BALANCING ACTS: COMPULSORY LICENSING, ACCESS TO MEDICINES, AND THE INTERSECTION OF PUBLIC HEALTH AND INTELLECTUAL PROPERTY LAW

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ABSTRACT

This research paper explores the intricate dynamics surrounding compulsory licensing, a governmental tool allowing the use of patented technology without the patent-holder's consent. It delves into the historical evolution of compulsory licensing, tracing its origins from early legal frameworks to its current manifestations under international agreements like the TRIPS Agreement. The paper examines case studies from India, Brazil, and Thailand, highlighting the diverse motivations, outcomes, and implications of compulsory licensing in different contexts. Furthermore, it discusses the intersection of intellectual property rights and public health policy, emphasizing the need to balance innovation incentives with equitable access to essential medicines. Issues such as the ambiguous language of Article 31 of TRIPS, remuneration for patent holders, and the role of Public-Private Partnerships are analyzed in depth. The paper concludes with insights into balancing human rights with intellectual property rights, proposing strategies like C-TAP, MPP, technology transfer, and innovative financing mechanisms. Overall, this research contributes to a nuanced understanding of compulsory licensing and its broader implications for global health, innovation, and human rights.

Keywords: Compulsory licensing, Access to medicines, Intellectual property law, International agreements, TRIPS Agreement, public health policy.

I. Introduction

A compulsory license is a government authorized non-voluntary license from a patent-holder to a third party. When granted, the third party can use the patented technology without the patent-holder's consent. The third party would nevertheless be required to pay an appropriate remuneration (a royalty) to the patent-holder, and the license would be valid only in the domestic market.[1] This is done to facilitate widespread utilization of the protected right. The granting of such a patent license typically serves one of three purposes: facilitating the large-scale production of patented products (such as pharmaceuticals to treat diseases), addressing antitrust concerns to promote fair competition (for example, among companies), and enabling non-commercial use (such as by the government) in the interest of the general public.

Before a compulsory licence is granted the proposed user must have first attempted unsuccessfully for a reasonable amount of time to obtain a voluntary licence on "reasonable commercial terms."[2] Nevertheless, the requirement of trying for a voluntary licence can be waived if there is "national emergency" or "other circumstances of extreme urgency."[3]Basically, compulsory licences could be granted by developing countries without prior negotiation with the holder of rights to key pharmaceutical patents in the case of a public health crisis of epidemic proportions.[4] However, the use of compulsory licensing shall be authorised "predominately for the supply of the domestic market of the Member authorising such use."[5] This has the practical effect of preventing exports of generic drugs to countries that do not have significant pharmaceutical industries themselves.[6]

Furthermore, the scope and duration of the use of compulsory licensing is "limited to the purpose for which it was authorised" and the authorisation of use can be terminated "if and when the circumstances which led to it cease to exist and are unlikely to recur."[7] Finally, if a compulsory licence is issued, right holders shall be paid "adequate remuneration in the

[1] WTO | intellectual property (TRIPS) - agreement text - Art.31(f) and (h), https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm (last visited Feb 18, 2024).
[2] TRIPS Article 31 (b).
[3] Ibid.
[4] Matthews, WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?, p 77
[5] TRIPS Article 31(f).
[6] Matthews, WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?, p 78
[7] TRIPS Article 31 (g)

circumstances of each case, taking into account the economic value of the authorisation."[8]

II. Historical Evolution of Compulsory Licensing

The historical evolution of compulsory licensing within the framework of intellectual property law is a multifaceted narrative influenced by diverse factors, including technological progress, shifts in global trade dynamics, and imperatives related to public health. Beginning in the late 19th and early 20th centuries, nations began recognizing the dual objectives of encouraging innovation through patent grants while also ensuring access to essential goods and services. As a stipulation, compulsory licensing can be traced back to the UK Statute of Monopolies in 1624, which ruled out monopolies associated with patent, and stated that grants should not be 'mischievous to the state' or hurt trade. However, compulsory licensing only became an official proposal in the early 19th century.[9]

Before the outbreak of World War I, compulsory licensing remained relatively constrained, primarily addressing issues of national security and public interest. However, the accelerating pace of industrialization raised concerns about monopolistic practices and equitable access to critical technologies. The interwar period witnessed a growing emphasis on balancing the rights of patent holders with broader societal needs, leading countries like Germany and the United States to introduce compulsory licensing provisions aimed at curbing patent abuse and fostering competition.

The post-World War II era heralded significant advancements in international intellectual property law, culminating in the establishment of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) by the World Trade Organization (WTO) in 1995. TRIPS represented a pivotal moment, setting minimum standards for intellectual property protection and introducing provisions related to compulsory licensing.

Under TRIPS, member states were granted flexibilities to issue compulsory licenses, particularly in response to public health crises. This departure from previous agreements marked a crucial step in reconciling intellectual property rights with public health imperatives. The Doha Declaration on the TRIPS Agreement and Public Health, adopted in 2001, further underscored the flexibility of TRIPS, providing a legal framework for countries to address health emergencies like HIV/AIDS, tuberculosis, and malaria through compulsory licensing.

[8] TRIPS Article 31 (h)
[9] JOHNS ADRIAN, PIRACY: THE INTELLECTUAL PROPERTY WARS FROM GUTENBERG TO GATES (2009).

The core of the Declaration states that "the TRIPS Agreement should not prevent Members from taking measures to protect public health" and encourages Member Countries to interpret TRIPS in a manner that protects public health and promotes access to medicines for all.

Subsequent years witnessed ongoing debates and developments in compulsory licensing, with various international agreements, regional initiatives, and national legislations shaping the landscape. Recent trends indicate a growing recognition of compulsory licensing's role in promoting access to essential medicines, especially in low- and middle-income countries. Initiatives like the Medicines Patent Pool[10] and voluntary licensing agreements complement compulsory licensing efforts, reflecting a nuanced approach to addressing global health challenges.

III. Human Rights and Access to Medicines

The right to health holds a prominent position in international human rights law (IHRL), standing alongside other fundamental rights such as the right to life and the right to freedom. This entitlement to health is enshrined in various international agreements and documents. The initial mention of a 'right to health' dates back to the Preamble of the Constitution of the World Health Organization (WHO), established in 1946. In this preamble, it is declared:

"[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."[11]

The 1948 Universal Declaration of Human Rights (UDHR), adopted unanimously by the United Nations General Assembly, asserts in Article 25:

"[e]veryone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services."[12]

The 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR) enhances the United Nations' stance on the right to health. Article 12 of the Covenant articulates a

[10] MPP Home - The Medicines Patent Pool, https://medicinespatentpool.org (last visited Feb 15, 2024).
[11] World Health Organization Constitution 1946, Preamble.
[12] United Nations General Assembly, Universal Declaration of Human Rights, United Nations, 217 (III), 1948, Article 25.

standardized expression of the right to health:

"[t]he States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."[13]

Through these and subsequent international legal instruments referencing them, the right to health has been to some extent formalized in international human rights law. However, in international law, customary practices and adherence significantly influence the normative significance of this right in practical terms. Nonetheless, a substantial majority of countries have ratified at least one treaty containing references to the fundamental components of the right to health, thus indicating their agreement to be bound by it. Consequently, there seems to be ample evidence supporting the recognition of the right to health as an integral component of the international human rights law framework.

Access to medicines represents a critical aspect wherein the human right to health is distinctly implicated, as the inability to obtain certain drugs directly impacts both individual and population health. Furthermore, some state constitutions explicitly address access to medicines, and it may also be considered as part of the 'minimum core' obligations that governments must fulfil for all their citizens. While it has been contended that certain definitions of the 'minimum core' obligations may be overly expansive, as they encompass various other duties, access to medicines consistently emerges as a pivotal requirement for achieving the highest standard of attainable health. Moreover, acknowledging governments' obligation to facilitate access to medicines does not necessitate an expansive interpretation of the right to health, as the connection between medicines and their effectiveness in addressing ailments is readily apparent and less abstract compared to other potential obligations.

IV. Legal Frameworks and International Agreements

Legal frameworks and international agreements are pivotal in shaping the practice of compulsory licensing, especially concerning intellectual property rights. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) stands out as a cornerstone international treaty in this domain. Administered by the World Trade Organization (WTO), TRIPS was adopted in 1994 and became effective in 1995. It establishes minimum standards

[13] United Nations General Assembly, International Covenant on Economic, Social and Cultural Rights, International Covenant on Civil and Political Rights and Optional Protocol to the International Covenant on Civil and Political Rights, 16 December 1966, A/RES/2200, Article 12(1).

for the protection of intellectual property, encompassing various rights, including patents. Notably, Article 31 of the TRIPS Agreement specifically addresses provisions related to compulsory licensing.

Article 31 delineates the conditions under which member states can grant compulsory licenses.[14] It stipulates that such licenses may primarily be issued for domestic use and delineates procedural requirements, including the necessity to attempt negotiation with the patent holder before resorting to compulsory licensing.

TRIPS incorporates flexibilities that permit member states to enact measures safeguarding public health interests. Particularly relevant to compulsory licensing for pharmaceuticals, these flexibilities enable countries to ensure access to essential medicines, especially when patent holders fail to offer them at affordable prices.

The Doha Declaration on TRIPS and Public Health, issued in 2001, reaffirmed TRIPS' flexibility in safeguarding public health. The declaration explicitly acknowledged member states' right to implement measures protecting public health and facilitating access to medicines, including resorting to compulsory licensing. This acknowledgment was especially significant in addressing public health emergencies such as HIV/AIDS, tuberculosis, and malaria.

Article 5A (2) of Paris Convention for the Protection of Industrial Property states that each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.[15]

In addition to TRIPS and the Doha Declaration, subsequent agreements and declarations have further clarified and reinforced the role of compulsory licensing in promoting public health. Regional agreements like the ASEAN Framework Agreement on Access to Medicines, along with national legislations, have been enacted by individual countries to align with international obligations and implement compulsory licensing provisions.

[14] WTO | intellectual property (TRIPS) - agreement text - standards, https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm (last visited Feb 15, 2024).
[15] WIPO Lex, https://www.wipo.int/wipolex/en/text/288514#P123_15283 (last visited Feb 18, 2024).

V. Intellectual Property Rights and Public Health Policy

The interplay between intellectual property rights (IPRs) and public health policy, particularly through mechanisms like compulsory licensing, presents a multifaceted challenge. While IPRs incentivize innovation, they can also restrict access to essential medicines, especially in low-resource settings. Compulsory licensing serves as a vital tool to address this imbalance by allowing governments to authorize generic production of patented drugs. This approach balances innovation incentives with public health imperatives, fostering competition to reduce drug prices and expand access. However, it also raises concerns about potential disincentives for pharmaceutical innovation and the need to navigate legal and economic complexities. Achieving policy coherence requires careful consideration of ethical, legal, and economic implications to ensure equitable access to medicines while promoting innovation in the pharmaceutical sector.

VI. Case Studies in Compulsory Licensing

India

In 2012, India issued its inaugural compulsory license for Bayer's cancer drug, Nexavar (Sorafenib)[16], marking a pivotal moment in global pharmaceutical regulation. The decision stemmed from mounting concerns over Nexavar's prohibitively high price, which rendered the medication inaccessible to a significant portion of the population. By invoking compulsory licensing, India aimed to address the affordability barriers hindering patient access to this life-saving treatment.

The issuance of the compulsory license enabled generic manufacturers to produce and distribute Sorafenib at substantially lower prices, thus expanding accessibility to a broader demographic. It was also decided to pay Bayer 6% of net sales as royalty. This intervention exemplified a proactive approach to promoting equitable access to essential medicines, particularly within the context of critical health conditions such as cancer. However, the Nexavar case also triggered extensive discourse surrounding the intricate balance between safeguarding patent rights and advancing public health imperatives.

[16] India's first compulsory licence granted to Natco for Bayer's cancer drug, BUSINESSLINE (2012), https://www.thehindubusinessline.com/companies/indias-first-compulsory-licence-granted-to-natco-for-bayers-cancer-drug/article64263394.ece (last visited Feb 18, 2024).

While compulsory licensing proved effective in mitigating affordability constraints, it prompted reflections on its broader implications. Key among these considerations were inquiries into the potential impact of compulsory licensing on pharmaceutical innovation and investment incentives. The Nexavar case thus catalyzed nuanced discussions on the complex interplay between intellectual property protection, public health priorities, and the socio-economic dimensions of healthcare accessibility.

Brazil

In 2007, Brazil issued a compulsory license for the antiretroviral drug Efavirenz, a critical component in HIV/AIDS treatment.[17] This decision was motivated by Brazil's commitment to reducing the exorbitant costs associated with HIV/AIDS treatment and improving access to affordable medication for its population. By invoking compulsory licensing, Brazil sought to address the financial barriers preventing many individuals from accessing life-saving treatment for HIV/AIDS.

The compulsory license facilitated the production of generic versions of Efavirenz, thereby fostering competition in the pharmaceutical market and driving down prices. As a result, Brazil's public health system experienced significant cost savings while simultaneously expanding access to essential medication for those in need. This outcome underscored the efficacy of compulsory licensing as a tool for promoting equitable access to life-saving medications, particularly in the face of global public health crises such as the HIV/AIDS pandemic.

Moreover, the case of Brazil's compulsory licensing of Efavirenz shed light on the tensions inherent between pharmaceutical companies' profit motives and public health priorities. While compulsory licensing served to prioritize public health interests by ensuring access to affordable medication, it also posed challenges to the profit margins of pharmaceutical companies holding patent rights. This tension underscored the need for a delicate balance between protecting intellectual property rights and addressing the urgent healthcare needs of vulnerable populations.

Thailand

Between 2006 and 2008, Thailand made headlines by issuing compulsory licenses for several

[17] William C. V. Rodrigues & Orenzio Soler, *[Compulsory licensing of efavirenz in Brazil in 2007: contextualization].*, 26 REV PANAM SALUD PUBLICA 553 (2009).

patented drugs used in the treatment of HIV/AIDS and heart disease.[18] This bold move was driven by the country's commitment to addressing pressing public health challenges, namely increasing access to essential medications and mitigating healthcare costs. By invoking compulsory licensing, Thailand aimed to break the monopolistic hold of pharmaceutical companies and make life-saving treatments more affordable and accessible to its population.

The outcomes of Thailand's compulsory licensing initiatives were significant. The licenses facilitated the production of generic versions of patented drugs, resulting in substantial cost reductions for both the government and patients. This, in turn, led to expanded access to treatment for individuals suffering from HIV/AIDS and heart disease, improving overall healthcare outcomes in the country. Thailand's proactive approach to addressing public health needs through compulsory licensing served as a powerful example of governmental intervention aimed at prioritizing the well-being of its citizens.

However, the case also sparked debates and raised concerns about the broader implications of compulsory licensing. It prompted discussions about its potential impact on pharmaceutical innovation, as well as its implications for international trade relations. Some argued that compulsory licensing could deter investment in research and development by pharmaceutical companies, potentially stifling innovation in the long run. Additionally, it led to tensions between Thailand and certain countries and pharmaceutical companies, highlighting the complex interplay between intellectual property rights, public health priorities, and global trade dynamics.

VII. Issues with Compulsory Licensing

Thailand's decision to issue a compulsory license for a heart disease medication under Article 13(b)'s 'public non-commercial use' provision instead of the 'national emergency' provision signifies an expansion of the spectrum regarding the severity of health issues that can justify overriding a patent. As 'public non-commercial use' is not explicitly defined in the TRIPS Agreement, Thailand's action exemplifies how this provision broadens the criteria for compulsory licensing. However, this development is concerning for pharmaceutical companies, as it poses a significant threat of substantial financial losses. The majority of money spent by pharmaceutical companies in research and development goes to drugs that are

[18] Jakkrit Kuanpoth, *Compulsory Licences: Law and Practice in Thailand*, 22 COMPULSORY LICENSING 61 (2014).

marketable in the developed world. While infectious diseases are more prevalent in developing nations, chronic diseases are found everywhere in the world. With the possibility of any patented drug being subject to compulsory licensing under the lenient language of the TRIPS Agreement, pharmaceutical companies face the risk of being unable to recover investments from their flagship drugs. This expanded scope of compulsory licenses is likely to prompt pharmaceutical companies to reduce investments across all drugs due to uncertainties regarding their profitability. Thailand's actions also promoted trade retaliation by the United States.

Brazil's approach, akin to that of Thailand, underscores how national governments can manipulate the flexible language of the TRIPS Agreement to their advantage. On May 4, 2007, Brazil opted to issue a compulsory license for Efavirenz, an HIV/AIDS medication owned by Merck. Despite Merck's offer to reduce the drug's price by 30%, Brazil justified its decision under the 'public non-commercial use' provision of the TRIPS Agreement, thus circumventing the need for negotiations with Merck. Brazil argued that importing a generic version of Efavirenz from India would save its anti-AIDS program $30 million annually.[19] Consequently, Brazil acquired the generic import for $0.45 per pill, significantly lower than Merck's offer of $1.11 per pill. Merck criticized Brazil's actions, asserting that they set a detrimental precedent by potentially encouraging widespread use of compulsory licensing. Brazil, classified as an upper-middle-income country with a robust economy, has a relatively low HIV/AIDS infection rate and an established AIDS program. Consequently, it is argued that Brazil has the financial means to afford HIV/AIDS medications compared to countries facing more severe epidemics with fewer resources. Merck further contended that Brazil's actions could deter future foreign investment, leading to a reduction in the introduction of new drugs into the country. This issuance of a compulsory license has tarnished Brazil's reputation as an industrialized nation striving to attract foreign investment.

VIII. Balancing Public Health with Intellectual Property Rights

The issuance of licenses is hindering competition and compromising both the affordability and availability of new medications. For example, PCV13, a current multi-strain pneumonia vaccine exclusively owned by Pfizer, commands a high price, making it inaccessible to many due to its monopoly status. In India, where over 100,000 infant deaths from pneumonia occur annually, the majority of which are preventable, Pfizer earns billions in revenue from vaccine

[19] Brazil bypasses patent on Merck AIDS drug | Reuters, https://www.reuters.com/article/idUSN04351721/ (last visited Feb 18, 2024).

sales. This monopoly on innovation has also impeded efforts in combating COVID-19. The rapid deployment of additional testing kits and N95 masks has created barriers for new manufacturers seeking to produce clinical-grade facial coverings on a large scale.

However, private entities invest substantial amounts of money in the research and development of medicines and vaccines. Many of these research endeavours do not yield successful outcomes, resulting in financial losses. Therefore, they rely on generating revenue from successful projects to offset losses incurred from unsuccessful research ventures. Thus, it is essential to strike a balance between Intellectual Property Rights and compulsory licensing.

Balancing human rights with (IPRs) necessitates a multifaceted approach that encompasses various strategies and mechanisms. Initiatives such as the COVID-19 Technology Access Pool (C-TAP) and the Medicines Patent Pool (MPP) exemplify collaborative efforts to ensure equitable access to essential goods and services while respecting IPR. However, ambiguities in Article 31 (b) of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement require clarification to prevent disputes and trade sanctions. Clear guidelines are essential to ensure that compulsory licensing provisions are applied judiciously to prevent misuse by national governments, striking a balance between public health needs and IPR protection. Additionally, establishing a fair remuneration formula for patent holders in cases of compulsory licensing is crucial to incentivize innovation while providing adequate compensation.

Public-Private Partnerships for medicine research foster collaboration between governments, pharmaceutical companies, and research institutions, promoting innovation and addressing public health challenges. Furthermore, technology transfer initiatives facilitate the sharing of knowledge and expertise to enhance local manufacturing capacity and access to essential medicines. Innovative financing mechanisms like vaccine bonds mobilize resources for global health initiatives, ensuring sustainable funding for vaccine research and access programs. By integrating these tools and initiatives, governments, international organizations, and stakeholders can effectively balance human rights with IPR, promoting equitable access to medicines and technologies while fostering innovation and development.