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A STUDY INTO COMPULSORY LICENSING IN THE PHARMACEUTICAL LANDSCAPE AND THE CONSEQUENCES OF GRANTING COMPULSORY LICENSE

AUTHORED BY - LUBNA FRIYAL

Abstract:

Compulsory licensing is the government's legal mechanism to permit a third person to use, produce, or sell previously patented products or processes without the patent owner's consent or plans to use the protected invention. Compulsory licensing, rooted in prioritising societal needs over exclusive patent rights, dates back to the 1624 UK Statute of Monopolies and gained international recognition in the 1883 Paris Convention. It was integrated into TRIPS in 1995, granting governments the authority to authorise the production and sale of patented products. The consequences encompass intricate impacts on competition, affordability, and innovation incentives. The first compulsory licensing case in India exemplifies the delicate balance required between intellectual property protection and public health. This underscores compulsory licensing challenges, emphasising the imperative for nuanced approaches that align proprietary rights with global health equity. This article thoroughly examines the historical context of compulsory licensing, elucidating its mechanisms and attendant consequences.

Key Words - Patents, Compulsory licensing, TRIPS agreement, patented pharmaceuticals, public health, international agreements, impact.

I. Introduction

Patents provide inventors with an exclusive right to their creation for a limited period, encouraging innovations through financial incentives. However, in pharmaceuticals, the high cost of research and development results in the inflation of drug prices, resulting in limited access to these vital drugs, particularly in developing countries. The challenge of restricted access to patented pharmaceuticals is a significant concern for developing nations. The issue has gained urgency since the World Trade Organization approved the Agreement on Trade-Related Aspects of Intellectual Property Rights. This is particularly true for local pharmaceutical industries in countries like Brazil and India, where the ability to reverse-engineer patented foreign medicines

and distribute them at lower prices in developing markets has been constrained. Post-TRIPS, governments in developing countries have sought ways to enhance consumer access to medications supplied by foreign pharmaceutical companies. One approach involves the imposition of price controls on these medicines. Such price controls are not exclusive to developing nations; even wealthy countries with robust public healthcare systems implement them. However, relying solely on price controls to improve consumer access has drawbacks. Pharmaceutical companies holding patents for certain medicines may opt not to sell their products in markets where these controls are too stringent. When faced with limited or no access to a patented foreign product, a country may opt for compulsory licensing. Compulsory licensing allows the government to intervene when public health is at stake, and let it act as a safeguard.

Compulsory licensing is a legal mechanism that the government uses to permit a third person to use, produce, or sell previously patented products or processes without the patent owner's consent or plans to use the protected invention. This licensing is often employed in pharmaceuticals to address issues related to public health, accessibility, and affordability of essential medicines. It is invoked when public health concerns or other economic or significant interests precede over the patent owner's exclusive rights. It raises complex questions over innovation incentives and strikes a balance between private rights and public health.

II. Historical Background

The concept of compulsory licensing emerged with the societal needs that could not be addressed by the exclusive patent rights granted to the patent owner. The United Kingdom Statute of Monopolies in 1624 ruled out the monopolies that lie with the grant of patents, where it was stated that granting patents should not be 'mischievous to the state'. Compulsory licensing's first official proposal was in the early 19th century during the Paris Convention of 1883. The concept was recognised internationally for the protection of industrial property. The convention laid down the grounds for the member states to cooperate on intellectual property matters and the provisions for compulsory licensing. Subsequently, in the TRIPS agreement under WTO in 1995, compulsory licensing became an obligation for member nations to deal with the public interest and handle non-commercial use and unfair competition. The agreement provides a framework for compulsory licensing and requires the signatories to take measures for public health protection and promote access to medicines. The HIV and AIDS epidemic in the late 20th century and early 21st century highlighted the need for affordable access to life-saving medicines, particularly in developing countries where the cost of patented antiretroviral drugs was a significant barrier. Compulsory

licensing became a tool for specific countries, such as Brazil and South Africa, to produce or import generic versions of these drugs, allowing for broader access to treatment. After the HIV/AIDS crisis, the Doha Declaration of the TRIPS agreement was adopted in 2001 for public health protection. The declaration affirmed the flexibility of TRIPS to permit countries to take appropriate measures to protect public health, including compulsory licenses. It was stated that the TRIPS agreement should not prevent countries from taking necessary steps for public health protection and promoting access to medicine.

III. Granting Compulsory Licenses

The international conventions and agreements all primarily focus on protecting public health by permitting the nations to grant compulsory licenses. The license is given when there is public interest, and vital medications are needed. Patents provide the patent holder the exclusive right to use, produce, sell and market the product or the process for the patent term. However, the patented product or process disables any third party from utilising such product without authorisation. The patent can be used by third parties only if the grant of such right is authorised and the patent owner consents to such use of the patent. However, in the case of compulsory licensing, the patent holder's consent is not required. It grants the government permission to permit a third party to use, produce, or sell the patented subject. The conflict of interest arises between the patent holder and the government, which grants the right to a third party. The reasoning behind this is primarily for the public welfare and the protection of the public health. The government gives other pharmaceutical companies the right to use and produce the drugs of the patented pharmaceuticals under compulsory licensing. Although such a license exists, it is not frequently sought after or granted easily.

IV. The TRIPS Agreement

When TRIPS was ratified in 1995, approximately 100 countries had previously incorporated some form of compulsory licensing into their regulations, each with varying usage requirements. The conditions governing the application of compulsory licensing by WTO members are outlined in Article 31 of TRIPS, explicitly addressing "use without authorisation of the right holder". Among these conditions, significant points include: (a) entities applying for a compulsory license must have been unsuccessful in obtaining consent from the right holder on "reasonable" commercial terms; (b) in the case a compulsory license is granted, the patent holder must receive "adequate remuneration" and (c) the primary purpose of a compulsory license is to fulfil domestic market needs. While not explicitly specifying when a country can issue a compulsory license, TRIPS does

recognise national emergencies, extreme urgency, and anti-competitive practices as potential grounds. The discretion afforded to countries seeking to utilise compulsory licensing concerns pharmaceutical companies and advocates of robust intellectual property rights. Ambiguities persist, such as defining "reasonable commercial terms" and determining what amount of remuneration qualifies as "adequate." Compulsory licensing has often resulted in patent holders receiving relatively low royalty rates. Despite being permitted under TRIPS, developing countries have not frequently employed compulsory licensing. Notably, the mere threat of issuing a compulsory license can influence the behaviour of patent holders to the advantage of developing nations, rendering its actual use unnecessary.

V. Consequences of Compulsory Licensing

The consequences of balancing in the pharmaceutical landscape have multifaceted repercussions. Compulsory licensing introduces a dichotomy in the realm of innovation. It can foster increased competition, potentially lowering the prices of patented medicines and making them more accessible to a broader population. However, pharmaceutical companies express concern that this diminishes the financial incentives for innovation. The scepticism of reduced returns on research and development investments may dissuade companies from pursuing high-risk projects, particularly in areas with limited market potential. In global trade and diplomatic relations, compulsory licensing can empower developing countries to negotiate better prices for essential medicines and address public health crises. However, it may also strain diplomatic relations. The affected pharmaceutical companies, might view these actions as threats to their intellectual property rights. This tension could lead to trade disputes and impact broader economic relationships between nations. The primary objective of compulsory licensing is to enhance access to medicines, especially in developing countries where affordability is a significant barrier. However, issuing and implementing compulsory licenses can be legally complex and administratively burdensome, potentially causing delays in obtaining critical medicines for patients in urgent need. On the one hand, compulsory licensing introduces competition into the market for a specific medication, potentially leading to lower prices and increased availability.

Conversely, the threat of compulsory licensing may discourage pharmaceutical companies from introducing certain drugs to particular markets, limiting treatment options and reducing incentives for developing new medications. While compulsory licensing provides a legal mechanism for countries to address public health needs, the complexity of the process can pose challenges. The legal and administrative burden of issuing compulsory licenses may deter some countries,

particularly those with limited legal and administrative capacities, from effectively utilising this tool. Compulsory licensing is a measure to protect public health and ensure broader access to essential medicines, potentially enhancing a country's reputation. However, concerns about the unpredictability of intellectual property protection and the perceived impact on investor confidence could hinder foreign direct investment in the pharmaceutical and related industries.

VI. The First Case of Compulsory Licensing in India

The compulsory license provisions are given in the Indian Patents Act of 1970. India's first case of granting compulsory license was granted on 9 March 2012 to Hyderabad-based Natco Pharma for Bayer Corporation Nexavar's generic product. The Bayer Corporation v. Union of India case represents a landmark legal battle between intellectual property rights and public health. The case unfolded against the backdrop of the pharmaceutical industry's efforts to protect patented medicines while addressing the imperative of making life-saving drugs more affordable and accessible. The case originated from Bayer's patent application for the anti-cancer drug Nexavar (sorafenib tosylate) filed in India. Bayer sought a patent for Nexavar in India. Still, the Indian Patent Office rejected its application in 2008, citing concerns about the drug's efficacy and the high cost, limiting patient access. In response, Bayer challenged this decision and filed a lawsuit against the Union of India. One pivotal aspect of the case centred on compulsory licensing to enhance access to essential medicines. The Indian government granted Natco Pharma a compulsory license in 2012 to address public health needs. This allowed Natco Pharma to produce and sell a generic version of Nexavar at a significantly lower cost. The decision to issue a compulsory license was grounded in the belief that making the drug more affordable would benefit a more significant segment of the population, especially in the context of a life-threatening illness like cancer. The case ignited a global debate on the responsibilities of pharmaceutical companies in balancing profit motives with humanitarian considerations. While patent protection is crucial for fostering innovation, critics argue that exorbitant drug prices limit access, particularly in developing countries with constrained healthcare budgets. This case exemplifies the role of compulsory licensing as a tool for governments to intervene in the interest of public health. It highlights pharmaceutical companies' challenges in protecting their intellectual property while addressing the urgent need for accessible and affordable medicines. As nations grapple with the delicate balance between proprietary rights and the well-being of their populations, this case provides important insights into the evolving landscape of pharmaceutical regulation and the global pursuit of health equity.

VII. Conclusion

In conclusion, limited access to patented pharmaceuticals is a critical concern for developing nations, exacerbated by high research costs. The nexus of patents, public health, and access to essential medicines presents a nuanced challenge. The TRIPS agreement amplifies the imperative to address limited access to patented pharmaceuticals. Despite TRIPS provisions, developing countries cautiously deploy compulsory licensing as a strategic lever, raising questions about innovation incentives and the delicate balance between private rights and public health. The consequences of compulsory licensing are multifaceted, impacting competition and affordability. The Bayer Corporation v. Union of India case centred on Nexavar exemplifies this delicate balance, offering insights into compulsory licensing challenges. Compulsory licensing significantly benefits developing countries by enabling pharmaceutical companies to produce and sell drugs relatively cheaply. The grant of compulsory licensing against the patent holder can be balanced by implementing comprehensive regulations for the royalty, which results in the counterbalances of the private interest of the patent holder with the public interest. Nations' legislative bodies need to implement comprehensive rules and regulations for granting compulsory licenses. This should focus on both the inventor pharmaceutical companies' perspectives and the companies seeking compulsory licenses, which would ultimately advance the industries parallel to the welfare of public health.

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