INTERNATIONAL DEVELOPMENT PLANNING REVIEW
ISSN:1474-6743 | E-ISSN:1478-3401

COMPULSORY LICENSING CONFRONTING GREEN DEVELOPMENT: A ANALYSIS OF THE INTERNATIONAL INTELLECTUAL PROPERTY RIGHTS REGIME

Ms. Shikha Bhardwaj
B.S.L. LL.B. LL.M. PhD Scholar

Dr. Ruchi Lal
Associate Professor Sharda, School of Law.

ABSTRACT

The Doha Declaration emphasises the importance of addressing public health issues in developing and least-developed countries, particularly those related to HIV/AIDS, tuberculosis, malaria, and other epidemics. It also highlights the necessity of the TRIPS agreement for dealing with these problems and stresses that intellectual property protection is crucial for developing new medicines(Abbott, 2005). Additionally, it clarifies that member countries are not prevented from taking necessary action to protect public health under the TRIPS agreement. However, while the Doha Declaration specifically focuses on pharmaceutical products and public health issues related to diseases like HIV/AIDS, there is a need for further clarification regarding its scope.

According to findings from WHO, there is a correlation between environmental factors and public health. The declaration focuses on access to medicine as having a strong immediate impact on public health crisis compared to green technology which aligns more with long-term environmental improvement goals.[1]

Both disease and climate change present real threats to public healthcare systems around the world; however one notable difference lies in their precise use of medicine compared to how loosely defined green technology's potential effect might be on global medical care system sustainability.

This is particularly important for developing countries that may face challenges in accessing affordable medicines and implementing effective healthcare infrastructure. Therefore, prioritizing access to affordable medicines and building strong healthcare systems are key

[1] (The WHO team was led by Nick Drager and included Robert Beaglehole, Debra Lipson, Zafar Mirza and early input from Matthew Hodge. Information on country health-trade cooperation was kindly provided by Suwit Wibulpolprasert of Thailand's Ministry of Health, and Jake Vellinga of Health Canada. Many WHO staff in Geneva headquarters and six regional offices supplied helpful information and comments at various stages of the report's preparation. We especially thank Orvill, n.d)

components in addressing both public health issues and the impacts of climate change. By focusing on the integration of climate change and public health initiatives, countries can work towards developing sustainable strategies that address both issues simultaneously(Abbott, 2011). Furthermore, it is crucial to engage in technology transfer and promote innovation in developing countries to ensure they have the capacity to develop their own therapies for prevalent diseases, rather than relying solely on imported medicines.

While access to medicine is undoubtedly crucial for addressing public health crises, it is important to consider the potential limitations of prioritising pharmaceutical products over other areas of public health concern. The emphasis on intellectual property protection and the development of new medicines may inadvertently overshadow the broader impact of environmental factors on public health.

Research conducted by environmental organisations has shown that addressing environmental issues, such as air and water pollution, deforestation, and climate change, is equally vital for ensuring public health and well-being.(Wellington, 2011) These factors can have immediate and long-term effects on the health of communities, ranging from respiratory illnesses to the spread of infectious diseases. By disregarding the significance of environmental protection and focusing solely on access to medicines, the Doha Declaration may not fully address the holistic needs of public health in developing and least-developed countries.

This research proposes various aspects of domestic nation’s stand on Compulsory licensing and the need to widen the scope to environmental technology as well. While access to affordable medicines and the development of healthcare systems are undeniably important, a comprehensive approach to public health must also consider the environmental factors that contribute to the prevalence of diseases and health challenges in vulnerable communities. Balancing the focus on pharmaceutical products with investments in green technology and environmental sustainability can lead to more comprehensive and impactful public health initiatives in developing countries.

1 Introduction

The introduction of obligatory licensing in the context of development and international

`intellectual property rights has sparked considerable debates and discussions. Nevertheless, some maintain that forced licensing can foster growth by enhancing access to vital technologies and encouraging invention. Still, others have raised concerns about the negative impacts on intellectual property rights and incentives to innovate. In this respect, the research aims at giving the international and Indian perception relating to compulsory licensing regarding development as well as international framework regarding intellectual property rights. For instance, India is a developing country with an influential pharmaceutical industry; thus, it has been a major participant in debates surrounding the concept of compulsory licensing and its effect on development and intellectual property rights. It therefore follows that compulsory licencing may also be useful in solving other global challenges such as environmental-friendly technologies and carbon footprint reduction.2.Compulsory licensing from an Indian perspective stresses the need for a balance between promoting development and shielding intellectual property rights3. (Reichman, 2009)

2. Background

The World Health Organization has recently highlighted the importance of air quality for people living in Asia. The organization expressed concern about the high levels of

[2] Ghosh, S. (2017). IPRS AND ENVIRONMENTALLY SOUND TECHNOLOGIES: POLICY OPTIONS FOR
THE DEVELOPING COUNTRIES. International Journal of Advanced Research, 5(5), 1807–1810.https://doi.org/10.21474/ijar01/4313

[3] Reichman, J.H. (2009). Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options. The Journal of Law, Medicine & Ethics, [online] 37(2), pp.247–263. doi:https://doi.org/10.1111/j.1748-720x.2009.00369.x.

air pollution seen in countries[4] such as India, Pakistan, Iran, and China. It emphasized the significant impact of air pollution on human health. Additionally, emerging nations have become central to manufacturing activities as many developed nations have relocated their production operations. Despite this shift, there is still no consensus on carbon dioxide emissions globally, creating an increasingly worrisome situation that calls for immediate action and collaboration between nations to address the issue of air pollution.

The World Health Organization finds the present uprise in health concerns related to to air pollution concerning. Efforts are ongoing through conferences, protocols, and treaties aimed at addressing the growing need for safer cohabitation within both developing and developed countries. The TRIPS agreement grants these nations the right - under specific conditions - to issue compulsory licenses for patents deemed essential for national and public health purposes. Given this context, it is crucial for policymakers and government officials to prioritize implementing plans to address air pollution as a imminent threat to human life and protect public health.

On the other hand, some argue that the focus on air quality in Asia is overemphasized and fails to consider the efforts made by developing countries to address pollution. They suggest that developed nations should also take responsibility for their historical contributions to global emissions. Additionally, there are concerns about the economic impacts of implementing strict measures to reduce air pollution, especially for emerging economies heavily reliant on manufacturing activities. Critics believe that a standardized may not be suitable and that each nation's unique circumstances must be considered when addressing this issue. Over the past twenty years, numerous debates have cantered around medication availability. While various proposals have been put forward regarding pharmaceutical products transfer to developing countries that are members of the World Trade Organization became more problematic due to TRIPS agreement constraints becoming evident—highlighting a lack not just laxed laws but also expertise knowledge or even necessary equipment needed pharmaceutical production was limited. To surmise, the problem of air pollution is a complex and multidimensional problem that needs global cooperation and policy implementation

[4] Moon, S. (2008). Does TRIPS Art. 66.2 Encourage Technology Transfer to LDCs? An Analysis of Country Submissions to the TRIPS Council . Centre for International Development, Kennedy School of Government, Harvard University, 1999–2007.

Considering these challenges, prioritizing collaborations and investments in research and development, technology transfer, and capacity building is essential to improve access to healthcare beyond just obtaining medicines.

there have been discussions around the world with respect to the potential of issuing a mandatory license for green technology patents to address public health needs. I and there have been emphasis laid on the importance of differentiating between accessing process patents and product patents related to green technologies. However no consensus has been reached in this regard.

The Group of 77 developing nations has argued for relaxing intellectual property rights on

environmentally beneficial technologies as crucial for advancing public health protection. They assert that each member state has the autonomy to define an emergency under Article 31 of the TRIPS agreement, including granting compulsory licenses when necessary.

Issuing a mandatory license for a "green technology patent" is feasible under TRIPS exceptions but also highlights complex challenges in defining health hazards and urgency criteria outlined in Article 31. The limited possibility of transferring green technology to least developed countries presents significant concerns amidst existing environmental issues identified by WHO. Moreover, obstacles exist regarding the transfer of technologies aimed at preventing or reducing air pollution due to current conditions within the TRIPS agreement. These obstacles hinder the transfer of crucial technologies that could effectively address air pollution and protect public health.

The BIC countries (Brazil, India and China) are known for actively using compulsory licensing, making them key players in driving development. This involvement also exposes them to potential disputes that may arise. Since 2008, they have advocated in international politics for the expansion of the TRIPS agreement to include environmental health considerations. This suggests that there is an ongoing effort to modify and expand the TRIPS agreement to better address public health and

environmental concerns, particularly in developing countries[5] (Haakonsson & Richey, 2007). In conclusion, addressing access to healthcare goes beyond simply obtaining medicines

3. International legal framework

The TRIPS agreement, established in 1994, was a significant milestone in the establishment of an international standard for protecting intellectual property. Before 1883, there were no global agreements addressing intellectual property rights. The Paris Convention was the first attempt to address this issue on an international level and while it represented progress in the globalization of IP rights, it still had some notable limitations. Signatory countries were given leeway in developing domestic IP laws, leading to diverse approaches across nations. A major limitation of the Paris Convention was its lack of a standardized definition for what could be patented. With such flexibility provided by the agreement, certain nations chose to keep medicine and/or biotechnology from eligibility for patents under their national legislation.

This diversity in national approaches created disparities and inconsistencies in the defence of (IPR)"intellectual property rights", especially in the field of biotechnology[6](Geertrui van Overwalle, 2008)

In 1967, a significant development occurred in the global alignment of intellectual property rights with the establishment of WIPO as a specialized agency under the UN. This marked an important milestone, though at that stage, WIPO still lacked an operational enforcement mechanism—an aspect also missing in the Paris Convention[7] (Halajian, 2013)

TRIPS agreement originated from deliberations on anti-counterfeiting rules of the "1986 GATT round". US representatives advocated for the inclusion of all forms of

[5] Haakonsson, S. J., & Richey, L. A. (2007). TRIPs and Public Health: The Doha Declaration and Africa.
Development Policy Review, 25(1), 71–90. https://doi.org/10.1111/j.1467-7679.2007.00360.x

[6] Geertrui van Overwalle. (2008). Biotechnology and patents: global standards, European approaches and national accents. *Cambridge University Press EBooks*, 77–108. https://doi.org/10.1017/cbo9780511494581.004

[7] Halajian, D. (2013). Inadequacy of TRIPS & the compulsory license: Why broad compulsory licensing is not a viable solution to the access to medicine problem. *Brooklyn Journal of International Law*, Vol 38:3, p. 1195. http://practicum.brooklaw.edu/sites/default/files/print/pdfs/journals/brooklyn-journal-international-law/volume-%2038/issue-3/bjil_v38iii_5.pdf

IPR in international trade and suggested a negotiation framework titled "Trade Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods" in 1987.

Before TRIPS was established, over 100 countries permitted Compulsory Licensing (CL) vide their national laws[8]. (Bond & Saggi, 2014) Compulsory licensing had already been part of many national laws before being officially codified in TRIPS.[9] (Stern & Charlene , 2007) It occurs when a government or third party uses a patent without consentdue to significant public need, overriding exclusive rights.

Compulsory licenses can also be used to maintain an efficient market economy by preventing abuse and violations of competition law while granting access to dominant patents for important innovations—often justified by considerations related to public health, environmental protection, security, and economic development. Recent developments have allowed for compulsory licenses facilitating medicine exportation to less developed countries lacking manufacturing capacity within their jurisdiction for non-commercial use[10].

In recent years there has been growing recognition toward compulsory licensing's essential

role ensuring access to vital medicines—especially in developing countries.[11]

Compulsory licenses of this kind are deemed to be in accordance with TRIPS Article 31, which permits the issuance of compulsory licenses in specific situations to ensure access to patented subject matter. According to Article 28.1, patent holders have exclusive rights that allow them to prevent others from using, selling, or importing the subject matter without authorization. These exclusive rights enable owners to utilize and enhance their patents and receive compensation through innovation production, licensing agreements, or sales. The purpose of compensation is to incentivize taking risks and making further investments in patent development. Additionally, Article 27.1

[8] Bond, E. W., & Saggi, K. (2014). Compulsory licensing, price controls, and access to patented foreign products. *Journal of Development Economics*, *109*, 217–228. https://doi.org/10.1016/j.jdeveco.2014.04.001

[9] Stern, D., & Charlene , A. (2007). Tripping over TRIPS: is compulsory licensing under E-bay at odds with
U.S. Statutory requirements and TRIPS? *Suffolk University Law Review*, p 249.

[10] Reichman, Jerome H, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA*, International Centre for Trade and Sustainable Development (ICTSD), Genève, 2003. p, 10. Available at: http://ictsd.org/downloads/2008/06/cs_reichman_hasenzahl.pdf

[11] The TRIPs Agreement and Pharmaceuticals, *Report of an ASEAN Workshop on the TRIPs Agreement and its Impact on Pharmaceuticals*, Jakarta, 2000, p. 32. Available at: http://apps.who.int/medicinedocs/pdf/h1459e/h1459e.pdf

outlines the conditions related to the external environment of patentable subject matter, stipulating that patents should be accessible and that patent rights should be enjoyed without discrimination based on place of invention, field of technology, or whether products are imported or domestically produced. Why did states sign up to TRIPS even if they had little to gain from intellectual property protection[12]?

The ability to transfer a patent, or any intellectual property right, is confirmed in Article

28.2. The owner of the patent can engage in voluntary licensing agreements, which are highly customizable but may be subject to regulation by national competition laws that could limit the future use of the license within that market.

The basic criteria for obtaining patent rights are designed to ensure fairness in determining what can be patented. The TRIPS agreement prohibits the denial of a patent

application on grounds related to the field of technology, requiring member countries to offer protection for fields such as medicine and biotechnology that were previously excluded in some countries under the Paris Convention.

Additionally, there are restrictions on the prerogative rights granted to patentees as outlined in Article-30, TRIPS; provisions for issuing compulsory licenses are further detailed in article 31.[13] (Reichman & Jerome, 2006) Overall, TRIPS established more stringent standards for intellectual property protection while also incorporating specificexceptions to allow flexibility when addressing certain situations.

Article 31 permits nations to permit compulsory licenses under some specific conditions/circumstances. Only if voluntary licence was not secured from the patent holder on reasonable terms can compulsory license be issued by the government.

---

[12] Drahos, P. (2004, September 30). *Who Owns the Knowledge Economy? | The Corner House*. http://www.thecornerhouse.org.uk/resource/who-owns-knowledge-economy

13 Reichman, & Jerome, H. (2006). *Compulsory Licensing of Patented Inventions: Comparing United States Law and Practice with Options under the TRIPS Agreement*. Association of American Law Schools. http://www.aals.org/documents/2006intprop/JeromeReichmanOutline.pdf

TRIPS addresses national emergencies and other urgent need situations as potential reasons for compulsory licensing. Inventions necessary safeguard public order or morals including those protecting human life or health cannot receive patents according to Article 27 emphasizing importance placed on public health. Articles-8& 27 of TRIPS as well as the Doha-Declaration highlight significant connection between TRIPS and public health[14]. However, a precise definition of measures available to promote public health is lacking, countries have the leeway to decide their own ways to promote public health within the framework of TRIPS highlighted in the measures they can take to public. health within the definition of framework articles There is no flexibility ensures available ad that were to promote precise measures, the TRIPS agreement establishes the basic parameters for patent protection and addresses issues such as field of technology, compulsory licensing, and exceptions for national emergencies

Articles 30& 31 cover patents in numerous arenas, not just limited to the health sector. Article 30 allow the nations to provide "limited exceptions"[15] to a patentee's unincumbered rights, as long as these exceptions do not unreasonably hinder the

normal use of the patent or unfairly damage its owner's legitimate interests while taking into account the legitimate interests of other parties. These provisions of TRIPS demonstrate the balance that the agreement seeks to strike between promoting innovation and protecting public health (Overwalle, 2008). In summary, the TRIPS Agreement was established through global trade negotiations to regulate intellectual property rights (Haakonsson & Richey, 2007). Specifically, it sets out minimum standards for patent protection and addresses issues such as compulsory licensing, exceptions for national emergencies, and the promotion of public health

Article 31 contains a wide array of exemptions for the unauthorized use of patents, particularly the compulsory licensing provision. It includes specific conditions that must be satisfied before a compulsory license can be granted. For instance, there is a requirement to engage in genuine negotiations within a designated timeframe and on fair terms to obtain a patent-related license when no agreement has been reached. Additionally, Article 31 permits the granting of compulsory licenses in cases of national

14 *Supra* Reichman in note 7, p. 2.

15 *Supra* Halajian in note 7 p. 1198.

emergencies or other situations requiring immediate action. Moreover, the TRIPS Agreement acknowledges the significance of public health by allowing for the utilization of compulsory licenses to tackle public health crises. In conclusion, the TRIPS Agreement provides room for flexibility in determining strategies to advance public health while considering patent rights.

When the government issues a compulsory license, it is granted for a limited duration determined by the original circumstances. Article 31(a) requires individual evaluation for each use under this authorization. The negotiation requirement can be exempted in cases of national emergency, extreme urgency, or public non-commercial use; however, proper remuneration remains necessary. Article 31(f) of the TRIPS Agreement specifies that production under compulsory licensing should primarily cater to the domestic market. This provision has played a key role in shaping the Doha Declaration on Public Health and the TRIPS Agreement, with an aim to enhance access to medicines for HIV/AIDS, malaria, and tuberculosis in developing and least developed countries by recognizing the importance of utilizing flexibilities within TRIPS Agreement." "Overall, the TRIPS Agreement provides a framework for governments to issue compulsory licenses under certain circumstances, ensuring that access to essential medicines and technologies is not.

Ultimately, Article 66.2 presents an intriguing requirement for advanced nations. "More economically advanced member countries are required to offer inducements to businesses and organizations within their borders with the aim of facilitating and stimulating the transfer of technology to the least developed member countries, thereby helping them establish a robust and sustainable technological foundation." In conclusion, the "TRIPS Agreement provides provisions for compulsory licensing, which allows governments to grant licenses for patented inventions in specific circumstances such as national emergencies or public health crises"[16] (Agada et al., 2009). Compulsory licensing is a tool provided by the TRIPS Agreement that allows

16 Agada, J., Gathegi, J., Britz, J., & Lor, P. (2009). Globalization of intellectual property rights: Implications of the TRIPs agreement for access to HIV/AIDS drugs in Africa. *Proceedings of the American Society for Information Science and Technology*, *46*(1), 1–11. https://doi.org/10.1002/meet.2009.1450460149

governments to grant licenses for patented inventions in specific circumstances such as national emergencies.

4. The Doha Declaration

The Doha statement consists of seven sections that discuss the extent, context, and fundamental principles of the Declaration. Paragraph 1 reaffirms the healthcare challenges in numerous developing and LDC countries, especially pertaining to HIV/AIDS, tuberculosis, malaria, and other widespread diseases. Section 2 underscores the necessity for international action within the TRIPS agreement to tackle these concerns. While recognizing the importance of intellectual property protection in developing new medicines, it also highlights its impact on medicine prices. Additionally, section 4 stresses members' rights to implement measures aimed at safeguarding public health without being constrained by the TRIPS Agreement. It reasserts their entitlement to utilize flexibility provisions in order to facilitate access to medications for all individuals.

"The TRIPS Agreement and the Doha Declaration on Public Health" intersect in their recognition of the need to balance IPR with health concerns (Haakonsson & Richey, 2007)

Significant issues arise regarding the extent and interpretation of flexibilities. Compulsory licensing is recognized as an important tool for limiting the exclusive rights of patent holders in developing countries, which raises questions about when such limitations are

necessary. discussing the crucial problem of production for “exportunder a compulsory license” must be further addressed. Additionally, there are concerns about the transitional period for Least Developed Countries regarding “Pharmaceutical Patent” implementation and protection of data where test results havenot been disclosed. “The Doha Declaration” also acknowledges a challenge posed by “Article 31(f) of TRIPS concerning the use of compulsory licenses”, which restricts them to goods manufactured "predominantly" within a country domestically. There have been proposals to have countries have the right to export a part of their production

as long as it primarily serves their domestic market; however, many developing countries lack sufficient “manufacturing infrastructure” or the niche for production of pharmaceuticals domestically and therefore could not effectively utilize a compulsory license. In light of these issues, IPR needs to be balanced by the policymakers with access to affordable medicines for all.

Some argue that stringent intellectual property protection is necessary to incentivize innovation and research in the pharmaceutical industry. They believe that weakening patent rights through compulsory licensing could stifle investment in new treatments and cures for diseases, ultimately harming public health in the long run. Furthermore, it is argued that allowing export under a compulsory license could lead to potential misuse and market distortion, undermining the principles of fair competition and free trade. In this view, prioritizing robust intellectual property protection may be crucial for fostering continued advancements in medical science while also maintaining an environment conducive to global trade and economic development. “The TRIPS Agreement and the Doha Declaration on Public Health intersect in their recognition of the need to balance intellectual property rights with public health concerns” (Haakonsson & Richey, 2007).

the WTO (GC) General Council on 30, August 2003, addressed the issue outlined in paragraph six of the Doha Declaration and reached a resolution. This response is also known as the "Implementation Decision" or "Paragraph 6 Decision," which established an “exemption for Article 31(f) of TRIPS. It allows a country without manufacturing capabilities to import a particular patented pharmaceutical product from another country with the necessary knowledge and manufacturing expertise.”[17] (Lee, 2013) However, this decision imposes several limitations on the waiver, creating complexities in the importing procedure. Therefore, it is crucial for policymakers to further examine and refine these limitations to ensure effective and efficient access to medicines that are affordable for everyone. Furthermore, the Doha Declaration emphasizes the importance of technology transfer to developing countries in order to enhance their capacity for pharmaceutical production (Abbott, 2011).

[17] Lee, S. B. (2013). Can Incentives to Generic Manufacturers Save the Doha Declaration's Paragraph 6?
Georgetown Journal of International Law, *44*(4), 1387

developing nations here, have an opportunity to utilize their manufacturing capabilities, such as India and China, to provide medicine to nations facing severe circumstances. It could be particularly important in cases where domestic production timelines in the least developed countries are long and meeting the conditions outlinedin paragraph 6 would be time-consuming.[18] (Andrew & Jennifer , 2011) Additionally, this action would comply with Article 66.2 of the TRIPS agreement. Overall, intellectual property protection and access to affordable medicines remains a critical challenge thatrequires careful consideration and policy adjustments in today's globalized world.

5. The European Union (EU) Treaty

The European Union is dedicated to upholding the "TRIPS agreement and the Doha Declaration". It has also earmarked important priorities, such as "emphasizing sustainability in the internal market among member states outlined in article 3 TEU". Sustainability has influenced not only the EU's obligations towards non-member countries but also its global operations, where it aims to be guided by democratic values and establish partnerships with third countries according to Article 21 TEU. Of specific relevance for this research are its interactions with "developing countries" and LDCs. "When formulating policies or engaging internationally with other nations or organizations, one of the EU's duties is to advance sustainable economic, social, and environmental development in developing countries (Article 21(2.d) TEU). Moreover, it should contribute to global efforts aimed at preserving and enhancing natural resource management for sustainable development (Article 21(2.f) TEU), as well as providing assistance to populations, countries, and regions affected by natural or man-made disasters (Article 21(2.g) TEU). The commitment of the EU to the TRIPS agreement and the Doha Declaration creates opportunities for developing nations' access to affordable medicines. Specifically, through its commitment to the TRIPS agreement and the Doha Declaration, the EU aims to ensure that developing nations have access to affordable medicines that are necessary for the treatment of diseases such as

[18] Andrew, & Jennifer , R. (2011). "Swine flu, bird flu, sars, oh my! Applying the precautionary principle to compulsory licensing of pharmaceuticals under article 31 of TRIPS. *Michigan State Law Review*, p. 418.
.http://www.msulawreview.org/wp-content/uploads/2012/10/2011-2-Andrew.pdf"

HIV/AIDS, tuberculosis, and malaria". The EU's dedication to upholding the TRIPS agreement and the Doha Declaration reinforces its commitment to addressing concerns regarding intellectual property rights and access to medicines.

6. European Union (EU) and the Treaty on its functioning

Article 3, TFEU clearly states that the EU has exclusive authority to form such agreements. However, there is no specific legislation at the EU treaty level regarding compulsory licensing of patents for public health purposes. Nevertheless, most EU countries have established rights through national laws to "grant compulsory licenses when it is deemed necessary for public interest or public health reasons."[19] (E.G. van Zimmeren & G.R.L. Van Overwalle, 2011) These same regulations on "compulsory licensing for public health" reasons apply in the European Union as they do for all other signatories to the TRIPS agreement. This enables member states to impose compulsory licenses after "good faith negotiations" fail to obtain a lease/license for essential pharmaceutical products under relevant patents or waivers during urgent health crises. Article 4 of the TFEU also mentions that the EU aims to share its expertise with other states in areas specified in Articles 3 and 6 of the TFEU, which may explain why only limited provisions are made in relation to compulsory patent licensing - primarily aimed at an efficient and competitive market sustenance.

Article 11, relevant to this thesis, emphasizes the importance of integrating environmental protection requirements into Union policies to foster sustainable development. The Treaty's Articles 34, 36, 101, and 102 delineate the extent and limitations of compulsory licensing related rules crucial for the upkeep of the domestic market. Additionally, A WIPO study revealed that specific laws concerning compulsory licensing of patents for public health reasons are present in three EU member states: (Hungary/Belgium/France) ; while an additional 07 member states have laws allowing compulsory licenses to serve public interest without explicitly mentioning public health rationale. National laws can address the implementation of public health through either a strict approach (as in France) or a more flexible one. Contrary wise, the flexible concept allows interpretation across different contexts but

[19] E.G. van Zimmeren, & G.R.L. Van Overwalle. (2011). *A paper tiger? Compulsory license regimes for publichealth in Europe*. *42*(1), 4–40.

may be less effective compared to its stricter counterpart. Clearly defining "public health" under national law could help mitigate future challenges as its interpretation evolves over time.[20]

Given these legal provisions and evolving understanding of public health, it is imperative for EU member states to establish precise definitions and guidelines for mandatory patent licensing for public health reasons.

Insufficient quantity or quality of available medications or methods, make access to medicines unrealistic. exploitation of patents contrary to public health interests, and anti-competitive practices resulting from patent utilization as determined in a final administrative or court decision are some instances where ex-officio compulsory licenses could be applied[21]. In the past, there was an effective form of "ex-officio compulsory license specifically targeting genetic diagnostic patents for breast and ovarian cancer". This allowed for the production and sale of these tests without needing permission from the patent owner to ensure patients had affordable access to effective diagnostics. Belgian patent law also supports public health reasons by allowing "innovation protected by a patent to be utilized in the interest of public health with expedited procedures under Art.31bis§1 Belgian Patent Act"[22]. Even though this support is not as explicit as under French law, Belgium's approach is further reinforced by a "ministerial statement" providing examples that may pose a public health risk. Notably, "Belgium does not justify this license through Article 31 but rather bases it on an interpretation of articles 8.1 and 30 of the TRIPS agreement".

Overall, it is crucial for EU member states to establish clear definitions and guidelinesin the interest of public health for compulsory patent licensing This will ensure that

[20] Survey on compulsory licenses granted by WIPO member states to address anti-competitive uses ofintellectual property rights, WIPO, 2011, p.7.

[21] Reichman, J. H. (2009). Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options. *The Journal of Law, Medicine & Ethics*, *37*(2), 247–263. https://doi.org/10.1111/j.1748- 720x.2009.00369.x *Compare, "Rushing, Steven, Plugging the Leak in § 1498: Coercing the United States into Notifying Patent Owners of Government Use. Vanderbilt Journal of Transnational Law, 2012.* "When the United States uses a patent for public, non commercial purposes, it is required under the Agreement on Trade- Related Aspects of Intellectual Property Rights (TRIPS) to provide notification to the patent owner. However, the United States has never implemented legislation to conform with its obligation and is therefore in violation of TRIPS."

[22] *Supra* Zimmerman in note 17 p. 24.

essential medicines and medical technologies are accessible and affordable, thus

addressing public health needs effectively.

"After the Doha Declaration, the EU opted to explicitly enforce a regulation outlining procedures for exporting drugs manufactured under compulsory license. Regulation No 816/2006 now governs the use of compulsory licensing for patents related to the production of pharmaceutical products destined for countries facing public health challenges". The goal was to standardize the application of paragraph 6 across EU member states and contribute internationally towards addressing public health issues in least developed countries and improving access to affordable medicine. Additional considerations included making a significant statement symbolically and harmonizing efforts among member states. Two key conditions outlined in this regulation are: first, "there are no restrictions on the range of diseases covered; it extends to all medicinal products as defined in Article 1 of Directive 2001/83/EC on medicinal products for human use, active ingredients, and diagnostic kits ex vivo. Second, compulsory licenses are obligatory:" "Member States shall grant a compulsory license to any person submitting an application following Article 6 provided they meet specified conditions." In contrast with the EU approach, while being a signatory to TRIPS agreement like other countries' US does not include provisions on mandatory patent licenses within its patent act; instead these matters fall under antitrust laws along with specific evolving statutes over time that regulate such cases.US legal framework Similarly as seen with many other nations. The U.S generally opposes implementation compulsory licensing provisions However it's worth noting relevant statutes allowing government-granted rights resembling a form of compulsory licensing such as might be observed through7U.S.C.§2404 stating plant varieties must be made available when deemed essential to ensure adequate fibre food or feed supplies domestically if the owner is unwilling unable to meet public needs at fair prices italics added The owner of the patent still has the right to receive compensation. US Code § 1498 deals with government use of patents, while 35 U.S.C. § 203 governs patents developed using government research funding under the Bayh-Dole Act. Additionally, according to 42 U.S.C. § 2183, certain patents related to atomic energy production can be deemed in the public interest.

It has been suggested that these laws may not fully meet all the requirements specified in TRIPS Article 31. Additionally, it is important to highlight that there is no overarching legislation in the United States permitting compulsory licensing of unused or patents with public benefits, although specific circumstances for granting such licenses do exist.

The statutory compulsory licensing of third-party benefiting patents seems significantly limited in the United States. This limitation is believed to originate from a strong adherence to free-market principles and factors such as returns on research and development investment and efficiency over fairness; however, this issue is more

complex than it initially appears. Notably, while the sovereign have the power to take over and use a "protected patent or intellectual property right", it must still provide compensation but can exercise this authority.

In conclusion, the United States has a nuanced approach to compulsory licensing of patents, primarily relying on antitrust laws and specific statutes for certain sectors.

Additionally, compulsory licensing could align the US with other nations that enforce a local working requirement for patents. However, some argue that compulsory licensing is only justified when there is significant public interest involved. While non-voluntary licensing on grounds of public interest has not been widely used in the US, it has been employed to reduce medical costs and further "environmental and economic development" objectives, such as large-scale projects like dam construction for electricity generation. Following the September 11, 2001 attacks, letters containing anthrax were sent to senators and news organizations resulting in five deaths. Concerns about a potentially dangerous strain of anthrax led the then-"Secretary of Health and Human Services to take action to improve access to necessary medication against anthrax - ciprofloxacin. The German company Bayer held the patent for this drug but was unable to meet demand until two years later. During negotiations with Bayer, Secretary Thompson threatened to use Section 1498" of law which allows government agencies use patented inventions without authorization from their owners if deemed necessary. There was a legitimate concern that fresh attacks could have negative impacts on public health so preparations had to be made accordingly.

Compulsory licensing of patents in the United States is limited but not non-existent. It is primarily used in cases where there is a significant public interest at stake, such as improving access to medication or addressing national security concerns.

A similar situation arose during the planning for a potential "bird flu outbreak. Roche owned the patent for Tamiflu," but like Bayer, they were unable to meet the demand in time. The option of licensing production of a generic version was considered and later used by the US in negotiations to secure its essential medications in case of an outbreak, with the threat of utilizing "Section 1498". Roche was obligated to "invest in laboratories in the US to ensure supply of Tamiflu" if a bird flu outbreak occurred.

7. Unequivocal inclusion of environmental health

Strong emerging economies, primarily led by Brazil India and China countries, are voicing disapproval towards the US and other developed nations. Their criticism stems from the heavy pollution caused globally, whether through local emissions or outsourcing production to cheaper and less environmentally regulated countries. Furthermore, there is concern that advanced pollution-reducing technology is being kept under patent

protection in developed nations, preventing access for countries in need.[23] (Gupta, 2012)

There is also backlash against developed nations demanding improved environmental standards in developing countries while they themselves contributed to increased pollution during their own economic growth. While it was true during the industrial revolution era, when such pollution may have been necessary for economic advancement at the time, this should not be accepted as a current standard. Unlike earlier times of industrialization, today's available technology provides an opportunity to mitigate these effects responsibly; failing to utilize it would be deemed irresponsible or even hypocritical.

It's not necessary to choose between environmental awareness and economic development. In 2008, “Brazil, China, and India proposed that the TRIPS flexibility”

23 Gupta, R. R. (2012). Compulsory Licensing in TRIPS: Chinese and Indian Comparative Advantage in the Manufacture and Exportation of Green Technologies. *Sustainable Development Law and Policy*, *12*(3), 5.

be further formalized to include green technology as well as medicines. The argument put forward is that the climate is a public good akin to health. Despite having funds, technology access, and production capability, BIC may advocate for least developed countries in need of technology transfer.[24] (OECD, 2012) Notably, China has emerged as the leading producer of clean technology with an estimated worldwide market worth

$2.2 trillion by 2020.[25] (“The Road to Rio+20, for a Development-Led Green Economy,” 2011) However, it should be recognized that without promotion and innovation of this technology in all countries including LDCs will impede prioritization; consequently hindering pollution control due to its high cost which would restrict licensing fees for companies if patented technologies are not made more accessible globally.

A relaxation of intellectual property rights would likely deter industries from investingin R&D within the “green technology” sector. Any potential solution to this issue would need to be initiated by relevant governments, which must also be willing to compensate or otherwise incentivize innovators in order to drive further innovation. Therefore, it is crucial that there is a debate about technology access, with BIC advocating on behalf of LDCs. While Intellectual Property (IP) rights promote “innovation in necessary green technology”, they may also hinder its ultimate purpose. Since most harmful emissions occur in developing nations where the need for such technology is greatest, accessibility becomes a key concern.

To address these issues, BIC (Brazil, India and China) , plus South Africa and Mexicohave issued a joint statement emphasizing the importance of access to "relevanttechnology if developing countries are expected to effectively contribute towards environmental challenges. The main concern among LDCs is that strong IP protection successfully prevents them from accessing green technology" due to exorbitant costingset by holders of these rights.

[24] OECD. (2012). *Green Growth and Developing Countries A Summary for Policy Makers*. http://www.oecd.org/dac/50526354.pdf

[25] The Road to Rio+20, For a development-led green economy. (2011). *UNITED NATIONS CONFERENCE on TRADE and DEVELOPMENT*, p 5. http://unctad.org/en/docs/ditcted2011d6_en.pdf.In light of this situation and recognizing the necessity for Least developed Countrys' use of green technology while ensuring appreciation and compensation for innovation efforts—there has been a serious proposal aimed at making transfer of such technologies accessible for Least developed Country's. This proposal suggests the relaxation of intellectual property rights specifically for climate-friendly technologies in order to facilitate technology transfer to developing countries. This proposal seeks to strike a balance between incentivizing innovation and promoting the widespread adoption of climate-friendly technologies in developing countries.

On the contrary, explicit incorporation may pose difficulties for Least Developed Countries that might have limited manufacturing capabilities. This is particularly challenging for green technology due to the significant obstacle of energy production costs that these countries must overcome in order to pursue sustainable development. Therefore, formally endorsed transfer mechanisms are crucial and should be advocated. Effective agreements focused on establishing sustainable energy facilities, especially in cases with intricate production processes, will strengthen the energy manufacturing infrastructure for Least Developed Countries and potentially result in reductions in greenhouse gas emissions. Encouraging foreign direct investment as a method of technology transfer is essential as it entails bolstering domestic manufacturing through participation from international investors. To successfully introduce green technology into Least Developed Countries, incentives for corporations must generate long-term advantages and contribute to genuine economic growth; short-term profits will not suffice for local advancement. Historically, developed countries have encountered challenges in directing technology transfer toward Least Developed Countries because TRIPS alone may not adequately facilitate the transfer of green technology patents or serve as an effective legal instrument.

One potential approach could involve implementing a comprehensive program or incentive

linking “businesses in developed countries with sustainability projects in developing countries or Least developed Country’s to propel development forward”. This program could provide financial support, technical assistance, and knowledge sharing to facilitate the transfer of green technology to developing countries (Alhelali,2017).

8. India

Section 84 , Indian Patent Act, allows for the granting of a compulsory license if the needs of the public regarding the patented invention are not met within three years, or if the invention is unreasonably priced and therefore inaccessible to the public. The act also requires that patents be worked in India. Applications for compulsory licenses are submitted to the Controller, who may grant them on suitable terms.

The first ever “compulsory license” in India was issued in 2012 to Natco, allowing them to manufacture and sell Bayer's cancer drug "Nexavar." This decision was made because Bayer had not been able to make the medicine readily available at an affordable price, importing only a grossly inadequate quantity which remained inaccessible to most people in need. By failing these conditions outlined in Indian patent law, Bayer led to this outcome. This case in India exemplifies the importance and efficacy of “compulsory licensing as a tool for technology transfer”, particularly in cases where access to patented inventions is essential for the well-being of the public. Compulsory licensing can be a valuable strategy for technology transfer, as demonstrated by the case of Natco and Bayer in India.

This ruling has been regarded as somewhat peculiar due to the interpretation of “TRIPS Article 27” . In the “Natco/Bayer case” , The Controller used the standard "worked to the fullest extent that is reasonably practicable" in evaluating Bayer's practices for meeting the local working requirement. Sections 84 and 89 specify that mere product importation does not satisfy the local working requirement. This application of the article is an intriguing use given that discrimination is prohibited under “TRIPS, whether products are imported or locally produced”. Utilizing Article 30 in conjunction with Article 31 might have been a more suitable option as it provides other avenues for unauthorized patent use. The implementation of compulsory licenses in India, exemplified by the Natco/Bayer case, underscores how important it is to strike a balance between patent protection and access to affordable medicines to safeguard public health and well-being.

9. Conclusion

In conclusion, the issue of "access to green technology in developing countries, especially the Least Developed Countries", is a critical one. While intellectual propertyrights are essential for promoting innovation, they can also hinder the widespread adoption of climate-friendly technologies. The proposal for the relaxation of IPR specifically for climate-friendly technologies for the purpose of facilitating technology transfer to developing countries presents a potential solution.

The joint statement by Brazil, China, India, Mexico, and South Africa emphasizes the importance of technology access for developing countries to effectively address environmental challenges. However, it is crucial to recognize the challenges that LDCs may face, such as the lack of manufacturing capacity and the significant barrier of energy manufacturing costs. Therefore, effective agreements aimed at establishing sustainable energy plants and promoting foreign direct investment are essential for technology transfer and sustainable development in LDCs.

In addition, the case of Natco and Bayer in India demonstrates the potential effectiveness of "compulsory licensing as a tool for technology transfer", particularly in cases where access to patented inventions is crucial for public well-being. While the ruling in the Natco/Bayer case has been regarded as somewhat peculiar, it underscores the importance of balancing patent protection and access to affordable medicines to safeguard public health.

Overall, the promotion of technology transfer and the relaxation of intellectual propertyrights for climate-friendly technologies can contribute to the widespread adoption of green technology in developing countries, ultimately aiding in the global efforts to address environmental challenges while promoting sustainable development.

References

1. Ghosh, S. (2017, May 31). IPRS AND ENVIRONMENTALLY SOUND TECHNOLOGIES: POLICY OPTIONS FOR THE DEVELOPING COUNTRIES. International journal of advanced research, 5(5), 1807-1810. https://doi.org/10.21474/ijar01/4313

2. Reichman, J H. (2009, January 1). Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options. Journal of Law, Medicine &Ethics, 37(2), 247-263. https://doi.org/10.1111/j.1748-720x.2009.00369.x

3. Bell, M L., Davis, D L., Cifuentes, L A., Cohen, A., Gouveia, N., Grant, L D., Green,

C., Johnson, T M., Rogat, J., Spengler, J D., & Thurston, G. (2002, November 1). International expert workshop on the analysis of the economic and public health impacts of air pollution: workshop summary.. https://doi.org/10.1289/ehp.021101163

4. Andrew, & Jennifer , R. (2011). Swine flu, bird flu, sars, oh my! Applying the precautionary principle to compulsory licensing of pharmaceuticals under article 31 of TRIPS. *Michigan State Law Review*, p. 418. .http://www.msulawreview.org/wp-content/uploads/2012/10/2011-2-Andrew.pdf
5. Haakonsson, S. J., & Richey, L. A. (2007). TRIPs and Public Health: The Doha Declaration and Africa. Development Policy Review, 25(1), 71–90. https://doi.org/10.1111/j.1467-7679.2007.00360.x
6. Geertrui van Overwalle. (2008). Biotechnology and patents: global standards, European approaches and national accents. *Cambridge University Press EBooks*, 77–108. https://doi.org/10.1017/cbo9780511494581.004
7. Agada, J., Gathegi, J., Britz, J., & Lor, P. (2009). Globalization of intellectual property rights: Implications of the TRIPs agreement for access to HIV/AIDS drugs in Africa. *Proceedings of the American Society for Information Science and Technology*, *46*(1), 1–11. https://doi.org/10.1002/meet.2009.1450460149
8. Abbott, F M. (2011, January 1). Intellectual Property and Public Health: Meeting the Challenge of Sustainability. https://doi.org/10.2139/ssrn.1965458
9. Alhelali, S. (2017, December 14). International transfer of technology under the TRIPS Agreement. http://eprints.nottingham.ac.uk/47722/
10. E.G. van Zimmeren, & G.R.L. Van Overwalle. (2011). *A paper tiger? Compulsory license regimes for public health in Europe*. *42*(1), 4–40.
11. Survey on compulsory licenses granted by WIPO member states to address anti-competitive uses of intellectual property rights, WIPO, 2011, p.7.
12. Reichman, J. H. (2009). Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options. *The Journal of Law, Medicine & Ethics*, *37*(2), 247–263. https://doi.org/10.1111/j.1748-720x.2009.00369.x
13. Gupta, R. R. (2012). Compulsory Licensing in TRIPS: Chinese and Indian Comparative Advantage in the Manufacture and Exportation of Green Technologies. *Sustainable Development Law and Policy*, *12*(3), 5.
14. OECD. (2012). *Green Growth and Developing Countries A Summary for Policy Makers*. http://www.oecd.org/dac/50526354.pdf
15. Green Growth and Developing Countries: A Summary for Policy Makers, OECD, 2012, p. 8. Available at: http://www.oecd.org/dac/50526354.pdf
16. The Road to Rio+20, For a development-led green economy. (2011). *UNITED*

NATIONS CONFERENCE on TRADE and DEVELOPMENT, p 5. http://unctad.org/en/docs/ditcted2011d6_en.pdf.

17. Bond, E. W., & Saggi, K. (2014). Compulsory licensing, price controls, and access to patented foreign products. *Journal of Development Economics*, *109*, 217–228. https://doi.org/10.1016/j.jdeveco.2014.04.001
18. Stern, D., & Charlene , A. (2007). Tripping over TRIPS: is compulsory licensing under E-bay at odds with U.S. Statutory requirements and TRIPS? *Suffolk University Law Review*, p 249.
19. Reichman, & Jerome, H. (2006). *Compulsory Licensing of Patented Inventions: Comparing United States Law and Practice with Options under the TRIPS Agreement*. Association of American Law Schools. http://www.aals.org/documents/2006intprop/JeromeReichmanOutline.pdf
20. Lee, S. B. (2013). Can Incentives to Generic Manufacturers Save the Doha Declaration's Paragraph 6? *Georgetown Journal of International Law*, *44*(4), 1387.
21. Drahos, P. (2004, September 30). *Who Owns the Knowledge Economy? | The Corner House*. http://www.thecornerhouse.org.uk/resource/who-owns-knowledge-economy