INNOVATION OR ACCESS? NAVIGATING PATENT RIGHTS AND PUBLIC HEALTH IN INDIA

Authored by Kunwar Shashank, LL.M. (IP LAWS)

ABSTRACT

This paper explores the critical tension between patent rights and the right to health in India, particularly in the context of pharmaceutical innovation and public access to essential medicines. It investigates how India's legal and constitutional frameworks attempt to reconcile intellectual property rights (IPR) with the human right to health, especially after the 2005 amendment to the Patents Act, which introduced product patents in line with the TRIPS Agreement. Through a doctrinal legal research methodology, the paper analyzes landmark case laws, statutory provisions, and international agreements to assess the impact of patent regimes on access to healthcare. It places a particular focus on the role and challenges of compulsory licensing as a mechanism to bridge the gap between innovation and accessibility. Key findings reveal that while India possesses a robust legal foundation to support compulsory licensing, practical application remains limited due to international pressures and domestic constraints. The research underscores the need for a nuanced approach that balances innovation incentives with public health imperatives, highlighting the strategic use of TRIPS flexibilities, judicial precedents favoring the right to health, and policy initiatives aimed at universal healthcare. The study concludes that while India's legal structure is equipped to uphold the right to health, stronger implementation and international cooperation are essential for achieving equitable access to medicines.

Keywords: patent law, compulsory licensing, right to health, TRIPS, Article 21, intellectual property rights, generic medicines, public health, pharmaceutical patents, Indian Constitution

INTRODUCTION

The Patents Act of 1970 was introduced in India with the primary aim of unifying and streamlining the nation's patent legislation, while also safeguarding inventors' interests. A key feature of the Act is its emphasis on securing patent holders' rights throughout the registration procedures conducted by the patent office. It governs both process[1] patents (methods of production) and product[2] patents (final inventions), extending legal protections to businesses and individuals, including pharmaceutical firms and manufacturers, whose innovations fall under its purview. Over the years, the Act has undergone revisions, with the most significant being the 2005 amendment, which formally recognized product patents. This pivotal change aligned India with global intellectual property standards but also ignited widespread discussions on balancing patent protections with public health concerns. Critics argued that stricter patent rules could limit access to affordable medications, framing the amendment as a clash between corporate innovation incentives and the fundamental right to healthcare accessibility.

Before 2005, India was the largest supplier of 'affordable generic medicines' with 'approximately 60,000 generic brands and 60 therapeutic categories'[3]. But the number of generics produced was reduced after 2005, when product patents were introduced following a trade agreement between India and the US, driving concerns over trade sanctions on generic producers and limited technology transfers. This decline can be partly attributed to the fact that patent holders maintain control over various components of their patents, which can make it challenging to produce generics after product patents have expired. Moreover, the increasing focus on profit-driven drug manufacturing has impeded the generics business.

In turn, this sparked a complicated clash of demands between human rights and intellectual property rights (IPR). Global health is concerned with collective and individual well-being, particularly in relation to access to healthcare, whereas IPR is concerned with individual rights. While the right to health is article 25 of the 1948 United Nations Declaration of Human Rights, not much research has been conducted on the interaction of this right and the knowledge

[1] A product patent is a form of patent protection granted for a specific, tangible invention the product itself rather than the process by which it is made. It gives the patent owner the exclusive right to prevent others from exploiting that product without permission

[2] A product patent in India is a statutory right granted under the Patents Act, 1970, over a specific tangible product such as a chemical compound, pharmaceutical molecule, or mechanical device rather than over the method by which it is made. Once granted, the patent confers on the patentee the exclusive right to prevent others from exploiting that product without permission

[3] Khanna S, TRIPS, pharmaceutical patents and health care for the poor in India, ILI Law Review, (2016) 74-75

obtained through intellectual property laws. In India, where a large part of the population stays below the poverty line, essential medicines like the ones for cancer, tuberculosis, and HIV/AIDS are inaccessible to the majority of the population. A 2016 report[4] published by the Indian Medical Association revealed that there is an increasing number of 14 lakh suffering from cancer each year in India. This rising public health issue emphasizes the defining need for further investigation and action, to navigate the restive conflict between patent safeguards and health rights.

Despite a strong legal framework recognizing both patent rights and the right to health, India continues to face challenges in ensuring equitable access to medicines. Problems with affordability, healthcare infrastructure, and legal enforcement hinder the realization of health rights. Given these complexities, this paper aims to address the following research question: How can India strike an effective balance between protecting patent rights and ensuring the right to health, particularly through the use of mechanisms like compulsory licensing within the existing legal and international framework?

Intellectual Property Rights and Human Rights

Intellectual property rights (IPR) were established in order to protect interests of creators by ensuring that their innovations are not only recognized but also provide them with financial rewards. These rights are often seen as "negative rights" since they restrict others from using or replicating the protected work without permission. In contrast, human rights are inherent and natural rights that every individual is entitled to from birth. They are fundamental, inalienable, and essential for the well-being and dignity of every person. India defines 'human rights' under **Section 2(d)** of "the *Protection of Human Rights Act, 1993*, as right relating to life, liberty, equality, and dignity of an individual recognized by the constitution and international covenants and enforceable into the court of law[5]".

The Indian judiciary has explicitly prioritized the right to health as a fundamental right under Article 21 of the Constitution. In *State of Punjab v. Mohinder Singh Chawla*[6] (1997), the Supreme Court held that the right to health is integral to the right to life, imposing positive obligations on the state to provide medical facilities.

[4] Indian Council of Medical Research, Department of Health Research – Ministry Health & Family Welfare Government of India, Media Report (2 November to 16 November)
[5] Section 2 (d) of the Protection of Human Rights Act, 1993.
[6] 1997 (2) SCC 83

A landmark application of this principle in the IPR context was *Hoffmann-La Roche Ltd. v. Cipla Ltd.*[7], where the Delhi High Court declined to grant an injunction to Roche against Cipla's generic version of the cancer drug Erlotinib. The Court explicitly cited the public interest and right to health under Article 21, underscoring that human rights considerations can override patent enforcement, particularly where lifesaving drugs are concerned.

Furthermore, in *Bayer Corporation v. Union of India*[8], the Intellectual Property Appellate Board upheld the grant of a compulsory license to Natco Pharma for the drug Nexavar. The decision cited the failure of the patent holder to make the drug available at an affordable price, aligning with Section 84 of the Patents Act and TRIPS Article 31. Here, India operationalized its positive obligation under international human rights law by using a TRIPS-sanctioned mechanism to promote access to health.

Despite the efforts made by the Indian Government to minimize the medicine accessibility issue through the implementation of Drug Price Control Order, 2013 and the setting up the National Pharmaceutical Pricing Authority (NPPA) to fix the prices of drugs in India[9]. In the past two decades, costs of necessary medicines have risen since the patent owners try to recover as much of their costs as possible. For example, one month's worth of the Atripla, anti- HIV drug, costs around $1300, a price that is too high for the inhabitants in the developing nations, where access to the life saving medications is still a dream leading to numerous preventable fatalities. The *"World Health Organization*" and the *"World Bank"* in their joint report for the year 2017 have revealed that, more than half of the world's population cannot afford essential medicines and or health care services.

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Right to Health and Patent Right in India

The rights to health and the patent regime have grown immensely in India, now holding legal importance under the Constitution and other legislative frameworks. Under the Constitution of India, an individual has the right to achieve a standard of physical and mental well-being that is as high as possible. In "*State of Punjab v. Mohinder Singh Chawla (1997)*[10]", the apex court reiterated that the right to health is an indispensable part of the right to life and that it mandates the state to provide essential medical facilities.

[7] 148(2008)DLT598,
[8] Writ Petition No.1323 of 2013
[9] ttps://www.thehindu.com/opinion/op-ed/paying-the-price/ article4912732.ece (accessed on 10 October 2020).
[10] AIR 1997 SUPREME COURT 1225

The most notable case wherein the right to health was given precedence over patent protection is that of "*Hoffmann-La Roche Ltd. v. Cipla Ltd.*[11]", wherein the Delhi High Court rejected Roche's application for an injunction against Cipla that had manufactured a generic version of a patented drug. This was so despite the court having adopted this approach based on the right-to-health perspective while relying on Article 21 of the Constitution of India, which guards the right to life and forms a basis for a right to health. In terms of balancing public interest against corporate interests, it acknowledged the fact that such medicines needed to be available at reasonable prices for consumers.

Several factors contribute to the lack of access to medicines, including poverty, inadequate healthcare infrastructure, and the high cost of medicines. One significant barrier is the patent protection granted to pharmaceutical companies, which restricts the production of affordable generic drugs. However, mechanisms such as compulsory licenses and voluntary licenses under patent laws offer potential solutions by allowing the production of generics[i]. Without such interventions, pharmaceutical companies retain exclusive rights over patented drugs, making it difficult for the underprivileged to afford newly developed treatments due to their high costs.

Thought for a couple of seconds

Pharmaceutical companies driven largely by profit strongly oppose compulsory licensing, arguing that it would undermine innovation and deter investment in R&D. Yet compulsory licensing exists precisely to curb the abuse of patent rights. Under Sections 84–92 of the Patents Act, 1970, the government may authorize third parties to manufacture and market a patented product without the patent holder's consent, once specified conditions are met. In this way, the provision safeguards public health by ensuring that essential medicines remain affordable when the need arises.

To grant a compulsory license, certain criteria under **Section 84** must be fulfilled:

a) "*The reasonable requirements of the public with respect to the patented invention are not being met*.

b) *The patented invention is not available to the public at an affordable price.*

[11] 48 (2008) DLT 598.

c) *The patented invention is not being worked or utilized within Indian territory."*

Section 84: A Legal Promise with Limited Delivery

Section 84 of the Indian Patents Act, 1970, provides a mechanism called **compulsory licensing**, which allows third parties to produce a patented product without the permission of the patent holder. This can be done after three years from the grant of a patent, but only if certain conditions are met. These include whether the invention meets the public's needs, whether it's available at an affordable price, and whether it is being properly used within the Indian territory. On paper, this seems like a powerful tool to ensure access to essential medicines. But in practice, it has proven far less effective than intended.

The "Reasonable Requirements" Dilemma

One of the key grounds for granting a compulsory license is that the public's reasonable requirements for a patented invention are not being met. While this sounds straightforward, the law doesn't clearly define what counts as "reasonable." This ambiguity gives a lot of room for interpretation, and courts or patent offices often hesitate to take bold decisions when the term is so vague. Moreover, the burden of proving that these requirements aren't being met rests on the applicant—usually a smaller generic drug manufacturer. Proving this involves gathering data, legal arguments, and often fighting against large multinational corporations with significantly more resources. As a result, the clause rarely benefits those it was meant to protect.

The Affordability Illusion

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Another condition under Section 84 is that the patented drug should be available at an affordable price. Again, this is noble in theory. But what exactly is "affordable"? For a multinational company, a cancer drug priced at $1,000 a month may seem reasonable compared to what it costs in the U.S. But for the average Indian, this is entirely out of reach. The problem is that affordability is often judged from a commercial perspective rather than a human one. The courts are cautious in interpreting this clause too liberally, fearing it might send the wrong message to international investors and trading partners. The result is that even when drugs are clearly unaffordable to a large part of the population, they remain protected under the guise of innovation incentives.

The Question of "Working" the Patent in India

The third condition relates to whether the patented invention is being "worked" in India. This means it should ideally be produced or utilized within the country. The original intent behind this clause was to ensure local manufacturing, which would, in turn, improve access and reduce costs. However, over time, "working" has been interpreted to include simply importing the product into India. So, even if a company is only shipping in a few units of an expensive drug from abroad, it can still claim compliance. This interpretation dilutes the purpose of the clause and allows companies to maintain monopolies without investing in local production or knowledge transfer.

The Larger Problem with Section 84

While Section 84 is a powerful tool in theory, it has hardly been used. Since the introduction of product patents in 2005, only one compulsory license has ever been granted in India—to Natco Pharma for the cancer drug Nexavar. Other applications, such as those by BDR Pharma and Lee Pharma, were rejected. These rejections sent a clear message that the bar for compulsory licenses is set very high. In practical terms, this discourages smaller companies from even trying. The process is expensive, time-consuming, and carries a high risk of failure.

Furthermore, India faces immense pressure from developed nations, particularly the United States, not to use compulsory licensing too liberally. When the Nexavar license was granted, the U.S. placed India on its "Special 301" watchlist, accusing it of violating trade agreements. These kinds of international pressures make the government and judiciary more cautious, even when public health emergencies should demand bold action.

The fear of offending international trade partners, combined with lobbying from powerful pharmaceutical companies, creates an environment where the spirit of Section 84 is often ignored. This leaves millions of people without access to life-saving medicines, despite the legal tools existing to help them.

The Human Cost

The biggest casualty of this inaction is the right to health. Despite being recognized under Article 21 of the Indian Constitution as a fundamental right, access to affordable medicine remains a challenge for millions of Indians. The disconnect between legal potential and real-world outcomes highlights a system that, while legally sound, is practically flawed.

Until the law is made more accessible, interpretations more public-focused, and implementation more transparent, Section 84 will continue to be more symbolic than functional. The right to health, though constitutionally enshrined, will remain elusive for those who cannot afford to buy their life back one patented pill at a time.

Compulsory licenses are given by the "*TRIPS Agreement under Article 31*", which puts some flexibility when emergencies arise. The decision of the **2001 Doha Declaration** can arguably be regarded as pivotal in public health policy that allows developing countries to have the right to issue compulsory licenses for the protection of health of their people from pharmaceutical monopolies. The "*paragraphs 5(b) and 6 of the Doha Declaration*" point out that countries can issue compulsory licenses to deal with health emergencies through access to such medicines that are patented because it violates patent protection during those health emergencies.

The Patents Act of 1970, which grants 20 years of protection to inventions, aims to incentivize innovation while addressing public welfare. Despite this, developing nations frequently avoid invoking compulsory licensing provisions—even when legally permitted—due to fears of trade-related retaliation or diplomatic pressure from wealthier countries. In India, Section 84 of the Act acts as a critical safeguard: after three years of patent issuance, the government can authorize third parties to produce or distribute patented products (e.g., life-saving drugs) without the rights holder's consent, provided certain criteria—such as unaffordable pricing or inadequate public access—are met. This mechanism seeks to prevent monopolistic abuse while ensuring access to essential goods, particularly medicines, thereby reconciling intellectual property rights with societal health needs.

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India's constitutional framework reinforces this balance. The right to health, integral to the right to life under Article 21 of the Constitution, is bolstered by Article 39 (Directive Principles of State Policy), which mandates equitable resource distribution for public welfare, and Article 47, which explicitly obligates the state to enhance public health, nutrition, and access to healthcare. These provisions collectively prioritize citizens' well-being over corporate monopolies, framing healthcare as both a legal and moral imperative.

To operationalize these commitments, India has rolled out initiatives like the National Health Mission (NHM) and Ayushman Bharat, which focus on universal healthcare coverage, maternal health, and disease prevention. Programs such as AMRIT (Affordable Medicines and Reliable Implants for Treatment) and Mission Indradhanush aim to reduce costs and improve availability of critical treatments for diseases like TB, HIV/AIDS, and

cancer. PMSSY (Pradhan Mantri Swasthya Suraksha Yojana) expands healthcare infrastructure, while AB-PMJAY provides insurance coverage to economically vulnerable groups, aligning policy with constitutional obligations.

Initiative	Full Form / Year	Objective	Focus Areas
NHM	**National Health Mission** (Launched in 2005)	Strengthen public health systems, especially in rural and underserved areas	Maternal and child health, immunization, communicable disease control
AB-PMJAY	**Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana** (2018)	Provide health insurance coverage to economically vulnerable families	Free secondary and tertiary care for up to ₹5 lakh per family per year
PMSSY	**Pradhan Mantri Swasthya Suraksha Yojana**	Reduce regional imbalances in tertiary healthcare	Establishment of AIIMS-like institutions and upgrading existing medical colleges
AMRIT	**Affordable Medicines and Reliable Implants for Treatment**	Provide essential drugs and surgical implants at affordable prices	Discounted cancer, cardiovascular, diabetes medicines and implants through AMRIT retail outlets
MISSION INDRADHANUSH	Launched in 2014	Improve immunization coverage in India	Focused on children and pregnant women in high-risk areas, providing vaccines against 12 preventable diseases

Internationally, India's stance is guided by treaties like the Universal Declaration of Human Rights (1948) and the International Covenant on Economic, Social, and Cultural Rights (1966), which recognize health as a fundamental human right. These agreements obligate signatory

states to prioritize public health over patent protections, particularly in crises. India's use of flexibilities like compulsory licensing though cautious reflects its effort to harmonize global IP norms with domestic health imperatives, ensuring that patent regimes do not undermine access to lifesaving treatments for marginalized populations.

Role of Nations in Patents and its Impact on Right to Health in India

There is no definition to a developed country and a developing country, but the World Trade Organization (WTO) categorizes them on specific criteria. Developed countries hold a strong position in patents and right to health issues. Access to essential medicines is the most basic and fundamental part of the right to health, known internationally in many instruments, as recognized by the United Nations[12].

Developed countries tend to align with pharmaceutical corporations, demanding stronger patent protections and arguing that the use of compulsory licenses will discourage investment in Research and Development (R&D). However, there is no concrete evidence that Compulsory licenses negatively impact pharmaceutical Research and development. In fact, developed countries, including the US, have demonstrated hypocrisy by invoking compulsory licenses or threatening to do so during times of national need, revealing a selective application of their intellectual property policies.

This "selective application" of patent flexibility mechanisms, such as compulsory licensing, is a striking example of double standards in global health governance. Developed countries, while pressuring developing nations to strictly adhere to patent rules, have themselves used or threatened to use CL provisions when it suits their national interests.

One well-documented case of this occurred in the United States in 2001, in the aftermath of the anthrax attacks. At that time, the U.S. government was faced with a sudden demand for Ciprofloxacin, an antibiotic used to treat anthrax exposure. The patent for Ciprofloxacin was held by the German pharmaceutical company Bayer AG, which had exclusive rights to manufacture and sell the drug in the U.S. However, the federal government expressed concern over Bayer's ability to supply the required quantity quickly and at a reasonable price.

[12] https://www.who.int/medicines/areas/human_rights/en/

In response, the U.S. government threatened to override Bayer's patent by issuing a compulsory license to generic drug manufacturers if the company did not drastically reduce its prices. Faced with this pressure, Bayer ultimately agreed to supply the drug at a significantly reduced cost, thus avoiding the formal issuance of a compulsory license. The message was clear: even the strongest proponents of patent protection are willing to bypass IP rights when public health is at risk.

This incident highlights the hypocrisy in the way compulsory licensing is viewed globally. When developing nations like India or Thailand attempt to use CL to improve access to affordable medicines for diseases like cancer or HIV/AIDS, they are often criticized and even penalized by developed countries and multinational corporations. For instance, India was placed on the U.S. Trade Representative's Special 301 Watch List after it granted a compulsory license for the cancer drug Nexavar in 2012. The same governments that defend public health exceptions domestically turn to diplomatic and trade tools to discourage other nations from exercising the same rights.

The case of Ciprofloxacin in the U.S. reveals a fundamental contradiction in global IP enforcement. It shows that even the most patent-conscious nations recognize the importance of public health over intellectual property—but only when it directly affects their own citizens. This selective enforcement of compulsory licensing provisions undermines the credibility of international patent norms and highlights the unequal power dynamics that developing nations must navigate when attempting to safeguard the right to health.

For India and other developing countries, this calls for a more assertive use of the legal tools already available to them under the TRIPS Agreement and domestic law. It also points to the need for international cooperation that is equitable and consistent, rather than one that serves the interests of a few powerful stakeholders.

The South African, Thai, and Indian experiences illustrate the myriad of problems other developing and least-developed nations face in employing TRIPS flexibilities to make life-saving medicines available at below-tariff prices. Notable among these is the three compulsory licenses issued by the government of Thailand of life-saving medicines: Plavix for heart disease treatment and Kaletra (Abbott) and Efavirenz (Merck) as AIDS treatments[13]. The government of Thailand said that these licenses were necessary for public benefits and would be a precedent

[13] Palmedo M, Analysis of Special 301 Listings 2009- 2020 [Scholarly project], https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf

for other countries as well to use compulsory licenses to benefit the society. But in doing so, this move led to significant diplomatic tensions and criticism from developed nations.

Issues with Compulsory Licensing in India

Two major concerns arise from India's experience with compulsory licensing. The **first issue** is the limited number of compulsory license applications, which restricts the production of generic medicines and negatively impacts public health. The **second issue** involves the influence of large pharmaceutical companies and developed nations, which pressure governments to strengthen patent protections and limit the use of compulsory licenses. This tension is inherently a matter of human rights, as the inability to access patented medicines directly violates the right to health.

While India recognizes the right to health as a fundamental right under **Article 21** of the Constitution, many people still struggle to access basic medicines, resulting in violations of their fundamental rights. TRIPS provisions under "**Article 31"** and "**Section 84"** of the Patents Act, 1970 provide a legal framework for issuing compulsory licenses. However, Article 31 offers broad discretion to state parties, creating inconsistencies in the application of compulsory licensing policies. Although the 2001 WTO Conference on Public Health and TRIPS acknowledged the importance of compulsory licensing during public health emergencies, it also placed restrictions on its use.

In contrast, Section 84 of India's Patents Act is more specific, yet only *one compulsory license has been granted so far*. The first and only successful compulsory license was awarded to NATCO Pharma to produce the cancer drug **Nexavar** in the "*Bayer Corporation v. Union of India*[14]*"* case. Two other applications for *BDR Pharma (2013)* and *LEE Pharma (2015)* were denied, further limiting the availability of affordable generic medicines. BDR Pharma's 2013 application for a compulsory license to produce Dasatinib was rejected primarily due to procedural and evidentiary shortcomings. The Controller General of Patents dismissed the application at a preliminary stage, citing that BDR had not made a genuine or serious effort to obtain a voluntary license from the patent holder, Bristol-Myers Squibb. This is a mandatory prerequisite under Section 84(6)(iv) of the Indian Patents Act. The company's approach was deemed too casual and insufficiently documented. Additionally, BDR failed to provide convincing evidence that the drug was either unaffordable or inadequately available to the

[14] W.P. No. 1323/2013

public. The data they submitted lacked the necessary rigor to establish unmet demand or market access issues, making it impossible for the Controller to conclude that public requirements were not being satisfied.

In the case of Lee Pharma's 2015 application for a compulsory license to manufacture Saxagliptin, the rejection was based on a weak prima facie case combined with insufficient evidence. The company argued that the drug was not available at a reasonably affordable price and that the public's requirements were not being met. However, the Controller found no substantial data to support these claims. The evidence provided was vague and failed to establish the extent of market demand, the pricing issues, or the inadequacy of supply. Moreover, Lee Pharma, like BDR, did not make a meaningful effort to secure a voluntary license from AstraZeneca before applying for a compulsory license, which further weakened its case. Thus, the denial stemmed from both a lack of substantive justification and an evidentiary failure to meet the burden of proof required under Section 84.

In both instances, the rejections underscore the Indian Patent Office's emphasis on procedural rigor and detailed evidentiary support when considering applications for compulsory licenses.

Challenges with Compulsory Licensing in Developing Countries

Compulsory licensing serves as a critical tool for developing nations, allowing domestic firms to utilize foreign-patented innovations without the rights holder's authorization and enabling third parties to research patented products. However, this mechanism faces significant hurdles. Multinational pharmaceutical corporations often exert political and economic influence, pressuring developing countries—via alliances with developed governments—to prioritize stringent patent protections over public health imperatives.

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At the domestic level, many developing nations grapple with systemic challenges, such as inadequate manufacturing capabilities and insufficient administrative frameworks to navigate the complex procedural requirements for issuing compulsory licenses. These limitations often force governments to sideline public health needs in favor of maintaining intellectual property (IP) protections, despite legal provisions aimed at balancing these interests.

India's experience underscores these complexities. While Section 84 of the Patents Act permits compulsory licensing after three years, only three applications have been filed since 2005, with

just one granted to NATCO Pharma for the cancer drug Nexavar[15] in 2012. The rejection of compulsory licensing applications in India has created a chilling effect that discourages others from even trying. After the first and only successful compulsory license was granted to NATCO Pharma in 2012 for the cancer drug Nexavar, the two applications that followed—one by BDR Pharma and another by Lee Pharma—were both denied. This sent a clear message: getting a compulsory license approved in India is not only difficult but highly unlikely. That message alone has been enough to make many generic drug manufacturers think twice before applying.

One of the biggest reasons for this chilling effect is how complicated and vague the process is. The law requires applicants to prove that a drug isn't affordable, isn't being made available to enough people, or isn't being produced in India. But what counts as "affordable" or "reasonable access"? The law doesn't really say. So decisions are often left to the interpretation of officials and judges, who tend to be very cautious—probably because they don't want to upset powerful pharmaceutical companies or foreign governments.

It's also extremely expensive and time-consuming to apply for a compulsory license. A small generic drug company has to gather mountains of data, hire legal experts, and go through a slow bureaucratic process, all while facing the possibility that their application will be rejected in the end. For many of these companies, it's simply not worth the effort, especially when there's only one success story to look at and a couple of very public failures.

On top of all this, there's a very real fear of international backlash. After India granted the license to NATCO, the United States put the country on a trade watchlist and accused it of violating global trade rules. That kind of pressure makes Indian regulators and courts more hesitant to grant licenses in the future, even when they might be justified. Smaller companies know this and don't want to risk getting caught in the crossfire between governments and big pharma.

All of this has made the law feel more like an empty promise than a real solution. In theory, Section 84 of the Patents Act is supposed to help people get access to essential medicines when the patent system fails them. But in practice, it's barely being used. And when the system looks broken, companies stop trying to use it—no matter how badly affordable medicine is needed.

[15] Press Information Bureau, Government of India, Ministry of Commerce and Industry, Clarification on Media Reports regarding Compulsory license, http://pib.nic.in/newsite/ Print Release

To change this, the process needs to be clearer, more transparent, and more supportive of the people it's supposed to help. Otherwise, the fear of rejection and retaliation will continue to keep companies from stepping forward, and millions of people will stay stuck on the wrong side of the patent wall, unable to afford the medicines they need to survive.

The global dynamics of this issue are further illustrated by the backlash India faced after granting the Nexavar license. The U.S. government, through its **Special 301 Report** (a unilateral trade tool under the U.S. Trade Act of 1974), accused India of violating World Trade Organization (WTO) and TRIPS Agreement norms. Similar criticisms have targeted countries like Brazil and Thailand for invoking compulsory licensing during public health crises, such as for HIV/AIDS medications. The report, frequently updated to reflect U.S. corporate interests, functions as a coercive instrument to deter nations from utilizing TRIPS flexibilities measures explicitly permitted under international law to address health emergencies.

The imbalance of power inherent in global intellectual property (IP) regimes underscores the tension between enforcing patent protections and safeguarding public health. While the TRIPS Agreement permits compulsory licensing to improve access to essential medicines, developed nations and pharmaceutical corporations frequently leverage trade policies and legal threats to stifle such measures. The Paragraph 6 Mechanism, a critical but underappreciated provision under TRIPS, was designed to address this gap by enabling countries with generic manufacturing capabilities to export medicines to nations lacking domestic production capacity. However, this mechanism has been hamstrung by bureaucratic hurdles, stringent eligibility criteria, and political resistance from industry actors, limiting its practical impact. The case of India—a major producer of affordable generics—exemplifies how corporate-driven IP frameworks continue to sideline ethical imperatives, even as developing nations face pressure to curtail their use of TRIPS flexibilities. This dynamic reveals a stark disconnect between the theoretical utility of global health safeguards and their real-world application, disproportionately affecting marginalized populations. Strengthening transnational solidarity, streamlining the Paragraph 6 process, and bolstering domestic manufacturing capacities in the Global South are urgent steps to realign profit-driven IP systems with the fundamental right to health, ensuring innovation incentives do not eclipse humanitarian priorities.

Conclusion

The human rights approach to patents and public health was prominently addressed in the "*Doha Declaration on TRIPS and Public Health (2001)"*. The declaration emphasized the importance of balancing IPR with public health needs, including the use of compulsory licenses to ensure access to essential medicines. The implementation of "Article 31 of the TRIPS Agreement and Section 84 of India's Patents Act" depends largely on the national policy decisions that determine the grounds for issuing compulsory licenses.

While the *"right to access essential medicines is recognized as a human right under international conventions*", there remains a disconnect between the political will of developed countries and their actions regarding compulsory licensing. This contradiction is evident from the US's reaction to India's grant of a compulsory license to NATCO Pharma in the Bayer Nexavar case. The backlash from the US following India's issuance of the license highlights how developed nations prioritize the interests of pharmaceutical giants over public health.

A significant example of the influence of political will is the *suo-motu* action by the National Human Rights Commission (NHRC) in 2016 against the Government of India. In 2016, India's National Human Rights Commission (NHRC) initiated a suo-motu action questioning the government's reluctance to issue compulsory licenses for life-saving drugs, framing it as a human rights concern tied to healthcare access. The government, responding through the Commerce Ministry, defended its stance by citing adherence to WTO's TRIPS Agreement (treating CLs as a "last resort"), fear of disincentivizing pharmaceutical innovation, and reliance on alternative measures like drug price caps and voluntary licensing. Critics argued this reflected capitulation to pressure from multinational pharmaceutical firms and developed nations, which opposed CLs as threats to intellectual property, leading to India's cautious approach and a global chilling effect on CL applications. Despite the NHRC's scrutiny, no new CLs were granted post-2016, underscoring the dominance of geopolitical and corporate interests over public health imperatives, even as activists condemned the government for prioritizing trade over health equity under India's own legal and constitutional framework.

The economic interests of pharmaceutical companies are largely tied to patented drugs, leading to high prices that make these medicines inaccessible to many people. As a result, patent laws often act as barriers to medicine affordability, undermining the right to health. Both

international and national legal frameworks on compulsory licenses and public health rights are insufficient to effectively enforce public health priorities. Ultimately, the influence of developed countries, particularly the United States, plays a critical role in determining the use of compulsory licenses in developing nations, including India. This external pressure limits the ability of developing countries to issue compulsory licenses freely, impacting their efforts to provide affordable medicines and uphold the right to health.

India's legal framework permits the issuance of compulsory licenses under Section 84 of the Patents Act, 1970, and Article 31 of the TRIPS Agreement, enabling the production of affordable generic versions of patented medicines during public health emergencies. However, this critical safeguard remains severely underutilized due to systemic challenges: ambiguous statutory criteria (e.g., undefined "affordability" thresholds), cumbersome procedural requirements, and sustained resistance from multinational pharmaceutical corporations, often amplified by external diplomatic and trade pressures from developed nations. The 2012 grant of a CL for the cancer drug Nexavar, India's sole successful case demonstrates the mechanism's potential but also highlights its limitations. Subsequent rejections of applications, coupled with retaliatory measures such as inclusion on the U.S. Special 301 Watchlist, have created a regulatory chilling effect, discouraging further attempts. Consequently, millions face barriers to accessing essential medicines, while reliance on indirect measures like price controls under the National Pharmaceutical Pricing Authority (NPPA) fails to address systemic inequities.

To rectify this, India must prioritize regulatory clarity by defining key terms in the Patents Act, streamline application procedures to reduce bureaucratic delays, and fortify international advocacy to legitimize TRIPS flexibilities through alliances with like-minded nations. Simultaneously, enhancing domestic generic manufacturing capacity and insulating public health decisions from corporate lobbying are imperative. By aligning policy implementation with constitutional obligations (Article 21's right to health) and global human rights norms, India can transform compulsory licensing from a theoretical tool into an actionable solution, ensuring that intellectual property regimes do not preclude equitable access to lifesaving treatments.