge lies in ensuring that patent laws do not create overwhelming obstacles to healthcare, particularly in developing nations like India, where large segments of the population rely on affordable medications. The National Pharmaceutical Pricing Authority (NPPA), the Jan Aushadhi Scheme, and Ayushman Bharat further signify state efforts to actualise the guarantees of Article 21 through accessible healthcare. Ultimately, India's approach is a sophisticated model in which global intellectual property responsibilities are harmonised with constitutional obligations. Rather than perceiving TRIPS compliance as contradictory to the right to health, India has illustrated that achieving a balance between innovation and public interest is feasible, thereby establishing a precedent for other nations facing similar challenges in the patent-access context.[31]

Evaluating the Effectiveness of TRIPS Flexibilities in India

India's pharmaceutical policy is frequently referenced as a model for harmonising intellectual property rights with public health necessities, particularly considering its strategic utilisation of TRIPS flexibilities. These flexibilities, incorporated within the TRIPS Agreement through clauses like Articles 8, 30, and 31, allow member countries to customise their domestic regulations to safeguard public interest, particularly in facilitating medication access.

The Indian patent system exemplifies the careful implementation of compulsory licensing, pre-grant opposition, and a narrow interpretation of patentability. Governed by Section 84 of the Indian Patents Act, compulsory licensing has become an essential mechanism. It allows third

[29] V Rakeshwari, 'A Study on Examining the Impact of Patent Protection and Right to Health' (2025) 8(2) IJLMH <https://ijlmh.com/paper/a-study-on-examining-the-impact-of-patent-protection-and-right-to-health/> Accessed 29 July 2025
[30] Aamir Zafar Khan, 'TRIPS Agreement and its Effect on Indian Patent Law' (2016) 3(10) LMLJ <https://journal.lawmantra.co.in/wp-content/uploads/2016/04/17.pdf> Accessed 29 July 2025
[31] Shubhra Khanna, 'TRIPS, Pharmaceutical Patents and Health Care for the Poor in India' (2016) Summer Issue ILI Law Review <https://ili.ac.in/pdf/paper5.pdf> Accessed 29 July 2025

parties to produce patented medications without obtaining permission from the patent owner under specific circumstances, such as public health emergencies or inadequacy in fulfilling reasonable public requirements. A notable illustration is the compulsory license granted to NATCO Pharma in 2012 for the cancer treatment Sorafenib, initially patented by Bayer. This ruling was grounded in Bayer's inability to provide the drug at a reasonable cost, marking a pivotal example of employing TRIPS-aligned public health protections.[32]

The success of such licensing practices has been discussed, particularly against pressure from developed nations and possible trade consequences.[33] Even with the international legal groundwork established by the Doha Declaration on TRIPS and Public Health (2001), many developing countries are cautious about compulsory licensing due to potential diplomatic fallout or administrative obstacles.[4] This hesitance is further intensified by the complex procedural requirements stipulated by TRIPS, which include prerequisites for prior negotiations with the patent holder, non-exclusive usage, and fair compensation.[34]

Nonetheless, the Indian legal system has persisted in utilising these flexibilities to counteract monopolistic pricing. Article 31 of TRIPS, while mandating national approval and compensation, allows for the waiver of certain obligations during emergencies. This provision has been strategically and selectively used. In India, Section 92 of the Patents Act facilitates accelerated compulsory licensing in situations of national emergency or severe urgency, ensuring that procedural challenges do not hinder accessibility. The interpretive flexibility of TRIPS, particularly concerning ambiguous terms such as "adequate remuneration" or "national emergency," has empowered India to legislate in ways that prioritise domestic health needs.[35]

In addition to compulsory licensing, other TRIPS-compliant methods like parallel importation, pre- and post-grant opposition processes, and working requirements mitigate patent-related exclusivity. For instance, the Indian Patent Office has denied numerous patent applications due

[32] NATCO Pharma Limited v. Bayer Healthcare LLC, (2019) 262 DLT 284
[33] Carlos María Correa, 'Interpreting the Flexibilities under the TRIPS Agreement' (South Centre Research Paper No 132, April 2021) <https://www.southcentre.int/research-paper-132-april-2021/> Accessed 29 July 2025
[34] n 21, arts 31(b) and 31(f)
[35] Raadhika Gupta, 'Compulsory Licensing under TRIPS: How Far it Addresses Public Health Concerns in Developing Nations' (2010) 15 JIPR <https://www.researchgate.net/publication/290856284_Compulsory_Licensing_under_TRIPS_How_Far_it_Addresses_Public_Health_Concerns_in_Developing_Nations> Accessed 30 July 2025

to insufficient novelty or effectiveness, thereby protecting the generic market.[36] This has led to greater availability of affordable medications and spurred the development of a strong domestic pharmaceutical sector.

India's pragmatic application of TRIPS flexibilities illustrates a balanced strategy fulfilling international commitments while integrating constitutional obligations within intellectual property legislation. Although the system is not flawless, with certain scholars pointing out political and practical challenges associated with issuing compulsory licenses, the presence of a legal framework that supports public health aims highlights the potential of TRIPS flexibilities when effectively integrated through legislative measures.

Comparative Perspective: India and Global South Responses

Developing nations across the Global South have utilised TRIPS flexibilities in ways that align with their unique constitutional values, public health concerns, and industrial capabilities. India, Brazil, and South Africa emerge as key players that have strategically leveraged TRIPS flexibilities to balance IP protection with public health and shape global standards regarding pharmaceutical patent regulation. A notable aspect of this engagement in India is the judiciary's careful stance on injunctive relief in patent infringement cases. Courts have shown a readiness to consider whether such enforcement would interfere with the larger public interest, particularly the right to health. In patent disputes, especially those concerning life-saving medications, courts have scrutinised whether granting an injunction would excessively hinder public access to affordable treatment options. This consideration of convenience extends beyond the parties involved to the broader socio-economic landscape, reflecting a sophisticated application of TRIPS enforcement flexibilities. However, this judicial trend is marked by inconsistency and has faced criticism for inadequately defining standards related to public interest. Nonetheless, India's strategy indicates a willingness to balance private rights with its constitutional and international human rights obligations.[37] In contrast, nations like South Africa have pursued a more restrained route, partly limited by historical IP laws and trade

[36] R Vigaasini, 'Impact of Flexibilities as to Pharmaceutical Patents: TRIPS Agreement and the Indian Patents Act' (Manupatra, 19 July 2024) <https://articles.manupatra.com/article-details/IMPACT-OF-FLEXIBILITIES-AS-TO-PHARMACEUTICAL-PATENTS-TRIPS-AGREEMENT-AND-THE-INDIAN-PATENTS-ACT> Accessed 30 July 2025

[37] Siva Thambisetty, Improving Access to Patented Medicines: Are Human Rights Getting in the Way? (SSRN, 6 April 2018) < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3130703#:~:text=Siva%20Thambisetty,-London%20School%20of&text=This%20paper%20examines%20the%20value,grant%20and%20exploitation%20of%20patents> Accessed 30 July 2025

pressures. Despite substantial advocacy for improved access to HIV medications, legislative progress in South Africa has been relatively slow. Courts have not consistently embraced the flexibility offered by the TRIPS Agreement, especially regarding interpreting public interest within injunctive contexts. Yet, civil society movements in South Africa have been crucial in advocating for reforms, illustrating that societal demands have significantly impacted the IP dialogue even when legal frameworks fall behind.

Brazil's strategy offers another valuable example. The nation's public health initiative has been pivotal in shaping its interpretation of TRIPS, with authorities proactively employing compulsory licensing to reduce drug costs and encourage local manufacturing. Brazil's IP structure notably encompasses a prior consent mechanism where the health regulator (ANVISA) can reject pharmaceutical patent applications. This extra layer of oversight introduces public health considerations directly into the patent approval process. The exercise of this regulatory power exemplifies a state-driven approach to ensure that patent law operates within broader social and economic objectives, rather than as a standalone commercial tool. These jurisdictions collectively embody the developing "South-South jurisprudence," which reconceptualises the TRIPS framework as not merely a limitation, but as a toolkit for affirming developmental and constitutional priorities. Unlike developed countries, where patent enforcement is often separated from broader socio-political considerations, nations in the Global South increasingly integrate access to medications, equitable innovation, and distributive justice into the foundational aspects of their IP enforcement strategies.

Recommendations for a Post-COVID IP and Access Framework

The COVID-19 pandemic vividly highlighted the shortcomings of the global intellectual property (IP) system in providing equitable access to crucial medicines, diagnostics, and vaccines. Despite swift scientific progress and extraordinary public investment in pharmaceutical research and development, numerous low- and middle-income nations faced delays in accessing vital treatments. This situation has reignited enduring concerns about the equilibrium between IP protection and public health, especially within the context of the TRIPS Agreement. For India, which has a strong history of utilising TRIPS flexibilities, this moment presents both a challenge and an opportunity to reform its IP framework to better align with constitutional obligations and global solidarity.

An essential initial reform would incorporate public health as a fundamental interpretative framework within domestic patent legislation. Currently, the Indian judiciary and executive bodies occasionally reference public interest, for instance, in decisions regarding compulsory licensing or when resisting injunctive relief in patent infringement cases involving life-saving medications. Nevertheless, the lack of a formal, legislative doctrine prioritising health equity restricts uniformity in its application. By establishing a public health exception within Sections 3, 83, 84, and 92 of the Patents Act, lawmakers can offer clear statutory direction to decision-makers, ensuring that innovation facilitates rather than hinders access to medicines.[38] As the pandemic underscored, the ability to suspend or bypass certain IP obligations must be codified in law and readily actionable in urgent situations.

Furthermore, the procedural obstacles surrounding compulsory licensing (CL) must be tackled. Although Sections 84 and 92 of the Indian Patents Act create a solid legal foundation for CL, this pathway remains underutilised. Only one successful CL has been granted since TRIPS compliance began in 2005 (the Bayer–Nexavar case), highlighting a disconnect between legal possibilities and practical implementation. The application process is overly bureaucratic and prone to delays due to the necessity of prior negotiations, extensive documentation, and the potential for political influence. A revamped framework could introduce a fast-tracked licensing mechanism activated during public health crises, as allowed under Article 31(b) and (c) of TRIPS. Additional regulations under Section 92 could be broadened to lessen dependence on executive declarations, instead relying on objective indicators like WHO declarations of global health emergencies.[39]

A centralised and transparent patent database should also be created to track the status of pharmaceutical patents, licensing agreements, public funding sources, and pricing information. The lack of public insight into patent environments diminishes the ability of civil society, healthcare organisations, and policymakers to monitor monopolies and advocate for affordable access. A legal requirement for disclosing licensing conditions—especially when public R&D

[38] Dr Payal Thaorey and Anushree Mukte, 'Compulsory Licensing of Pharmaceutical Patents in India: Issues and Challenges' (2023) 1(1) IPRJMNLUN < https://www.nlunagpur.ac.in/PDF/Publications/5-Current-Issue/1.%20COMPULSORY%20LICENSING%20OF%20PHARMACEUTICAL%20PATENTS%20IN%20INDIA.pdf> Accessed 30 July 2025

[39] Nazim Akbar, 'Access to Medicines as an Element of Right to Health: With Special Reference to Pharmaceutical Patents in India' (2018) 10(1) DLR <https://www.dehradunlawreview.com/wp-content/uploads/2020/06/8-Access-to-medicine-as-an-element-of-right-to-health-with-special-reference-to-pharmaceutical-patents-in-India.pdf> Accessed 30 July 2025

subsidies are involved—would inject much-needed accountability into the IP system. Moreover, this database could be a crucial resource for pre- and post-grant opposition, particularly for grassroots organisations aiming to prevent evergreening patent applications.

On a regional level, India should spearhead efforts to foster South-South legal collaboration on pharmaceutical IP matters. The lessons from COVID-19 revealed that unilateral national actions are often inadequate for confronting global monopolies or securing reliable supplies. Cooperative approaches such as pooled procurement, shared strategies for patent opposition, and coordinated licensing negotiations can significantly enhance the collective bargaining power of developing nations. Leveraging its pharmaceutical manufacturing capabilities and legal insights, India can aid in capacity-building initiatives for other low- and middle-income countries, particularly in Africa and Southeast Asia, thereby establishing a collaborative model that counters the disjointed nature of current responses.[40]

Equally significant is the categorical repudiation of TRIPS-plus obligations, which are frequently incorporated through bilateral and regional free trade agreements (FTAs). Provisions such as extensions of patent terms, data exclusivity about clinical trial information, and limitations on compulsory licensing and parallel importation directly undermine the policy autonomy safeguarded by TRIPS. In the post-COVID context, such obligations would hinder the state's ability to respond effectively to prospective pandemics or public health emergencies. Consequently, India must formulate a national intellectual property strategy that explicitly constrains its engagement with TRIPS-plus provisions, while concurrently advocating at the World Trade Organisation (WTO) and the World Intellectual Property Organisation (WIPO) for a reinterpretation or recalibration of intellectual property regulations in favour of the public interest.

Furthermore, reforms should address the economic rationale underpinning intellectual property law, which frequently prioritises monopoly rights over societal welfare. The legal framework must restrict anti-competitive behaviours such as evergreening, pay-for-delay arrangements, and strategic patent thickets. Price control mechanisms exemplified by those established under the Drug Price Control Order (DPCO) should be fortified, and the promotion of generic

[40] Dr Sandip Satbhai, The Law Relating to Right to Health and Patenting of Life Saving Drugs- With Special Reference to Novartis AG vs. Union of India (Academia, 1 August 2020) <https://www.academia.edu/17138449/The_Law_Relating_to_Right_to_Health_and_Patenting_of_Life_Saving_Drugs_With_Special_Reference_to_Novartis_AG_vs_Union_of_India> Accessed 30 July 2025

competition should be actively encouraged through incentives and expedited approval processes. These initiatives enhance affordability and resonate with India's constitutional mandate to guarantee access to healthcare as enshrined in Article 21.

Ultimately, the post-COVID era necessitates a reconfigured intellectual property regime that harmonises innovation with inclusivity, exclusivity with equity, and profit with the public good. India is positioned to spearhead this reform initiative, leveraging its legislative, judicial, and manufacturing capabilities. By institutionalising these reforms, India can exemplify that access to medicine transcends mere policy preference, embodying a legal and moral obligation rooted in constitutional and international human rights frameworks.[41]

Conclusion

India's strategy regarding pharmaceutical patents following the adoption of the TRIPS Agreement demonstrates a thoughtful equilibrium between its global responsibilities and its constitutional promise to public health. Implementing product patent protection represented a significant transformation in India's pharmaceutical sector. Although essential for compliance with WTO standards, it sparked worries about the availability of necessary medications. Nonetheless, India has effectively leveraged the flexibilities inherent in the TRIPS framework, such as compulsory licensing, measures against evergreening, and protections for public health, to establish a system that fosters innovation without sacrificing accessibility. A key aspect of this framework is Section 3(d) of the Patents Act, which limits the evergreening of pharmaceutical patents unless the modified medication shows improved therapeutic efficacy. This provision was upheld in a pivotal ruling where a multinational company was refused a slightly modified anti-cancer drug patent. This verdict highlighted that patent law cannot be employed to maintain monopolies without authentic innovation. Likewise, India's issuance of its first compulsory license in the NATCO Pharma case highlighted its commitment to prioritising affordable access to medications over exclusive patent privileges. The licensing mechanisms outlined in Sections 84 and 92 of the Patents Act remain crucial legal instruments for protecting public health.

India's legislative and judicial stance on pharmaceutical patents aligns with its constitutional principles. The right to life, as established in Article 21, has been interpreted to encompass the

[41] Paras Aneja & Veer Vikram Singh, 'Patented Medicine and the Life of Patients' (2021) 9(9) JRHSS <https://www.questjournals.org/jrhss/papers/vol9-issue9/Ser-4/I09096167.pdf> Accessed 30 July 2025

right to health and access to affordable healthcare. Holding the state accountable for denying medical services and its obligation to provide necessary health services reinforces the notion that excessive intellectual property rights must not compromise public health. Article 47 further bolsters this idea by placing the responsibility on the state to enhance public health and nutrition. However, challenges in access continue, particularly due to the steep prices of patented medicines and the increasing influence of multinational companies in India's pharmaceutical industry. Therefore, India needs to sustain its resistance against TRIPS-plus regulations and external pressures that aim to weaken its health-centric patent framework. Initiatives such as the Jan Aushadhi scheme and the integration of essential medicines into a national regulatory framework exemplify a pro-public health stance. India's patent policy in the wake of COVID-19 offers important lessons for other developing nations dealing with the balancing act between innovation and access. The Indian experience illustrates that access to medications is not solely an intellectual property issue; it is fundamentally a matter of justice, equity, and constitutional ethics.