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Balancing Patent Protection and Public Access: A Study of Compulsory Licensing in India Post-COVID-19

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ABSTRACT

The conflict between patent protection and the right to public health has emerged as a central legal and ethical dilemma in the field of intellectual property law, particularly in the aftermath of the COVID-19 pandemic. Patents, while essential for incentivizing pharmaceutical innovation, often result in monopolies that can restrict access to affordable medicines and life-saving technologies. This tension became especially visible during the global health emergency, as countries struggled to secure equitable access to vaccines, diagnostics, and therapeutics in the face of rigid patent regimes and supply chain monopolies. The COVID-19 crisis highlighted the urgent need to reassess the balance between private intellectual property rights and the collective right to health. Countries like India, which faced severe public health challenges, were compelled to explore mechanisms such as compulsory licensing under the Patents Act, 1970, and flexibilities allowed under the WTO's TRIPS Agreement. At the international level, debates surrounding the TRIPS waiver proposal brought forth the critical question of whether global IP norms are adequately equipped to address health emergencies. This paper aims to critically analyse the existing legal framework governing patent rights in India, with a focus on provisions related to public health. It examines landmark judicial decisions such as Novartis AG v. Union of India and Bayer Corporation v. Union of India, which underscore the Indian judiciary's role in upholding access to medicine. Additionally, it delves into India's obligations under the TRIPS Agreement and the Doha Declaration, exploring how these international commitments interact with domestic legal provisions. The paper concludes that while India's legal framework provides significant safeguards for

public health, there are persistent challenges in implementation and global cooperation. It recommends strengthening compulsory licensing processes, advocating for TRIPS flexibilities, enhancing domestic manufacturing capacities, and promoting international legal reforms that prioritize public health over patent exclusivity in times of global crisis.

KEYWORDS

Patent, Licensing, Intellectual Property, TRIPS Agreement, Innovation.

1. INTRODUCTION

Patent law forms a critical pillar of the broader intellectual property rights framework, particularly within the pharmaceutical sector, where innovation is driven by the promise of exclusive market control. The rationale behind granting patents is to incentivize research and development by allowing innovators to recoup their investments and earn profits through temporary monopolies. This is especially vital in pharmaceuticals, where the costs of drug discovery, clinical trials, and regulatory approvals are prohibitively high. However, this legal exclusivity creates a fundamental tension between the interests of private innovation and public welfare. While patents reward inventors, they often result in high prices, limited supply, and delayed entry of generic alternatives—thereby restricting access to life-saving medications for large segments of the population, particularly in low- and middle-income countries. [1]

This dilemma becomes even more pressing during public health crises, where the need for rapid, affordable, and widespread access to medical innovations becomes paramount. The COVID-19 pandemic exemplified this conflict starkly. As the virus spread globally, so did the demand for vaccines, diagnostics, and treatments. Yet, these crucial medical tools were largely controlled by a handful of pharmaceutical companies that held exclusive rights under international patent laws. [2]

As a result, supply shortages, price disparities, and vaccine nationalism emerged, with wealthier nations securing large quantities of doses while poorer countries were left behind. This situation prompted countries like India and South Africa to propose a temporary waiver of certain provisions of the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement to enable broader access to COVID-related medical products. The proposal sparked intense global debate, revealing the limitations of the existing IP regime in responding to health emergencies and

reinforcing concerns that the current legal structure favours profits over lives.[3]

At the heart of this debate lies the TRIPS Agreement, a binding treaty under the World Trade Organization that sets minimum standards for IP protection, including pharmaceutical patents. [4] While TRIPS do include flexibilities—such as compulsory licensing and parallel imports—many countries, including India, often face legal and diplomatic challenges when trying to invoke them. For instance, when India issued its first compulsory license for the cancer drug Nexavar in 2012, it faced significant backlash from multinational pharmaceutical firms and their host governments. [5] the complexity of TRIPS implementation, coupled with pressure to adopt "TRIPS-Plus" provisions in bilateral trade agreements, makes it difficult for developing countries to fully leverage these flexibilities without repercussions. [6]

Nevertheless, India's patent law framework, largely shaped by the Patents Act of 1970 and amended in 2005 to comply with TRIPS, incorporates important safeguards that aim to balance innovation with access. Notable provisions include Section 3(d), which prevents evergreening of patents by disallowing protection for minor modifications of known drugs unless they enhance therapeutic efficacy, and Section 84, which permits compulsory licensing in situations where patented inventions are not available to the public at reasonable prices or in adequate quantities. [7]

Judicial interpretations of these provisions have further cemented India's approach to prioritizing public health. One of the landmark cases in this context is *Novartis AG v. Union of India* (2013), in which the Supreme Court denied patent protection for the cancer drug Glivec on the grounds that it did not demonstrate enhanced efficacy.[8] the judgment emphasized India's commitment to preventing the abuse of patent rights and ensuring access to affordable medicines. Similarly, in the *Bayer v. Natco* case (2012), India granted a compulsory license for a life-saving drug, setting a global precedent for the use of TRIPS flexibilities in favour of public health.[9] These cases highlight India's proactive stance in using its legal framework to strike a balance between private rights and public interest.

Yet, the challenge remains formidable. India must navigate the dual pressures of complying with international IP obligations and fulfilling its constitutional mandate to protect the right to health. Although the Indian legal regime includes robust mechanisms to mitigate the adverse effects of patent monopolies, the political and economic costs of using them—such as threats of trade sanctions or investor-state disputes—cannot be ignored. [10] as global health

emergencies become more frequent and interconnected, the adequacy of current legal tools must be reconsidered. This paper therefore aims to explore the effectiveness of India's patent law in ensuring both innovation and access in times of public health crises. It seeks to evaluate the legal and policy mechanisms available under domestic and international law, assess the impact of key judicial decisions, and propose reforms that can help reconcile the imperatives of public health with the demands of a knowledge-driven global economy. In doing so, the paper addresses the critical question of whether the existing legal framework can bridge the gap between patent protection and the fundamental human right to health

2. PATENT LAW OVERVIEW

India's patent regime, as enshrined in the Patents Act, 1970, is a product of the country's long-standing effort to harmonize the protection of intellectual property with the socio-economic realities of a developing nation. [11] from its inception, Indian patent law was designed not merely to reward innovation but also to ensure that such innovation did not come at the cost of public health. This concern was especially pronounced in the field of pharmaceuticals, where patent monopolies could significantly restrict access to life-saving medicines. [12]

Consequently, for several decades, India adopted a process-patent system for pharmaceuticals and agrochemicals, which allowed generic manufacturers to produce affordable versions of patented drugs by using alternative processes. [13] This framework played a crucial role in establishing India as the "pharmacy of the developing world," enabling domestic pharmaceutical companies to supply affordable medications both locally and internationally. [14]

However, this approach came under pressure following India's accession to the World Trade Organization (WTO) in 1995 and its subsequent obligation to comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). [15] TRIPS mandated the adoption of product patent protection, which India had historically avoided in sensitive sectors. To align with its international commitments while still safeguarding public health, India introduced significant amendments to the Patents Act in 2005. [16]

The 2005 Amendment marked a turning point, as it formally introduced product patents for pharmaceuticals and agrochemicals. [17] This shift was met with considerable apprehension, particularly from public health advocates, who

feared a drastic increase in drug prices and reduced accessibility to essential medicines. However, India did not adopt the TRIPS standards in a wholesale or uncritical manner. Rather, it incorporated a series of legal safeguards to ensure that patent rights did not become absolute and could be overridden when public interest demanded it. [18]

One of the most significant safeguards embedded in the amended law is the provision for compulsory licensing, found in Section 84 of the Patents Act. [19] This provision allows any person to apply for a compulsory license for a patented invention after three years from the date of grant, provided that certain conditions are met. These include situations where the reasonable requirements of the public are not being satisfied, the patented invention is not available at a reasonably affordable price, or the invention is not being worked in the territory of India. [20] Compulsory licensing serves as a crucial tool for preventing the abuse of patent rights, particularly when the exclusivity granted to patentees is used to withhold life-saving medicines from those who need them most. [21]

The landmark case of Bayer v. Natco in 2012 highlighted the application of this provision, where the Indian Patent Office granted Natco Pharma a compulsory license for the cancer drug Nexavar, citing high prices and lack of local manufacturing as grounds for intervention. [22] This decision not only underscored the practical utility of Section 84 but also reinforced India's role as a leader among developing nations in balancing intellectual property rights with public health needs. [23]

Complementing Section 84 is Section 92 of the Patents Act, which provides for compulsory licenses in cases of national emergency or extreme urgency.[24] Unlike Section 84, where an applicant must prove the need for intervention through a quasi-judicial process, Section 92 allows the government to proactively issue a notification enabling compulsory licenses without waiting for an individual application.[25] This mechanism is particularly important during public health crises, such as pandemics, where delays in access to patented drugs or vaccines could result in catastrophic consequences. The COVID-19 pandemic reignited interest in this provision, with public health experts and civil society organizations urging the government to utilize Section 92 to increase vaccine and drug production capacity. [26] Although the government refrained from issuing compulsory licenses during the pandemic, the existence of this provision served as a strategic policy tool that could be activated in future emergencies. [27]

Together, these sections represent India's nuanced approach to patent protection—one that recognizes the importance of

incentivizing innovation but not at the cost of human lives. They reflect a constitutional commitment to the right to health, enshrined in Article 21 of the Indian Constitution, which has been interpreted by the judiciary to encompass access to affordable healthcare. [28] The Indian patent system, thus, stands as a model for how developing countries can implement TRIPS-compliant legislation without compromising public health imperatives. Through a combination of statutory provisions and judicial interpretation, India has crafted a legal landscape that prioritizes both innovation and equity—a balance that is particularly crucial in an age where global health emergencies are becoming increasingly frequent and interconnected.

3. COMPULSORY LICENSING PROVISIONS

The Indian Patents Act, 1970, reflects a careful attempt to reconcile the enforcement of patent rights with broader societal obligations, especially in matters related to public health.[29] A central feature of this framework is the provision for compulsory licensing, a legal mechanism that allows the government or any interested party to override a patent holder's exclusivity under certain conditions.[30] The most significant of these provisions is enshrined in Section 84 of the Act, which authorizes the Controller of Patents to issue compulsory licenses after three years have passed since the grant of a patent.[31] This provision may be invoked by any person, including generic pharmaceutical companies, who can demonstrate that the patentee has failed to meet one or more statutory requirements intended to protect the public interest.

The first ground on which a compulsory license can be granted is when the reasonable requirements of the public with respect to the patented invention are not being met.[32] This situation may arise when the product, especially a life-saving drug, is being made available in insufficient quantities or only to a limited demographic—such as urban hospitals or elite institutions—while excluding vast sections of the population.[33] In such cases, even though the invention exists, its benefits are not equitably distributed.[34] The law recognizes that a patent must serve not only the patentee's commercial interest but also the broader health needs of the population.[35]

The second and perhaps most critical ground is that the patented invention is not available at a reasonably affordable price.[36] This is particularly relevant in a country like India, where the majority cannot afford high treatment costs.[37] One prominent example is the case of the cancer drug Nexavar, priced by Bayer at around ₹2.8 lakhs per month, rendering it inaccessible to over 99% of

patients.[38] Such pricing, though justified by patentees as necessary to recoup R&D costs, conflicts with the constitutional right to health under Indian law.[39]

A third and equally important ground for issuing a compulsory license is the failure of the patentee to work the invention in India.[40] This requires either local manufacturing or adequate importation to meet demand.[41] Mere token imports or full dependence on foreign manufacturing does not fulfil this requirement, particularly when domestic production would improve availability and affordability.[42]

The landmark case of *Natco Pharma Ltd. v. Bayer Corp.* (2012) was the first judicial application of Section 84.[43] Natco Pharma applied for a compulsory license for Nexavar, citing all three statutory grounds: insufficient availability, unaffordable pricing, and absence of local working.[44] The Controller of Patents granted the license, allowing Natco to sell the drug for around ₹8,800 per month—a price reduction of over 95%.[45] The decision was widely hailed as a precedent-setting affirmation of India's commitment to public health within a TRIPS-compliant IP framework.[46]

The procedural safeguards under Section 84 are designed to ensure fairness.[47] The applicant must wait three years from the grant of the patent and must present clear evidence of the patentee's failure on one or more statutory grounds.[48] They must also demonstrate capacity to manufacture and distribute the drug.[49] The Controller hears both parties and may grant the license with specific terms, including a royalty (generally 4–6% of net sales) to the patentee and limits on export.[50] Humanitarian exceptions such as those under the WTO's Paragraph 6 System also apply.[51]

In contrast, Section 92 of the Patents Act offers a more urgent mechanism.[52] It is invoked through a government notification declaring a national emergency, extreme urgency, or public non-commercial use.[53] Here, no private application or waiting period is required.[54] This provision is essential during health emergencies like pandemics, where even brief delays can cost lives.[55]

While Section 92 was not formally invoked during the COVID-19 pandemic, it had significant indirect impact.[56] Amid shortages of drugs and vaccines such as Remdesivir and Tocilizumab, legal experts and public health advocates urged its use.[57] The mere existence of this provision prompted voluntary licensing agreements from multinationals with Indian firms, enabling scale-up of manufacturing and stabilizing supply.[58] Thus, even

uninvoked, Section 92 served as a diplomatic and policy instrument.[59]

In sum, Sections 84 and 92 are foundational to India's public health-cantered patent policy.[60] They do not merely create exceptions but affirm that IP rights must align with constitutional and humanitarian values.[61] These provisions also comply with TRIPS, which recognizes the right of member states to protect public health and promote access to medicines for all.[62] India's use of these tools—especially in *Bayer v. Natco* and during COVID-19—provides a strong model for other developing nations.[63] As future health crises

4. INTERNATIONAL PERSPECTIVE

The global legal discourse on the intersection between patent rights and public health has evolved significantly, particularly within the framework of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), administered by the World Trade Organization (WTO).[64] Adopted in 1994, TRIPS sought to harmonize minimum IP standards across WTO members but also included provisions for flexibility in national implementation, especially in health emergencies.[65] One such provision is Article 31, which permits the use of a patented invention without the right holder's authorization, including through compulsory licensing.[66] Article 31 includes conditions such as case-by-case authorization, prior efforts to obtain a voluntary license, and domestic market use. However, in emergencies, these preconditions may be waived. [67]

Despite these flexibilities, developing countries hesitated to invoke them, fearing trade retaliation and diplomatic pressure.[68] This reluctance became evident during the HIV/AIDS crisis in sub-Saharan Africa, where access to antiretrovirals was limited due to high prices imposed by patent holders.[69] In response, the WTO adopted the Doha Declaration on the TRIPS Agreement and Public Health in 2001, which reaffirmed that TRIPS should not hinder members from protecting public health.[70] It clarified the sovereign right of nations to determine public health emergencies and affirmed the legitimacy of compulsory licensing and parallel importation.[71] Furthermore, the 2003 WTO Decision enabled countries lacking manufacturing capacity to import medicines produced under compulsory licenses, strengthening global access.[72]

- ***BRAZIL***

Brazil's 2007 compulsory license for Efavirenz, an antiretroviral patented by Merck, remains a pivotal example. [73] After failed price negotiations, Brazil issued the license and began importing generics from India, saving substantial costs while expanding access. [74] This move, fully TRIPS-compliant, illustrated that compulsory licensing can align with both economic and humanitarian objectives. [75]

- ***THAILAND***

Thailand invoked TRIPS flexibilities aggressively between 2006 and 2007, issuing compulsory licenses for Efavirenz, Kaletra, and Plavix.[76] Citing drug unaffordability, the Thai government acted under domestic laws modeled on TRIPS Article 31.[77] Although met with resistance from pharmaceutical firms and foreign governments, Thailand's move was protected by the Doha Declaration, and it led to substantial price reductions and broader coverage under the Universal Coverage Scheme.[78] This approach exemplifies strategic compulsory licensing for long-term health policy goals.[79]

- ***SOUTH AFRICA***

South Africa's efforts in the late 1990s sparked one of the most prominent global access-to-medicine debates.[80] Facing an HIV/AIDS emergency, it amended its Medicines and Related Substances Control Act to include compulsory licensing and parallel imports.[81] In response, the Pharmaceutical Manufacturers Association (PMA), backed by nearly 40 drug companies, filed a lawsuit in 1998 claiming TRIPS violations.[82] Widespread backlash and global advocacy led to the withdrawal of the case in 2001, heralding a landmark victory for access to medicines and laying groundwork for the Doha Declaration.[83] South Africa's experience revealed the political risks of exercising TRIPS rights but also demonstrated the power of international solidarity.[84]

- ***INDIA***

India has taken a measured yet principled approach to TRIPS flexibilities. After the 2005 amendment to its Patents Act to comply with TRIPS, it embedded safeguards such as Section 84 (compulsory licensing) and Section 92 (emergency licensing).[85] India's first major application was in *Natco Pharma Ltd. v. Bayer Corp.* (2012), granting a license for Nexavar, a cancer drug.[86] Natco priced its generic at ₹8,800/month, a dramatic drop from

Bayer's ₹2.8 lakh price.[87] The case established that TRIPS-compliant law can prioritize affordability and public interest.[88]

Unlike South Africa, India faced no legal backlash, due to its robust statutory process and clarity. [89] Although India hasn't issued multiple licenses like Thailand, its legal framework is globally respected for balancing innovation and access.[90] Further, India's pharmaceutical manufacturing capabilities position it not only as a user but also as a global supplier of generics, even under licenses issued abroad.[91]

The international experience with TRIPS flexibilities shows that compulsory licensing is a legitimate and necessary tool in achieving public health equity. Brazil and Thailand exemplify assertive use, South Africa demonstrates the power of advocacy, and India offers a balanced, rule-based model. Together, these cases prove that IP rights and health rights need not be mutually exclusive. As health emergencies increase in frequency and complexity, the international community must embrace the flexibility and adaptability within the TRIPS framework to ensure universal access to essential medicines.

5. JUDICIAL INTERPRETATION AND TRIPS-PLUS AGREEMENTS

Patent law forms a critical component of the broader intellectual property rights regime, aimed at promoting innovation by granting inventors exclusive rights over their creations for a limited period. In the pharmaceutical context, patents incentivize research and development (R&D) by ensuring that innovators can recoup their investments and profit from their inventions. [92] This legal monopoly, however, creates a complex dilemma—while it fosters innovation, it may simultaneously limit public access to essential medicines due to high prices and restricted supply. [93]

This inherent tension between rewarding innovation and ensuring equitable access to healthcare is particularly stark in the realm of public health. [94] Patents on life-saving drugs, vaccines, and medical technologies can effectively place them beyond the reach of millions, especially in low- and middle-income countries. [95] This challenge becomes more pressing in times of health emergencies when the need for rapid, affordable, and widespread access to medical innovations becomes paramount. [96]

The COVID-19 pandemic brought this conflict into sharp focus. As the world grappled with a rapidly spreading virus, the demand for vaccines, treatments, and diagnostics surged globally. Patent protections held by a few pharmaceutical companies raised

concerns about supply shortages, price barriers, and vaccine nationalism. [97] In response, India and South Africa proposed a temporary waiver of certain provisions of the TRIPS Agreement to facilitate broader access. [98] This proposal ignited international debate, exposing limitations in the existing IP framework to address public health crises.

India's patent framework, shaped by the Patents Act, 1970 (as amended in 2005), includes public interest safeguards like Sections 3(d), 84, and 92. [99] These legal mechanisms aim to ensure innovation does not override the right to health. Judicial interpretations of these provisions reveal a proactive effort to balance patent protection with public welfare.

The landmark judgment in *Novartis AG v. Union of India* (2013) exemplifies this balance. The Supreme Court refused to grant a patent for a beta crystalline form of Imatinib Mesylate (Glivec) on the grounds that it did not satisfy the enhanced efficacy requirement under Section 3(d). [100] The Court held that minor modifications to existing drugs must demonstrate significant therapeutic benefit to merit patent protection. [101] This decision curbed the practice of evergreening, where pharmaceutical companies seek patent extensions by making trivial changes to existing drugs. [102]

Similarly, in *Natco Pharma Ltd. v. Bayer Corp.* (2012), the Indian Patent Office granted the country's first compulsory license under Section 84, allowing Natco to manufacture and sell a generic version of Bayer's cancer drug Nexavar.[103] The decision was later upheld by the Intellectual Property Appellate Board (IPAB), reinforcing the validity of public health–oriented licensing.[104] These rulings showcase India's ability to interpret TRIPS obligations flexibly while asserting its sovereign right to protect access to medicine.[105]

However, India's approach is increasingly challenged by TRIPS-plus provisions embedded in bilateral and regional Free Trade Agreements (FTAs).[106] These provisions often extend patent durations, introduce data exclusivity, and limit the scope for compulsory licensing—thereby reducing the flexibility allowed under the TRIPS Agreement.[107] For instance, FTAs promoted by the European Union or the United States often include clauses that restrict generic drug entry and expand patent-holder rights.[108] These provisions can severely constrain the ability of developing countries to maintain a pro-public health patent regime.

To date, India has resisted pressure to adopt TRIPS-plus obligations in most of its trade negotiations, including in the Regional Comprehensive Economic Partnership (RCEP) and bilateral talks with the European Union. [109] Nevertheless, continued global pressure from developed nations and pharmaceutical lobbies poses an ongoing threat. [110]

India must remain vigilant in preserving policy space under its patent law and avoid trade agreements that undermine domestic legal safeguards. [111] Maintaining this autonomy is critical for upholding the constitutional right to health, recognized under Article 21 of the Indian Constitution, and interpreted by the judiciary to include access to affordable healthcare. [112]

Judicial decisions and policy choices must work in tandem to ensure that patent law evolves in a manner consistent with public interest. India's experience shows that it is possible to implement a TRIPS-compliant, innovation-friendly patent system that also prioritizes health equity. In a world increasingly shaped by global health threats, preserving this balance is not only a legal necessity but also a moral imperative.

6. LANDMARK INDIAN AND INTERNATIONAL CASE STUDIES

- *Natco Pharma Ltd. v. Bayer Corporation (2012)*

India's compulsory licensing jurisprudence was fundamentally shaped by *Natco Pharma Ltd. v. Bayer Corporation*, the first case in which the Controller of Patents invoked Section 84 of the Patents Act, 1970.[113] The dispute concerned Sorafenib Tosylate (Nexavar), an anti-cancer drug priced at ₹2.8 lakhs per month—an amount beyond the reach of over 95% of Indian patients.[114] Natco applied for a compulsory license, citing Bayer's failure to meet the public's reasonable requirements, unaffordable pricing, and the absence of domestic manufacturing.[115]

The Controller granted the license, enabling Natco to sell a generic version at ₹8,800 per month—a reduction of over 95%.[116] The license came with conditions: a 6% royalty to Bayer, a distribution restriction to the Indian market, and free supply to a segment of economically disadvantaged patients.[117] Bayer challenged the decision, but the Intellectual Property Appellate Board (IPAB) upheld the license, reaffirming India's TRIPS-compliant approach to balancing patents with access.[118]

- *BDR Pharmaceuticals v. Bristol-Myers Squibb (2013)*

In contrast, *BDR Pharmaceuticals v. Bristol-Myers Squibb* highlighted the procedural rigor of Indian patent law. BDR's application for a compulsory license for Dasatinib, another expensive anti-cancer drug, was rejected due to insufficient effort to obtain a voluntary license. [119] The Patent Office found that BDR had sent only a single letter to Bristol-Myers and failed to pursue negotiations in good faith, violating Section 84(6)(iv). [120] the case demonstrated that procedural compliance is just as critical as substantive justification.

- *Lee Pharma v. AstraZeneca (2015)*

In *Lee Pharma v. AstraZeneca*, the Controller denied a compulsory license for Saxagliptin, an anti-diabetic drug. [121] the applicant failed to establish that the drug was unaffordable or that public demand was unmet. Moreover, the drug was not considered therapeutically indispensable, as alternatives existed. [122] the ruling illustrated the growing evidentiary and legal threshold for compulsory licensing in India.

- *Novartis AG v. Union of India (2013)*

Though not a compulsory licensing case, *Novartis AG v. Union of India* remains a cornerstone of access-to-medicines jurisprudence. [123] Novartis sought a patent for Glivec, a new form of an existing drug. The Supreme Court rejected the application under Section 3(d) of the Patents Act, finding no enhanced therapeutic efficacy. [124] the ruling was a strong stance against "evergreening" and reaffirmed India's commitment to affordability in pharmaceuticals. [125]

- *Abbott Laboratories v. Cipla (2019)*

During the COVID-19 pandemic, Cipla began manufacturing Lopinavir/Ritonavir—drugs under patent by Abbott—for emergency use. [126] While no formal compulsory license was granted, the government considered invoking Sections 92 and 100 of the Patents Act. [127] the implicit threat of such action encouraged negotiated solutions, showcasing how the mere presence of emergency licensing powers can influence market dynamics and public health outcomes. [128]

6.1 International Case Studies

- *Thailand (2006–2008)*

Thailand issued compulsory licenses for several drugs, including Efavirenz and Clopidogrel, citing unaffordability and limited access. [129] Despite backlash from pharmaceutical companies and developed nations, the policy achieved significant reductions in drug prices and improved national access. [130] Thailand's approach demonstrated that TRIPS flexibilities could be exercised assertively and lawfully.

- *South Africa and the PMA Case (1997–2001)*

South Africa's amendments to the Medicines Act in 1997 enabled compulsory licensing and parallel imports of patented HIV drugs. [131] The Pharmaceutical Manufacturers Association (PMA), backed by 39 multinational companies, sued the government. [132] the case triggered global outrage and advocacy, leading to the suit's withdrawal in 2001. [133] This marked a pivotal moment in the access-to-medicines movement, highlighting the primacy of public health over IP protection.

- *Brazil's Strategic Licensing Approach*

Brazil has often used the threat of compulsory licensing to negotiate lower drug prices. In 2007, it issued a compulsory license for Efavirenz after failed negotiations with Merck. [134] More often, Brazil succeeded in securing price reductions through strategic pressure. [135] Its approach underscores how legal preparedness and negotiation leverage can serve public health goals without necessarily resorting to litigation. [136]

These case studies—spanning India, Thailand, South Africa, and Brazil—offer a comprehensive picture of how compulsory licensing can be operationalized as a tool of health diplomacy and legal intervention. India's experience, especially in *Natco v. Bayer*, demonstrates the value of having a clear statutory and judicial framework. Meanwhile, countries like Thailand and Brazil show that political will and international law can be harmonized to make life-saving drugs accessible. Together, these examples validate the TRIPS Agreement's flexibilities and highlight how they can be used pragmatically to advance the human right to health.

7. COMPULSORY LICENSING IN THE COVID-19 CONTEXT

The COVID-19 pandemic was an unprecedented global health crisis that revealed profound structural inequities in the global pharmaceutical supply chain and access to essential medical products. In India, the initial waves of the pandemic (2020–2021) resulted in acute shortages of critical drugs like Remdesivir, Tocilizumab, and Favipiravir, along with significant delays in

vaccine rollout. [137] These deficiencies were compounded by export restrictions from developed nations, raw material shortages, and the limited production capabilities of patent-holding multinational pharmaceutical corporations. [138]

Under Indian law, Sections 84 and 92 of the Patents Act, 1970 provide the legal basis for compulsory licensing.[139] Section 84 allows any person to apply for a compulsory license three years after a patent is granted, provided that the invention is not reasonably priced, not sufficiently available, or not "worked" in India.[140] Section 92, more immediate in scope, allows the government to issue compulsory licenses during a national emergency or in cases of extreme urgency.[141] Despite the availability of these legal mechanisms, the Indian government did not formally invoke either section to issue compulsory licenses during the COVID-19 crisis.

Instead, India pursued a dual-track strategy that favoured voluntary licensing and international diplomacy. On the international front, India and South Africa submitted a proposal to the World Trade Organization (WTO) in October 2020 seeking a temporary waiver of certain TRIPS provisions related to COVID-19 products.[142] The waiver aimed to remove IP-related barriers to the manufacture and distribution of vaccines, diagnostics, and therapeutics by suspending enforcement of patents and trade secrets.[143] The proposal received support from WHO, public health advocates, and numerous countries from the Global South, but faced resistance from high-income countries that argued it would discourage innovation and jeopardize product quality.[144] Ultimately, a compromised and diluted version of the waiver was adopted in June 2022, limited to vaccines and excluding therapeutics and diagnostics.[145] Given the timing, its real-world impact was minimal.

Domestically, the government opted for non-coercive voluntary licensing. Pharmaceutical companies were encouraged to enter into non-exclusive agreements with Indian manufacturers. For instance, Gilead Sciences licensed Remdesivir production to Indian firms including Cipla, Hetero, and Jubilant. [146] Similarly, Merck & Co. licensed Molnupiravir to several Indian generic's companies. [147] These voluntary licenses facilitated large-scale domestic production and significantly lowered drug prices in India. While this strategy helped avoid diplomatic fallout, critics argued that the Indian government underutilized its legal powers under Section 92, despite having a constitutionally and morally grounded obligation to prioritize public health. [148]

Several factors contributed to India's restraint. First, the government was wary of diplomatic repercussions and potential trade conflicts with countries hosting major pharmaceutical giants.[149] Second, there were practical challenges related to biologics and mRNA vaccines—technologies that require more than patent access; they necessitate technology transfer, tacit know-how, and highly specialized production facilities.[150] Issuing a compulsory license alone, without access to the full suite of technical information, would have been ineffective. Third, India's position as a trusted global manufacturing hub, including its key role in the COVAX initiative, incentivized a more collaborative and less adversarial stance. [151]

However, this cautious approach drew criticism from civil society groups, legal scholars, and health rights activists. They contended that the severity of the pandemic justified more assertive legal action. [152] the lack of any formal compulsory license issuance was seen as a missed opportunity to reaffirm India's leadership in advocating TRIPS flexibilities and to set a global precedent for equitable access during health crises. [153]

The pandemic also reignited debates around global IP governance, particularly the limitations of TRIPS in addressing emergency health needs. While the adoption of a partial waiver by the WTO was a step forward, it failed to deliver a comprehensive solution. [154] More importantly, the crisis revealed that voluntary cooperation—often subject to market incentives—cannot be solely relied upon in global emergencies. A proactive, legally grounded framework is essential to guarantee access to life-saving technologies. India's strategy during the COVID-19 pandemic was marked by diplomacy over legal confrontation, and partnership over compulsion. Although voluntary licensing yielded short-term results, it also exposed the fragility of relying on corporate goodwill. Going forward, India must reassess its legal preparedness and policy posture. This includes streamlining compulsory licensing procedures, enhancing domestic manufacturing capabilities for complex biologics, and advocating for a reformed, more equitable global IP regime. [155] the pandemic has made it clear that access to medicines is not just a legal or economic issue—it is a matter of fundamental human rights and global justice.

8. CHALLENGES AND CRITICISM

Despite being a critical legal tool designed to reconcile the conflict between intellectual property (IP) rights and public health, the implementation of compulsory licensing (CL) in India faces numerous challenges. These range from international geopolitical

pressure and procedural delays to technological barriers and ideological opposition. Collectively, they hinder the robust deployment of CL mechanisms during health emergencies.

One of the most persistent obstacles is international pharmaceutical lobbying and trade pressure. Global pharmaceutical giants, often represented by bodies like the Pharmaceutical Research and Manufacturers of America (PhRMA), have aggressively lobbied against compulsory licensing in developing countries.[156] They argue that such licenses erode the incentive structures underpinning pharmaceutical innovation by threatening the exclusivity granted through patents.[157] India, for instance, has frequently been placed on the United States Trade Representative (USTR) Special 301 Priority Watch List for its alleged "insufficient" IP enforcement.[158] This designation can tarnish India's reputation as a pro-investment jurisdiction and expose it to retaliatory trade measures under U.S. law.[159] The mere threat of CL issuance has often triggered diplomatic backlash, creating a chilling effect on state action, even in genuine public health emergencies.

At the domestic level, Section 84 of the Patents Act, 1970—the general CL provision—requires a three-year waiting period after the grant of a patent before an application can be made. [160] While intended to allow time for commercial exploitation, this lag severely limits responsiveness during fast-evolving health crises. Further, the applicant must prove that the patented invention is unaffordable, insufficiently available, or not worked in India—all of which require extensive, sometimes subjective, documentation. [161] The process involves multiple layers of review, beginning with the Controller General of Patents, followed by potential appeals to the High Courts or previously the Intellectual Property Appellate Board (IPAB), resulting in procedural delays that blunt the tool's effectiveness in emergencies. [162]

Although Section 92 provides an expedited route for compulsory licensing in national emergencies or cases of extreme urgency, it requires a formal notification by the central government, which has rarely been issued—largely due to political caution and diplomatic sensitivities. [163] the COVID-19 pandemic, arguably qualifying as an emergency under Section 92, witnessed no such invocation, illustrating the gap between statutory authority and political will.

A further constraint emerges from the limitations in India's domestic pharmaceutical capacity, particularly in complex biologics and advanced therapies. While India is globally renowned for manufacturing generic small-molecule drugs, the

same does not hold true for mRNA vaccines, monoclonal antibodies, or other biologics. [164] These therapies depend not only on patent access but also on tacit know-how, trade secrets, and specialized infrastructure, which compulsory licenses do not compel companies to disclose. [165] Without technology transfer agreements, a compulsory license for such products may remain ineffectual or purely symbolic.

On a more ideological level, compulsory licensing is often accused of disincentivizing innovation. Patent holders argue that fear of losing exclusivity discourages investment in high-cost R&D, particularly in areas that affect low-income populations.[166] This concern is frequently echoed in bilateral trade negotiations, where developed countries seek to limit CL flexibilities in exchange for market access or foreign direct investment.[167] Although public health advocates counter that much foundational research is publicly funded, the perceived regulatory uncertainty remains a potent argument wielded by multinational corporations.[168] Consequently, compulsory licensing remains a contentious subject in global IP discourse.

Despite the landmark ruling in Natco Pharma Ltd. v. Bayer Corporation, India has rarely issued compulsory licenses since, underlining the exceptional, rather than routine, nature of CL deployment. [169] Bridging the gap between India's TRIPS-compliant statutory framework and its limited real-world application demands more than legal reform; it requires a paradigm shift in policymaking and governance. At the national level, this includes:

- Expanding domestic capacity in biologics and complex drug manufacturing.
- Streamlining bureaucratic procedures for compulsory license issuance.
- Clarifying the legal thresholds for emergencies under Section 92.

At the international level, India must advocate for TRIPS reforms that recognize health equity as a fundamental global concern. [170] the COVID-19 pandemic exposed the shortcomings of voluntary licensing models and rekindled debate on IP barriers in public health emergencies. Without structural changes in both domestic infrastructure and international IP law, compulsory licensing may remain a legally potent but politically restrained instrument.

9. RECOMMENDATIONS

To ensure that compulsory licensing (CL) fulfils its potential as a mechanism for safeguarding public health without eroding

incentives for innovation, India must undertake targeted legal, administrative, industrial, and diplomatic reforms. These reforms are especially urgent in the post-COVID-19 era, where global inequities in access to life-saving medicines have laid bare the limitations of voluntary licensing regimes and the urgent need for stronger public health safeguards.

A key recommendation is to streamline the procedural aspects of Section 84 of the Patents Act, 1970, which governs compulsory licensing in India. [171] the existing three-year waiting period after patent grant, coupled with a heavy evidentiary burden and lengthy hearings, creates unnecessary obstacles in time-sensitive health scenarios. [172] India should introduce procedural amendments including:

- Fixed statutory timelines for adjudication of CL applications.
- Simplified documentation requirements for drugs classified as essential or emergency-related by the National List of Essential Medicines (NLEM) or World Health Organization (WHO).
- Fast-track provisions during public health emergencies were delays risk widespread morbidity or mortality. [173]

Although Section 92 provides for expedited compulsory licensing in national emergencies or cases of extreme urgency, its implementation has been tepid. [174] The government must proactively issue notifications during such crises and develop pre-defined emergency protocols that automatically trigger the use of Section 92, thereby ensuring rapid access to critical treatments without bureaucratic delay.

Simultaneously, there is an urgent need to revive and modernize India's public pharmaceutical manufacturing infrastructure. State-run entities such as Hindustan Antibiotics Ltd. (HAL) and Indian Drugs and Pharmaceuticals Ltd. (IDPL) were once the bedrock of India's medicine sovereignty but have since become dormant due to chronic underfunding. [175] Revitalizing these institutions through public investment, technology transfer partnerships, and public-private collaborations would help establish the manufacturing backbone necessary to implement CLs effectively. [176]

The mere issuance of a compulsory license, especially for biologics or mRNA-based therapies, is meaningless unless manufacturers have the technical and infrastructural capacity to produce quality generics at scale. [177] in this context, India must offer incentives for R&D in the public sector, develop process expertise, and build

institutional capacity to translate licenses into affordable and safe treatments. [178]

India must also navigate its international obligations under TRIPS and bilateral or regional trade agreements with caution. While TRIPS Article 31 provides flexibilities for public health, TRIPS-plus provisions in Free Trade Agreements (FTAs) often limit these rights.[179] Therefore, any invocation of compulsory licensing must be legally robust, procedurally transparent, and backed by strong public interest documentation.[180] Such an approach helps preserve India's credibility as a responsible WTO member, shields it from retaliatory action, and reinforces the legitimacy of its health-based interventions in the global IP regime.[181]

India should also intensify diplomatic engagement with patent-holding nations and pharmaceutical MNCs to depoliticize the use of compulsory licensing. CLs must be presented not as acts of protectionism, but as lawful and TRIPS-compliant tools to safeguard human lives under extraordinary circumstances. [182] the country must build coalitions with other developing nations and global civil society to jointly advocate for health-oriented interpretations of IP law.

Long-term success depends on India's active leadership in pushing for TRIPS reform at the WTO, particularly in the wake of its joint 2020 proposal with South Africa for a temporary IP waiver during the COVID-19 pandemic. [183] Though the final agreement in 2022 was narrow and delayed, it signalled a growing consensus for reform of international IP law to serve health equity. [184] India must now work toward:

- Expanding the Doha Declaration to include automatic CL triggers for WHO-declared health emergencies.
- Advocating for mandatory technology transfer mechanisms and access to trade secrets, biologics data, and know-how during crises.
- Supporting the creation of an international pandemic preparedness IP framework with enforceable obligations.

India's existing legal architecture for compulsory licensing is commendably TRIPS-compliant and pro-public health, but its practical effectiveness remains undercut by procedural delays, manufacturing limitations, and global trade pressures. By simplifying legal processes, rebuilding domestic manufacturing, asserting sovereign rights within WTO norms, and leading global efforts for structural IP reform, India can revitalize compulsory licensing as a dynamic and equitable tool of public health governance. In doing so, it can fulfil its constitutional mandate to

protect health and emerge as a global leader in ensuring universal access to essential.

10. CONCLUSION

The relationship between intellectual property (IP) rights and public health has become increasingly significant in today's legal and ethical discourse, particularly in the context of developing nations like India. The debate is not about rejecting the value of patents but rather about ensuring that patent laws serve both innovation and public welfare. In a country with vast socio-economic disparities, the patent system must be calibrated to prevent monopolistic exploitation, especially when it concerns life-saving medicines and critical healthcare technologies. The very purpose of a balanced patent regime is to encourage innovation while simultaneously ensuring that such innovation benefits society at large. India's Patents Act, 1970, particularly Sections 84 and 92, embodies this balance by embedding legal tools such as compulsory licensing (CL) that can be invoked when exclusivity leads to unaffordability, limited access, or insufficient supply of essential medicines.

India's legal framework is commendable for its explicit incorporation of public health safeguards, and its alignment with the TRIPS Agreement reflects the country's commitment to international obligations while preserving national interest. The landmark ruling in *Natco Pharma Ltd. v. Bayer Corporation* (2012) stands as a testimony to the ability of the Indian legal system to prioritize the needs of patients over the profit motives of multinational pharmaceutical companies. The decision not only ensured access to an essential cancer medication at an affordable price but also reaffirmed the legitimacy of compulsory licensing as a constitutional and ethical tool. It demonstrated the successful operationalization of Section 84, wherein a domestic manufacturer could intervene when the patent holder failed to meet the reasonable needs of the public. The case offered a glimpse of what is possible when public interest is placed at the center of patent law enforcement.

However, the experience of the COVID-19 pandemic revealed a sharp disconnect between legislative intent and governmental action. Despite the severe public health crisis marked by shortages of essential drugs, ventilators, oxygen, and vaccines, India refrained from formally invoking its compulsory licensing powers under Section 92. Instead, the government relied heavily on voluntary licensing arrangements and diplomatic negotiations with pharmaceutical giants. While these strategies yielded results in some cases, they also exposed structural limitations, including

delays, inadequate coverage, and dependence on the goodwill of private companies. The reluctance to use the robust legal tools at its disposal during one of the gravest global health emergencies in recent memory raises serious questions about administrative will, geopolitical pressures, and the prioritization of economic diplomacy over urgent healthcare needs.

This hesitation underscores the broader challenge of translating legal possibilities into administrative action. Legal provisions are only as effective as their implementation. While India's compulsory licensing framework is among the most progressive in the world, its underutilization during crises like COVID-19 reflects a need for stronger institutional readiness, political commitment, and public health foresight. The government must ensure that mechanisms such as Sections 84 and 92 are not viewed merely as symbolic or theoretical safeguards but are actively used when public interest is at stake. There must be clarity in procedure, readiness in institutional response, and courage in policy decisions that prioritize the well-being of citizens above corporate concerns.

From a global perspective, it is increasingly recognized that intellectual property must be interpreted through a human rights lens, especially in the domain of health. The right to health is enshrined in numerous international conventions and national constitutions, including India's. When patent monopolies restrict access to essential medicines, they not only violate ethical norms but also risk breaching fundamental human rights. Therefore, a reimagining of global IP frameworks—especially in emergency contexts—is essential. The TRIPS Agreement, despite its flexibilities, often falls short in enabling countries to act quickly and decisively. The partial success of the TRIPS waiver initiative during the COVID-19 crisis only reinforced the need for deeper, structural reforms at the World Trade Organization (WTO) level. India has a unique opportunity—and arguably a responsibility—to take the lead in these reforms, advocating for a more inclusive and equitable global IP regime that prioritizes public health over profit.

India stands at a crucial juncture. With its vast pharmaceutical manufacturing capacity, democratic legal system, and commitment to equitable healthcare, it has both the moral authority and practical capability to shape global discourse on the balance between patents and public health. Moving forward, it must ensure that the spirit of the Patents Act—particularly its provisions on compulsory licensing—is not diluted by inaction or external pressures. Instead, these tools must be institutionalized as part of a broader public health strategy that treats access to

medicine not as a privilege, but as a right. Only then can India uphold the constitutional promise of justice—social, economic, and political—and truly serve as a model for other nations grappling with similar challenges in the 21st century.

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