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# EXPLORING COMPULSORY LICENSING IN THE BIOTECHNOLOGY SECTOR: BALANCING INNOVATION, ACCESS, AND ETHICAL CONSIDERATIONS AND ITS ALIGNMENT WITH THE BROADER PRINCIPLES OF THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH WITH RESPECT TO HIV/AIDS

AUTHORED BY - KEERTHI NARENDRAN

**ABSTRACT:**

*The use of compulsory licensing to manage public health emergencies is at the forefront of current discussions as the relationship between intellectual property rights (IPR) and public health continues to drive worldwide policy debates. The Doha Declaration on TRIPS and Public Health played a crucial role in influencing the discourse, and this research paper explores the complex interplay between these subjects. Compulsory licensing, a mechanism entrenched within international trade agreements such as the Trade-Related Aspects of Intellectual Property Rights (TRIPS), offers a complex approach to reconciling IPR protection and the imperative of ensuring timely access to essential medicines. Nevertheless, this mechanism is not immune to potential loopholes and challenges that may impact its effectiveness. The paper scrutinises these potential pitfalls, including the scope, duration, and criteria for issuing compulsory licenses and the broader implications of trade tensions and diplomatic relations. The Doha Declaration on TRIPS and Public Health is central to the analysis, a pivotal turning point in the evolution of global IPR discourse. This landmark declaration acknowledges the primacy of public health interests and facilitates flexibility in implementing TRIPS provisions to safeguard access to medicines for all. The study emphasises the Doha Declaration's crucial influence in defining the moral and legal parameters of forced licensing, particularly in responding to public health emergencies. Through a comprehensive examination of case studies and policy developments, the paper illuminates the practical application of compulsory licensing and its resonance with the principles espoused in the Doha Declaration. It explores the delicate balance between intellectual property protection and the fundamental human right to health, shedding light on the intricate negotiations and considerations that underscore the decision-making process. Ultimately, this research paper provides a multidimensional understanding of the intricate relationship between compulsory licensing, the Doha Declaration on TRIPS and Public Health, and the broader landscape of intellectual property and global health. By shedding light on the potential loopholes inherent in*

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*compulsory licensing and contextualising its implementation within the framework of the Doha Declaration, the paper contributes to informed policy discourse aimed at fostering innovation, safeguarding public health, and achieving equitable access to essential medicines on a global scale.*

**KEYWORDS:**

Public health, compulsory licensing, Doha declaration, TRIPS

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## INTRODUCTION:

Access to medicines is a highly debated issue in intellectual property. To provide further access would mean the companies have to give the licenses to their patents to help manufacture on a grander scale. Another problem is that of compulsory licensing.

Compulsory licensing is a legal mechanism that allows governments to grant licenses to third parties to produce and sell patented pharmaceuticals without the patent holder's consent. This is typically done in public health emergencies or when the patented drugs are unaffordable or unavailable to a significant portion of the population.

Advocates of compulsory licensing argue that it is a crucial tool for ensuring access to life-saving medicines, particularly in developing countries where the cost of patented drugs can be prohibitively high. They contend that compulsory licensing can help address public health crises by making essential medications more affordable and accessible.

The central debate revolves around whether compulsory licensing negatively affects biotechnological innovation. Critics argue that it may disincentivise companies from investing in research and development if they fear that their patents could be subject to compulsory licensing. This argument suggests that weakening intellectual property protections may hinder the development of innovations.

International trade agreements, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), set guidelines for compulsory licensing. Countries must adhere to these guidelines when issuing compulsory licenses to ensure that they are used for legitimate public health purposes and that patent holders receive adequate compensation.[1]

In this paper, the authors will examine how compulsory licenses will benefit access to life-saving drugs for those affected with HIV/AIDS. Further, they will be analysing the current legislation in India to examine the applicability of compulsory licensing for this purpose.

## HISTORICAL TRENDS IN THE USA AND CANADA:

In the 1960s, the United States frequently used "government use" to import pharmaceuticals, indicating compulsory licensing for pharmaceutical access. On the other hand, Canada employed compulsory licensing for pharmaceutical imports and local production to manage healthcare expenditures. As early as 1923, the Canadian government amended the Patent Act to encourage domestic pharmaceutical manufacturing and market competition through compulsory licensing. By the 1960s, public concerns about high pharmaceutical prices prompted significant

[1]Berman D, *AIDS, Essential Medicines, and Compulsory Licensing.*, 54 J INT ASSOC PHYSICIANS AIDS CARE. 24-5. (1999)

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amendments to the Patent Act, allowing compulsory licensing for the manufacture or import of previously restricted pharmaceuticals. These measures in Canada resulted in increased market competition, with several follow-on drugs entering the pharmaceutical market.

The United States and Canada have historically employed compulsory licensing to address pharmaceutical accessibility, affordability, and competition, reflecting the evolving dynamics of pharmaceutical regulation and healthcare expenditure management.

**THE BENEFICIARIES:**

The debate is particularly between high-income countries and low and middle-income countries (LMICs). The primary argument favouring compulsory licensing is rooted in the need to make essential medicines more affordable and accessible, especially in LMICs, to improve public health outcomes. This approach is aligned with public health and humanitarian principles, as demonstrated by the Doha Declaration, which reaffirmed the right of World Trade Organization (WTO) member countries to issue compulsory licenses for public health reasons. Compulsory licensing is seen as a counterbalance to the robust protection of intellectual property rights, particularly in high-income countries, and is considered necessary to address the potential negative consequences of excessive intellectual property rights on innovation in the pharmaceutical industry. The debate over compulsory licensing revolves around balancing incentivising innovation and ensuring access to essential medicines.

Low- and middle-income countries (LMIC) argued that they needed compulsory for their citizens. The drugs were costly, whereas high-income countries feared that extensive issuance of compulsory licenses could have adverse consequences for the pharmaceutical industry, particularly in terms of its profitability and long-term research and development capabilities. The crux of their argument rested on the notion that limiting the exclusive rights of patent holders through compulsory licensing might discourage innovation by reducing the financial incentives for pharmaceutical companies to invest in research and development efforts. This concern about striking a balance between promoting access to medicines and fostering innovation in the

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pharmaceutical sector has been at the heart of the international debate on intellectual property rights and compulsory licensing.[2]

It must also be considered that branded or patented medicines are often expensive due to the lack of competition. Since only one drug like that is available everywhere, they are unaffordable for many people,[3] especially in low and middle-income countries where the burden of this disease is often the highest.[4]

Further, patients with HIV/AIDS are ostracised in most societies. They have difficulties in obtaining regular medicines. To them, if a specific medicine is available at a lower cost through compulsory licensing, it could save their life.

**WHY SHOULD COMPULSORY LICENSING BE ALLOWED**:

"*Patents motivate companies to engage in capital-intensive and inherently risky biomedical research because of the possibility of charging monopoly prices and reaping high profits. On the other hand, that very monopoly prevents generic manufacturing and affects the price and availability of the finished medicine to consumers. A successful intellectual property regime must strike a balance between creating incentives for innovation and protecting consumers' access to essential medicine*."[5]

This is a standard set of arguments regarding compulsory licensing where the perspectives of society and the manufacturers are given.

There are several reasons why it is beneficial for society. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) allows countries to issue compulsory licenses

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[2] Kyung-Bok Son, *Importance Of The Intellectual Property System In Attempting Compulsory Licensing Of Pharmaceuticals: A Cross-Sectional Analysis*, (June 27, 2019), https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-019-0485-7.

[3] Urias E, Ramani SV. *Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence*. 3(4): J INT BUS POLICY 367–84 2020.

[4] Zaidel, EJ, *Inclusion In The World Health Organization Model List Of Essential Medicines Of Non-Vitamin K Anticoagulants For Treatment Of Non-Valvular Atrial Fibrillation: A Step Towards Reducing The Burden Of Cardiovascular Morbidity And Mortality*, vol. 15, no. 1 *GLOBAL HEART* 52 2020

[5] Linda L. Lee, *Trials and TRIPS-Regulations: Indian Patent Law and Novartis AG v. Union of India* Vol. 23, No. 1, ANNUAL REVIEW OF LAW AND TECHNOLOGY (2008), pp. 281-313

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for public health reasons. Some countries have invoked this provision to produce or import generic versions of patented HIV/AIDS drugs, thereby reducing costs and increasing availability.[6] The debate around compulsory licensing for HIV/AIDS medications is centred on the balance between protecting intellectual property rights and ensuring access to essential medicines. Advocates argue that compulsory licensing is necessary to address public health crises, while opponents contend that it may discourage pharmaceutical innovation.

It provides for Access to Antiretroviral Drugs. Compulsory licensing has been considered to increase access to antiretroviral drugs (ARVs) used to treat HIV/AIDS. Some countries, particularly those with high HIV/AIDS prevalence and limited resources, have explored compulsory licensing to ensure affordable access to these life-saving medications.[7]

Various global initiatives, such as the Medicines Patent Pool, have aimed to facilitate access to essential medicines, including ARVs, through voluntary licensing agreements with pharmaceutical companies. These initiatives seek to strike a balance between ensuring access and protecting intellectual property.[8]

The application of compulsory licensing for HIV/AIDS drugs varies by country and context. It depends on factors like the prevalence of HIV/AIDS, the availability of affordable treatments, and the willingness of pharmaceutical companies to negotiate pricing and licensing agreements.[9] Developing countries argue that their distinct economic, public health, and developmental challenges necessitate flexibilities in intellectual property regimes, particularly regarding compulsory licensing for HIV/AIDS medications. These nations face significant economic disparities and limited resources, making it challenging to afford essential healthcare services and life-saving treatments. In severe public health challenges, such as the high prevalence of HIV/AIDS, ensuring access to affordable medicines takes precedence over protecting intellectual property rights. Developing countries emphasise the need for tailored solutions that safeguard public health and foster innovation. They also utilise TRIPS flexibilities to protect public health and argue that innovation should not hinder access to essential medicines. These countries aim to address their healthcare needs effectively through compulsory licensing while respecting international trade agreements.

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[6] Ndlovu, Precious N. *Has Doha Achieved Its Mandate regarding Access to Essential Medicines? a Developing World's Perspective*. 2009

[7] Wong H. *The case for compulsory licensing during COVID-19*. J GLOB HEALTH. 2020.

[8] Sherer, Mark, *Prognostic Importance of Self-Reported Traits/Problems/Strengths and Environmental Barriers/Facilitators for Predicting Participation Outcomes in Persons With Traumatic Brain Injury: A Systematic Review*. ARCHIVES OF PHYSICAL MEDICINE AND REHABILITATION, 2014,

[9] *Id*

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**WORLD HEALTH ORGANISATION (WHO) AND THE DOHA DECLARATION:**

The WHO has a long recognized the importance of the agreement on Trade related aspects of intellectual property rights (TRIPS) in shaping the global intellectual property landscapes for medicines. [10]TRIPS was a significant concern for the WHO because it required member countries to provide patent protection for Pharmaceuticals.

The WHO played a central role in the DOHA Declaration on the TRIPS Agreement and public health which was adopted in 2001. This declaration affirmed the right of countries to take measures to protect public health and promote access to medicine. It clarified that TRIPS should not prevent countries from taking action to address public health crisis like HIV/AIDS.

The Doha Declaration also explicitly recognized the important of compulsory licensing as one of the flexibilities provided by TRIPS. Compulsory licensing allows a country to grant licensing to generic manufacturers to produce patented medicines without the consent of the patent holder, under certain conditions.

The WHO has consistently advocated for equitable access to essential medicines as a fundamental human right. This includes access to antiretroviral drugs (ARVs) for HIV/AIDS treatment and drugs for hepatitis.[11] The organization has encouraged countries to implement policies that facilitate access to these medicines. The WHO has also provided technical assistance and guidance to countries on how to use TRIPS flexibilities effectively, including compulsory licensing, to enhance access to medicines. This assistance includes legal and technical support to countries in navigating the intellectual property landscape.[12]

[10] Hays, Thomas S. *The Free Movement (or Not) of Trademark Protected Goods in Europe*. Edward Elgar Publishing EBooks, 2008

[11] *Supra* note 9.

[12] WHO, *Access To Affordable Medicines for HIV/AIDS and Hepatitis: The Intellectual Property Rights Context*

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**INDIAN CONTEXT**:

In the case of Novartis AG v Union of India,[13] by providing a detailed background, including the specific patent application and Novartis's legal arguments, along with the reasons for the patent rejection by the Indian authorities. It may delve into the relevant provisions of the Indian patent law, particularly section 3(d) of the Indian Patent Act, which sets strict criteria for patentability, especially in pharmaceutical innovations. The article may discuss legal and ethical considerations regarding intellectual property rights and access to essential medicines. It also discusses the potential long-term ramifications of the Novartis case on patent law in India and its influence on future legal battles and policies related to pharmaceutical patents.

TRIPS flexibilities enable compulsory licensing for public health reasons, while global initiatives, market competition, and partnerships further enhance access to medications. Moreover, public funding for research and development and prioritising public health interests in emergencies contribute to a comprehensive strategy for effectively combating HIV/AIDS while fostering innovation in the pharmaceutical industry.

A similar approach was tested in Kenya, and it was found that the specific legislation was created to make licenses for patents stringent. This would increase the high death toll of HIV/AIDS in Kenya. It is a lesson that India should be aware of during policy discussions.[14]

In India, the utilisation of patents and compulsory licensing holds immense significance in the context of HIV/AIDS. India struggles with a substantial burden of HIV/AIDS, and ensuring access to affordable and effective treatments is a critical public health imperative. The country's diverse population includes economically disadvantaged communities, underscoring the vital importance of medication affordability.

[13] Novartis AG v Union of India (2013) 6 SCC 1

[14] *See* Ben Sihanya, *Patents, Parallel Importation and Compulsory Licensing of HIV/AIDS Drugs: The Experience of Kenya,* WTO

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## CONCLUSION:

To address the challenges posed by HIV/AIDS, involving patents and compulsory licensing is vital. Patents serve as incentives for pharmaceutical innovation, encouraging companies to develop new and improved treatments. However, when patented HIV/AIDS medications become excessively expensive and hinder access, compulsory licensing can be employed judiciously to authorise generic drug production. This facilitates affordability and broadens access to patients. Striking the balance between protecting intellectual property rights and ensuring public health is crucial. India's robust generic pharmaceutical industry has earned it the moniker "Pharmacy of the developing world," primarily due to its compulsory licensing grants that allow it to produce and distribute cost-effective generic versions of HIV/AIDS medication. The Indian Patents Act, featuring provisions like section 3(d) and flexibility in issuing compulsory licenses for public health reasons, provides a legal framework that enables the government to balance intellectual property rights with the urgent need for accessible medicines. Compulsory licensing has been essential in improving access to life-saving HIV/AIDS treatment and setting an international example, contributing to global discussions on patent protection and public health. India's prioritisation of public health and stringent intellectual property enforcement in emergencies underscores its commitment to combat HIV/AIDS effectively.