DRUG PATENTS VS. PUBLIC HEALTH: HOW INDIA, THE UK, AND THE US BALANCE ACCESS TO MEDICINES

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ABSTRACT

Compulsory licensing in the pharmaceutical sector serves as a pivotal legal and ethical mechanism intended to balance public health needs and intellectual property rights. The price of essential medicines can be staggering especially in developing countries.[1] Millions struggle to afford necessary treatments, leading to dire health outcomes. Pharmaceutical patents are essential for incentivizing innovation, but they often restrict access to life saving medicines. The government can approve the manufacturing of generic versions of patented medications without the patent holder's approval through a legal mechanism known as compulsory licensing, which guarantees access to reasonably priced medications in times of public health emergencies. Compelled licenses may be granted under certain circumstances in accordance with Article 31 of the TRIPS Agreement.[2] The Doha Declaration of 2001 changed this by permitting member nations to grant mandatory licenses for the manufacture of pharmaceuticals meant for export to nations that can demonstrate they have limited or no capacity to manufacture pharmaceuticals. Between 2001 and 2021, there were 45 documented compulsory licensing episodes in the us and 17 comparator countries. Only a minority resulted in the actual issuance of a compulsory license, and even fewer led to a measurable price discount for pharmaceuticals. In high-income countries, compulsory licensing is rarely used as a direct response to high drug prices. In contrast, developing countries like India and Brazil have used compulsory licensing to improve access to essential medicines, sometimes achieving price reductions of over 50%. In this article, the legal systems in India, the UK, and the US that

[1] Amado, R., & Gewertz, N. M. (2004). Intellectual property and the pharmaceutical industry: A moral crossroads between health and property. *Journal of Business Ethics*, 55, 295-308.
[2] Bartelt, S. (2003). *Compulsory licences pursuant to TRIPS article 31 in the light of the Doha Declaration on the TRIPS Agreement and public health*. J. World Intell. Prop., 6, 283.

regulate pharmaceutical patents and compulsory licensing are compared.[3] Through case studies and a detailed table of drugs, their patent status, and compulsory licensing outcomes, the article highlights the disparities in these jurisdictions. It concludes with policy recommendations to address existing gaps and promote equitable access to medicines globally.

Keywords: Pharmaceutical patents, compulsory licensing, India, UK, US, TRIPS Agreement, Doha Declaration, Public Health.

I. INTRODUCTION

A controversial topic in the pharmaceutical sector has been the relationship between public health and intellectual property rights. Patents allow businesses to recover their R&D expenses by giving them the sole right to manufacture and market medications. This exclusivity, however, frequently results in high drug costs, which restricts access for patients in low- and middle-income nations. According to a 2022 study, between 2001 and 2021, only a minority of the 45 documented compulsory licensing episodes globally led to actual price reductions for pharmaceuticals, underscoring both the potential and the limits of this legal tool. Article 31 of the Trade Related Aspects of Intellectual Property (TRIPS) Agreement contains a clause stating that compulsory licensing may be granted subject to certain restrictions, such as failed attempts to secure voluntary licenses, national emergencies, or non-commercial use. This tension between innovation and access lies at the heart of the debate over pharmaceutical patents and compulsory licensing.

This was changed by the Doha Declaration of 2001, which permitted member nations to grant mandatory licenses for the manufacture of pharmaceuticals meant for export to nations that could demonstrate they lacked the capacity to manufacture drugs. While compulsory licensing is recognized as a legitimate toll under international law, its application varies significantly across countries. Some nations, like India, have embraced compulsory licensing to address public health challenges, while others, like UK and US, have been more cautious, prioritizing patent protection and market-based solutions.[4]

[3] Lin, Y., Yang, J., & Zhou, D. (2025). *A study on compulsory licensing of medicines from the perspective of international law. In Addressing Global Challenges-Exploring Socio-Cultural Dynamics and Sustainable Solutions in a Changing World* (pp. 111-118). Routledge.
[4] Thrasher, R. (2024). *Reigniting the Spirit of the Doha Declaration. Why a TRIPS Waiver Extension is Key to the Legitimacy of the World Trade Organization*. Boston, 2.

This article examines the legal frameworks governing pharmaceutical patents and compulsory licensing in India, the UK and the US. These three jurisdictions represent distinct approaches to balancing intellectual property rights with public health needs. India, with robust generic pharmaceutical industry and proactive stance on compulsory licensing, serves as a model for other developing countries. The UK, with its balanced approach to patent rights and public access, provides insight into the challenges of implementing compulsory licensing is developed economies. The US, with its strong patent protection system and limited use of compulsory licensing, highlights the tensions between innovation and access in a market-driven healthcare system.

Through a comparative analysis of case studies and a detailed table of frugs, their patent status, and compulsory licensing outcomes this article aims to identify the strengths and weakness of each system. It also explores the broader implications of compulsory licensing for global health equity and innovation. This article concludes how compulsory license affects the nations, depending upon its impact and application.

II. LEGAL FRAMEWORK

1. **INDIA:** India's patent system is based on the 1970 Patents Act, which was modified in 2005 to conform to the TRIPS Agreement. The Act's Sections 84, 92, 92A, and 94 are principally responsible for regulating compulsory licensing under the Indian Patent regime.[5]

A. Section 84: Under specific circumstances, this section allows any interested party to apply for a compulsory license three years after a patent is granted.

-The public's reasonable demands are not satisfied.

- The medication is not reasonably priced.

-The patent has not been used in India.

Applications are assessed by the Controller General of Patents according to criteria like the invention's nature, the applicant's capacity to use the invention for the public good, and the

[5] Shah, K. (2024). Vasudhaiva Kutumbakam & India’s Paradox: How Indian Pharma Both Enables And Undermines State Power (Doctoral dissertation).

amount of time that has passed since the patent was issued.[6]

B. Section 92: This clause empowers the Central Government to make a notification in the Official Gazette that a national, state of emergency, or a state of public non-commercial use exists, hence facilitating the granting of compulsory licenses by the Controller without awaiting the three-year timeline under Section 84.[7]

C. Section 92A: This topic addresses the export compulsory license for patented drug products. It provides that compulsory license can be issued only to the manufacture and export of the drug product to the poor country. Controller General can impose some conditions and terms as per need. Patented drugs comprise:[8]

1. Drugs
2. Materials required for their production
3. Diagnostic kits required

D. Section 94: A compulsory license may be terminated in accordance with this section. Anybody who has title or interest in the patent, including the patentee, may request termination if the conditions that gave rise to the compulsory license are no longer present and are not likely to occur again. The Controller is responsible for making sure that the license holder's interests are not unduly harmed in the process.

India has been a pioneer in using compulsory licensing to address public health concerns. The landmark case of *Bayer* v *Natco (2012)*[9]*,* where a compulsory license was garneted for the cancer drug Sorafenib, set a precedent for other developing countries. In this case Natco, and Indian generic manufacturer, argued that Bayer's drug was unaffordable for most patients, and the Indian patent Office agreed, granting the license under Section 84. This decision was a turning point in India's approach to

[6] Jha, R. (2024). Pharmaceutical patents: Cathartic or inhibiting. *The Journal of World Intellectual Property,* 27(3), 428-445.
[7] Jain, S. A. (2023). Critical Analysis of Article 31 (B) of Trade Related Intellectual Property Rights Agreement r/w Section 92 of Indian Patents Act 1970. Issue 1 *Indian JL & Legal Rsch*., 5, 1.
[8] Mathur, H. (2008). Compulsory licensing under Section 92A: Issues and concerns.
[9] 50 PTC 432 (IPAB)

balancing patent rights with public Health needs.

Another significant case is *Lee Pharma* v *AstraZeneca (2015)*[10], where Lee Pharma applied for a compulsory license for the diabetes drug Saxagliptin. Although the application was rejected, it highlighted the growing demand for affordable medicines in Inda. Similarly, in *Roche* v *Cipla (2012)*[11], the Delhi High Court upheld Roche's for the cancer drug Erlotinib but allowed Cipla to continue selling its generic version at a lower price, demonstrating India's commitment to ensuring access to medicines.

2. **UNITED KINGDOM:** The UK's patent system is governed by the Patents Act 1977, which includes provisions for compulsory licensing. The UK's legal provisions are encapsulated in the following sections:[12]

   a. Section 48 to 54: These sections outline the circumstances under which the compulsory licenses may be granted, including:

      i. Failure of the patent holder to meet demand for the patented product on reasonable terms.

      ii. Prevalence of anti-competitive practices by the patent holder.

   Applications for compulsory licenses can be made to the Controller of Patents, who assesses whether the grounds for issuance are satisfied.

b. Crown-Use Provisions (Sections 55 to 59): According to these clauses, the government may use patented inventions for public, non-commercial uses without the patent holder's permission. In these situations, the patent holder has a right to sufficient payment.

   In high-income countries, including the uk, compulsory licensing is rarely employed for pharmaceuticals. Of 21 petitions outside the us between 2001 and 2021, only three resulted in government threats to issue a compulsory license. However, the UK has rarely used this provision, relying instead on market competition and voluntary

[10] (C. L. A. No. 1 of 2015)
[11] 2015 SCC ONLINE DEL 13619
[12] Sola-Elesin, B. (2023*). A Critical Analysis of The Possible Implications of Ai on Patent Law in The Uk.*

licensing agreement. The UK's approach to patent rights was exemplified in the case of *The Warner-Lambert* v *Actavis (2018)*[13] case involving the drug Pregabalin, balancing patent rights with public access. Pfizer held a patent for a specific medical use of Pregabalin, but generic manufacturers sought to produce it for other approved uses. In this case, the UK courts ruled that the patent for Pregabalin's second medical use was partially invalid, allowing generic manufacturers to produce the drug.

3. **UNITED STATES:** In US, compulsory licensing in the pharmaceutical sector is addressed through specific legal provisions and has been shaped by notable case law. While the US does not have a general system for compulsory licensing, mechanisms such as 28 U.S.C. § 1498 and the Bayh-Dole Act provide pathways for government use of patented pharmaceuticals under certain conditions.[14]

    - **28 U.S.C. § 1498:** Title 28, Section 1498 of the United States Code allows the federal government to use or manufacture any patented invention without the patent holder's consent, provided that the patent hold receives "reasonable and entire compensation" for such use. This statute effectively acts as a compulsory license, enabling the government to ensure access to essential technologies, including pharmaceuticals, especially during emergencies.

    - A landmark case illustrating the application of § 1498 is *United States* v *Glaxo Group Ltd., 410 U.S. 52 (1973).* In this case, the U.S. government challenged Glaxo's restrictive licensing practices violations. The Supreme Court ruled that the government may contest the legality of a patent if it is directly linked to an antitrust violation. Additionally, the Court acknowledged that "mandatory patent licensing at reasonable charges and mandatory selling on specified terms are recognized antitrust remedies." This decision underscored the government's authority to intervene in patent rights to address antitrust concerns and ensure public access to essential medications.

    - **The Bayh-Dole Act's March-In Rights:** Universities, small businesses, and non-profit organizations are permitted to keep their patent rights for inventions

[13] [2018] UKSC 56
[14] Bell, J. A. (2021). *Patent Prophylaxis: Expanding Access to PrEP through 28 USC Se*c. 1498. Wm. & Mary L. Rev., 63, 2057.

that result from federally funded research thanks to the Bayh-Dole Act of 1980. The "march-in rights," a noteworthy clause in the Act, give federal agencies the power to license patented inventions to third parties without the patent holder's consent in certain circumstances, including:[15]

- Failure of the patent holder to achieve practical application of the invention.
- Failure to satisfy health or safety needs.
- Failure to meet public use requirements specified by the federal regulations.

III. COMPARISON WITH OTHER NATIONS

- **INDONESIA:** The Indonesian government has utilized compulsory licensing to address public health challenges, particularly concerning Hepatitis C medications. Despite these efforts, issues persist regarding the affordability and accessibility of these medicines, underscoring the complexities involved in implementing compulsory licenses effectively.[16]

- **BRAZIL:** Brazil has a history of leveraging compulsory licensing, especially in response to the HIV\AIDS crisis. The government negotiated with pharmaceutical companies to lower drug prices and, when necessary, issued compulsory licenses to produce generic versions of essential antiretroviral medications. This strategy significantly improved treatment accessibility and set a precedent for other nations.[17] For example, after Brazil threatened to issue a compulsory license for efavirenz, the price dropped by 59%.

- **SOUTH AFRICA:** Facing a severe HIV\AIDS epidemic, South Africa amended its patent laws to facilitate compulsory licensing and parallel imports of affordable generic

[15] Rights, M. I. (2022). Updating the Bayh-Dole Act March-in Rights and Transparency.
[16] Sahlan, S., Nurman, I., Uddin, A. K., & Kunu, A. B. D. (2024). Compulsory Licensing in Intellectual Property Rights (IPR): Current Application and Future Prospects in Indonesia. Fiat Justisia: *Jurnal Ilmu Hukum*, 18(2), 127-150.
[17] Le, V. A., & Le, V. A. (2022). *The Brazilian case study of compulsory licensing. Compulsory Patent Licensing and Access to Medicines: A Silver Bullet Approach to Public Health,* 113-143.

medicines. This move, while pivotal in expanding access to life-saving treatments.[18]

- **RUSSIA:** In response to geopolitical tensions and the withdraw of certain pharmaceutical products from its market, Russia has employed "compulsory licensing" to allow local firms to manufacture generic versions of medications without its diabetes drug Ozempic, Russian companies began producing generic versions to fill the market gap. While this move was deemed essential for public health, it raised concerns about undermining pharmaceutical innovation and intellectual property.

Below is a table representing a comparative analysis of drugs, their patents and whether the compulsory licensing was granted or not.

Drug Name	**Company\Industry**	**Country Of Patent**	**Compulsory License Granted?**	**Case Reference**
Sorafenib	Bayer	India	Yes	Bayer v. Natco: First compulsory license in India.
Erlotinib	Roche	India	No	Roche vs. Cipla: Patent upheld, but price reduced.
Saxagliptin	AstraZeneca	India	No	Lee Pharma vs. AstraZeneca: Application rejected.
Pregabalin	Pfizer	UK	No	Warner-Lambert vs. Actavis: Patent partially invalidated.
Ciprofloxacin	Bayer	US	Yes	Federal Government vs. Bayer: Anthrax scare.
Sofosbuvir	Gilead Sciences	India	No	Generic manufacturers allowed under voluntary licensing.
Trastuzumab	Roche	India	No	Biosimilar versions available at lower costs.
Imatinib	Novartis	India	No	Novartis vs. Union of India: Patent denied (Glivec case).

[18] Kianzad, B., & Wested, J. (2021). 'No-One Is Safe until Everyone Is Safe'-Patent Waiver, Compulsory Licensing and COVID-19. *EPLR*, 5, 71.

Tenofovir	Gilead Sciences	India	No	Voluntary licensing to Indian generic manufacturers.
Rituximab	Roche	India	No	Biosimilars introduced, reducing prices significantly.
Pemetrexed	Eli Lily	India	No	Patent upheld, but generics available post-expiry.
Abacavir	ViiV Healthcare	UK	No	Generic versions widely available.
Atazanavir	Bristol-Myers Squibb	US	No	Generic versions introduced post-patent expiry.
Ledipasvir/ Sofosbuvir	Gilead Sciences	India	No	Voluntary licensing for generic production.
Darunavir	Johnson & Johnson	India	No	Generic versions available at lower costs.

IV. ANALYSIS OF THE ABOVE TABLE

A review of compulsory licensing cases reveals that while India and Brazil have leveraged this tool to improve access and reduce prices, developed countries like the UK and us prefer voluntary licensing or judicial solutions. The effectiveness of compulsory licensing is often contingent on local manufacturing capacity and regulatory oversight. The mere threat of compulsory licensing can be a powerful negotiation tool, sometimes achieving price reductions without the need to issue a license.

The application for compulsory licensing in India, the UK, and the US reflects their differing priorities and legal frameworks. India has positioned itself as a leader in using compulsory licensing to address public health concerns, particularly for life saving drugs like cancer medications and antiretrovirals. The Bayer case set a precedent for other developing countries to follow. In contrast, the UK and the US have been more conservative, prioritizing patent protection and market-based solutions.

India's proactive stance on compulsory licensing is rooted in its commitment to public health and its robust generic pharmaceutical industry. The country has used Section 84 of the Patents Acts to ensure that essential medicines are available at affordable prices. For instance, in

Novartis v *Union of India (2013)*[19]*,* the Supreme Court denied a patent for Novartis' cancer drug Imatinib(Glivec), citing lack of therapeutic efficacy over the known substance. This case reinforced India's commitment to preventing evergreening of patents and ensuring access to affordable medicines.

In contrast, the UK has rarely used compulsory licensing, relying instead on voluntary agreements and market competition. *The Warner-Lambert* v *Actavis (*2018)[20] case demonstrates the UK's preference for judicial solutions over compulsory licensing. Post-Brexit, the UK has the opportunity to reform its patent laws to better address the public health needs.

The US, on the other hand, has a strong patent protection system, with limited provisions for compulsory licensing. *The Federal Government* v *Bayer (*2001) case remains an outlier, as the US generally avoids using compulsory licensing even during public health emergencies. Instead, the US relies on voluntary licensing and tiered pricing models.

Compulsory licensing may be seen as a restriction to the patent holder's rights under Article 19(1)(g) of the Indian Constitution. However, this must be balanced with Article 12, which ensures the right to health. The Novartis case highlighted this conflict, where the Supreme Court ruled that public health considerations take precedence over commercial interests. The limited scope for compulsory license was rejected due to the lack of proof that the drug was unaffordable, reinforcing the legal complexities surrounding its application.

V. IMPACT OF COMPULSORY LICENSING ON INDIAN PHARAMACEUTICAL INDUSTRY

Compulsory licensing in India serves as a critical mechanism to balance public health needs with patent rights, particularly in the pharmaceutical sector. Its implementation has multifaceted implications for domestic pharmaceutical companies, foreign investors, and the broader landscape of drug innovation.

1. **EFFECT ON DOMESTIC PHARMACEUTICAL COMPANIES:** For Indian pharmaceutical manufacturers, compulsory licensing offers a pathway to produce and

[19] 2013 AIR SCW 2047
[20] [2018] UKSC 56.

market generic versions of patented drugs without the consent of the patent holder, especially when such drugs are unaffordable or inadequately supplied. This provision enhances competition and can lead to significant reductions in drug prices, as seen in the sorafenib case.

The Landmark case of *Natco Pharma* Ltd. V. *Bayer Corporation* (2012)[21] exemplifies this impact. Natco Pharma was granted a compulsory license to produce a generic version of Bayer's cancer drug, Nexavar, significantly reducing the cost from approximately INR 280,000 to INR 8,800 for a month's therapy. This decision not only made the drug accessible to a broader patient population but also demonstrated the potential for domestic companies to engage in the production of life-saving medications under Compulsory Licensing provisions.

2. **EFFECTS ON FOREIGN INVESTMENTS:** The innovation of compulsory licensing can be a double-edged sword for foreign pharmaceutical companies operating in India. On one hand, it ensures that life-saving drugs become accessible to the matters, aligning with public health objectives. On the other hand, it raises concerns about the security of intellectual property (IP) rights and the potential erosion of profits derives from patented drugs.

The Natco Pharma case, while beneficial from a public health perspective, signalled to foreign investors that patent protections could be overridden to meet public health needs. This possibility may deter investment in the Indian pharmaceutical sector, as companies might fear inadequate returns on their R&D investments. Moreover, the lack of clarity and consistency in the application of CL provisions can contribute to an uncertain business environment.

3. **IMPACT ON INNOVATION IN DRUG DEVELOPMENT:** The relationship between compulsory licensing and pharmaceutical innovation is complex. Critics argue that potential for compulsory licensing undermines the incentives for innovation, as companies may be reluctant to invest in R&D without assured patent protection and the prospect of recouping their investments.

Conversely, the presence of compulsory Licensing provisions can stimulate domestic innovation by encouraging local companies to develop alternative processes or formulations

[21] (2012) 50 PTC 356 (IPAB)

that circumvent existing patens. Additionally, the threat of compulsory licensing can motivate patent holders to engage in voluntary licensing agreements or adopt differential pricing strategies, thereby enhancing access to medicines without compromising innovation.

4. **IMPACT ON INNOVATION AND R&D:** while compulsory licensing can threaten patent holders' revenues and potentially discourage R&D investment by pharmaceutical companies, evidence from other sectors (e.g., Us telecommunications) suggests it may also stimulate innovation by fostering competition. The overall impact on innovation depends on the frequency and predictability of compulsory licensing: rare, targeted use is less likely to deter R&D than frequent or unpredictable interventions.

5. **ENHANCEMENT OF GLOBAL HEALTH LEADERSHIP:** India's proactive use of compulsory licensing has not only improved domestic access to essential medicines but has also established the country as a global leader in advocating for affordable healthcare. By challenging the dominance of multinational pharmaceutical companies and prioritizing public health, India has inspired other developing nations to adopt similar measures. This leadership role has increased India's influence in international health policy forums, such as the World Health Organization and World Trade Organization, where it often champions the interests of the Global South and pushes for more flexible intellectual property regimes to address public health emergencies.

6. **TECHNOLOGY TRANSFER AND INDUSTRIAL GROWTH:** Compulsory licensing has acted as a catalyst for technology transfer from multinational patent holders to Indian generic manufacturers. When a compulsory license is issued, the patent holder is required to share the necessary know-how or technical information with the licensee, enabling local firms to develop the capacity to produce high-quality generic medicines. This process has contributed to the rapid growth and modernization of India's pharmaceutical industry, allowing it to compete globally and supply affordable medicines to other developing countries, especially during health crises like HIV/AIDS and COVID-19.

7. **EMPOWERMENT OF CIVIL SOCIETY AND PATIENT GROUPS:** The legal precedent set by compulsory licensing has galvanized patient advocacy groups and non-governmental organizations in India. These groups have become more active in policy debates, litigation, and public campaigns for affordable medicines, holding both the

government and pharmaceutical companies accountable. Their advocacy has led to greater transparency in drug pricing, more patient-centred policies, and increased public scrutiny of patent practices, ultimately strengthening democratic participation in health governance.

VI. PROBLEMS FACED BY INDIA

- A significant issue in the Indian compulsory licensing framework is the three-year waiting period before an application can be made. This restriction delays the availability of essential medicines, as seen in the Bayer case, where the High Court upheld the three-year waiting period requirement. Additionally, the Indian Patent Act does not specify the financial and infrastructural requirements needed for an applicant seeking a compulsory license. This loophole can be exploited by competitors with no intention of manufacturing the medicine, leading to delays in accessibility. A similar issue was observed in Bristol-Myers Squibb case where the court denied a compulsory license, citing incomplete efforts to obtain a voluntary license.

- Section 92 of the Indian Patents Act allows direct government intervention in granting compulsory licenses, yet its exact scope remains unclear. During the COVID-19 pandemic, despite global vaccine shortages, India did not invoke Section 92, highlighting the passive approach of the government. Judicial overload and delays further complicate the process, as seen in the Bayer case, where the Supreme Court upheld licensing but the legal battle spanned several years, delaying drug accessibility.

- Despite the urgent need for affordable medicines, the Indian Government has not proactively issued compulsory licenses, often due to political pressure from developed nations advocating for stricter patent protections. The economic implications of compulsory licensing further deter its implementation. Pharmaceutical research is costly, and royalty rates under compulsory licensing are often insufficient to cover the R&D expenses. This discourages investment in drug innovation, as seen in the *Eli Lilly v Canada*[22] case, where Cananda faced trade disputes over its flexible patent laws,

[22] IIC 771 (2016).

setting an example of the international pressure faced by countries adopting compulsory licensing.

- In comparison the UK follows the Patents Act 1977, which allows compulsory licensing if a patent is not being sufficiently worked within the country. The Crown use previsions enable the government to use patented inventions for public interest without requiring the patent holder's consent. The UK government considered using Crown use during the COVID-19 pandemic for vaccine accessibility but ultimately did not enforce it. The US, on the other hand, does not march-in rights under the Bayh-Dole Act and the Defence Production Act, which grants the government authority to intervene in national emergencies. A notable example was in 2001 when the US government threatened compulsory licensing for ciprofloxacin (Cipro) during the anthrax attacks, demonstrating its willingness to invoke such measurers in extreme situations.[23]

- To improve the compulsory licensing framework in India, policy reforms are necessary to provide clear guidelines on revoking licenses once their necessity ceases. Balancing patent rights with public interests is crucial, ensuring fair compensation to patent holders while maintaining affordable healthcare. Expanding the scope of compulsory licensing by defining the affordability as a valid ground and fast-tracking licensing during health emergencies can significantly enhance accessibility. Waiving the three-year waiting period in pandemics and critical health crises, as demonstrated during COVID-19, would allow for timely interventions.

- Due to insufficient laws in regard to compulsory licensing, the creation of gray markets gradually increases. When a country issues a compulsory license, generic versions for patented drugs become available at significantly lower prices. However, traders may exploit these prices differences by diverting low-cost generics to higher priced markets, leading to parallel trade and supply chain disruptions. This can result in shortages in intended markets, regulatory risks due to improper storage and handling, concerns over counterfeit products. To mitigate gray markets risks, stronger regulatory controls, cross-border cooperation, and ethical strategies are necessary to ensure that compulsory

[23] Spence, E. A. (2022). Existing Patent Laws Promote Competition and Lower Drug Prices, but Is This Appropriate for COVID-19 MRNA Vaccines?. *Cal. WL Rev.,* 59, 183.

licensing fulfils its intended purpose-enhancing accessibility without enabling unauthorized trade.

Furthermore, stricter criteria for applicants should be introduced to prevent abuse, alongside a fixed timeline for voluntary licensing negotiations to avoid unnecessary delays. Harmonizing Section 84 and 92 by clearly distinguishing their applications would improve legislative coherence. Judicial efficiency measures, such as alternative dispute resolution mechanisms, can reduce the burden on courts and expedite licensing decisions.

A proactive government approach is essential in ensuring compulsory licensing is implemented where necessary, particularly for life-saving drugs. Incentivizing pharmaceutical R&D through subsidies and financial incentives can encourage companies to continue investing in research despite compulsory licensing risks. India should also engage in international negotiations to post for TRIPS flexibilities, safeguarding the rights of developing countries to exercise compulsory licensing without facing economic sanctions. A fair pricing mechanism allowing patent holders to negotiate pricing with the government can prevent coercion while ensuring affordability.[24]

By addressing these issues and implementing the recommended solutions, India can create a more balanced and effective compulsory licensing framework. Learning from the UK's Crown Use provisions and the US's march-in rights can help refine India's approach to ensure equitable healthcare access while maintaining incentives for pharmaceutical innovation.

VII. RECOMMENDATIONS TO IMPROVE THE CURRENT SCENARIO

- **RE-EVALUATE THE THREE-YEAR WAITING PERIOD:** The current stipulation under section 84 of the Indian Patents Act mandates a three-year period from the grant date before a compulsory license application can be filed. This delay can hinder timely access to essential medications during public health crises. Amending this provision to allow for immediate applications in cases of national emergency or extreme urgency would enable swifter responses to health challenges, ensuring that critical treatments

[24] Gopakumar, K. M. (2015). Twenty years of TRIPS agreement and access to medicine: a development perspective. *Indian Journal of International Law,* 55(3), 367-404.

reach patients without unnecessary delays.[25]

- **CLARIFY GOVERNMENT INTERVENTION MECHANISMS**: Section 92 of the India Patents Act permits the government to issue compulsory licenses during national emergencies or in circumstances oof extreme urgency. However, lack of detailed guidelines on invoking this provision can result in hesitancy or inconsistent application. Developing comprehensive protocols would facilitate decisive and uniform government action when public health imperatives demand it.

- **ENHANCE JUDICIAL EFFICIENCY:** Protracted legal proceedings can significantly delay the availability of life-saving medications. Implementing alternative dispute resolution mechanisms, such as specialized patent arbitration panels pr fast-track processes, would expedite the burden on courts and ensure that disputes do not impede the timely access to essential medicines.

- **BALANCE PATENT RIGHTS WITH PUBLIC HEALTH NEEDS**: While protecting intellectual property rights is crucial for encouraging pharmaceutical innovation, it is equally important to address public health needs. Establishing a balanced framework that offers fair compensation to patent holder through negotiated royalty rates, while allowing for compulsory licensing in specific circumstances, would maintain incentives for research and development. This equilibrium ensures that the pursuit of innovation does not come at the expense of public access to affordable healthcare solutions.[26]

- **STRENGTHEN MEASURES AGAINST GRAY MARKET EXPLOITATION:** The introduction of generic versions of patented drugs through compulsory licensing can inadvertently lead to gray market activities, where products are diverted to unauthorized markets. To combat this, robust regulatory oversight is essential. Implementing stringent tracking systems, enhancing cross-border cooperation, and imposing severe penalties for violations would protect the integrity of supply chains.

[25] Jain, S. A. (2023). Critical Analysis of Article 31 (B) of Trade Related Intellectual Property Rights Agreement r/w Section 92 of Indian Patents Act 1970. *Issue 1 Indian JL & Legal Rsch*., 5, 1.
[26] Mercurio, B. (2021). *WTO waiver from intellectual property protection for COVID-19 vaccines and treatments: A critical review.*

These measures ensure that the benefits of compulsory licensing reach the intended populations without being undermined by illicit trade practices.

- **PROMOTE INTERNATIONAL COLLABORATION AND ADVOCACY**: Engaging proactively in international forums allow India to advocate for the rights of developing nations under agreements like TRIPS Agreement. Collaborative efforts can lead to the adoption of policies that support the use of compulsory licensing as a legitimate tool for public health. By building alliances and sharing best practices, India can strengthen its position against external pressures and ensure that its public health strategies are respected on the global stage. [OBJ]

- **LEVERAGE DIGITAL AND SUPPLY CHAIN TECHNOLOGIES:** Integrating digital technologies such as blockchain, electronic track-and-trace systems, and AI-driven logistics can enhance the transparency, efficiency, and security of medicine distribution. These tools help ensure that generic drugs produced under compulsory licenses reach the intended populations, reduce the risk of counterfeiting, and enable real-time monitoring of supply chains during emergencies.

- **ENHANCE LEGAL CLARITY AND INTERNATIONAL DIALOGUE:** Clearly defining the legal criteria and procedures for compulsory licensing can reduce uncertainty for all stakeholders and minimize the risk of legal disputes. Engaging proactively in international dialogue—through the WTO, WHO, and bilateral forums—can help harmonize standards, address trade concerns, and promote global consensus on balancing intellectual property rights with public health.

- **INCENTIVIZE VOLUNTARY LICENSING AND TIERED PRICING:** Encouraging patent holders to engage in voluntary licensing or adopt tiered pricing models—where prices are adjusted based on a country's income level—can improve access to medicines without resorting to compulsory licensing. Governments can offer incentives such as tax benefits, expedited regulatory review, or public recognition to companies that proactively address public health needs, fostering a more collaborative approach to access.

- **INSTITUTIONALIZE POST-LICENSING IMPACT ASSESSMENTS:** Regularly evaluating the outcomes of compulsory licenses—such as improvements in drug

access, affordability, health outcomes, and effects on innovation—would provide valuable feedback for policymakers. These assessments could identify best practices, highlight unintended consequences, and inform future reforms, making the policy more adaptive and evidence based.

Implementing these recommendations would fortify India's compulsory licensing framework, ensuring a harmonious balance between the protection of intellectual property rights and the imperative of public health. Such reforms would not only enhance access to affordable medicines domestically but also position India as a leader in advocating for equitable solutions worldwide.

VIII. CONCLUSION

Compulsory licensing remains a contentious yet essential tool in the global effort to balance intellectual property rights and public health needs. The experiences of India, the UK, and the us illustrate the diversity of approaches and outcomes. While India has demonstrated the potential for compulsory licensing to improve access to medicines, developed countries have been more cautious, favoring voluntary solutions. A nuanced, evidence-based approach, supported by robust legal frameworks and international cooperation, is necessary to ensure equitable access to life-saving medicines without stifling innovation. The three-year waiting period under Section 84 of the Indian Patents Act remains a significant barrier to timely access to essential medicines, delaying the production of affordable generics. Cases like *Bayer* v *Natco (2012)* highlight how such restrictions contradict the purpose of compulsory licensing to ensure equitable access during public health crises. To address this, India must reform its compulsory licensing framework by eliminating or relaxing the waiting period, particularly in national emergencies. Adopting fast-tracks mechanisms, as seen in the UK's Crown Use provisions and the US Defence Production Act, would allow immediate intervention when critical medicines are needed. Additionally, enhancing judicial efficiency and establishing clearer government intervention protocols would ensure a more effective response in future health crises. By removing bureaucratic delays and strengthening its licensing framework, India can create a more responsive and balanced system- one that protects public health while maintaining incentives for pharmaceutical innovation.

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