THE ROLE OF COMPULSORY LICENSING IN ENSURING ACCESS TO ESSENTIAL MEDICINES IN INDIA

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ABSTRACT

In India, compulsory licensing is critical for maintaining access to crucial medicines, particularly during public health crises. It is a legal procedure that permits the government to approve the manufacture of generic versions of patented pharmaceuticals without the patent holder's permission. This is especially crucial in countries like India, where a large proportion of the population cannot afford costly proprietary pharmaceuticals. Therefore, this paper focus on compulsory licensing and its role in access to essential medicines in India.

Keywords- Compulsory Licensing, Essential Medicines, Patents, Public health, Pharmaceuticals etc.

I. Explanation of compulsory licensing

Compulsory licensing empowers the government to intervene and issue licenses for patent use without the owner's consent, enabling broader access to essential innovations. In India, compulsory licensing provisions are outlined in the Indian Patents Act 2005, which allows for the issuance of compulsory licenses in certain situations, such as public health emergencies or national interest. The strength of intellectual property rights regimes plays a significant role in determining whether compulsory licensing is necessary, with weaker regimes often attracting compulsory licensing interventions. (Yugank) (Reto and Kung-Chung)

Importance of access to essential medicines in India

Compulsory licensing is an effective mechanism to lower drug prices and improve access to affordable healthcare in India. A systematic review found a mean price reduction between 66.2 and 73.9% for 24 compulsory licensing events with available price data. Compulsory licensing

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can also be used as an instrument of industrial policy to create local manufacturing capacity. However, there are limitations to compulsory licensing, and alternative approaches like price negotiations and voluntary licensing agreements may sometimes be more effective. There is evidence supporting the impact of compulsory licenses on drug affordability, but more long-term studies are required to evaluate the effects on access to medications. (Shyama) Compulsory licensing is crucial for ensuring access to vital medications in India's healthcare system.

II. Overview of Compulsory Licensing

Compulsory licensing is when a nation allows a third party to practice a patented invention without the patent owner's permission, requiring that third party to pay a government-specified royalty to the patent owner. The scope and duration of compulsory licenses must align with the purpose for which the license is issued, ensuring that the terms of the license address the harm to be alleviated and are proportionate to that harm. National authorities have broad discretion in setting the scope of the licenses, but they must be carefully crafted to achieve the specific purpose for which they are issued. Compulsory licensing is a tool used to ensure access to medicines and address public policy concerns. (Madieha) (Bagley)

The key criteria for obtaining compulsory licensing include negotiating Article 31, allowing compulsory licensing for easier access to patented technology, and addressing concerns of developed and developing countries regarding compulsory licenses. (deus.) (Harris).

III. Legal framework for compulsory licensing in India

The implementation of compulsory licensing in India is intricately tied to the robustness of intellectual property rights (IPR) frameworks, shaping the landscape of access to essential medicines. Weak property rights regimes like India tend to attract compulsory licensing, while strong property rights regimes like Canada favour voluntary licensing. India's history of weak IP rights has led to a high level of piracy and infringement. Compulsory licensing can impact domestic innovation and pharmaceutical companies' incentives to invest in life-saving drugs. The frequency of compulsory licenses in a country can indicate the strength of its IP regime. India's shift towards TRIPS in the mid-1990s led to an increase in R&D efforts. Compulsory licensing may not always align with public interest concerns, and alternative solutions may be needed. (Yugank)

Recent amendments or developments in the legal framework for compulsory licensing in India are not explicitly mentioned in the provided sources. However, there is a discussion on the challenges and potential benefits of compulsory licensing in India, especially in the context of access to essential medicines like ARV drugs. The Indian government's decision to issue compulsory licenses for broader access to drugs globally, including ARV drugs, is seen as a positive step. There is a need for amending the Indian Patent Act to simplify administrative procedures and ensure reasonable royalty rates for compulsory licenses. Compulsory licensing has been used in other countries, and it may be a promising means of facilitating access to drugs in India. (Jonathan)(Randall)

Examples of compulsory licensing cases in the pharmaceutical industry

Compulsory licensing in the pharmaceutical industry in India has been a topic of discussion due to weak patent rights and the need for access to affordable medicines. India shifted from a process-based patent regime to a product-based one in compliance with the TRIPS Agreement, allowing for compulsory licensing. The first case of compulsory licensing in Canada involved the export of an antiviral medication to Rwanda. Compulsory licensing can impact domestic innovation and pharmaceutical companies' incentives to invest in certain drugs. India's IP regime has evolved over time with the adoption of TRIPS and product patents. Compulsory licensing remains a viable option for developing countries like India to ensure access to medicines while balancing international commitments. (Yugank)(Meghna)

IV. Advantages of Compulsory Licensing in India

1. **Lowering the cost of essential medicines**

   Compulsory licensing has the potential to drive down the prices of crucial medicines by enabling local generic companies to manufacture and distribute them at reduced costs compared to original manufacturers, fostering affordability and accessibility. This process should be done through competitive tendering to ensure the lowest feasible price is charged. However, the risk of permitting compulsory licensing is that it may lead to countries using it to avoid contributing to R&D costs. Under the TRIPS agreement, compulsory licensing is permitted during national emergencies, such as combating widespread diseases like HIV/AIDS, tuberculosis, and malaria, underscoring its vital role in crisis response and healthcare provision. The case against compulsory licensing is stronger if licensees do not have a significant production cost

advantage over originator firms. Labour costs are a small part of production costs, and originator firms may have additional costs related to safety and monitoring. (Patricia and Adrian)

2. **Promoting competition in the pharmaceutical industry**

Compulsory licensing in the pharmaceutical industry promotes competition by allowing governments to issue licenses for patents that are not being adequately used, leading to decreased prices and increased access to essential medicines. The Doha Declaration confirmed that compulsory licensing is a right of member countries of the WTO and is intended to improve access to needed medicines, especially in low- and middle-income countries. Countries with mature patent systems, like China and Germany, have integrated compulsory licensing into their patent systems to ensure access to essential medicines. Compulsory licensing can also be used to export pharmaceuticals to countries lacking production capacity, providing a legal basis for generic suppliers to manufacture and export medicines. (Son)

3. **Improving access to life-saving drugs for marginalized populations**

In regions with feeble property rights systems such as India, compulsory licensing serves as a valuable recourse when voluntary licensing negotiations prove unproductive, ensuring continued access to essential medications. It can increase innovation by about 20% and ensure access to medicines at affordable prices. However, It may weaken incentives for pharmaceutical companies to invest in life-saving drugs for diseases prevalent in countries with strong compulsory licensing. The frequency of compulsory licenses in a nation can indicate the strength of its IP regime. India shifted to a product-based patent regime after joining TRIPS in the mid-1990s, leading to increased R&D efforts. Compulsory licensing is a viable option for developing countries like India to ensure access to medicines while complying with international commitments."(Yugank)(Meghna)

- Availability: Compulsory licensing increases the availability of essential medicines (Ooms and Hanefeld). It does this by bypassing the patent owner's legal monopoly, allowing more manufacturers to produce the drug (Reinsch et al.)

- Public Health: Compulsory licensing is particularly important in the context of public health emergencies, such as pandemics. In such situations, it can sensure that life-saving drugs are widely available (Reinsch et al.)
- Long-term Impact: Compulsory licensing can have a long-term impact on access to medicines. When issued for local production, it cans help track the prices of licensed drugs over time and assess the long -term impact on access to medicines. (Shyam).
- Future Relevance: The importance of compulsory licenses may grow in the future due to the loss of generic drugs sources after introduction of pharmaceutical product patents in India, the continuing high prevalence of epidemics, such as HIV/AIDS, in developing countries and the increase in noncommunicable diseases in these nations (rice).

V. Challenges and Criticisms of Compulsory Licensing

Countries face challenges in accessing essential medicines through compulsory licensing due to legal, institutional, and political pressures. Developing countries in Sub-Saharan Africa struggle to obtain compulsory licenses for affordable medicines and distribute them according to need. While some countries, like Brazil and India, have successfully implemented national measures on compulsory licenses, the complex provisions of free trade agreements (FTAs) hinder access to affordable medicines. A regional system for compulsory licensing could potentially overcome these challenges by providing a common legal infrastructure for the procurement and distribution of essential medicines. The expansion of patents under TRIPS has raised controversy over compulsory licensing, but evidence shows that countries have used it for public interest purposes. The EU recognizes compulsory licensing as crucial for public health protection in Least Developed Countries (LDCs). The WHO emphasizes the importance of essential medicines being available in adequate amounts, at affordable prices, and with assured quality to ensure access at a national level. (Deus.) (Ajzental)

Concerns about potential negative impact on innovation

Compulsory licensing can have potential negative impacts on innovation. Here are some concerns:

1. Reduced Incentives for Research and Development (R&D): Critics argue that compulsory licensing may discourage pharmaceutical companies from investing in new

drugs as they deprived of the benefit of monopoly rights. This could lead to less incentive and fewer resources to invest in new innovative, lifesaving medicines (Reinsch et al.)

2. Potential Impact on Prices and Public Access: Compulsory licensing's impact on innovation is theoretically ambiguous. It may encourage innovation by increasing competition or discourage innovation by reducing expected returns to R&D (Nicola & Petra).
3. Adverse Effects on Innovation: American Law traditionally is hostile to the idea of compelling use or licensing of patent rights because of the adverse effects such schemes may have on innovation. ("Compulsory Licensing to Regulated Licensing: Effects on the Conflict Between Innovation and Access in the Pharmaceutical Industry on JSTOR")
4. Erosion of Intellectual Property Rights: The use of competition law as an external balancing tool has gradually eroded the protection conferred by Intellectual Property Rights (IPR), creating a potentially detrimental effect on competition and innovation. (Ezrachi and Maggiolino)
5. Lack of awareness and understanding of compulsory licensing among stakeholders: Developing nations may be dissuaded from using compulsory licenses due to these legal barriers. (Ni)

VI. Case Study: Compulsory Licensing of Cancer Drug in India

Background of the case

India issued a compulsory license over Bayer's anticancer drug Naxaver (Sorafenib) to the generic company Natco Pharma Ltd. The license requires Natco to pay Bayer a 6% royalty on its net sales and sell the drug for a significantly lower price than Bayer. The decision was made due to the drug's unaffordability and limited usage in India. This move was criticized by the United States, but it was seen as beneficial for providing cheaper generic medicines in developing countries." (Deepak and Arun)(Van and Van)

Impact of compulsory licensing on access to the cancer drug

Compulsory licensing is an effective mechanism for reducing drug prices and increasing availability, with a mean price reduction between 66.2% and 73.9% in available data. However, it is unclear if it is the most effective alternative for making patented medicines more

affordable. Compulsory licensing can also be used as an industrial policy to create local manufacturing capacity. The impact of TRIPS on compulsory licensing and access to medicines in the future is uncertain, with challenges in global collaboration and funding. More research is needed to fully understand the impact of compulsory licensing on drug prices and access to medicines. (Shyama)

The Indian Union Health Ministry has recommended three cancer drugs- dasatinib, trastuzumab, and ixabepilone- for compulsory licensing. (Three cancer drugs recommended for compulsory license in India- Pharmacoeconomics and Outcomes News"). The recent announcement of the Indian Government for granting Compulsory Licenses (CL) for three more patented drugs has been outrageously cheered by health activists and patients across the country (Gupta).

Lessons learned from the case for future implementation of compulsory licensing in India

The TRIPS flexibilities, including compulsory licensing, have benefited developing countries like India by allowing them to import medicines when they lack manufacturing capacities. The legal challenges faced by the Indian pharmaceutical industry post-implementation of the product patent regime in 2005 have brought attention to issues of compatibility with the TRIPS Agreement." (Van and Van) (Han Kamini) (Kogan).

VII. Conclusion

In conclusion, the case of compulsory licensing in India has shown the importance of balancing intellectual property rights with public health needs. Moving forward, it is crucial for policymakers to continue exploring ways to ensure access to affordable medicines while upholding international trade agreements.

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