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Compulsory Licensing and Pharmaceuticals Sectors in India with special reference to Right to Health

Mr. Gaurav Gupta*
Research Scholar,
University School of Law and Legal Studies,
Guru Gobind Singh Indraprastha University, Delhi

ABSTRACT

India's pharmaceutical industry is critical in ensuring the availability of essential medicines, especially given the country's extensive public health needs. A key legal mechanism that helps reconcile the protection of patent rights with public health priorities is compulsory licensing. This allows third parties to manufacture a patented drug without the patent holder's approval, but only under certain conditions. This research investigates the legal framework that governs compulsory licensing in India, with a focus on its effects on the pharmaceutical sector and the constitutional Right to Health, safeguarded by Article 21. It examines the relevant sections of the Patents Act, 1970, along with India's compliance with international standards set by the TRIPS Agreement and the Doha Declaration. Furthermore, the research analyzes significant court rulings that have influenced the legal discourse on compulsory licensing, illustrating how the judiciary has balanced intellectual property rights with public health needs, ensuring access to critical medicines. Additionally, the article connects the concept of compulsory licensing with the Right to Health, discussing how Indian courts have expanded this right through judicial activism and Public Interest Litigations (PILs).

Keywords: Compulsory licensing, Pharmaceuticals, Patent Act, Right to health, IPRs, TRIPS, Doha Declaration

INTRODUCTION

Compulsory licensing is a legal tool enabling governments to permit the manufacturing of a patented product or the application of a patented process without the patent owner's approval, often to serve public welfare. In the pharmaceutical industry, this mechanism is mainly employed to improve access to vital medications that might be too costly or inaccessible due to existing patent restrictions. Its significance lies in its ability to balance two competing interests: the patent holder's right to benefit from their innovation and the public's need for affordable healthcare, especially during emergencies like pandemics or widespread health crises. By enabling generic manufacturers to produce life-saving medicines at lower costs, CL serves as an essential tool in

*Research Scholar, University School of Law and Legal Studies, Guru Gobind Singh Indraprastha University, Delhi

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safeguarding public health, particularly in developing countries where access to expensive drugs is limited.[2]

Intellectual property rights, particularly patents, grant pharmaceutical companies' exclusive control over the production, pricing, and distribution of their innovations for a fixed period. IPRs, while crucial for promoting innovation by guaranteeing financial returns, often lead to elevated costs for patented medications. This can restrict access to vital treatments, particularly in low- and middle-income nations. The ongoing debate surrounding IP rights and access to medicine stems from the inherent conflict between fostering innovation and ensuring fair access to healthcare. Although patents play a key role in driving pharmaceutical advancements, they can also hinder access to affordable healthcare when essential medicines are priced out of reach for most people. Compulsory licensing emerges as a middle-ground solution that allows governments to ensure that public health needs take precedence over profit in cases of urgent necessity or market failure.

The Right to Health is widely acknowledged as a basic human right and is protected by numerous global agreements, such as the International Covenant on Economic, Social, and Cultural Rights (ICESCR).[3] The concept of health extends beyond merely the absence of illness, incorporating access to comprehensive healthcare services, such as essential medications, preventive measures, and basic health determinants like clean water, proper sanitation, and adequate nutrition. Regarding pharmaceuticals, the Right to Health asserts that people should be able to obtain life-saving drugs without encountering excessive costs or discriminatory obstacles. While the Right to Health is not explicitly outlined in India's Constitution, the judiciary has interpreted it as part of the Right to Life under Article 21. This interpretation requires the state to implement measures to safeguard public health, including policies like compulsory licensing, which aim to provide affordable access to essential medicines.

India presents a unique socio-economic landscape where public health needs are often in conflict with market-driven pharmaceutical interests. As a developing country with a large population, India faces numerous health challenges, including the high prevalence of diseases like HIV/ AIDS, cancer, tuberculosis, and cardiovascular diseases. The country's healthcare system, though evolving, remains under-resourced and overburdened, especially in rural areas where access to affordable healthcare is limited. The high cost of patented drugs exacerbates these issues, as many life-saving treatments remain out of reach for the average Indian citizen. In this context, compulsory licensing has become an important policy tool for ensuring that essential medicines are available at affordable prices, aligning with India's broader goal of promoting public health.[4]

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[2] *Compulsory Licensing*, 48 CHEM. & ENG'G NEWS 14, (1970), https://doi.org/10.1021/cen-v048n047.p014a.

[3] Deepa Kansra & Mallika Ramachandran, *Introduction to ICESCR Optional Protocol [OP-ICESCR]*, 2020 SSRN ELEC. J., https://doi.org/10.2139/ssrn.3637246.

[4] PHARMACEUTICALS: A SECTOR STUDY (Export-Import Bank of India ed., 1991).

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India is also one of the world's largest producers of generic medicines, often referred to as the "pharmacy of the world." As a result, the country has been at the forefront of global debates on balancing patent protections with public health imperatives. Compulsory licensing in India, particularly in the pharmaceutical sector, is not just a legal issue but a socio-economic necessity to address inequities in healthcare access. It reflects the country's commitment to prioritize public health over intellectual property rights when necessary, ensuring that the benefits of medical advancements are accessible to all, regardless of their economic status.

LEGAL FRAMEWORK OF COMPULSORY LICENSING IN INDIA

The Patent Act, 1970, marked a watershed moment in India's IPR framework, setting the stage for the country's current stance on compulsory licensing in the pharmaceutical sector.[5] Before 1970, India followed a colonial patent system that favored foreign patent holders, leading to high drug prices and limited access to essential medicines. The need for an indigenous, pro-public health patent regime prompted the Indian government to reform its laws, which led to the enactment of Act, 1970. This legislation, while protecting inventors' rights, prioritized public health and development by allowing the issuance of compulsory licenses under specific conditions.

Act, 1970, initially excluded pharmaceutical products from patentability, which encouraged the growth of India's generic drug industry. However, with India's adherence to the WTO's TRIPS Agreement in 1995, significant changes were made to comply with global intellectual property standards.[6] The introduction of product patents in 2005, post-TRIPS, raised concerns about access to affordable medicines, particularly for life-threatening diseases. The inclusion of provisions on compulsory licensing under Sections 84 and 92 was a deliberate measure to balance patent rights with public health needs, allowing India to safeguard access to essential medicines even in the face of stringent global IP norms.

Section 84 of the Indian Patents Act: Conditions for Granting Compulsory Licenses

Section 84 of Act, 1970, lays down the fundamental legal basis for granting compulsory licenses in India.[7] It allows any interested party to apply for a compulsory license three years after the date of the grant of a patent, provided specific conditions are met. These conditions revolve around three primary concerns:

[5] Prashant Reddy, *A Diagnosis of the Damage Done to the Patents Act, 1970*, 2013 SSRN ELEC. J., https://doi.org/10.2139/ssrn.2362184.

[6] S. Saxby, *The TRIPS agreement*, 22 COMPUT. L. & SEC. REV. 421, (2006), https://doi.org/10.1016/j.clsr.2005.12.010.

[7] *Compulsory Licensing*, S.S. RANA & CO., https://ssrana.in/ip-laws/patents/compulsory-licensing-patents-in-india/ (last visited Oct. 20, 2024).

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- *Reasonable Requirements of the Public:* If the patent holder fails to meet the reasonable requirements of the public regarding the patented product, such as by not supplying it in sufficient quantities, a compulsory license may be granted.
- *Affordability:* If the patent product is not available at a reasonably affordable price, making it inaccessible to a significant portion of the population, this constitutes grounds for issuing a compulsory license. This provision reflects India's commitment to ensuring that essential medicines are accessible to all, particularly in a country where healthcare affordability is a pressing issue.
- *Working of the Patent in India:* Section 84 emphasizes that the patent must be "worked" within the territory of India, meaning the patented product should either be manufactured domestically or be made available within the country in sufficient quantities. If this requirement is not met, the patent holder risks losing exclusive rights through the issuance of a compulsory license.

The conditions u/s 84, thus, provide a legal pathway for ensuring that patented medicines, especially for critical diseases like cancer and HIV, are not only available but also affordable to the masses.

Grounds for CL under Section 84: Availability, Reasonable Pricing, and Public Interest

The Indian government, through Section 84, ensures that patents do not become tools of monopolistic exploitation. Availability of the patented product in the Indian market is a crucial condition; mere possession of a patent without making the drug accessible is not tolerated. Reasonable pricing is another core issue addressed under this section. Indian courts have reiterated that patent holders must price their drugs in a manner that ensures broad public access, particularly in cases where the product addresses public health needs.[8]

Public interest plays a pivotal role in decisions regarding compulsory licenses. The government can intervene in cases where granting a license is necessary for protecting public health. This principle emphasizes that the right to health is paramount, even over patent holders' monopoly rights.

Special Provisions in Cases of National Emergency or Public Health Crises

Section 92 of Act, 1970 provides for compulsory licensing during national emergencies, extreme urgency, or public health crises, such as epidemics or pandemics.[9] Under this provision, the

[8] *Compulsory License: India*, KLUWER PATENT BLOG, https://patentblog.kluweriplaw.com/2021/08/16/compulsory-license-india/ (last visited Oct. 20, 2024).

[9] Harsha P. Patil, *Compulsory Licensing under Indian Patents Act*, 9 INT'L J. INFO. DISSEMINATION & TECH. 125, (2019), https://doi.org/10.5958/2249-5576.2019.00026.8.

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government can issue a compulsory license without the usual requirement for an application or a waiting period of three years, bypassing the standard procedures u/s 84. This provision ensures that in times of national health crises, like the COVID-19 pandemic, essential medicines or vaccines can be made widely available, even if they are under patent protection.

By issuing compulsory licenses u/s 92, the Indian government aims to secure timely access to life-saving medications and medical technologies, ensuring that public health is not compromised due to legal or commercial barriers.

Doha Declaration on TRIPS and Public Health

India's accession to the WTO in 1995 brought with it compliance with the Agreement on TRIPS, which sets minimum global standards for protecting and enforcing intellectual property rights, including patents. TRIPS, however, had raised fears among developing countries like India that strict enforcement of pharmaceutical patents could hinder access to affordable medicines for large sections of the population. Recognizing this tension, the Doha Declaration on TRIPS and Public Health (2001) clarified that the TRIPS Agreement should be interpreted in a manner that supports public health by promoting access to medicines for all.[10]

India has strategically leveraged the flexibilities under TRIPS, as reaffirmed in the Doha Declaration, to balance its IP obligations with the pressing need to ensure access to affordable healthcare. This has allowed India to maintain its role as a major producer of generic medicines while complying with international patent standards.

The Doha Declaration was a critical development for public health advocates, emphasizing that the TRIPS Agreement should not prevent member states from taking measures to protect public health. It affirmed that countries have the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are issued. For India, this declaration was significant in maintaining its long-standing policy of prioritizing public health over stringent patent protection, particularly in the pharmaceutical sector. The declaration provided India with the legal backing to grant compulsory licenses for essential medicines, thus preventing situations where patents could hinder access to life-saving drugs. This has been particularly crucial in India's role as the "pharmacy of the world", supplying affordable generic medicines to developing countries.

The TRIPS Agreement allows member states to incorporate certain flexibility into their national laws, enabling them to issue compulsory licenses for patented inventions. These flexibilities are vital for developing countries like India, which face the dual challenge of protecting intellectual property rights while ensuring the public's right to access affordable healthcare. The Doha

[10] ALEX WELLINGTON, *Doha Declaration*, *in* ENCYCLOPEDIA OF GLOBAL JUSTICE 264, (2011), https://doi.org/10.1007/978-1-4020-9160-5_745.

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Declaration reaffirmed that countries have the sovereign right to determine the criteria for granting compulsory licenses, a power India has exercised through its provisions in the Patents Act.

JUDICIAL PERSPECTIVE

Bayer Corporation v. Natco Pharma Ltd.[11] marked a watershed moment in India's legal landscape concerning compulsory licensing. This case was notable for being India's first instance of the issuance of a compulsory license under the Patents Act of 1970. Natco Pharma sought a compulsory license for Nexavar, a drug used in the treatment of liver and kidney cancer, which Bayer had patented. The primary contention in this case revolved around the non-availability of Nexavar at affordable prices. Bayer had priced Nexavar at approximately ₹2.8 lakhs per month, rendering it inaccessible for most patients. Natco Pharma argued that such exorbitant pricing violated the rights of Indian citizens to access essential medicines.

The Controller of Patents, while granting the compulsory license, emphasized the importance of public interest and reasonable requirements. The ruling indicated that the conditions for granting a compulsory license were met, particularly under Section 84(1) of Act, 1970 which mandates that a patent should be exploited to the fullest extent to meet public demand.[12] The decision underscored that the public interest must take precedence over the rights of patent holders, especially in cases where life-saving drugs are involved. The implications of this case extended beyond its immediate context; it established a precedent for subsequent cases concerning compulsory licensing and highlighted the ability of Indian law to prioritize public health over patent exclusivity. The ruling served as a significant warning to global patent holders about the Indian judiciary's willingness to leverage compulsory licensing as a tool to ensure access to essential medications.

The case of *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.*[13] brought to the fore the complex tension between patent rights and the necessity for life-saving drugs in the Indian market. This case involved Roche's patented drug, Tarceva, used in the treatment of non-small cell lung cancer. Roche accused Cipla of infringing its patent by marketing a generic version of Tarceva at a fraction of the cost, approximately ₹1,200 as opposed to Roche's pricing of ₹16,000 for the branded drug.

In this context, the court's deliberations revolved around the concept of "public interest." Roche's argument rested on protecting its patent rights, which, if upheld, would mean limited access to a drug crucial for many cancer patients. Cipla countered that the availability of its generic version was essential for public health, given the financial burden of cancer treatment on patients in India. The ruling ultimately sided with Cipla, reinforcing the idea that public health considerations could supersede patent rights, especially in life-or-death scenarios. This decision resonated deeply within

[11] CS(COMM) 343/2019 & I.As. 8878/2019, 9685/2019.
[12] *Id.*
[13] RFA(OS) 92/2012.

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the pharmaceutical sector, showcasing the judiciary's willingness to prioritize patient access to essential medicines over stringent adherence to patent laws. It set a benchmark for future cases, reinforcing the notion that intellectual property laws should align with public health imperatives.

Novartis AG v. Union of India & Ors.[14] represented a landmark decision regarding the patentability of pharmaceutical inventions in India, specifically concerning the cancer drug Glivec. Novartis sought patent protection for a modified form of the drug, arguing that it represented a novel invention. However, the Indian Patent Office rejected the application under Section 3(d) of the Indian Patents Act, which prohibits the patenting of new forms of known substances unless they demonstrate significantly enhanced efficacy.

The Supreme Court's ruling clarified the interpretation of "efficacy," asserting that the mere discovery of a new form of an existing compound does not meet the standards for patentability if it does not provide therapeutic benefits beyond the original compound. This decision had far-reaching implications, as it effectively curtailed the practice of "evergreening," where pharmaceutical companies attempt to extend their patent monopolies by making minor modifications to existing drugs. The significance of this ruling lay in its potential to enhance access to generic medications, allowing Indian manufacturers to produce and sell affordable versions of essential drugs. By safeguarding the availability of generic alternatives, the ruling reinforced the broader right to health, ensuring that life-saving treatments remain accessible to a larger segment of the population.

In *Bristol-Myers Squibb Company v. BDR Pharmaceuticals*,[15] the Indian judiciary faced a critical decision regarding the denial of a compulsory license for the cancer drug Dasatinib. BDR Pharmaceuticals sought a compulsory license for the production of Dasatinib, which was patented by Bristol-Myers Squibb. The request was based on the argument that the patented drug was not being made available to the public at a reasonable price, hindering access to an essential treatment for cancer patients.

However, the Controller of Patents denied the application, citing that the applicant failed to demonstrate that the patented product was not available to the public at a reasonable price and that there was no sufficient evidence showing that the patent holder had failed to meet public demand. This case was significant as it illustrated the challenges faced by generic manufacturers in successfully obtaining compulsory licenses. The ruling highlighted the courts' meticulous approach in evaluating claims for compulsory licensing, emphasizing the need for substantial evidence to support arguments related to public interest and access. The denial of the license reflected the ongoing balancing act within Indian jurisprudence between protecting patent rights and ensuring public health. While the outcome was a setback for BDR Pharmaceuticals, it

[14] 13 S.C.R. 148.

[15] CS (COMM) 27/2020.

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nevertheless underscored the ongoing discourse on the role of compulsory licensing in enhancing access to life-saving medications within the framework of India's evolving pharmaceutical landscape.

RIGHT TO HEALTH: CONSTITUTIONAL PERSPECTIVE

The Right to Health has emerged as a pivotal aspect of the broader Right to Life enshrined in Article 21 of the Indian Constitution. The Supreme Court of India has interpreted this provision expansively, recognizing that the right to life includes the right to health. In landmark judgments, such as *Francis Coralie Mullin v. Union Territory of Delhi*,[16] the Court affirmed that the right to life encompasses the right to live with human dignity, which inherently includes the right to health and medical care. This interpretation aligns with the understanding that health is a critical component of individual dignity and well-being, reinforcing the state's obligation to create conditions conducive to good health for its citizens.

The DPSPs further elucidate the state's role in promoting public health. Articles 38, 39, and 47 of the Constitution explicitly emphasize the responsibility of the state to ensure that the health and well-being of the people are prioritized. Article 38 mandates the state to strive for a social order in which justice, social, economic, and political, shall inform all institutions of national life, thereby creating an environment conducive to health. Article 39(a) specifically enshrines the right to an adequate means of livelihood, implicitly suggesting that economic stability is vital for health. Meanwhile, Article 47 obligates the state to raise the level of nutrition and the standard of living and to improve public health, specifically targeting the vulnerable and marginalized sections of society. Collectively, these provisions reflect the framers' vision of a welfare state committed to the health and well-being of its citizens, thereby reinforcing the constitutional mandate to ensure access to health care as a fundamental right.[17]

The judicial expansion of the Right to Health has been significantly propelled through PILs, which allow individuals and organizations to seek judicial intervention on behalf of those whose rights have been violated. The Supreme Court has played a transformative role in recognizing health rights through various PILs. In cases like *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*,[18] the Court emphasized the state's responsibility to provide adequate medical facilities to all citizens, ruling that failure to do so amounts to a violation of the right to life. This proactive approach not only affirms the judiciary's role in health matters but also highlights the necessity for the state to ensure equitable access to healthcare services for all, particularly for marginalized populations. Through these judicial pronouncements, the Right to Health has become a robust legal guarantee, compelling the state to prioritize health care as part of its constitutional duties.

[16] 1981 CRILR(SC MAH GUJ) 437.
[17] THE RIGHT TO HEALTH (World Health Organization ed., 2008).
[18] (1996) 3 ICC 269.

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India's commitment to the Right to Health is also enshrined in various international human rights frameworks, notably the ICESCR. Adopted by the UN in 1966, the ICESCR articulates the right to the highest attainable standard of physical and mental health, obliging state parties to take steps to achieve full realization of this right. Article 12 of the ICESCR specifically obligates countries to improve the underlying determinants of health, including nutrition, housing, sanitation, and health facilities.[19] India's ratification of the ICESCR reinforces its constitutional provisions, positioning the Right to Health as a vital component of its international obligations.

By ratifying the ICESCR, India has committed to ensuring equitable access to healthcare services, particularly for marginalized and vulnerable groups. This international framework compels the Indian government to integrate health rights into its policy and legislative frameworks, ensuring that access to health services is not merely a privilege but a guaranteed right for all citizens. The state's commitment to aligning national laws with international human rights obligations reflects an acknowledgment of the intrinsic link between health and human rights, affirming that a healthy populace is fundamental to a just and equitable society.

INTERSECTION OF COMPULSORY LICENSING AND THE RIGHT TO HEALTH

Compulsory licensing serves as a crucial mechanism to safeguard the Right to Health, especially in contexts where access to essential medicines is compromised by patent protections. The legal foundation for viewing it as a vehicle for fulfilling the Right to Health can be traced to both national and international frameworks. In India, the Constitution recognizes the Right to Health as an intrinsic aspect of the Right to Life under Article 21.[20] Additionally, the Directive Principles of State Policy, particularly Articles 38 and 47, underscore the State's obligation to promote public health and provide adequate healthcare services. The Indian Patents Act, 1970, further reinforces this obligation by allowing for compulsory licensing under circumstances where patented medicines are not available at affordable prices, thereby addressing the needs of the public. This alignment of health rights and patent law demonstrates a conscious effort to prioritize public health over exclusive commercial interests.

A notable example of this alignment is seen in *Bayer Corporation v. Natco Pharma Ltd*.,[21] wherein the Patent Office granted a compulsory license for the cancer medication Nexavar, citing the high cost and limited availability of the drug. The ruling underscored the notion that patent rights should not hinder patients' access to life-saving treatments, effectively establishing a legal precedent that links compulsory license directly to the Right to Health. This decision illustrates how the law can

[19] M. Dowds et al., *Article 12*, 87 ARCHIVES PHYSICAL MED. & REHAB. e4, (2006), https://doi.org/10.1016/j.apmr.2006.07.015.
[20] INDIA CONST., art. 21.
[21] *Supra* note 10.

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be utilized to ensure that critical medicines are accessible to those in need, particularly in a country where a significant portion of the population remains underserved in terms of healthcare.

The Role of the Judiciary in Balancing Interests

The judiciary plays a pivotal role in balancing patent rights with the public's right to access essential medicines, particularly in the context of compulsory licensing. Indian courts have increasingly adopted a public health-oriented approach in their rulings, recognizing the need to prioritize access to medicines over the monopolistic interests of patent holders. A critical analysis of relevant case law reveals a consistent judicial trend favoring public health, as evidenced in decisions that highlight the necessity of making affordable medicines available to the populace.

One of the most significant cases in this regard is *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.*,[22] which dealt with the patent rights of the cancer drug Tarceva. In this case, the court acknowledged the right of the public to access life-saving medications, underscoring that patent protections should not impede the av[23]ailability of affordable alternatives. The ruling emphasized that public interest must be a significant consideration when adjudicating patent disputes, effectively setting a precedent for subsequent cases where health concerns are paramount.

Similarly, the case of *Novartis AG v. Union of India & Ors.* provided a critical perspective on the balance between innovation and public health. The Supreme Court of India ruled against Novartis's patent application for the drug Glivec, invoking Section 3(d) of Act, 1970, which disallows the patenting of minor modifications to existing drugs. This decision reaffirmed the importance of ensuring that essential medications remain accessible to the public, particularly in a healthcare system where affordability is a critical issue. By prioritizing the public's right to health over the exclusivity of patent rights, the judiciary has effectively redefined the contours of intellectual property law in favor of greater health equity.

CONCLUSION

Compulsory licensing in India represents a crucial legal mechanism that balances the protection of intellectual property rights with the need to ensure access to life-saving medicines for all. It serves as a vital tool in advancing public health goals, particularly when essential drugs are either unavailable or unaffordable for a large section of the population. The Indian judiciary has played a pivotal role in shaping the application of compulsory licenses, carefully weighing the rights of patent holders against the public's right to health, as enshrined under Article 21 of the Constitution. Notable rulings have demonstrated that the courts are willing to prioritize public health over exclusive commercial interests when justified by the circumstances. However, challenges remain, including concerns about the potential negative impact of compulsory licensing on pharmaceutical

[22] *Supra* note 12.
[23] *Supra* note 13.

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innovation and foreign investment. Nonetheless, as India continues to evolve as a global leader in the production of affordable generic drugs, its compulsory licensing framework offers a model for balancing innovation with equity, particularly in times of health crises. Looking ahead, it is essential to continue refining this framework to ensure that the country remains a hub for affordable medicines while fostering an environment that encourages research and development. In conclusion, compulsory licensing, when aligned with the Right to Health, exemplifies how legal tools can be leveraged to promote public welfare, ensuring that intellectual property laws do not act as barriers to essential healthcare in a developing economy.