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Breaking Barriers: How Compulsory Licensing in Indian Patent Law Unlocks Access to Essential Medicines

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ABSTRACT

The patent protection regime in India provides compulsory licensing, which forms part of an effective attempt to strike the right balance between IPRs and the public interest when it comes to affordable and effective treatment for diseases. This paper aims to discuss the extent and effect of compulsory licensing in India its provisions and its application within the Indian legal framework as to the TRIPS Agreement, as well as the role of compulsory licensing in providing affordable medicines for citizens. Such provisions as "Section 84" and "Section 92" of the "Patents Act, 1970" serve as foundations for compulsory licensing as the mechanism that helps India tackle patents in certain conditions when drug prices become the cause of people's access denial. Using cases such as is *Natco Pharma Ltd. v. Bayer Corporation*; the paper shows how the judiciary has supported compulsory licensing and its usefulness in reducing the prices of essential drugs in the interest of accessing justice in the medical field. Besides, the paper discusses the ethical issues and economic consequences associated with compulsory licensing, the effects it has on the pharmacy sector, and the stimulation of innovations. Last, proposals like reducing the complexity of the application, bringing more clarity on royalties, and the use of TRIPS flexibilities are put as suggestions to build on the framework and foster the continued exercise of leadership in health equity in India. This paper therefore aims at offering a clear insight into compulsory licensing as a mechanism of guaranteeing public use of essential products such as medicinal products without prejudice to the rights of inventors and owners.

Keywords: Compulsory Licensing, Patent Law, Public Health, TRIPS Agreement, Intellectual Property, Affordable Healthcare, Pharmaceutical Industry, Patent Act 1970

Introduction

Patent law has always been the decisive contributor in the development of the invention by granting certain monopolies to inventors or anyone who creates. This understandably makes these markets rather exclusive, especially within the pharmaceutical sector, to guarantee that the creators can recover the significant amounts spent on the R&D if new medicines are to be developed. While patent law seems to affect the availability of essential medicines in several ways, drawing a consensus on the effects of the laws is hard. A top-shelf patent regime is another important factor in developed countries due to the stability of innovative processes. Nevertheless, in the developing world, such as India, where a major population lives in abject poverty and where health care is wanted, patent protections come in the way of affordable prices for these essential commodities. Patented medicines may be expensive, and despite their benefits, the costs bring them out of reach for those at the lower end of society or with limited resources. This highlights the core issue: On one hand, patents promote innovation; on the other hand, they restrict people's access to medicine in states where this need is most significant.[1]

Compulsory licensing is a way of exclusivity; the government has the right to grant third-party permission to produce and sell a patented medicine in circumstances that the patent holder is reluctant to do so. This provision under what has been referred to as "Section 84 of the Indian Patents Act" has emerged as a useful weapon in health care access litigation, where high costs of drugs are at the heart of a health crisis. As they cut the patent holder's monopoly, compulsory licensing provides competition that is usually translated to affordability and availability. The leading case about the grant of permission in appropriate cases is *Natco Pharma Ltd. v. Bayer Corporation*[2] here, the Indian Patent Office awarded Natco Pharma a compulsory license to manufacture Bayer's patented cancer remedy Nexavar on account of its high costs. This fact served as the basis for the decision of the expert to mention that the inability of the patent holder to make a drug available at reasonable prices may lead to the granting of a compulsory license.

Therefore, this paper aims to critically analyze the impact of compulsory licensing under the Indian patent regime in the removal of barriers that patents pose to access to indispensable products such as essential medicines. Its purpose is to discuss compulsory licensing in the context of state legal

[1] P. Narayanan, *Patent Law* 185 (Eastern Law House, Kolkata, 4th edn., 2023).
[2] (2012) 50 PTC 356 (Bom).

regulation in India and to study the activities of the judiciary in applying this mechanism. Through exploring key case laws and statutes, this paper aims to answer questions central to the issue: This paper aims to answer the question of how compulsory licensing operates in the Indian patent regime. What are the conditions necessary for its use, and to what extent has it ensured medicines' availability? Further, the paper examines whether India's strategy complies with international protocols, especially the TRIPS Agreement to which India is a member.

The topic of this paper is general enough to provide exposure to the legislative provisions regarding compulsory licensing, the judgments made in this aspect, and the comparative outlook from international jurisdictions. It also answers the issue regarding the limitation of compulsory licensing in India: hostility from multi-national pharmaceutical industries and apprehensions about the effects on inventive space. The subsequent sections will analyze practical and legal issues of imposing compulsory licensing, the international legal basis for CL, and its effects on public health and patent law development in India. In this manner, this paper seeks to advance knowledge of how and the contexts in which compulsory licenses are used as a pivotal tool in regulating patent rights within the public interest of meeting the general healthcare needs of the populace.

The Concept of Compulsory Licensing

A significant aspect of patent law is compulsory licensing, a tool that allows government authorities to control granting permission to other subjects of patent rights to manufacture products based on patented inventions or use the patented processes. This legal instrument is very important where the safety of the public and emergencies in the country call for the provision of expensive but unavailable drugs. In India, the general provision of compulsory licensing is rooted in Section 84 of the Patents Act, 1970." even though it spells down detailed standards for issuing obligatory licenses. Under this provision, any person may, after the expiration of three years from the date of the grant of the patent, apply to the Controller of Patents for the grant of a compulsory license on the following grounds where the invention is not being used in the territory of India and the invention is not available to the public on reasonable terms. [3]

The framework for procuring the compulsory license in India is dispatched, starting with applying to the Controller of Patents, then a comprehensive examination of obtaining the grounds prescribed in 'Section 84'. If the license application is granted, it is done subject to certain conditions, and these factors have regard to the amount of royalty that the patent holder is to be charged. A good example of this mechanism at work is marked in the *Natco Pharma Ltd. v. Bayer Corporation*[4] here, Natco was awarded India's first compulsory license to manufacture a generic version of Sorafenib, which is a drug needed for treating kidney and liver cancer. The court found that Bayer made the drug unreasonably priced to maintain its monopoly and thus did not address the public needs of the people of India. This case gives practical examples of how employing compulsory licensing strengthens the availability of various essential medicines to the public and avoids monopolistic practices that often come with patenting grants in India. The ruling highlighted the delicate equality the Indian Patents Act aims to achieve between owners of patent rights and users of inventions for advancing public health.

Importance in the Context of Public Health

The role of compulsory licensing in public health applications can be seen in no other country than India, where the poverty rate is high and access to healthcare services remains a luxury to many. By requiring that royalties of patented drugs be produced locally at cheaper costs, compulsory licensing makes it possible for patented drugs to be made accessible to people in dire situations. This intervention is particularly useful during moments of health emergencies or pandemics where the usage of some drugs may go up and patent rights may cause hitches in drug availability, as was demonstrated in the COVID-19 calamity. [5]

For developing nations, compulsory licensing under the "Patents Act, of 1970" is a crossroad between promoting innovation and ensuring public welfare at the same time. The Doha declaration on the TRIPS agreement and public health supported TRIPS' flexibility in adopting compulsory licensing measures in the face of public health problems that supported Indians' policy of cheap essential medicines. Compulsory licensing is not only required to make availability an economic reality in India but is mandated by constitutional and legal rights that the state owes to any of its citizens to protect their right to life as enshrined in Article 21 of the Constitution of India which guarantees 'Right to Health'. In *Bandhua Mukti Morcha v. Union of India*[6], the Supreme Court reemphasized the linkage between the right to health and the right to life holding that being a limb of right to life implied an obligation on the state to do everything to ensure the heath safety of the people.

Furthermore, compulsory licensing policy guarantees to ensure that basic medicines, including those under patent monopoly, are available in the course of emergencies and diseases that primarily affect the poor. This approach has enabled Indian manufacturers of generic drugs to fill the market with cheap copies of pricey cures at home and across the globe, hence earning the country the title "pharmacy of the developing world." The implications of this policy outlined extend the role of compulsory licensing in redressing health disparities, as well as provide evidence of India's immeasurable commitment to public health concerns without compromising the foundational tenets of patent law.

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[3] Pratima Narayan, *EBC Learning Course on IPR: Mod 3 - Law of Patents* 90 (Eastern Book Company, 2022).

[4] (2012) 50 PTC 356 (Bom).

[5] Colin Birss, Tim Austen, and Stuart Baran, *Terrell on the Law of Patents* 197 (Sweet and Maxwell, London, 19th edn., 2022.).

[6] [1984] 3 SCC 161.

Legal Framework of Compulsory Licensing in India

The legal rationale for compulsory licenses in India is in the Indian Patent Act, of 1970. Compulsory licensing in the framework of Indian patent legislation is an important tool aimed at the protection of public interests together with ensuring the availability of affordable and sufficient patented drugs. It enables the government to issue licenses to a third party or a generic manufacturer to produce patented drugs against the wishes of the patent owner. It is, however, practiced, albeit and contested by the pharmaceutical patent holders, respected as a just and fair policy that does not violate India's constitutional provision on the provisions of public health and its transient agreement with the TRIPS agreement. It contains elaborate provisions of officially authorized compulsory licenses with peculiar concern for public interest, and, therefore, India has emerged as the global debate over the protection of patents versus the availability of affordable essential medicines. [7]

The Indian Patent Act, 1970—Key Provisions

The Indian Patents Act 1970 also lays a special thrust on the public interest through provisions enhancing mandatory licensing under specific circumstances. Section 84 of the Act itself is equally important, as this section provides the conditions under which a compulsory license may be issued. As provided by "Section 84(1)" of the Act, any person desiring to do so may apply for a compulsory license, three years after a patent has been granted, but under the following conditions: These bases for this application include a situation where the reasonable needs of the public about the patented invention have not been met, the patented invention is not available to the public at a reasonable price, or the patented invention is not being practiced in the territory of India. This provision allows a country to control the exercise of patent rights in a manner that will not be prejudicial to the public interest, especially in accessing essential medicines.

"Section 92" of the Act supplements the above discussion by providing for compulsory licenses for licensees in situations of national emergency, extreme urgency, or in the case of public non-commercial use. While in the case of the general process provided under Section 84, an interested party has to apply for the license, under Section 92, the government itself can step in and facilitate the availability of medicines in the face of public health emergencies. This section was particularly brought to attention in the year 2012, when India issued the first 'compulsory license' to Natco Pharma to manufacture a generic version of Bayer's patented cancer drug, Nexavar, because of its high cost. This was approved by the Intellectual Property Appellate Board and the Supreme Court of India and has set up India to protect public health rights above corporate gains, which was on par with the objective of the Patent Act to ensure affordable healthcare. [8]

Role of the Controller of Patents

The Controller of Patents is central to compulsory licensing in India as the authority to grant compulsory licenses if the circumstances laid down in the Statute exist. The controller's duties in this regard are twofold: on the one hand, to make sure that the patent regimes are properly protected, and, on the other hand, to make sure that the public effectively has access to those basic medicines. Under Section 84, it lies with the Controller to revise the applications for compulsory licenses based on the grounds specified under the Act. This involves determining whether or not the reasonable needs of the public about the patented invention have been fulfilled, whether or not the patented drug is affordable, and whether or not adequate efforts have been made to work the patent in India. Nonetheless, the decision-making of the controller is also prompted by equity owing to the likely health implication on the generality of the public.

Furthermore, under what has been labelled as "Section 92', the controller may compulsorily grant a license to the applicant where a national emergency or circumstances of extreme urgency exist. In this case, those powers granted to the controller are exercised in a balanced consideration of interests. For instance, in *Natco Pharma Ltd. v. Bayer Corporation*[9], was given primarily on the evaluation of the price offered, availability of the drug, and the patentee's failure to meet the demand in the country adequately. The intervention of the Controller was required at this juncture to reduce the cost of the drug to statistically nearly Rs. 8800 for thirty days from the cost of approx. Rs. 2.8 lakhs and therefore serves the purpose of compulsory licensing to address the need for health care per se.

Criteria for Granting a Compulsory License

The conditions specified in Section 84 of the Indian Patent Act 1970 for the compulsory licensing include non-working of a patent for its exploitation for any lapse of 3 years from the date of grant or inclusion in the Indian Patent register, the essential nature of the patented product for the satisfaction of reasonable requirements of the public, and the ability of the owner of the patent to work the patented invention within India within reasonable terms of royalty. The other factor is cost since the patent holder is under pressure to make his invention available at cheap prices to the population. Were the patented drug to be priced out of the reach of a large population, a compulsory license could be obtained. This principle formed the basis of *Natco*

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[7] Sumeet Malik, *Patent Law Manual* 190 (Eastern Book Company, Lucknow, 2nd edn., 2014).

[8] Mathew Thomas, *Patent Prosecution: Practice and Procedure* 165 (Eastern Book Company, Lucknow, 1st edn., 2019).

[9] (2012) 50 PTC 356 (Bom).

Pharma Ltd. v. Bayer Corporation[10], where the actual cost to the patients was exorbitant and they could not afford the expensive Neptune by Natco Cancer drugs that led the compulsory license to be granted issuance.

The idea of reasonable requirements of the public also requires that patented drugs must be supplied in sufficient quantities to meet demand within a given nation. When a patent holder does not guarantee adequate availability, it creates the necessary circumstances for applications for compulsory licensing. This is achieved by the Patent Act to ensure that the means for developing virtues are not monopolized and that once this is done, the availability of the same is denied to other contenders, and the prices skyrocket, putting public health in harm's way. In his treatment of this section, the preoccupation has informed the protraction of capacity that a patent holder may output for the public by asking whether the production capacity meets the needs of society; this was provided in *"F. Hoffmann-La Roche Ltd. v. Cipla Ltd."*[11]

Last but not least is the 'working' requirement, which means that a patented invention should be used or made in India. It is made to guarantee that patents are not only kept for monopolistic objectives but are utilized to benefit the citizens of the place. The Controller, as evidenced in the *Natco Pharma Ltd. v. Bayer Corporation*[12] case, this principle has been interpreted very strictly with a focus on local manufacturing as a way to spur the local economy and ease drug availability. In circumstances where the patent owners simply import drugs but have not made investments in setting up manufacturing companies or marketing networks in India, a compulsory license acts as a balancing measure in creating healthy competition that must go a long way to benefit patients and consumers.

Judicial Approach to Compulsory Licensing

The Indian judiciary has intervened in the operation of optional licensing under the Indian Patent Act to address the conflict between patent ownership and the availability of patented drugs in the country. This judicial approach is also sensitive to the interpretative process with a view to the social realities of India and its people and their specific need for inexpensive healthcare. I have reviewed several cases decided by the Indian courts, and while protecting patents, their owners, and exclusive rights, the courts have suggested that a creator and owner of a product cannot be allowed to control the destiny of a nation, especially where human lives are at stake. Analysing key decisions and developments within Indian legal precedents helps understand the legal approach to compulsory licensing, reference to which gets stronger, primarily after high-profile cases touching the legal domains, health, and social justice of society.

Landmark Case Study: Natco Pharma Ltd. v. Bayer Corporation

Compulsory licensing got its roots in India with the verdict of *Natco Pharma Ltd. v. Bayer Corporation*[13], a prestigious case wherein India provided the first compulsory licensing of patented pharmaceutical products. The Bayer Corporation had a patent for Sorafenib Tosylate, known trading as Nexavar, used in the treatment of advanced-stage renal and liver cancer. By costing nearly Rs. 2,80,000 per month, the drug was not available and affordable for most of the Indian population suffering from cancer as they didn't have access to this essential medicine. Natco Pharma Ltd., India's generic pharmaceuticals firm, requested a Section 84 license from the Controller of Patents for the Indian because the patent holder from the UK failed to supply the consolidated demand at an affordable price and consistently supply adequate quantities of the drug in the territory.

Natco Strings Limited finally succeeded in getting the application granted by the Controller of Patents, an epoch-making development in the history of Indian patent law. The ruling, later upheld by the Intellectual Property Appellate Board and the Supreme Court of India, rested on three essential grounds as outlined in "Section 84": the inability to meet reasonable needs of the public, the unaffordable price of Nexavar, and the absence of adequate local manufacturing or working of the patented drug in India. The court said that Bayer had not made Nexavar reasonably available in India because it sold very few units of the drug and charged a very high price for it. Also, Bayer's attempt to argue that they had complied with the "working" requirement by importing the patented invention was dismissed by the Controller because he wanted to clarify that to make these essential medicines available, they needed to be produced locally. This decision was not only in Favor of Natco Pharma but also in Favor of one of the major vigorous steps made by India to strengthen its position regarding the question of the priority of public health over exclusive patent rights.

The effects from this case of were rather felt internationally; many countries regarded India as a provider of affordable healthcare for nations in the developing world. As a result of this forced license, the judiciary was emphatic in saying that patent exclusivity did not allow the public access to cheap products such as lifesaving drugs. Judiciary interpretative flexibility was seen in this case when the patent law was bent to fit the social justice call for the availability of health care services. As a result of this decision, the price of the generic version of Nexavar dramatically came down to affordable levels for a much larger potential market. This leading judgment discussed an area of law over which there have been increasing global debates about compulsory licensing of patents and stressed that there are ways to justify the restriction of IP rights where these rights are inconsistent with a larger public interest—a rationale that bolsters further the premise of compulsory licensing found within India's patent laws. [14],

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[10] (2012) 50 PTC 356 (Bom).
[11] [2015] SCC OnLine Bom 1882.
[12] (2012) 50 PTC 356 (Bom).
[13] (2012) 50 PTC 356 (Bom).
[14] N.S. Gopalakrishnan and T.G. Agitha, *Principles of Intellectual Property* 230 (Eastern Book Company, Lucknow, 2nd edn., 2014).

Other Judicial Interpretations and Trends

In addition to the Bayer case, even other Indian courts have given vital interpretations on the provisions relating to compulsory licensing under the Indian Patent Act and have been creating laws that have focused on the welfare of the public. Jurisprudence has inclined towards supporting the use of compulsory licenses based on the argument that inventors ought to produce a sufficient volume of patented products for use in fulfilling public needs, especially for lifesaving drugs. For instance, in *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.*[15], while hearing the case in Bombay High Court has specified that the public cannot be deprived of cheap drugs. Although this case did not concern compulsory licensing as such it revealed the readiness of the judiciary to weigh the general interest of public health if massive amounts are at stake in patented drug.

The following review is focused on the trends to reveal that the current judicial system in India is sensitive in protecting the rights of the patent holders, and on the other hand, it is also sensitive towards life-threatening diseases in cases where the patented drug is needed. Indian courts have also interpreted the "working" requirement in patent law as overly restrictive and requiring that patent owners must not simply bring in patented goods but must make them available domestically, including for critical medicines. This concept of 'working' has had some drastic consequences, especially when the Controller of Patents or the judiciary demanded that the patentee provide domestic work by putting up manufacturing facilities to ensure an adequate availability of the patented product in India. [16]

Further, Indian courts have always emphasized the intention of the Patent Act to deal with the public's reasonable necessities; the Act has seemed in light of its legislative intent to uphold public health. Included decisions, such as *Bayer Corporation v. Union of India*[17] and *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.*[18], show that Indian courts are willing to consider existing and prospective patent laws, side by side with social justice principles as well as public interest. In *Intellectual Property Attorneys Association v. Union of India*[19], this approach was further endorsed by the judiciary expressly providing an affirmation to India of its continued devotion to shaping its patent laws to respond to social and public welfare goals. This approach is consonant with India's obligations under the TRIPS Agreement and the country's right under this agreement to resort to compulsory licensing for public health causes. Interestingly and importantly, under Article 31 of the TRIPS agreement, member countries are permitted to grant compulsory licenses where the owner of the new product patent has not made the patented technology available to the public at reasonable terms or where the technology is necessary for the national emergency or the exercise of government non-commercial use. India's judiciary has therefore been assertive of its nettles commitment to leverage this international provision to improve domestic public health performance through its support of compulsory licensing under the Indian Patent Act.

From these judicial decisions, this will seek to decipher how Indian courts do not acknowledge the patent rights as infinite; rather, they are given under the premise of fulfilling a wider general interest. Such an approach is in synergy with the implication, to some extent, that patents while awarding market exclusivity are imbued with the responsibility of satisfying public needs and not just monopolistic ones. Their shift is indicative of a latent legal ideology that has respect for public health, especially when measured against private rights to patented drugs. Thus, maintaining a public interest perspective, Indian courts insist on the feasibility of accessible healthcare and further develop a judicial theory of compulsory licensing essential for critical patent legislation.

Comparative International Perspective

The use of compulsory licenses in the patent law of India takes its works under the broad spectrum of the TRIPS Agreement, which is an international treaty currently governed by the WTO that gives minimum standards concerning various forms of IP regulation. The TRIPS agreement plays a crucial role in determining India's policy on future compulsory licensing by explaining how member states can provide such licenses in specific circumstances, mainly in the social interest. Article 31 of TRIPS provides flexibility to its member country for the grant of a compulsory license for patents on its necessities in its approach, additionally to some procedural regulation, i.e., negotiation with the patent holder and fair remuneration. The provision from the TRIPS agreement, however, was further elaborated by the 2001 Doha declaration on TRIPS and Public Health, saying that members have the right to accord compulsory licensing to protect health and, in particular, to promote the latter for all. This international framework not only establishes India's domestic policies but also provides India with global legitimacy when engaging in practices such as issuing a compulsory license to the cancer drug Nexavar in *Natco Pharma Ltd. v. Bayer Corporation*[20]. India was able to afford access to essential medicines devoid of trade repercussions, thereby strengthening the congruity between the Indian national agenda and global intellectual property standards while invoking provisions of TRIPS.

Although the TRIPS Agreement places some degree of obligation on members, it is also a fact that these provisions leave a lot of room for nations to implement these provisions to best fit public health goals. This flexibility has been particularly useful for India, primarily because it is among the world's largest manufacturers and exporters of affordable generic drugs to the developing world. The Doha Declaration has guided India, and other developing countries to continue to issue compulsory licenses without violating any of the TRIP'S obligations, particularly where public health concerns are of paramount importance. India's compulsory licensing regime under 'Sections 84 and 92' of the Indian Patent Act is therefore both

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[15] (2015) SCC OnLine Bom 1882.

[16] Harshita Mathur, "Compulsory Licensing under Section 92A: Issues and Concerns", *13 Journal of Intellectual Property Rights* 464 (2008).

[17] Writ Petition No.1323 of 2013.

[18] RFA(OS) 92/2012 And RFA(OS) 103/2012.

[19] 2014 SCC OnLine Del 1912.

[20] (2012) 50 PTC 356 (Bom).

compliant with TRIPS but also positioned to advance Indian health care objectives. The compliance with TRIPS is an affirmation of its loyalty to patent protection, but at the same time, a clear stand on its people's right to retain access to essential medicine not hindered by patents. [21]

Examples from Developing Nations

Besides India, other developing countries also employ similar strategies, such as compulsory licensing, to fulfil public health needs while coming across the rigorousness of international intellectual property law. Compulsory licensing, for instance, has been particularly busy in Brazil with a concerning issue of high costs of HIV/AIDS treatment. The first one occurred in 2007 when the government of Brazil launched a compulsory license for Efaveirenz, an antiretroviral drug used in the treatment of HIV, after negotiations with the holder of the patent about the drug. Brazil's efforts to import the cheaper generic versions of the drug showed how compulsory licensing enables breaches of patents to promote the public health needs of the population. Thailand, for instance, has granted several compulsory licenses for HIV/AIDS treatments and, later, for cardiovascular disease products. Such a measure is in tune with Thailand's approach to compulsory licensing while perceiving the act as more than a somewhat urgent relief step but as a proactive pull towards more affordable prices for essential drugs. In doing so, Thailand has maintained the principle of health over patents, especially where access to affordable medicines is concerned.

Just like in India, the experience of South Africa has also been equally instructive, though it has had its problems in the face of international condemnation and pressure from multinational pharmaceutical industries. Late in the 1990s, the South African government changed the Medicines Act, enabling compulsory licensing for cheap access to crucial medicines—in particular, ARVs during the AIDS pandemic. This action received lots of opposition from cross-sections of international pharmaceutical firms and trading partners, culminating in a legal and diplomatic battle that raised awareness of the access to medicines problem internationally. Yet, the support of the public both nationally and internationally culminated in the provision of a resolution that was favourable to the constitution of South Africa's right to protect the health of its people. As this paper has shown, the general application of compulsory licensing can be a useful policy instrument in the enhancement of public health in South Africa and other developing countries, even though it may not be immune to undue pressure from the global pharmaceutical industry. [22]

Compulsory Licensing as a Tool for Access to Essential Medicines

The necessity for compulsory licenses to reduce the large access gap of essential medicines within India is widely recognized due to millions still being unable to afford treatment. India has been making progress in this field, although the problem of the high cost of patented drugs makes it difficult for the majority of people to access the treatment they need. This access gap is especially felt in fatal illnesses such as cancer and HIV/AIDS, for which patent medicines are out of reach for the common citizen. To ensure the poor and low-middle-income groups in the country can access patented medicines, compulsory licensing under the Indian Patent Act, of 1970 provides a legal tool whereby the government can grant licenses to third parties, including generically driven manufacturers, to manufacture low-priced generic medicines containing the protected inventions. This provision again gives the right to the state to act in the interests of the health of the public, and thus India reaffirms its stand for the right to health care as provided in the Constitution of India. Although compulsory licensing is widely accepted as the last option, in the areas where patent owners do not address public needs in terms of price and availability, it becomes inevitable.

The Access Gap in India

Essential medicines' accessibility in India continues to reveal a huge divide, and this is the case in millions of people's lives every year. This is one of the most valid reasons why patented drugs are expensive, and this has been compounded by the fact that research and development costs enormously. But to a major chunk of India's population, especially the rural dwellers and the low-income earners, these prices are very expensive, making essential drugs out of their reach. This was evident in the case of the cancer drug Sorafenib Tosylate, marketed as Nexavar, whose approximate cost of around Rs. 2.8 lakh per month was inclusive enough to make target customers in India shy away from it. As a result, rare and expensive threshold drugs are scarce, thus patients suffer severe consequences if they cannot afford good drugs. The intended purpose of the Indian government through compulsory licensing is to inherently minimize these disparities to ensure that essential products such as drugs are provided to those who require them most. The scarcity of cheap medicines also shows that health facilities are still not well developed within the country; huge dependence on private medical facilities makes the cost of the treatments unbearable to many citizens. This access gap is why we require mechanisms such as compulsory licensing that alleviate the impact of expensive drug costs on health. [23]

Impact of Compulsory Licensing on Accessibility and Affordability

The effects of compulsory licensing on medicine access and price in India have been exemplary, especially in enhancing the stock of essential medicines. The judgment of compulsory license for Nexavar in the case of *Natco Pharma Ltd. v. Bayer Corporation*[24]: The power of compulsory

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[21] Abhinav Gupta and Aqa Raza, "Patent Law and Compulsory Licensing: Indian Perspective", 29 *Journal of Intellectual Property Rights* 5 (2024).

[22] V. Parthasarthi, "Analysis of Compulsory Licensing in India and its Perceived Impact During the Covid Era", 4 GLS Law *Journal 21 (2022).*

[23] Rajeshkumar Acharya and Girishchandra Tanna, "Compulsory Licensing of Patents in India", 8 *Journal of the Licensing Executives Society* 4 (2019)

[24] (2012) 50 PTC 356 (Bom).

licenses for serving public health has created hope for copyright owners in India through a new legal milestone in Indian patent law. The case not only drastically reduced the price of Nexavar to one-third of the actual price but also extended access to the drug to hundreds of thousands of Indian cancer patients who could have never afforded it before. Compulsory licensing compels generic manufacturers to produce patented drugs at low prices, which affects monopolistic control and the entrance of rigorous price competition since the healthcare market is characterized by highly priced patented drugs. Besides, the compulsory licensing structure has furthered the development of generic pharmaceutical manufacturing companies in India and boosted India's capability to serve its health care requirements. The objective of compulsory licensing, in addition to the benefits it offers at the bedside, is to promote equitable access to treatment for life-threatening diseases. Furthermore, compulsory licensing is consistent with the regulations allowing the production of cheap drugs in India and consolidates India's position as an important supplier of cheap generics, thereby underlining the country's commitment to the right to health.

Potential Limitations and Challenges

Still, compulsory licensing has come with some constraints that are observed to affect the development of the pharmaceutical industry and the economy at large. One is the conflict of interest when assessing the validity of this forsaken commercially viable public healthcare on the one hand and, on the other, the protection of the patent rights of the multinational company shareholders. These companies cite that by forcing them to license the product, their capacity to get returns on their investment, primarily research and development costs, is hampered, especially when the product is one of the new drugs on the market. As a result, compulsory licensing is generally met with caution by the pharmaceutical industry because it tends to assume that similar actions may discourage the development of new drugs. This issue is well founded, especially for developing nations that depend on FDI and international collaborations as key approaches to building the pharmaceutical sector. Via Section 84 of the Indian Patent Act, the government could compulsorily license a patented drug, but if this measure is too often, pharmaceutical companies around the world may refrain from introducing new drugs to the Indian market, preventing them from accessing the latest in medical technology.

Moreover, compulsory licensing itself is not an easy process because it requires a wide evaluation and approval by the Controller of Patents, and when the owners of patents try to defend their rights, this process can sometimes take months or years because of litigation. The challenges associated with compulsory licensing are well illustrated in *Bayer Corporation v. Union of India*[25], where Bayer Corporation challenged the constitutional of the grant of compulsory license issued to Natco Pharma. This case attracted international interest owing to some of the legal issues raised on patent legislation, especially in relation to public health. It is also known that such legal disagreements not only prolong the decision-making process of granting compulsory licenses but also engross a lot of time and energy and generate a lot of ambiguities within the healthcare and pharmaceutical industries and trade. Furthermore, compulsory licensing does look into the aspect of cost but does not exhaustively correct the question of quality and distribution of the much-needed drugs, which equally play a vital role in ensuring that the developed and democratically accessible drugs get to the targeted patient. These legal prescriptions call for supervision to ensure that generics produced under compulsory licenses meet appropriate quality standards because poor quality is sacrificial to the fundamental quality of the compulsory license regime in India. [26]

Ethical and Economic Implications

The legislation on compulsory licensing, as it applies to Indian patent law, provides for several sociopolitical ethical questions, and economic questions as relates to the rights of patent holders and the health of the public. The provision of compulsory licensing in India, which stems from Section 84 of the Patents Act, of 1970, laid down that availability of affordable medicines to the people is a legal right. This framework would permit intervention with patent rights in certain circumstances where the public health and welfare of the country require it, making the state bear a special responsibility in the provision of these vital products. From the standpoint of human rights, compulsory licensing has some basis for it because it acknowledges a fundamental prohibition that says that post-orthogonal rights, the right to health, cannot be limited by expensive patents as far as essential medications are concerned. The introduction of new patented medicines, especially those for chronic or life-threatening illnesses, has usually come with a high price, making such medicines unaffordable to a large proportion of the population in low- and middle-income countries, including India. Compulsory licensing is therefore revealed to be an unavoidable measurement that can help break prevailing anti-competitive pricing mechanisms that constrain fair distribution of needed health care.

The precedent case *Bayer Corporation v. Union of India*[27] enshrines an extremely important example of how India has implemented compulsory licensing solely in the interest of public health. Here, Bayer set expensive prices for its patented drug Nexavar, appropriately used for the treatment of kidney and liver cancer. In this case, the Indian government was able to provide compulsory licensing for the same while allowing the cheap local generic manufacturers to produce the drug and subsequently sell it to a broader populace at an affordable price, the latter being the goal of access to lifesaving drugs. This case makes our ethical analysis valid that any patent rights should not deprive the other basic human rights, such as the right to life and health. The above-mentioned arguments on compulsory licensing are also backed up by the ethics of the Gota Declaration on the TRIPS Agreement and Public Health, 2001, which acknowledges that health issues could take an upper hand over such rights to allow for compulsory

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[25] Writ Petition No.1323 of 2013.

[26] E. Urias and S.V. Ramani, "Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence", 3 *Journal of International Business Policy* 367 (2020).

[27] Writ Petition No.1323 of 2013.

licensing of essential drugs. In essence, through Section 92 of the Patents Act, India submits that the welfare of its people, especially in issues to do with life and death, cannot be dominated by mere business considerations of relatively wealthy multinationals.

Balancing Intellectual Property Rights and Public Health Needs

The ethical issue of addressing both patent protection and public health requirements is a presumed one. Pharmaceutical companies, on the one hand, support patents because they create a temporary monopoly, which enables companies to recover large investments in research and development. These firms argue that if they failed to seek patent protection, they would not get sufficient incentive to take the high risk and high cost of pharmaceutical research. This perspective is however met with a robust rebuttal when placed under the lens of public health, especially concerning a country like India where the availability of patented drugs due to social and economic inequalities that defeat their cost makes most of it financially unattainable. Thus, the Indian patent law embodies this somewhere-in-between attitude in allowing exclusive rights to drug manufacturers under a rather novel provision dubbed "Section 84 of the Patents Act."

In addition, compulsory licensing brings into play the moral legal-analytical perspective of legal justice, whereby the state's moral responsibility comes into play every time the corporate giants infringe on public utility. That is why the concept is closer to the principles of international law, for example, Article 12 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR), which states the right of every person to attain the highest standard of physical and mental health possible. In this regard, states are under legal compulsion to work towards preventing, diagnosing, and managing epidemic and endemic diseases, including through access to medicines (which may require walking over patents). The position of compulsory licensing in the management of these rights assumes even more significance in the context of the country's peculiar circumstances, where the government's agenda to deliver affordable health care to its citizens is best pronounced. A balance, according to legal scholars, is not simply a matter of an economic policy but is a manifestation of the freedom with which India continues to maintain the right to life guaranteed under "Article 21 of the Indian Constitution." It is therefore considered a justifiable intervention, which aligns with India's constitutional and legal requirements as well as obligations towards the protection of public health, even if this may cause disturbance in the monopoly rights of the corporate bodies.[28]

Economic Impact on the Pharmaceutical Industry

Cost considerations of compulsory licensing to the industry are normally a sensitive issue since it involves issues of revenues and exclusivity. By granting a compulsory license, the market share of the patented drug is liable to lose highly. This is because when generics are on the market, they tend to swamp the market, charging prices far below those of the patented drugs. These erosions of pricing capabilities can discourage multinationals from launching new drugs into markets that are deemed to have a high risk of compulsory licensing. Some critics say that this deterrent impact may slow the number of new, more innovative drugs in India, which harm patients. The economic consequences include the facts revealed in the case of *Natco Pharma Ltd. v. Bayer Corporation*[29], wherein a compulsory license was made to formulate the generic version of the cancer drug Nexavar. After the grant of this license, Bayer raised a concern over the potential of bearing negative financial costs in case it lost its monopoly of the drug, which could deter other investors in the Indian pharma sector.

But as for the role of compulsory licensing, enemies have forgotten that its negative economic effects should be considered in the context of public welfare on the market. Thus, compulsory licensing of the key drugs encourages competitive local production in developing countries in part by licensing local manufacturers the production of the essential drugs at a cheaper price to consumers, especially those in low-income brackets. Moreover, compulsory licensing also helps boost the growth of the domestic generic drug industry, an important factor needed to improve drug access and cost. India, the world's largest supplier of low-cost copy-version patented drugs, takes advantage of its well-established laws that occasionally issue compulsory licenses to cater to local health requirements. The policy approach that can be derived from the Indian government consequently endeavours to accommodate the public health need for affordable medicines and the pharmaceuticals' incentives to innovate protected by strong patents, with the idea that patent rights are not inviolable and may be trumped in the public interest.

Moreover, there are various economic effects, starting from the direct losses for the owners of patents up to the availability of affordable prices and essential medications in other developing countries for compulsory license impact global pricing policies. Other nations with similar socioeconomic demographics that require such measures often use India's legal provisions to borrow from in enacting their compulsory licensing policies. It forms a structure within which pharmaceutical companies have now to align their structures to the reality that the prices they set for drugs, especially where patents would otherwise lock entire regions out from access to these products, largely depend on the health needs of the local populace. For this reason, as much as one can argue that the economic effects have affected the pharmaceutical business, this is done in the light of spearheading equity in access to health commodities within countries where revenue is often a hindrance to the procurement of medications.[30]

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[28] Joe Chen, "Balancing Intellectual Property Rights and Public Health to Cope with the COVID-19 Pandemic", *available at:* https://scholarship.shu.edu/cgi/viewcontent.cgi?article=2197&context=student_scholarship (last visited on October 12, 2024).

[29] (2012) 50 PTC 356 (Bom).

[30] Qunaj L, Kaltenboeck A, Bach PB, "Compulsory Licensing of Pharmaceuticals in High-Income Countries: A Comparative Analysis", 100 *Milbank Quarterly* 284 (2022).

Conclusion

Compulsory licensing in India patent legislation appears to be a supreme tool to facilitate the IP system to operate in consonance with the health of the population. India, in the "Patents Act 1970, 'has formulated a much-considered system in which although the rights accorded to patents are honoured nonetheless, the institution of patents is not sacred or unquestionable when public interest is involved. This balance is well illustrated in a case like *Natco Pharma Ltd. v. Bayer Corporation*[31], as it portrays how independent judiciary forces on the producers of highly-priced essential medicine recognize public health as against monopolization of pharmaceutical products. The same is achieved through legal provisions such as "Section 84" and "Section 92" to make patented medicine inaccessible to defined poor groups in India. This approach is consonant with India's constitutional obligation under 'Article 21' to preserve life and health, thereby declaring that the rights accorded to owners of intellectual property shall not deny people access to such drugs.

The ethical implication relevant to compulsory license is best understood by appreciating the human right to health. This approach not only meets the requirements of India's domestic legislation but also fully complies with international legal norms, including the Doha Declaration on the TRIPS Agreement and Public Health, which allow countries to protect their public health in patent legislation. Allowing compulsory licenses, India underscores its intellectual devotion to fair distribution of healthcare goods and services, as high prices and limited availability of drugs affect the health of vast segments of the population. The compulsory licensing policy of a government therefore pays consideration to the concept of public interest, thus allowing access to essential drugs without discounting the tangibility of the property rights system so much.

From an economic point of view, although compulsory licensing can be problematic in many ways for pharmaceutical companies because it will reduce their ability to make high profits and act as a disincentive for research and development, it will at the same time spur competition in the domestic market. This competition is welcome for the Indian generic drug industry and improves access to affordable medicines both locally and internationally. The greater significance of this development is a robust, competitive pharma industry that can respond to pressures on the international system to deliver cheap medical solutions. As the "pharmacy of the developing world', India benefits from this development. It can be concluded that compulsory licensing has not only improved the domestic healthcare system in India but has also solidified the country's position as a global champion for health equity.

In conclusion, compulsory licensing in India is a constructive example that demonstrates that a legal and ethical position that uses the principles of patent law for the public benefit is achievable. The current system under the "Patents Act, 1970" practiced in India fosters affordable access to essential medicines but does not cause total erosion of the intellectual property of the pharmaceutical industry. Shows that compulsory licensing, which focuses on healthcare equity in India, can be used as a template for other developing countries struggling to cope with such challenges in light of patent law. Finally, India's experience with compulsory licensing indeed sends a whole-some message that the legal framework can transform to encourage innovation and sustain the cardinal human right to health for all.

Suggestion

Compulsory licensing under the Indian patent law plays a key role in ensuring the chances of providing affordable medicines. Nevertheless, there are areas in this framework that could be strengthened to increase the effect on the health of the population and to consider questions that different interested participants pointed out. To further strengthen and balance compulsory licensing with innovation incentives, the following measures are suggested:

- Reducing bureaucratic procedures that allow the making of a compulsory license will also take its toll. It will make the system more efficient and quickly respond to the emergencies related to the epidemic disease spread, presumably with some clear criteria and definite timeframes for the application assessment.
- Effective laws that provide more explicit rules for royalty payments would contribute to a fair relationship between owners of patents and licensees. Efficient royalty calculation mechanisms are effective in preventing confounding issues, making the process less probable to end in a court case.
- Discussions with domestic and international players involved in pharmaceutical businesses through consultation on aspects such as price policies and access to essential products could easily reduce rivalry. Compulsory licenses may, however, be replaced by voluntary licenses, which would be supported by incentives so as to give access to more drugs than a compulsory license may force.
- Another strategy to improve the local production capacities of manufacturers in India would be providing them with incentives that include tax exemption or soft credit. This would guarantee the availability of licensed medication within the country to advance towards the idea of producing most if not all, drugs locally.
- India could have used other flexibilities under TRIPS in support of its public health interests much more effectively. Better compliance with the TRIPS regulations as well as some clear and more explicit procedures for providing and issuing compulsory licenses during and about

[31] (2012) 50 PTC 356 (Bom).

health crises or when addressing non-commercial governmental uses will strengthen the Indian legal standing as well as, at the same time, help to preserve the governmental and public health interests.

- Supervision of compulsory license productions is crucial to ensuring the quality of drugs produced within the Drugs and Pharmaceutical Sciences. Further action to control the distribution network can help to get rid of unequal distribution and guarantee that all authorized medicines can be distributed in all segments of the population to the utmost level.
- Encouraging pharmaceutical firms to invest more in diseases affecting low-income groups like tuberculosis and malaria could help stimulate growth in an area that generally receives little funding. It could be achieved through PPPs, grants, or R&D tax credits.
- India could undertake the creation of a model framework of compulsory licensing for the rest of the developing world based on its experience. This would construct a global pattern that resulted in the provision of inexpensive access to medicines across the world and, at the precise time, cement India's stance on healthcare equity.

By adopting these suggested changes, it would be possible to make the framework for compulsory licensing in the Indian context more efficient, fair, and on par with the country's health needs and obligations under both the national and international policies governing the protection of intellectual property rights. Such would eventually improve public health and facilitate the notion within the paradigm of sustainable procurement of essential medicines.