THE INTELLECTUAL PROPERTY WAIVER AND ACCESS TO COVID-19 TREATMENT


بسم الله الرحمن الرحيم

APPROVAL SHEET

It is certified that we have evaluated the thesis entitled, **"The Intellectual Property Waiver and Access to COVID-19 Treatment"** submitted by Mr. Hassan Ibrahim Khan, Registration No. 235-FSL/LLMITL/S-20 and we judge that this thesis is up to the required standard for its acceptance by International Islamic University, Islamabad for award of degree LLM International Trade Law.

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DECLARATION

I, Hassan Ibrahim Khan, hereby declare that this dissertation entitled, **"The Intellectual Property Waiver and Access to COVID-19 Treatment"** is my effort, carried out under the guidance and supervision of respected **Ms. Attiya Madni, Lecturer of Law**. I also declare that this dissertation has never been used before for any examination or degree in any other institution. Moreover, all sources that have been used in this dissertation are completely acknowledged with reference.

HASSAN IBRAHIM KHAN

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Date: _____

DEDICATION

Every challenging work needs self-effort, as well as the guidance of elders especially those who are very close to our hearts. This research work is affectionately dedicated to my “Parents, Teachers and all those valuable lives that were lost during the deadly COVID-19 pandemic”. My parents and teachers have been a consistent wellspring of motivation and support throughout all my scholarly ways. They have given me the drive and train to handle any errand with eagerness and assurance.

HASSAN IBRAHIM KHAN

Date: _____

ACKNOWLEDGEMENTS

Foremost, I am grateful to Almighty Allah (SWT) for giving me the strength to successfully conduct my research and for sustaining my efforts.

Moreover, I would like to express my sincere gratitude to my advisor and supervisor **Ms. Attiya Madni, Lecturer of Law**, for continuous support and guiding me through my research work. Her guidance helped me a lot during all the time of writing this thesis.

Besides my supervisor, I would like to thank all of my teachers who have taught me during my LLM degree. I would also like to especially thank Mr. Noman Amin Farooqi, who has always been an inspiration, guiding light, and mentor to my practical career.

Last but not least, I would like to thank my family, especially my father Muhammad Masood Khan who is also an advocate by profession and my uncle Irfan Ahmed Khan; who have been supportive in every aspect of my life and without whose support I could have never been what I am today.

LIST OF ABBREVIATIONS

TRIPS:	Agreement on Trade-related Aspects of Intellectual Property Rights
WTO:	World Trade Organization
SARS-CoV 2:	Severe Acute Respiratory Syndrome Coronavirus 2
ISDS:	Investor-State Dispute Settlement
BITs:	Bilateral Investment Treaties
LDCs:	Least Developed Countries
NGOs:	Non-Governmental Organizations
GATT:	General Agreement on Tariffs and Trade
IPR:	Intellectual Property Rights
WIPO:	World Intellectual Property Organization
PCT:	Patent Cooperation Treaty
IPC:	Intellectual Property Classification
PLT:	The Patent Law Treaty of 2000
EU:	European Union
UPOV:	The International Union for the Protection of New Varieties of Plants
IPO:	Intellectual Property Organization of Pakistan
FDA:	U.S Food and Drug Administration
MSF:	Médecins Sans Frontières
LICs:	Low-Income Countries
HIV/AIDS:	Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
FTAs:	Free Trade Agreements
OECD:	The Organization of Economic Cooperation and Development
UDHR:	Universal Declaration of Human Rights
ICESCR:	International Covenant on Economic, Social and Cultural Rights
SEC:	US Securities and Exchange Commission
CTAP:	Covid-19 Technology Access Pool

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ABSTRACT

Intellectual Property Rights (IPR) provide the framework to secure the commercial benefits for the stakeholders and creators of the property. A range of rights from patents, copyrights and trademarks fall under this category. However, in times of crisis or pandemic, the WTO member countries find it inconvenient to ease their people and demand to suspend the IP on life-saving medicines. In October 2020, after the outbreak of coronavirus, India and South Africa came up with a proposal to the WTO on COVID-19 vaccines, therapeutics and other diagnostics till widespread vaccination could be ensured in lower- and middle-class countries. The WTO after the long 18 months of consideration partially accepted the proposal by limiting it to only patents for regulatory approval. This study examines whether the proposed Intellectual Property (IP) waiver under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) aligns with its original intent of addressing issues related to distribution of COVID-19 vaccinations. Additionally, the study highlights the persistent disparities between the demand for equitable solutions and the readiness of the World Trade Organization (WTO) to address inequalities in potential future pandemics impacting the global South. The findings suggest that the framework of IPRs and the WTO needs to be more holistic in their approach to addressing the issues of inequalities and exclusivity.

Chapter 1: Introduction

Upon careful consideration of the proposed TRIPS waiver under the World Trade Organization (WTO) law, a comprehensive legal analysis can offer valuable insight and provide important guidance. Examining the TRIPS flexibilities and the accompanying "August 2003 TRIPS waiver" can identify potential impediments to countries achieving the desired outcomes of these legal instruments.[1] The flexibilities outlined in Article 31 of TRIPS are inadequate, leading certain countries to submit a waiver proposal to the WTO. Additionally, the proposal also reveals several areas of potential ambiguity within the current WTO regulations. If WTO members can't agree on the new TRIPS waiver proposal, some suggest that clarifying the existing WTO agreements on intellectual property could serve as a viable alternative. The international health sector has voiced unconsent with the proposed outcome of negotiations between the EU, USA, India, and South Africa; not meeting expectations. As John Zarocostas has reported from Geneva that the potential agreement brokered by the Quad (EU, US, India, and South Africa) at WTO, which talks over an IP waiver to the COVID-19 vaccines, has been met with mixed reactions. The agreement bestows eligible WTO members the right to employ patented ingredients and processes for producing and supplying COVID-19 vaccines, devoid of obtaining consent from the patent holder. WTO members have agreed to decide on the extension of WTO coverage for COVID-19 diagnostics and therapeutics for no more than six months from the date that they decide upon vaccines. The period of the waiver is still in debate at the WTO and may last 3 or 5 years.[2]

As the world faces the most pressing COVID-19 challenge, yet the lack of infrastructure has presented significant roadblocks in manufacturing and distributing vaccines to combat this

[1] Jessica Fayerman, "The Spirit of TRIPS and the Importation of Medicines Made under Compulsory License after the August 2003 TRIPS Council Agreement," *Northwestern Journal of International Law & Business* 25, no. 1 (January 1, 2004): 257, accessed December 19, 2023.

[2] John Zarocostas, "Mixed Response to COVID-19 Intellectual Property Waiver," *The Lancet* 399, no. 10332 (April 2, 2022): 1292–93, doi:10.1016/S0140-6736(22)00610-9, accessed December 16, 2023.

pandemic. This devastating scarcity is felt by those areas that are suffering from its highest disease burden. As the scarcity challenge persists, many answers in debate to eradicate this ongoing challenge have been recommended as a way to address this issue.

Access to medicine is a fundamental component of global public health, especially amidst the COVID-19 pandemic.[3] The Intellectual Property Waiver proposal has sparked debates regarding its potential impact on improving access to COVID-19 treatments worldwide. Central to this discussion is the recognition that access to medicine is not solely determined by the absence of intellectual property barriers but also by a multitude of factors, including manufacturing capacity, regulatory frameworks, and distribution networks.

This thesis aims to make COVID-19 treatments more widely accessible but also questions how effective it is in dealing with the complexities of medicine accessibility. It is imperative to acknowledge that while intellectual property rights can pose barriers to accessing medicines, they are not the sole determinant of accessibility. Factors such as production capacity, supply chain resilience, and regulatory approval processes play equally significant roles in determining access to medicines, including COVID-19 treatments.

Furthermore, the challenges associated with medicine access extend beyond intellectual property barriers. Issues such as affordability, particularly in low- and middle-income countries, pose significant hurdles for ensuring equitable access to COVID-19 treatments. Additionally, logistical challenges in vaccine distribution, storage, and administration further complicate efforts to improve access to COVID-19 treatments on a global scale.

The COVID-19 pandemic has underscored the importance of addressing systemic issues in global health infrastructure to ensure equitable access to medicines for all populations, regardless of socioeconomic status or geographical location. While the proposal may have the

[3] Vijay Kumar Chattu et al., "Access to Medicines through Global Health Diplomacy," *Health Promotion Perspectives* 13, no. 1 (April 30, 2023): 40–46, https://doi.org/10.34172/hpp.2023.05.

potential to enhance access to COVID-19 treatments, it is essential to adopt a holistic approach that addresses the multifaceted challenges of medicine accessibility comprehensively.

The concept of relinquishing intellectual property rights on vaccines has been a popular debate lately and is seen by some experts as an effective solution for the issue of scarcity and effective distribution of vaccinations. Today, we investigate the potential benefits of a waiver for eradicating patented regulations that impede the distribution or utilization of vaccine technology. ‘The term "proprietary" is utilized here to denote special sorts of privileges, such as patents, trade secrets and other technical know-how regarding vaccine technology transfer.[4] All in all, the suggested protocol fails to tackle both the intertwined issues of deficient infrastructure and the passage of tacit knowledge. This proposal is far too overdue and inaccurately presents the facts. This response is far from satisfactory in this unique circumstance.

This comes as a massive surprise, Germán Velásquez, special adviser on policy and health at the South Centre think-tank, exclaimed before The Lancet, Germán cautioned that a lack of unity could lead to disastrous consequences. Germán also urged for patience while awaiting the WTO's final resolution on the proposal and its acceptance among members. Velásquez, a former top official at the World Health Organization (WHO), noted that the draft proposal fails to address copyrighted information and trade secrets needed for vaccine production, treatments or devices related to COVID-19; and thus, would be disadvantaging multiple nations. As per the proposed draft, only WTO developing countries that exported less than 10% of global COVID-19 vaccine shipments in 2021 would be qualifying for aid - thereby nations such as China.[5]

[4] Julia Barnes-Weise, Ana Santos Rutschman, and Reid Adler, “Assessment of the Proposed Intellectual Property Waiver as a Mechanism to Address the COVID-19 Vaccine Scarcity Problem,” *J Epidemiol Community Health* 76, no. 4 (April 1, 2022): 317–18, doi:10.1136/jech-2021-218409, accessed December 23, 2023.

[5] Zarocostas, “Mixed Response to COVID-19 Intellectual Property Waiver.”

Virtually all experts concur that the fastest way to protect our world from COVID-19 is by vaccinating as many people as we can; however, disagreement abounds regarding how it should be accomplished. After the American President Joe Biden voiced his support for a provisional suspension of intellectual property rights on COVID-19 vaccines, this debate quickly became a prominent topic in the international policy arena. After gaining support from the US Senate, he has been joined along by a wide range of organizations and individuals across the globe from the World Health Organization to Médecins Sans Frontières and even Pope Francis. The UK's Independent Scientific Advisory Group for Emergencies also stands behind him in solidarity. Despite the passage of six months, certain European nations remain firmly against the accord and the head of the WTO has cautioned that negotiations are at a standstill. Despite the efforts of Amnesty International and the warnings from patients and healthcare representatives to challenge it legally, this remains an issue.

Concurrently, the Covax scheme is created to uphold existing market mechanisms and maintain current power dynamics. Despite the potential for transforming our intellectual property system, those opposed to reform cite that financial compensation is necessary to cover the risks associated with researching and producing new drugs. Without providing a tangible return on this costly investment, progress towards treating an otherwise untreatable diseases would stagnate.[6] Considering the COVID-19 vaccines, it's difficult to ascertain how much risk pharmaceutical companies face due to large government contributions for research and development as well as pre-purchasing a significant quantity of the vaccine.[7] However, the question remains valid that whether the governments that have invested in vaccine research be rewarded with lower prices and greater access to vaccines for impoverished people across the

[6] Luke Hawksbee, Martin McKee, and Lawrence King, "Don't Worry about the Drug Industry's Profits When Considering a Waiver on Covid-19 Intellectual Property Rights," *BMJ (Clinical Research Ed.)* 376 (January 31, 2022): e067367, doi:10.1136/bmj-2021-067367, accessed December 25, 2023.

[7] Gregg Gonsalves and Gavin Yamey, "The Covid-19 Vaccine Patent Waiver: A Crucial Step towards a 'People's Vaccine,'" *BMJ (Clinical Research Ed.)* 373 (May 17, 2021): n1249, https://doi.org/10.1136/bmj.n1249, accessed December 17, 2023.

globe, to bolster global immunity? Or would abandoning intellectual property rights amount to state robbery, which could threaten any further public health studies necessary in future?

Unsurprisingly, pharmaceutical companies maintain that waiving intellectual property rights over their patents would severely hamper profits and consequently weaken the incentive to develop new drugs. The emergence of the omicron variant is a stark reminder that we must do better. It must be an obligation, both moral and practical, to increase vaccination rates.[8] Doing so not only protects us from this existing strain but would also create a barrier against other variants which could be even more dangerous if they ever emerge in the future. Moreover, we strongly believe that a waiver would not endanger drug development in the future since the relationship between profits and innovation is unreliable. Additionally, public sector contributions are already having a major impact on much of the advancement in public health.

The outbreak of SARS-CoV-2, the primary cause of COVID-19, has sparked a heated discussion regarding the need to temporarily waive parts of The WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Doing so would provide greater access to essential medicines and medical technology needed to combat this disease.

This study extensively examines TRIPS rules and related legal ideas in order to determine how the TRIPS waiver could balance two competing forces: protection of intellectual property rights and public health. This thesis argues that, notwithstanding the TRIPS waiver's potential as a useful legal tool for easing access to medications and medical equipment, its current wording and structure are problematic. Consequently, these flaws significantly reduce its efficacy. Although the TRIPS waiver would offer a number of significant benefits, including supporting decolonization, distributive justice, and re-humanization objectives, there are several flaws in the way it was drafted. Although there are

[8] Melody Okereke, "Towards Vaccine Equity: Should Big Pharma Waive Intellectual Property Rights for COVID-19 Vaccines?," *Public Health in Practice* 2 (July 30, 2021), doi:10.1016/j.puhip.2021.100165, accessed December 19, 2023.

a few issues that need to be resolved, the TRIPS waiver, which was approved at the WTO's 12th Ministerial Conference, has the potential to be fully effective in granting access to COVID-19 vaccines and other medicinal items required to overcome this pandemic. To get the most impact, we need to make this waiver's current safeguards stronger.[9]

There has been a lot of discussion regarding whether the TRIPS should temporarily be suspended in light of the spread of SARS-CoV-2 or not? which is the primary cause of COVID-19.[10] By this temporary suspension over TRIPS regulations regarding the intellectual property rights over the vaccinations, we will have access to medical technologies and other life-saving medications that are essential in the fight against this deadly disease.

In order to ascertain how a TRIPS waiver can reconcile two opposing interests' i-e public health and intellectual property rights protection, this thesis delves deeply into the legal analysis. To comprehend how this could be accomplished, it thoroughly analyses the current TRIPS legislation and the other legal arguments in support. Although the waiver provided in TRIPS is an effective legal mechanism that can facilitate people's access to critical medications and medical technologies, it still has to be enhanced in order to serve its intended purpose.[11]

The current form and language of the waiver provided in TRIPS is inadequate. As a result, despite its noteworthy benefits, such as distributive justice and decolonization goals, the TRIPS waiver has several defects that considerably hinder its effectiveness. At the 12th Ministerial Conference of the WTO, parties adopted a TRIPS waiver proposal that has immense potential to create an expansive and efficient global supply chain for COVID-19

[9] Shelton T. Mota Makore, Patrick Osode, and Nombulelo Lubisi, "Reconciling the Global Public Health Interest with Intellectual Property Protection through the Waiver of Certain Provisions of the WTO TRIPS Agreement," *Yuridika* 37, no. 3 (September 1, 2022): 633–72, doi:10.20473/ydk.v37i3.37237, accessed December 17, 2023.

[10] John Zarocostas, "What next for a COVID-19 Intellectual Property Waiver?," *The Lancet* 397, no. 10288 (May 22, 2021): 1871–72, doi:10.1016/S0140-6736(21)01151-X, accessed December 24, 2023.

[11] Hawksbee, McKee, and King, "Don't Worry about the Drug Industry's Profits When Considering a Waiver on Covid-19 Intellectual Property Rights."

medical products like vaccines, drugs, and therapeutics.[12] This waiver temporarily suspends some provisions in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement which will enable countries around the world to cooperate towards providing equitable access to these essential health care items amidst this pandemic.[13] Countries should also modify their domestic IP laws to facilitate the waiver, depending on its specific conditions. Although it will provide immunity from WTO legal claims regarding IP-related regulations, multinational pharmaceutical companies can still contest such measures using investor-state dispute settlement (ISDS) processes provided under the bilateral investment treaties (BITs).[14]

Following eighteen months of stalemate, the WTO's political breakthrough is being applauded by international powerhouses and healthcare accessibility companies. Nevertheless, they express that some greater improvements must be made to guarantee initial investments for curative treatments and diagnostic procedures. According to the WHO, any waiver of TRIPS must encompass all health products for it to be efficacious. Nonetheless, the agency likewise endorses every appropriate method to safeguard intellectual property during this pandemic and beyond. As a result of such tumultuous times, only extreme measures can suffice. Every obstruction blocking access to life-saving vaccines and treatments must be eradicated. In a statement, Max Lawson, Head of Inequality Policy for Oxfam and Co-Chair of the People's Vaccine Alliance, implored member states of the WTO to come back to negotiations with a comprehensive waiver that will drastically reduce this pandemic and ensure everybody is safeguarded.[15] South Africa and India put forth an initial proposal in October 2020 which was

[12] Lee Hyo-young, "Overview of the Twelfth WTO Ministerial Conference (MC12) and Implications for the Multilateral Trading System," *IFANS FOCUS (영문)* 2022, no. 20 (2022): 1–3, accessed December 24, 2023.

[13] Monirul Azam, *Intellectual Property and Public Health in the Developing World* (Open Book Publishers, 2016), https://doi.org/10.11647/obp.0093. accessed December 19, 2023

[14] Lorand Bartels, "Applicable Law in WTO Dispute Settlement Proceedings," *Journal of World Trade* 35, no. 3 (2001), accessed December 16, 2023.

[15] Reshma Ramachandran, Joseph S. Ross, and Jennifer E. Miller, "Access to COVID-19 Vaccines in High-, Middle-, and Low-Income Countries Hosting Clinical Trials," *JAMA Network Open* 4, no. 11 (November 18, 2021), doi:10.1001/jamanetworkopen.2021.34233, accessed December 18, 2023.

endorsed by over one hundred countries; it entailed waiving TRIPS rights on COVID-19 medical products such as vaccines, medicines, diagnostics, protective gear and ventilators.

IP waivers are legally binding documents that allow the transfer of intellectual property rights from one party to another. IP rights can include copyright, trademark, and patent rights, among others. Waivers of IP are crucial for companies because they facilitate the exchange of concepts, findings, and designs that might have been produced by the original creator. People who wish to transfer their rights to a third party may find it useful to waive their IP rights. IP waivers are beneficial because they allow creators to share their works without fear of infringement claims or other legal repercussions.[16] Additionally, these waivers protect the parties from future disagreements by establishing a contract that is enforceable and has legal effect between them. Thus, these waivers offer a way for companies and individuals to work together on ideas and initiatives while preserving their own interests.

In the current corporate world, IP waivers are a crucial instrument that should be taken into account before signing any contracts or working together. In addition to offering participants legal protection, these contracts foster innovation by encouraging the exchange of concepts and blueprints. Therefore, in order to safeguard their assets while collaborating, organizations and individuals must sign intellectual property waivers. Intellectual property waivers are a useful tool for individuals and organizations seeking to protect their rights while exchanging or transferring intellectual property. IP releases guarantee that any transfer of rights conforms with relevant laws and regulations and establish a legally binding agreement. Therefore, IP waivers are necessary for the creation, transfer, and maintenance of IP.[17]

[16] Rakesh Basant, "Intellectual Property Rights Regimes: Comparison of Pharma Prices in India and Pakistan," *Economic and Political Weekly*, 2007, 3969–77, accessed December 24, 2023.

[17] Kamal Saggi, "Trade, Intellectual Property Rights, and the World Trade Organization," *Handbook of Commercial Policy* 1 (2016): 433–512. accessed December 17, 2023

Moreover, the IP waiver permits the public to utilize specific intellectual property without the owner's express consent.[18] This type of waiver is often used in academic and research environments, allowing individuals or organizations to access intellectual property for non-commercial purposes. IP waivers are helpful instruments for promoting creativity and teamwork since they allow scientific communities to work together on projects without worrying about infringing on one other's intellectual property rights. Additionally, these exclusions may benefit society as a whole by helping to maintain the public's access to valuable and unique intellectual property.

IP waivers let individuals and organizations to benefit from the creativity and abilities of those who develop it by protecting the intellectual property itself. IP waivers are essentially required to ensure that everyone has access to intellectual property and to foster collaboration between different businesses.[19]

The TRIPS agreement is an international agreement that specifies the minimum standards for protecting IP. Since the WTO established it in 1995, it has grown to rank among the most significant accords in the world pertaining to intellectual property rights. A comprehensive set of regulations known as TRIPS mandates that all WTO members enact legislation safeguarding intellectual property, including patents, trademarks, copyrights, and other types. Furthermore, TRIPS makes sure that trade sanctions or dispute resolution procedures are used to hold WTO members accountable for any agreement infractions. Essentially, TRIPS gives companies that operate internationally legal clarity and gives them the confidence to enter new markets. TRIPS continues to influence intellectual property rights

[18] Khorsed Zaman, "The Waiver of Certain Intellectual Property Rights Provisions of the TRIPS for the Prevention, Containment and Treatment of COVID-19: A Review of the Proposal under WTO Jurisprudence," *European Journal of Risk Regulation*, 2022, 1–19, accessed December 22, 2023.

[19] Mohammad Farooq, Tariq Mahmood, and Ejaz Ghani, "WTO Regulations and the Audio-Visual Sector—An Analytical Framework for Pakistan [with Comments]," *The Pakistan Development Review* 42, no. 4 (2003): 587–606, accessed December 16, 2023.

globally and has been a major driver of innovation and prosperity in the global economy.[20] Main argument of this study is that Waiver proposal to access the COVID-19 vaccinations and medicines will prove to be an effective mechanism and hence it needs to be adopted and implemented at all levels.

1.1 Literature Review

The foundation of this thesis is a thorough review of the body of literature, forming the basis of research approach used in this thesis. Legal instruments, especially international treaties and agreements, serve as the main points of reference and are essential to the discussion. Furthermore, the academic setting is enhanced by a careful review of academic publications, journals, and some empirical data from respectable bodies like the WHO.

The COVID-19 pandemic has brought attention to the difficulties and disparities in the world's access to treatments and vaccines, particularly for developing and least-developed nations. The WTO in October 2020, saw the introduction of a proposal by India and South Africa to waive some IP rights for the pandemic health items and technologies, which could be an efficient way to address this problem. The waiver proposal has caused a contentious discussion on the function and effects of IP rights on the development and dissemination of COVID-19 health goods and technologies among WTO members as well as academics, experts, and civil society organizations.

For the enhanced access to treatment, proponents argues that waiving patents on COVID-19 treatments, particularly vaccines, would enable local manufacturers in the developing countries to locally manufacture the essentials needed to combat COVID-19,

[20] Sue Ann Ganske, "TRIPS AND DISPUTE SETTLEMENT AT THE WTO: THE TRIPS DISPUTES AND CURRENT ISSUES UNDER TRIPS AND THE DSU," *IDEA – The Journal of the Franklin Pierce Center for Intellectual Property* 62, no. 1 (2022), https://ipmall.law.unh.edu/sites/default/files/hosted_resources/IDEA/62/nhidea_62n1-2_text_issue_1_trips_dispute_1-36.pdf. accessed December 14, 2023

thereby reducing dependence on expensive imports and increasing access for underserved populations. *Tahir Amin and Aaron S. Kesselheim*[21] emphasizes the necessity of an IP waiver, as suggested by South Africa and India, in order to satisfy the multilateral aims of the WTO and boost manufacturing capacity for COVID-19-related medicines, vaccines, and other technology. For global health equity, they also argue that a waiver is necessary to address the vast disparity in access to COVID-19 treatments between wealthy and developing nations, promoting global health equity.

Jillian Kohler et al.[22] have evaluated stance of the WTO members and other important stakeholders on the TRIPS waiver. The majority of them declined to specifically contextualize the waiver within the framework of the human right to health, which highlights the importance of IP waiver to enhance access for public health. They also provided that local production could potentially bring down treatment costs, making them more affordable for low- and middle-income countries.

Opponents to the waiver argue that waiving patents could discourage pharmaceutical companies from investing in future research and development (R&D) in case of outbreaks for example, COVID-19 treatments and other diseases. One reason for this may be as their profits would be at risk as shown by *Alden Abbott and Christine McDaniel.*[23] They also argue that a waiver might not significantly increase production or reduce prices, as other factors like

[21] Tahir Amin and Aaron S. Kesselheim, "A Global Intellectual Property Waiver Is Still Needed to Address the Inequities of COVID-19 and Future Pandemic Preparedness," *Inquiry: A Journal of Medical Care Organization, Provision and Financing* 59 (September 20, 2022), doi:10.1177/00469580221124821, accessed December 18, 2023.

[22] Jillian Kohler, Anna Wong, and Lauren Tailor, "Improving Access to COVID-19 Vaccines: An Analysis of TRIPS Waiver Discourse among WTO Members, Civil Society Organizations, and Pharmaceutical Industry Stakeholders," *Health and Human Rights* 24, no. 2 (December 2022): 159–75, accessed December 24, 2023.

[23] Alden Abbott and Christine McDaniel, "A WTO Trips Agreement Waiver to Promote the Dissemination of COVID-19 Diagnostics and Therapeutics Is Unneeded and Would Impose Harm," Mercatus Center, May 5, 2023, https://www.mercatus.org/research/public-interest-comments/wto-trips-agreement-waiver-promote-dissemination-covid-19. accessed December 15, 2023

manufacturing capacity and raw material availability could play a larger role, which would cause uncertain impact on supply.

Chnag[24] mentions about the implementation challenges that even with a waiver, logistical and technical hurdles could hinder local production in developing countries, potentially limiting the impact on access.

In the article by *Mercurio*[25], the debate over the necessity and potential consequences of waiving intellectual property rights (IPRs), particularly in the context of pharmaceuticals, is rigorously examined. The essay evaluates the primary arguments supporting the waiver, namely the potential enhancement of access to affordable vaccines and the perceived complexity of alternatives within the World Trade Organization's agreement on IPRs, especially for developing nations. It is contended that the proposed waiver might not effectively address the challenges related to accessibility and affordability of medicines and vaccines. Additionally, there's concern that such a measure could impede research, development, and innovation within the pharmaceutical industry. emphasizes the unpreparedness of the world for the COVID-19 pandemic, attributing this to the lack of prioritization for severe but unlikely events by governments and the private sector. The article highlights instances where the pharmaceutical industry invested in R&D for emerging pandemics like SARS and Ebola, only for those efforts to yield minimal commercialization due to the swift resolution of the crises. However, COVID-19 presented a different scenario, with extensive resources being mobilized for research and development. This research posits that waiving IPRs may not significantly improve access to COVID-19 treatments and vaccines, as it overlooks the complexities of vaccine manufacturing and distribution. He argues that real obstacles to accessibility lie in production, logistics, and distribution capacity rather than solely

[24] Eric Chin-Ru Chang, "The WTO Waiver on COVID-19 Vaccine Patents," *UCLA Law Review*, 2023, https://www.uclalawreview.org/the-wto-waiver-on-covid-19-vaccine-patents/, accessed December 24, 2023.

[25] Bryan Mercurio, "WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review," SSRN Scholarly Paper (Rochester, NY, February 12, 2021), https://doi.org/10.2139/ssrn.3789820.

in intellectual property protections. Moreover, concerns about companies withholding supply seem unfounded given the approval of multiple vaccines across various jurisdictions. The article underscores the need to focus efforts on reinforcing supply chains, upgrading infrastructure, and ensuring efficient distribution rather than solely relying on waiving IPRs. This emphasizes the lack of evidence demonstrating that IPRs hinder the manufacturing and distribution of COVID-19 vaccines and treatments, advocating for a nuanced approach that addresses practical challenges rather than solely targeting intellectual property rights.

The debate surrounding the IP waiver is complex, with valid arguments on both sides. Ultimately, finding a solution that balances promoting access to treatments in developing countries while protecting the incentives for pharmaceutical innovation remains a critical challenge. This literature review discusses the ongoing negotiations at the WTO and various perspectives on this proposal, including the EU's alternative mechanisms. The potential impact of an IP waiver on COVID-19 vaccines is explored, including its role in expediting production, overcoming bottlenecks, and increasing vaccine availability. The limitations of voluntary licenses and the challenges associated with compulsory licensing are addressed, emphasizing the need for more effective solutions in the face of public health demands. The importance of knowledge transfer is highlighted, not only in waiving IP rights but also in ensuring technology and know-how are shared with manufacturers to enhance vaccine production in low- and middle-income countries. The role of governments in facilitating these transfers is also discussed.

1.2 Research Questions

The research questions are as following:

i. What is an intellectual property (IP) waiver?

ii. What is the TRIPS framework regarding patent protection across borders?

iii. What are the exceptions to the exclusivity under the patent laws of Pakistan?

iv. Whether SARS Cov-19 vaccinations be accorded intellectual property waiver or be given patent protections under the patent laws?

1.3 Research Methodology

This thesis employs a multi-faceted research methodology that aligns with established academic practices, encompassing, qualitative research techniques. This research is based on a thorough review of the literature. This thesis includes a methodical review of books, academic journals, scholarly articles, and other relevant materials. The goal is to compile a thorough understanding of the scholarly discussion surrounding the topic.

Academic publications that address relevant topics along with books and articles are analyzed for content. This entails recognizing the main ideas, points of contention, and revelations made in these sources. It aids in the synthesis of relevant concepts and theories.

Ethical considerations will be diligently observed throughout the research process. This includes ensuring proper citation of sources and adherence to academic integrity standards.

By integrating these research methods and techniques, this thesis aims to provide a comprehensive exploration of the Waiver proposal to access COVID-19 vaccinations and recommends its approval and implementation at all levels.

1.4 General Framework Under Trips and Other Laws

As part of the Marrakesh Agreement, WTO member states are concerned about the distinction between enforcing intellectual property (IP) rights, leading to issues in the global economy as non-tariff barriers to international trade. The TRIPS agreement aims to integrate instead of

independently protecting and enforcing the IP in Member States by maintaining minimum global standards.[26]

The preamble identifies the "need to promote the effectiveness and adequate protection of IP rights to implement the enforcement as the primary goal of the TRIPS Agreement". TRIPS guarantees that the fundamental tenets of the GATT and other international accords, which offer the structure for multilateral prevention and party dispute settlement, are applicable. Member states appreciate the necessity for an international framework to prevent the trade in counterfeit goods on a global scale and the importance of IP rights in ensuring that regulations form the foundation of the IP system.

TRIPS provide the framework for the least-developed countries to be taken into consideration in the implementation of the national legislation so that a maximum degree of flexibility can be achieved. The preamble of the TRIPS establishes clear references in integrating the bond between the protection of intellectual property rights and the GATT rules on international trade. The interpretation of provisions of the TRIPS can't be done in isolation but as an essential part of the WTO system. Same can be found in the instance of "*India-Patent Protection for Pharmaceutical and Agricultural Chemical Products"*.[27]

Although the Preamble cannot be enforced as a tool for the modification and obligations assumed in the agreement, rather Article 7 and 8 of the TRIPS must be taken into account and interpreted to establish the objectives and guiding principles of the Agreement. Article 7 establishes the premises for the enforcement and protection of IP rights to promote technological innovations. Article 7 also balances the "protection and promotion of IP rights for the socio-economic welfare and technological discoveries by transferring technology".

[26] UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (Cambridge: Cambridge University Press, 2005), doi:10.1017/CBO9780511511363, accessed December 24, 2023.

[27] INDIA - PATENT PROTECTION FOR PHARMACEUTICAL AND AGRICULTURAL CHEMICAL PRODUCTS, WT/DS50/AB/R (Report of the Appellate Body, 1997).

These provisions of the TRIPS reflect the balance of IP rights which seek "innovation and securing access to science, technology, and culture".[28] It offers the basis upon which strategies for the defense and upholding of intellectual property rights within the Agreement's framework are built. The principles for policy making that underpin the Agreement have been outlined in Article 8 of TRIPS, and member nations are required to take these principles into account while implementing any of the Agreement's provisions. It safeguards the member states' rights to implement the policies and practices required to preserve public nutrition and health. As a result, these regulations stop the infringement of intellectual property rights in accordance with TRIPS and stimulate public interest in fields that are essential to socioeconomic and technical growth. This came into effect as a result of the proposal put forth by the developing nations, which had an impact on Article 7.77 under the guidance of Article 8.1. Member states may be able to impose price controls on pharmaceutical products, as well as other financial incentives and taxes that may be deemed necessary for the standpoint of the national economy and the businesses of all sizes being carried out nationwide. These provisions permit actions conducted that could affect patentee rights, such as price control i-e where they are thought appropriate in conjunction with other agreement conditions.[29] Article 8.2 of the TRIPS sets the conditions for the member states to take preventive measures against the possible misuse of IP rights such as the practices that might disrupt the trade and could severely damage the transfer of technology. These preventive measures should fulfil certain prerequisites for the practices in question. Specifically, they should be: (i) appropriate, meaning they should be sufficient and commensurate with the gravity of the practice that needs to be curbed; (ii) in compliance with other TRIPS provisions, particularly articles 3, 4, 27 and 40; and (iii) necessary. The member states are permitted to implement the rules and regulations

[28] Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights*, 3rd ed. (Kluwer Law International, 2010). accessed December 23, 2023

[29] Daniel J. Gervais, *The TRIPS Agreement: Drafting History and Analysis* (London: Sweet & Maxwell, 1998),accessed December 20, 2023

that prohibit abusive clauses under certain conditions.[30] Thus, it is concluded that Articles 7 and 8 make the case for the freedom of member states to regulate these policies in coherence with their national interests. Contrarily, the provisions have also provided the basis for debate concerning the consideration of TRIPS, keeping in line the public health issues, while doing any legislation. Moreover, other than consideration of Article 7 and 8, which provides the guidelines as essential principles of TRIPS related to IP rights, they also concern the national, territorial and most-favored nation status.[31] However, the principles of TRIPS do not provide the territoriality principle according to which the sovereignty of member states adopt the adequate implementation method of the provisions of the agreement. Similarly, intellectual property rights remain subject to the national law according to which member states force the protection of rights within their territory.

According to Article 28.1 of the TRIPS Agreement, member states are required to guarantee the availability of the rights within the scope of the patent holder's exclusive rights in order to prevent the unlawful use of their products. Thus, the importation of patent rights must be exercised within a country's jurisdiction. The agreement also implicitly refers to the guidelines given in Article 2 which determine the Articles 1, 12 and 19 of the Paris Convention to comply with the Parts II, III and IV of TRIPS substantially. Article 4 sets out that the grant of the patent according to the Paris Convention to one country remains independent of other grants provided in the same conventions to other countries.

This independence reiterates the importance of TRIPS and the scope of the agreements which are necessary not only to acquire the license but also for the invalidity and exhaustion

[30] Carvalho, *The TRIPS Regime of Patent Rights*.

[31] Joseph Straus, "Implications of the TRIPs Agreement in the Field of Patent Law," *Beier & Schricker (Eds.) From GATT to TRIPs-The Agreement on Trade-Related Aspects of Intellectual Property Rights. IIC Studies* 18 (1996): 160–215, accessed December 19, 2023

of the patent in which one country may lead to the invalidation of the exclusivity of another country.[32]

Nonetheless, the TRIPS agreement aims to balance disparate legal frameworks and establish minimal requirements for patent applications, which inadvertently compromises the sovereignty of its member states. It shows the nations' limitations following the legal ramifications. It is also important to examine the effects of patent rights on territory. The various legal factors that affect patentability and the extent of protection are also to be considered. Without eroding the territorial concept or undermining member states' sovereignty in the subject, TRIPS offers a remedy to the detrimental effects of intellectual property rights in international trade.[33] Albeit, it is not justified to misconstrue the national treatment principle "about the maintenance of trademark rights as preventing the grant of tariff, subsidy or other measures of support to national companies because this would render the maintenance of trademark rights by foreign companies wishing to export to that market relatively more difficult".[34] Therefore, it is compulsory for the member states to comply with the rules and regulations established for international trade while keeping in view the framework of TRIPS and IP rights.[35] However, there are some exceptions to the rule defined by the TRIPS that might cause discrimination in developing countries.[36]

[32] Bartels, "Applicable Law in WTO Dispute Settlement Proceedings."

[33] Tolulope Anthony Adekola, "Compulsory Licenses in a Regional Context: An Appraisal of the TRIPS Amendment's Special Regional Treatment," *GRUR International* 71, no. 9 (2022): 822–30, accessed December 24, 2023.

[34] Siva Thambisetty et al., "ADDRESSING VACCINE INEQUITY DURING THE COVID-19 PANDEMIC: THE TRIPS INTELLECTUAL PROPERTY WAIVER PROPOSAL AND BEYOND," *The Cambridge Law Journal* 81, no. 2 (July 2022): 384–416, doi:10.1017/S0008197322000241, accessed December 24, 2023.

[35] Philip Loft, "Waiving Intellectual Property Rights for Covid-19 Vaccines," *House of Commons Library*, December 19, 2023, https://commonslibrary.parliament.uk/research-briefings/cbp-9417/. accessed December 18, 2023

[36] Getachew Mengistie, "The Impact of the International Patent System on Developing Countries," *Journal of Ethiopian Law* 23, no. 1 (2009): 161–219, accessed December 24, 2023.

1.5 Research Design

Chapter 2: This chapter explores the complex legal environment pertaining to patents, both globally and in Pakistan's particular jurisdiction. After a basic introduction, the investigation proceeds to examine the relationship between patents and the WTO. A thorough examination of the TRIPS Agreement reveals the worldwide legal duties pertaining to patent protection. The crucial balance between public health and patent protection is also covered in this chapter, with a focus on life-saving medications. Additionally, it explores the dynamic field of patent exclusivity and its significance within the scope of the Covid-19.

Chapter 3: Based on critical research, this chapter examines the existing framework for intellectual property waivers and draws attention to the intricate legal challenges and underlying inequities. Historical patterns and the evolution of waiver provisions are examined. One can learn about the circumstances in which waivers might not be applicable as well as the underlying reasoning for these exceptions by focusing on IP waiver exclusions. The chapter, which thoroughly examines the impact of intellectual property waivers on the development and distribution of SARS-CoV-19 vaccines. Through this in-depth examination, the chapter aims to bring nuanced perspectives to the discussion on vaccine accessibility.

Chapter 4: This chapter functions as the concluding chapter, providing a brief overview of the research methodology as well as a summary of the key findings from each previous chapter. Subsequently, the focus shifts to developing insightful conclusions that underscore the research's broader implications for the domains of intellectual property and public health. The thesis concludes with a well-reasoned list of recommendations appropriate for international organizations and attorneys. Apart from offering potential options for future adjustments or enhancements to the existing legal framework, these concepts offer workable solutions and add to the ongoing global discourse on the connection between intellectual property and public health.

Chapter 2: CONCEPT OF PATENTS UNDER INTERNATIONAL AND LOCAL LAWS OF PAKISTAN

2.1 Introduction

The patent system is crucial to the advancement of invention and innovation in the context of the global economy. With the help of patents, inventors can profit from their creations by gaining a monopoly over a certain good or service. Patents encourage further creation by providing a potential source of revenue, in addition to aiding innovators in recouping their research and development expenses.[37] Furthermore, patents prevent infringement, ensuring the protection of the rights of the inventor and their capacity to get fair and just compensation for their work. Furthermore, by encouraging competition among producers, patents support economic progress as new products and services are introduced to the market. As a result, patents protection is required under WTO regulations to maintain an innovative environment. Furthermore, patents are essential for guarding against the illicit use of intellectual property and guaranteeing that the legal owners are compensated fairly. Patents are essential for defending the IP rights of inventors and motivating businesses to spend money on R&D projects that will boost the world economy. The WTO plays an important role in regulating patent protection and providing an international framework for its enforcement. Patents are a key part of the TRIPS agreement and provide exclusive rights to creators, allowing them to benefit from their inventions by establishing a monopoly over the invention. The patent system is essential in promoting innovation and invention, which helps to drive economic growth.[38]

[37] Barnes-Weise, Rutschman, and Adler, "Assessment of the Proposed Intellectual Property Waiver as a Mechanism to Address the COVID-19 Vaccine Scarcity Problem."

[38] Walter G. Park, "International Patent Protection: 1960–2005," *Research Policy* 37, no. 4 (2008): 761–66. accessed December 19, 2023

The treaties signed under the World Intellectual Property Organization (WIPO) along with the regional and national laws, administers and forms the international legal framework for patents. Paris Convention for the Protection of Industrial Property is the first treaty that was signed to protect the patent, trademark and repression of unfair competition.[39] The repression of unfair competition does not fit into the established definition of property; it was entered into the treaty first time in 1925. The Paris Convention treaty has been revised six times since its adoption in 1883. Thus, the Paris Convention Treaty remains one of the old treaties for the protection of now called Intellectual Property Rights.[40]

The Patent Cooperation Treaty (PCT), an international agreement dating back to 1970, helps streamline and simplify the process of seeking patent protection. It enables inventors to file a single patent application with one foreign patent office rather than having to separately apply for patents in each country they wish to protect their invention. The WIPO oversees the PCT system, which offers numerous important advantages to both applicants and approved national patent offices.[41] The PCT gives applicants the option to postpone the submission of direct applications to several nations until they have additional knowledge about the invention's commercial potential or whether it would be a wise investment. This considerably reduces the costs related to obtaining patents worldwide by doing away certain requirement to perform research along with payment of registration fees to different patent offices. Furthermore, the PCT simplifies the process of applying for patents in multiple countries. It allows the applicants to submit a single worldwide application that complies with the set of rules and regulations in all the participating nations.[42] This reduces the amount of paperwork required in addition to

[39] G. H. C. Bodenhausen, ed., *Guide to the Application of the Paris Convention for the Protection of Industrial Property (G.H.C. Bodenhausen)* (Geneva, Switzerland: World Intellectual Property Organization, 1969), doi:10.34667/tind.28637, accessed December 24, 2023.

[40] Ibid.

[41] Jay Erstling and Isabelle Boutillon, "The Patent Cooperation Treaty: At the Center of the International Patent System," *William Mitchell Law Review* 32, no. 4 (January 1, 2006), https://open.mitchellhamline.edu/wmlr/vol32/iss4/9, accessed December 24, 2023.

[42] Khalid Kabir, "Patent Law & Economic Development: Empirical Evidence from Pakistan" (Master's Thesis 2020).

enabling faster access to patents in those countries where they would otherwise need to wait for their national filing. Moreover, it provides enhanced information about patents that are pending in each country, allowing innovators to ascertain whether a previous patent could affect the legality or commercial feasibility of their innovation. All things considered, the PCT has greatly aided in the protection of patents around the world and has streamlined and expedited the patent application procedure in a number of countries. It gives applicants a single international application and permits them to delay filing individual applications until they have additional information, helping inventors save costs of registrations while yet ensuring that their patents are adequately protected internationally. By ratifying the PCT, participating countries and their patent office's gain access to a unified patent system that provides better information regarding patents that already exist.[43] This facilitates their ability to identify infractions and, if required, take appropriate action. Moreover, governments, businesses, and people can save time by cross-referencing patents more readily while conducting research or requesting licensing if patent systems are harmonized globally. This facilitates their ability to identify infractions and, if required, take appropriate action. A vital component of making sure patents is protected across borders is the Patent Cooperation Treaty, which has shown to be a useful instrument for patents worldwide. The PCT assists innovators in better protecting their patents, saving money while still enabling them to benefit from their creations, by giving applicants a single application, expediting the patent application submission process, and thereby improving access to patent information.

The International Patent Classification (IPC), which was adopted through the Strasbourg Agreement, categorizes technology into eight main groups, each of which has over 80,000 specific subcategories. In order to retrieve patent materials for "prior art investigation", classification is necessary. The quest would be practically impossible without it. Patent-issuing

[43] Mengistie, "The Impact of the International Patent System on Developing Countries."

entities, inventors in the making, and research and development divisions, among others involved with technology implementation or progression demand such retrieval.[44] The Patent Law Treaty 2000 (PLT) was enacted to simplify and modernize the formalities surrounding patent applications, granting them on a national or international level. This treaty was designed to make the process more accessible for users by eliminating redundant steps for filing of patent applications and to ensure the consistency between countries in their procedures. Apart from filing date requirements, the PLT offers Contracting Parties the highest set of standards that can be applied in their office.[45]

In Pakistan, The Drug Regulatory Authority of Pakistan (DRAP) plays a pivotal role in ensuring the safety, efficacy, and accessibility of medicines within Pakistan. Established under the Drug Regulatory Authority of Pakistan Act,[46] DRAP is tasked with regulating the registration, manufacturing, import, export, distribution, and pricing of pharmaceutical products in Pakistan.

Within the framework of the COVID-19 pandemic, DRAP has been instrumental in expediting the regulatory approval process for COVID-19 treatments and vaccines, thereby facilitating timely access to essential medicines for the Pakistani population. Through its regulatory oversight, DRAP evaluates the safety and efficacy of COVID-19 treatments, ensuring that only authorized and quality-assured products are made available to the public.

Furthermore, DRAP plays a crucial role in price regulation to ensure that medicines, including COVID-19 treatments, remain affordable and accessible to all segments of society. By implementing pricing policies and regulations, DRAP strives to prevent the exploitation of

[44] ANNEX VI, "International Patent Classification," n.d, accessed December 24, 2023.

[45] Jerome Reichman and Rochelle Dreyfuss, "Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty," *Duke Law Journal* 57, no. 1 (October 1, 2007): 85–130, accessed December 24, 2023.

[46] "Drug Regulatory Authority of Pakistan Act" (2012).

consumers and mitigate the financial burden associated with accessing essential medicines during public health emergencies such as the COVID-19 pandemic.

In the context of the Intellectual Property Waiver proposal, DRAP's regulatory functions are integral to balancing the objectives of promoting innovation and ensuring access to medicines. While intellectual property rights confer exclusive rights to pharmaceutical companies, DRAP's regulatory oversight ensures that these rights do not impede access to affordable and quality-assured medicines for the Pakistani population.

2.2 Concept of Patents and WTO

The Uruguay Round of General Agreement on tariffs and trade (GATT) negotiations, running from 1986 to 1994, was the most extensive and extended multilateral trade negotiation process of all eight rounds sponsored by the GATT. The groundbreaking agreement included negotiations with 125 countries, and it was particularly progressive in that it covered trade services as well as rules regarding intellectual property rights (IPRs), topics that the GATT had not touched since its inception in 1947. The US was deeply in discontent with the lack of Intellectual Property Rights (IPR) protection throughout the world, particularly with regards to imitation and piracy occurring frequently in developing countries - even though multiple international IPR treaties exist that prohibit these actions. Thus, negotiations were conducted to ensure that adequate IPRs are safeguarded globally. Backed by the EU and Japan, the United States pushed firmly to have Intellectual Property Rights (IPRs) included in the last GATT round of multilateral negotiations, The Uruguay Round. After a series of intense IPR negotiations, TRIPS was created, one of today's most contentious multilateral trade agreement.[47]

[47] Saggi, "Trade, Intellectual Property Rights, and the World Trade Organization."

According to the TRIPS Agreement, patent protection must be granted for novel inventions in all technological sectors that involve creative and revolutionary steps and utilization of this protection on a commercial level. Inventions eligible for patent protection can be either products or processes. To ensure protection, patentability of an invention must be kept in effect for a minimum of two decades. On the other hand, if safety or ethical issues arise, governments may decline to issue a patent for an invention. In addition, diagnostic, therapeutic and surgical techniques, plants or animals (other than micro-organisms) as well as biological processes used in their production (excluding microbiological methods), can all be exempted from patent protection. To ensure the safety of plant varieties, patents and a special system like the breeder's rights provided by UPOV (the International Union for the Protection of New Varieties of Plants) must be in place. These methods provide the protection from exploitation or theft. The TRIPS Agreement lays out the essential privileges that a patent owner is entitled to and details any exceptions that can be made in certain circumstances. The Agreement grants governments the authority to grant compulsory licenses, which permit another entity to manufacture a product or apply the process without obtaining consent from its owner. Nevertheless, this can only be done under specific circumstances laid out in the TRIPS Agreement that ensure the protection of the patent-holder's interests.[48]

A patent issued for the invention of a process must grant legal protection to any product derived directly from said process. In some cases, a court may require alleged patent violators to demonstrate that they have not engaged in the patented process. The availability of affordable medicines in times of crisis is a key indicator of a country’s resilience. This access is made possible in large part by the heavily integrated multinational production and commerce networks of today, especially during pandemics. WTO and the WHO play a synergic role in

[48] Steve Charnovitz, “Patent Harmonization under World Trade Rules,” *The Journal of World Intellectual Property* 1, no. 1 (January 1998): 127–37, doi:10.1111/j.1747-1796.1998.tb00007.x, accessed December 20, 2023.

assuring affordable access to goods globally. WHO regulates world health care, the medical supply chains originated in a few developed countries, manufactured in developing countries at low cost and finally traded worldwide. Here, the WTO's function, which offers the foundation for global economic cooperation and intellectual property rights monitoring becomes significant. These components serve as important pillars for the manufacture of medical supplies. Most of the global reaction to COVID-19 has been disjointed, despite calls for cooperation to lessen the virus. The lack of consensus and cooperation has had serious repercussions for developing countries.[49]

2.3 International Framework on Patent Protection and TRIPS

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) lays forth minimum requirements for the defense and enforcement of IP rights, including patents. The GATT Uruguay Round was used to negotiate it, and it went into effect on January 1st, 1995.[50]

TRIPS mandates that, with certain restrictions, all WTO members give patent protection for all inventions in all technological disciplines. Any innovative, inventive, and practical product or procedure must be eligible for a patent, which must also be awarded for a set amount of time. The minimum term of a patent under TRIPS is 20 years from the filing date. In addition to establishing minimum standards for patent protection, TRIPS requires countries to provide effective means of enforcing patent rights. This covers both civil and criminal remedies for patent infringement in addition to steps taken to prevent the importation of goods that breach patents. TRIPS also allows countries to 'grant compulsory licenses, which allow third parties to use a patented invention without the patent holder's permission as long as certain requirements are met". These situations include those in which the invention must be

[49] Mrityunjay Kumar, Ayesha Fatma, and Nalin Bharti, "Access to Medicines and Medical Equipment during COVID-19: Searching Compatibility between the WTO and the WHO," *India Quarterly* 78, no. 1 (March 1, 2022): 68–87, doi:10.1177/09749284211068461 accessed December 18, 2023.

[50] Valentyn Fedorov et al., "Theoretical Problems of Legal Regulation of Innovations in the Medical Field: Experience in Counteracting Covid-19," *Ius Humani. Law Journal* 9, no. 2 (October 15, 2020): 251–89, doi:10.31207/ih.v9i2.254, accessed December 24, 2023.

made available owing to public interest or in which the patent holder has declined to give a reasonable license for the invention.[51]

TRIPS allows countries the freedom to adopt stricter regulations to protect public health, improve drug access, and foster innovation, even if it also establishes the fundamental conditions for patent protection. For instance, it enables nations to exempt from patent infringement specific uses of protected ideas, including those carried out for public health protection. The TRIPS agreement strikes a balance between the need to promote innovation and access to necessary medications, while also offering a framework for the protection and enforcement of intellectual rights in international trade.

2.4 TRIPS and Life-Saving Medicines

Even though TRIPS has significantly benefited in the promotion of innovation and economic growth, debate has arisen because of its effect on the cost and availability of life-saving medications. The 20-year patent protection period under TRIPS, which grants the patent holder exclusive rights to produce and market the goods, is one of the primary issues with the agreement. Life-saving medications can be extremely expensive for many people, especially those who don't have access to government assistance or health insurance and live in low-income nations. To address this issue, the TRIPS agreement contains a clause that permits nations to impose mandatory licenses on patented goods under specific circumstances, such as a public health emergency. This provision allows for the manufacture or importation of generic copies of patented medications, which are able to be marketed for significantly less money.[52]

However, there has been debate surrounding the use of compulsory licenses. Some claim that this reduces the incentives for innovation and the defense of IP rights. Others contend

[51] Siva Thambisetty et al., "The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to End the COVID-19 Pandemic," *SSRN Electronic Journal*, 2021, doi:10.2139/ssrn.3851737, accessed December 24, 2023.

[52] Priti Krishtel and Rohit Malpani, "Suspend Intellectual Property Rights for Covid-19 Vaccines," *BMJ*, (May 28, 2021) doi:10.1136/bmj.n1344, accessed December 18, 2023.

that the high cost of life-saving drugs creates an unfair burden on people and governments and that compulsory licensing is an essential tool for guaranteeing that everyone has access to affordable medicines. All things considered, there are substantial implications for the economy, innovation, and public health from the complex and multidimensional relationship between TRIPS and life-saving drugs.[53]

Finding a solution within the current system is much more challenging than it was before as there is a big gap in understanding, regarding the provision of life-saving medications and patent protection in developing and Least Developed Countries (LDC). Many developing nations and non-governmental organizations have been waiting for the WTO members to respond to their issues and guarantee access to developing nations for a long time. The people of these underdeveloped nations have endured worse and lost the fight against diseases like malaria, tuberculosis, and HIV/AIDS, highlighting the need for structural and operational adjustments to be made by the WTO. However, many health-related issues weren't resolved until the Fourth Ministerial Conference held in Doha, Qatar in 2001.[54] These parties managed to somehow get their agenda accepted during the Seattle Conference in 1999. (Doha round). Throughout the Doha round. The WTO is a global organization with the mission of advancing trade and economic growth. One of the main issues that the WTO has addressed is the availability of affordable drugs in developing and least developed countries while still protecting the intellectual property rights of pharmaceutical companies. The Doha Round, a set of talks, was initiated in 2001 to address a number of issues regarding international commerce, including the availability of pharmaceuticals.[55] Approved in 2001, the Doha Declaration on the

[53] Irene Calboli, "Trade Mark Licensing and Covid-19: Why Fashion Companies Have a Duty to Comply with Their Legal Obligations," *Journal of Intellectual Property Law & Practice* 15, no. 7 (June 1, 2020): 489–90, doi:10.1093/jiplp/jpaa088, accessed December 24, 2023.

[54] Reto Hilty et al., "Covid-19 and the Role of Intellectual Property: Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021," *SSRN Electronic Journal*, 2021, doi:10.2139/ssrn.3841549, accessed December 24, 2023.

[55] Ling Jin, "Alternative Protection of Intellectual Property Rights in Vaccine Production and Use under Covid-19," *Journal of Education, Humanities and Social Sciences* 1 (July 6, 2022): 147–53, doi:10.54097/ehss.v1i.654, accessed December 19, 2023.

TRIPS Agreement and Public Health recognized the concerns of the least-developed and developing nations. It explained that member states should not be prevented by the TRIPS agreement from taking steps to safeguard public health. The WTO members developed a set of protocols that enable developing countries to use compulsory licensing to manufacture or import generic versions of patented medications in order to address public health emergencies. Giving developing and least developed countries access to reasonably priced drugs was made possible by this important move. Concerns have been raised about the Doha Declaration's requirements not being completely followed and the continued lack of access to reasonably priced drugs. In response, a few developing and least-developed nations have demanded greater flexibility, citing the possibility of using mandatory licensure in non-emergency scenarios as well as an expansion of the illnesses that the rules cover. Global health development is affected by the complex and crucial challenges that the WTO and its members continue to face with access to inexpensive medicines and the protection of IP rights. Despite including several difficult issues on their agenda, the Doha Round was unable to tackle the important problem of required licensing. As a result, the subject of mandatory licensing[56] is still open.

Inventors continue to have a dominant position, which causes prices to soar in comparison to the remaining market competition. Thanks to patent protection, which grants the creators the sole right to use, this monopolistic position is justified. Consumers cannot afford copyrighted goods or commodities as a result. However, patenting becomes dubious when the product is crucial for human health, such as life-saving medications. With the implementation of the TRIPS in 1995, the discussion became more heated. The prices of patented medications, however, were unanimously increased without affecting access. TRIPS also contains several mechanisms to facilitate access, including the issuance of mandatory licenses, parallel imports,

[56] M.D. Nair, "TRIPS and Access to Affordable Drugs," *Journal of Intellectual Property Rights* 17 (July 1, 2012): 305–14, accessed December 20, 2023.

and technical incentives. Therefore, the crucial question is whether these tools are adequate to provide access to patented medicines that can save lives in the event of an emergency or pandemic.[57]

2.5 Patent exclusivity and TRIPS framework on Covid-19

The SARS-CoV-2's outbreak and rapid spread has sparked a discussion regarding public health emergencies and the structure of patents under TRIPS. It has spurred discussion about the need to waive some of the TRIPS requirements on patents in order to make it easier for people to get access to the necessary drugs and medical supplies to fight this disease. Even if there has been a drop in the trend of infection instances, the conversation surrounding it is still very important to prevent future occurrences of the same problems. There are two sides to the argument for waiving certain of the TRIPS's requirements. The supporters contend that there is a mechanism in place to balance the protection of IP rights with easing access to vaccines, diagnostic tools, and equipment in times of public health emergencies. Critics contend that the TRIPS waiver might not be necessary because current laws already permit states to violate intellectual property rights in times of public health emergencies by using forced licensing. When authorization is given to a third party to use, sell, produce, or use a patented process without the owner's express consent, licensing becomes necessary.[58]

The COVID-19 pandemic has highlighted the crucial need of having universal access to vaccines, medications, and other health technologies. A collection of international laws covering intellectual property rights, including patents, known as the TRIPS (Trade-Related Aspects of Intellectual Property Rights) framework was developed and adopted by WTO. The TRIPS agreement mandates that member nations guarantee protection for intellectual property rights, including patents, and defines minimum requirements for their protection and

[57] Krishtel and Malpani, "Suspend Intellectual Property Rights for Covid-19 Vaccines."

[58] Bryan Oronsky et al., "Patent and Marketing Exclusivities 101 for Drug Developers," *Recent Patents on Biotechnology* 17 (January 11, 2023), doi:10.2174/1872208317666230111105223, accessed December 24, 2023.

enforcement. However, it also permits some leniency in how patents are issued and upheld, particularly in the situations of crises including the public's health.

The power of nations to grant compulsory licenses, which enable a government to permit a third party to produce and market a patented product without the patent holder's approval, is one of the key flexibilities. During a public health emergency like the COVID-19 outbreak, compulsory licensing can be a crucial instrument for increasing access to necessary medications. Additionally, the TRIPS agreement gives nations the option to waiver under certain circumstance e-g Article 31 that provides compulsory licensing in order to preserve public health. After the waiver proposal was iroduced, some nations have used this clause to temporarily waive some TRIPS requirements relating to patents and other intellectual property rights for COVID-19 vaccines and medications in response to the COVID-19 pandemic. The crucial need of having universal access to vaccines, medications, and other health technologies has been duly enlightened during the Pandemic.[59]

One of the important flexibilities is the ability of nations to give compulsory licenses, which allow a government to allow a third party to make and market a patented product without the patent holder's consent. Mandatory licensing can be a vital tool for expanding access to essential pharmaceuticals during a public health emergency like the COVID-19 outbreak.[60] The TRIPS agreement also provides nations with the ability to waive specific provisions when doing so is necessary in order to protect the public health. In response to the COVID-19 pandemic, certain countries have made use of this clause to temporarily disregard some TRIPS restrictions concerning patents and other intellectual property rights for COVID-19 vaccinations and treatments.

[59] Charles E. Phelps, "Extending Exclusivity for Biopharmaceuticals to Deter Competing Generics: A Review of Strategies, Potential Mitigation, and Similarities to Infringement," *Technology & Innovation* 21, no. 3 (August 29, 2020): 215–27, doi:10.21300/21.3.2020.215, accessed December 24, 2023.

[60] B. H. Hall, "Patents and Patent Policy," *Oxford Review of Economic Policy* 23, no. 4 (December 1, 2007): 568–87, doi:10.1093/oxrep/grm037, accessed December 18, 2023.

The COVID-19 pandemic has brought to light the critical need for having ubiquitous access to drugs, vaccinations, and other health technologies. Members of the WTO adopted the TRIPS (Trade-Related Aspects of Intellectual Property Rights) framework, a group of international regulations governing IP rights, including patents. The TRIPS agreement establishes basic standards for the protection and enforcement of intellectual property rights, including patents, and requires that member countries ensure a specific degree of protection for such rights. However, it also allows for some flexibility in how patents are granted and upheld, particularly in instances where there is a public health emergency.[61]

The power of nations to grant compulsory licenses, which enable a government to permit a third party to produce and market a patented product without the patent holder's approval, is one of the key flexibilities. During a public health emergency like the COVID-19 outbreak, mandatory licensing can be a crucial instrument for increasing access to necessary medications. Additionally, the TRIPS agreement gives nations the option to waive particular clauses were doing so is required to preserve public health. Some nations have used this clause to temporarily waive some TRIPS requirements relating to patents and other intellectual property rights for COVID-19 vaccines and medications in response to the COVID-19 pandemic. Some rich nations and the pharmaceutical industry have opposed the waiver, which was proposed by India and South Africa and backed by many developing nations, claiming that it will weaken innovation and intellectual property rights. In the event of a global health emergency, supporters of the waiver argue that it is imperative to guarantee that everyone, regardless of wealth or geography, has access to life-saving drugs and vaccines. The COVID-19 pandemic has brought to light the importance of striking a compromise between the need to ensure access to critical medical advancements and the preservation of intellectual property

[61] Fabian Gaessler and Stefan Wagner, "Patents, Data Exclusivity, and the Development of New Drugs," *The Review of Economics and Statistics* 104, no. 3 (May 2022): 571–86, doi:10.1162/rest_a_00987, accessed December 24, 2023.

rights.[62] How to ensure that intellectual property rights do not prevent people from getting access to critical medications and immunizations during international health emergencies is a persistent concern till now. Countries have an option within the TRIPS framework to respond to public health emergencies as has been discussed above.

2.6 Conclusion

In conclusion, it is critical for Pakistani researchers, businesses, and inventors to understand the complex terrain of local and international patent rules. Gaining a thorough grasp of patentability standards, infringement rules, and enforcement methods enables people to safeguard their intellectual property, promote innovation, and advance the economy of their country. Understanding the changing nature of this area and the continuous conversation between national laws and worldwide norms, being knowledgeable and involved is still essential to maximizing the benefits of Pakistan's patent system.

Even though Pakistan's patent environment has changed dramatically in recent years, bringing it into compliance with international norms and encouraging a thriving innovation culture, there are still issues that need to be acknowledged. Important areas for future development in this regard include the improving enforcement methods, increasing public understanding of intellectual property rights, and streamlining administrative procedures. But there are a lot of advantages to having a strong patent system. In addition to encouraging innovation and entrepreneurship, safeguarding and valuing innovations can draw in outside capital and help Pakistan’s transition to a knowledge-based economy. A vibrant and dynamic patent ecosystem in Pakistan will emerge from seizing these opportunities and tackling the current issues with a dedication to the constant development.

[62] Maarten Pieter Schinkel, “Effective Cartel Enforcement in Europe,” *SSRN Electronic Journal*, 2007, doi:10.2139/ssrn.948641, accessed December 22, 2023.

A fundamental question arises as we find ourselves at the intersection of national and international patent laws: How can Pakistan use patents to protect individual inventions while simultaneously promoting a more expansive innovation culture that tackles the complex issues facing the country and the world? Pakistan can unlock a future in which technology developments act as catalysts for prosperity and growth by embracing the transformational power of intellectual property, fostering collaboration, and placing a high priority on education. As this chapter explains, the path to the future starts with a thorough comprehension of the present. This has been addressed in the recent legislations enacted to safeguard the intellectual property rights at national level.

Chapter 3: INTELLECTUAL PROPERTY WAIVER TO SARS-COV-19 VACCINATIONS

3.1 Critical Analysis of the Framework Dealing with Intellectual Property (IP) Waivers

On October 2, 2020, "India and South Africa made a collective appeal to the WTO to temporarily waive coronavirus-related intellectual property rights such as patents, industrial designs, copyrights, and confidential information protection".[63] By March 2021, the proposal had been embraced by developing countries and backed by fifty-eight members, with an additional one hundred nations in support. [64] Despite the proposal, many developed countries including the US, the UK, the EU, Switzerland and Japan initially resisted. However, in a surprise move, The US under Biden's Administration reversed its stance to only allow for vaccine patents to be waived off as part of the TRIPS Waiver.[65] Although this action was encouraging it still lacked enough support from other nations to guarantee the success of the proposal. On May 31, 2021, the TRIPS Council reignited negotiations on the TRIPS Waiver; however, due to opposition from European countries like the EU and Switzerland as well as the UK - no tangible progress was made at talks.[66]

The 12th Ministerial Conference of the WTO was due to take place in November 2021, with the TRIPS Waiver over the COVID-19 vaccinations on its agenda. However, this event has been deferred again due to a new strain of COVID-19 - Omicron variant - thus continuing the current deadlock indefinitely.[67] After the outbreak of SARS-CoV-2, in less than a year researcher has successfully developed a safe and effective vaccine against the virus. "Eight

[63] Ann Danaiya Usher, "South Africa and India Push for COVID-19 Patents Ban," *The Lancet* 396, no. 10265 (December 5, 2020): 1790–91, doi:10.1016/S0140-6736(20)32581-2, accessed December 24, 2023.

[64] Eric Chin-Ru Chang, "The WTO Waiver on COVID-19 Related Intellectual Property Rights: Why It Should Be Adopted and Why It Is Not Enough," SSRN Scholarly Paper (Rochester, NY, February 18, 2022), doi:10.2139/ssrn.4041630, accessed December 20, 2023.

[65] Ibid.

[66] Zarocostas, "What next for a COVID-19 Intellectual Property Waiver?"

[67] Hyo-young, "Overview of the Twelfth WTO Ministerial Conference (MC12) and Implications for the Multilateral Trading System."

vaccines got emergency use authorizations, while the Pfizer-BioNTech mRNA was approved by the U.S. Food and Drug Administration (FDA)". According to the Data Project at the University of Oxford, only 26.52% of the population of the world was fully vaccinated by September 2021. The official data shows the inequitable distribution of vaccines to the developing and the least developed nations. In the UK 62.6% and 51.3% of the population have been fully vaccinated while the percentage of vaccinated people in Africa remains relatively quite low. In Nigeria, only 0.7% of the population and 1.5% of the Kenyan population are fully vaccinated".[68] Similarly, 41.6% of the North American population is fully vaccinated and 47.5% of the European population is vaccinated in comparison to 2.63% African population. It was obvious in 2021, that the pandemic will not be completely controlled 2021 due to the policies adopted by most of the rich countries.

WTO negotiators ultimately came to an agreement in June 2022 and released the Ministerial decision on the TRIPS agreement after months of discussions. Trade-Related Aspects of Intellectual Property Rights, or TRIPS for short, is an international convention that establishes principles for safeguarding intellectual property rights globally.[69] As compared to its initial blueprint in 2020, the agreement is more restrictive. It:

• By providing a way for developing countries to utilize patented materials in the production of vaccines without seeking permission from rights holders, vaccine manufacturers have been encouraged to produce the vaccine domestically and abroad. Moreover, those whose assets are being used will be recompensed for their contribution.

• Spanning five years waiver to the intellectual property rights.

• The WTO has proclaimed that within the next 6 months, they will contemplate expanding their parameters to include diagnostics and therapeutics.

[68] Emrah Altindis, "Inequitable COVID-19 Vaccine Distribution and the Intellectual Property Rights Prolong the Pandemic," *Expert Review of Vaccines* 21, no. 4 (April 3, 2022): 427–30, doi:10.1080/14760584.2022.2014819, accessed December 18, 2023.

[69] Loft, "Waiving Intellectual Property Rights for Covid-19 Vaccines."

The WTO Director General, Ngozi Okonjo-Iweala insists that the compromise text will:

> "Contribute to ongoing efforts to deconcentrate and diversify vaccine manufacturing capacity."

Nevertheless, the agreement has drawn criticism from both charitable organizations and drug manufacturers.

- Charities like Oxfam and Médecins Sans Frontières (MSF) have expressed their dissatisfaction with the agreed text as it does not cover the related technologies. Therefore, they are calling for a revision to ensure that all necessary elements are included.
- The International Federation of Pharmaceutical Manufacturers & Associations vehemently oppose any attempt to reduce their capacity to battle global health crises, such as the pandemic. They declare that infrastructure deficiencies and trade constraints are much more decisive factors in determining why vaccinations have not been distributed equitably around the world.

According to Reuters, six nations - India, South Africa, Pakistan, Indonesia, Egypt and Tanzania - are actively striving for a prolonged agreement for access to treatment and testing by December 2022. When this news broke in July it was met with optimism from the global medical community that affordable care could soon become accessible. Several businesses have expressed their dismay over the proposed extension, warning that several Covid-19 treatments and tests are also used to fight other contagious illnesses. Such an action could seriously erode our potential for future pandemic preparedness. [70]

[70] Altindis, "Inequitable COVID-19 Vaccine Distribution and the Intellectual Property Rights Prolong the Pandemic."

3.1.1 Inequalities as to access and Legal Framework

The unequal access to a global vaccine to Low-Income Countries (LICs). As of 30 June 2022, 16% of the population in LICs have been reported as fully vaccinated, in comparison to the 74% in high-income states.[71] Africa still has the lowest rate of vaccination. Less than 15% of people had received all recommended vaccinations as of March 2022. The arguments against the 2020 waiver proposal are outlined in these disparities. Africa and India sought at the WTO in October 2020 to waive the intellectual property rights for three years on COVID-19 vaccines and related pharmaceuticals, a move known as the TRIPS Waiver. The dispute between the industrialized and developing countries first put a stop to the WTO deliberations. This dispute about the waiver of intellectual property rights stretches back to the 2001 WTO ministerial session that engendered the Doha Declaration. Public health and the preservation of intellectual property rights are inherently at odds, as the TRIPS Waiver shown. That was not, however, a recently discovered phenomena. The TRIPS agreement has preserved the balance between the public health and intellectual property rights of WTO members, as stated in Articles 7(5) and 8(6) of TRIPS. One of these facilitations is compulsory licensing, which is outlined in Article 31 of the TRIPS agreement:

> "Where the law of a member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government".[72]

Albeit, some conditions are to be met for the issuance of compulsory licensing. Article 31 (b) requires reasonable authorization on commercial terms before compulsory licensing may be issued other than in the case of a "national emergency". Similarly, Article 31(f) requires

[71] Sivaramjani Thambisetty et al., "Addressing Vaccine Inequity during the COVID-19 Pandemic: The TRIPS Intellectual Property Waiver Proposal & Beyond," *Cambridge Law Journal*, 2022, accessed December 17, 2023.

[72] Nirmalya Syam, "STATEMENT TRIPS WAIVER: AN INSUFFICIENT MULTILATERAL RESPONSE. TRIPS-CONSISTENT NATIONAL ACTIONS ARE CALLED FOR," 2022.

"any such use shall be authorized predominantly for the supply of domestic market of the member authorizing such use." Article 31 (h) states that "the right holder shall be paid adequate remuneration."

Despite the good intentions of this provision, the procedural requirements are cumbersome to follow in order to gain compulsory licensing, especially for the countries that lack the administrative, legal and necessary technical expertise and capacity to fulfil these requirements. Furthermore, the developed countries pressurized the developing countries not to issue the compulsory licenses which occurred in the case of India, Brazil, Thailand and South Africa.[73] The situation got worse for the developing countries that lack the manufacturing capabilities, as Article 31 (f) limits the use of compulsory licenses for domestic purposes, had no choice but to import pharmaceutical products usually at a price that is not affordable for the majority of the people. In 2001, a Special Ministerial Declaration was adopted during the WTO Ministerial Conference in Doha, which is known as the Doha Declaration. The Doha Declaration does not guarantee the new flexibilities rather it emphasizes the existing flexibilities under the TRIPS Agreement.[74] Paragraph 4 of the Doha Declaration states that

> "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. In this connection, we reaffirm the right of WTO members to use to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

Paragraph 5 requires that

> "Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."

[73] Zaman, "The Waiver of Certain Intellectual Property Rights Provisions of the TRIPS for the Prevention, Containment and Treatment of COVID-19."

[74] Wahyu Pratama Aji, "Legal Discourse of United States Pharmaceutical Industry Mandatory License and Trips Agreement Post Doha Declaration," *Activa Yuris: Jurnal Hukum* 2, no. 1 (February 1, 2022), doi:10.25273/ay.v2i1.11878, accessed December 15, 2023.

Albeit paragraph 6 does not deal with the issue of the countries that have insufficient capacities. It states that, "Insufficient or no manufacturing capacities in the pharmaceutical sector" could have difficulty in using the compulsory licensing provision of TRIPS agreement. In 2003, WTO members broke the ice to settle the issue regarding paragraph six of the Doha Declaration. The WTO members agreed to waiver of Articles 31 (f) and 31 (h) and lifted the prohibition allowing the countries to export life-saving products through the compulsory licensing framework. In 2005, WTO members sealed the amendments to the TRIPS agreement and solidified the 2003 waiver permanent in Article 31. This amendment has been the first-ever to the WTO agreement. Article 31 later got ratified and enforced in 2017 after two-thirds of WTO member states endorsed it.

A study examining the application of compulsory licensing, since 2001 in the wake of the Doha Declaration discovered that, of 176 possible uses, 100 (56.8%) involved public noncommercial use licenses or compulsory licenses, 137 (77.8%) related to HIV/AIDS or related diseases, and just twelve (6.8%) instances included cancer medications. It is important to highlight that the sole agreement to apply the guidelines in paragraph six of the Doha Declaration was one involving the shipment of HIV/AIDS medications from Canada to Rwanda. Still, it took nearly two years to fulfil all the prerequisites.[75]

Despite the Doha Declaration, which declared that WTO members have the right to use all provisions of the TRIPS Agreement to its fullest, it is still evident that there are general limits when it comes to flexibilities provided in TRIPS as explained in the in the article 31 for the use of compulsory licensing. Despite the prevalence of compulsory licensing in many developing countries, developed nations still put pressure on them when they attempt to use it. For instance, back in 2007-2008, Thailand took the drastic measure of instituting mandatory

[75] Anna Wong, Clarke Cole, and Jillian C. Kohler, "TRIPS Flexibilities and Access to Medicines: An Evaluation of Barriers to Employing Compulsory Licenses for Patented Pharmaceuticals at the WTO," SSRN Scholarly Paper (October 28, 2022), https://papers.ssrn.com/abstract=4274546, accessed December 17, 2023.

licenses for drugs to treat cardiovascular diseases and cancer. This licensing scheme for non-communicable diseases sparked widespread condemnation from European states and the United States. India's compulsory license to Bayer's cancer drug in 2012 also brought sharp criticism from Washington D.C.

Furthermore, wealthier nations have utilized their economic clout to convince less developed countries to accept greater standards of IP rights protection (known as the "TRIPS-plus standards"). By doing this, we will create higher minimums and more stringent requirements to obtain compulsory licensing through free trade agreements (FTAs). All of this, points towards the fact that even after adopting the Doha Declaration, there is still a long journey ahead.

With a succinct overview of the TRIPS Waiver proposal provided, we now move forward to discuss the legal foundations underlying it. The legal justification behind the TRIPS Waiver can be located within Article IX Paragraph 3 of the Marrakesh Agreement Establishing the WTO (hereafter referred to as "Marrakesh Agreement"), which states:

> "In exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a Member by this Agreement or any of the Multilateral Trade Agreements."

Article IX's fourth paragraph also granted:

> "A waiver shall state the exceptional circumstances justifying the decision, the terms and conditions governing the application of the waiver, and the date on which the waiver shall terminate."

As outlined in Article IX of the Marrakesh Agreement, a waiver is an extraordinary and temporary solution; under only special circumstances will it be imposed and should then be

appraised every year at the Ministerial Conference. [76] On only two occasions the WTO has granted a waiver since its formation. In 2003, the first exemption to be made was for the "Kimberley Process" which dealt with sending and receiving “Blood Diamonds”.

In 2003, in accord with the 2001 Doha Declaration, the TRIPS Agreement’s compulsory licensing regulations were suspended. Even though Article IX of the Marrakesh Agreement states that a waiver can be passed if three-fourths i-e 123 out of 164 WTO members vote in favor, it is unlikely to sway from its customary rule which requires consensus decision-making. Given the deadlock within the TRIPS council, it appears unlikely that a TRIPS Waiver will be adopted shortly.[77]

3.2 Exceptions to the IP Waivers

The propriety of a nation's business and economic operations depend critically on the balance that exists between the proprietors of rights and users of protected works. When protected works can be used without the owner's consent and/or without payment of compensation, Intellectual Property laws place restrictions on the users.

Following the adoption of the WTO Ministerial Decision on June 17, 2022, concerning intellectual property rights about COVID-19 countermeasures agreements, there may be some uncertainty about all possible methods countries have for overcoming IP barriers and enabling alternate production, distribution, and utilization of these measures. To effectively understand the patent landscape regarding products, ingredients, and manufacturing processes for a particular item, it is essential to have visibility into this information. Fortunately, organizations like the Medicines Patent Pool MedsPaL and VaxPaL are available along with research done by other professionals regarding COVID-19 vaccine and therapeutics patents that make this task much simpler. Even if patent holders possess a monopoly on certain ingredients, accessing

[76] Sue Ann Ganske, “TRIPS and Dispute Settlement at the WTO: The TRIPS Disputes and Current Issues under TRIPS and the DSU,” *IDEA* 62 (2022): 1, accessed December 19, 2023.

[77] Wong, Cole, and Kohler, “TRIPS Flexibilities and Access to Medicines.”

them will not be an issue if the suppliers have adequate stocks and offer prices that are cost-effective. If forced licenses are required for import/export sources of ingredients, the journey to obtain freedom to operate becomes increasingly difficult.[78]

According to Article 44.2 of the TRIPS, member states can legally restrict the judicial remedies for patent infringement to merely compensating adequately for such infringements. As the E-Bay ruling in 2021 has indicated, granting judicial licenses is a widely accepted practice throughout America yet it often fails to meet the requirements of Article 31(f). As Jamie Love has noted, US E-Bay rulings have both enabled unrestricted exportation and taken into account matters of trade secrecy as well as patent law. Article 30 provides Members with the opportunity to create an additional exception to Article 31(f), which was previously proposed during the negotiations of the August Waiver Decision. This concept has also been put into practice within some countries, such as Uganda.

Under Article 31, countries have the option to "implement regional exhaustion regulations that allow them to import products produced under compulsory licenses without requiring explicit approval from right holders".[79]

Article 31 of the compulsory license states that "when issuing a regular license, members automatically grant licenses to export non-dominant quantities between countries". This could be an advantageous option for producers from larger countries and those producing smaller amounts; if there are "emergency circumstances or matters of extreme urgency", such as with COVID-19, negotiations would not be mandatory beforehand. By utilizing the Article 31, countries may grant a compulsory license to produce for export, provided that they meet all notifications and limitations requirements. The 30 key restrictions include informing the WTO of inadequate domestic production in non-LDC importing nations (with LDCs enabled

[78] Amin and Kesselheim, "A Global Intellectual Property Waiver Is Still Needed to Address the Inequities of COVID-19 and Future Pandemic Preparedness."

[79] Loft, "Waiving Intellectual Property Rights for Covid-19 Vaccines."

automatically), distinguishing their products' appearance (not applicable to vaccinating materials), enforcing measures against potential diversion risks (though not as drastic as those issued on June 22nd by the WTO's TRIPS Decision), strictly restrict exporting only within notified amounts, and submit further notices when needed. The positives of the new Decision are that there are no restrictions on countries eligible to manufacture and export or import and use (even though some have foolishly opted out from obtaining import rights or limited them for national emergency circumstances). Additionally, only a single payment is needed when CLs are issued in both exporting and importing countries. Lastly, regional groups with LDC members enjoy some privileges related to exports/imports.[80]

Jamie Love conducted a comprehensive examination of the proposed TRIPS Decision and found that, by utilizing Article 39.2 of TRIPS, countries can create exceptions to confidentiality protections for public health and interest concerns; this is why in America there are regulations like SEC disclosure requirements or food labeling requisites which enforce companies disclosing confidential information. Article 39.2 adopted on 17 July 2022, does not prohibit exceptions that grant access to COVID-19 countermeasures, as it is necessary to guarantee the right of compulsory licensing and ensure adequate disclosure of patent information for practical implementation. This often necessitates obtaining trade secrets or confidential data which can be difficult when many patents are incompletely revealed. In addition, there are restrictions on who can produce or import the vaccines such as developed countries and China, as well as any other developing country that has chosen not to opt in. The proposed authorization period for this program is short, just five years with the potential for extensions; additionally, there are numerous notification obligations to adhere to as well as

[80] Brook K. Baker, "TRIPS-Compliant Alternatives for Overcoming Intellectual Property Barriers to COVID-19 Countermeasures," SSRN Scholarly Paper (July 13, 2022), https://papers.ssrn.com/abstract=4178596, accessed December 18, 2023.

stringent anti-diversion standards. There's also a risk of double remuneration that must be weighed when considering participating in such programs.

3.2.1 The IP Waiver and Access to COVID-19 Treatment

The global discourse over drug access, particularly in light of the COVID-19 pandemic, emphasis on the relationship between intellectual property rights and the necessity of exemptions in order to guarantee treatments to be widely accessible. The idea of an IP Waiver is a major source of disagreement, especially with regard to COVID-19 treatment, which has generated a lot of discussion.

IP rights, particularly patents, provide inventors with a brief time of exclusivity, which encourages innovation. But the COVID-19 pandemic has highlighted how such exclusivity could prevent timely and cost-effective access to therapies that can save lives. A framework aiming to strike a compromise between public health concerns and intellectual property protection is provided by the TRIPS. The principal aim is to enable the manufacturing and dissemination of COVID-19 generic vaccines and therapies, and thereby, mitigating the worldwide inequity in vaccination accessibility.[81]

The flexibility provided by Article IX of the WTO Agreement serves as the legal basis for the IP Waiver. Supporters contend that in order to remove obstacles from the development and delivery of COVID-19 medicines, this waiver is essential.[82] Opponents, notably some wealthy nations and pharmaceutical firms, worry that it may lessen the incentives for further research. When the global distribution of COVID-19 vaccinations and treatments is examined, considerable differences are found, with high-income nations obtaining a higher share of the doses that are available. Due to this, vaccination campaigns in low- and middle-income

[81] Thambisetty et al., "Addressing Vaccine Inequity during the COVID-19 Pandemic."

[82] Bryan Mercurio and Pratyush Nath Upreti, "From Necessity to Flexibility: A Reflection on the Negotiations for a TRIPS Waiver for Covid-19 Vaccines and Treatments," *World Trade Review* 21, no. 5 (December 2022): 633–49, doi:10.1017/S1474745622000283, accessed December 20, 2023.

countries have become increasingly difficult, raising ethical questions and compromising international attempts to contain the pandemic.[83]

The IP Waiver and access to COVID-19 vaccinations entails striking a careful balance between preserving innovation and guaranteeing fair access to necessary medications.[84] A holistic strategy should be taken by policy suggestions, integrating technology transfer channels, temporary intellectual property exemptions, and greater funding for vaccine production capacity worldwide.[85] To promote a more just and equitable global health system, this multimodal approach seeks to find a balance between encouraging innovation and addressing the urgent need for access to COVID-19 treatments.

3.3 Effects of Vaccine Development

Since the states consider health to be a human right, they must guarantee that people have access to timely, appropriate, and reasonably priced medical care.[86] The COVID-19 pandemic has brought attention to how crucial vaccine development is to the security and health of the world at large. But the availability and cost of vaccinations are also impacted by the controversial and complicated topic of IP rights, particularly in underdeveloped nations. This section will look at a few case studies and illustrations of the beneficial and bad effects that IPRs have had on the distribution and development of vaccines.

[83] Sansone Pasquale et al., "COVID-19 in Low- and Middle-Income Countries (LMICs): A Narrative Review from Prevention to Vaccination Strategy," *Vaccines* 9, no. 12 (December 14, 2021): 1477, doi:10.3390/vaccines9121477, accessed December 20, 2023.

[84] Kohler, Wong, and Tailor, "Improving Access to COVID-19 Vaccines."

[85] Ibid.

[86] Ibid.

3.3.1 Developed Vaccines

Some accessible vaccines have been created and provided to low- and middle-income countries (LMICs) through a variety of partnerships and processes, despite the obstacles presented by IP rights.[87] Among these are a few instances of:

a) COVAX

The WHO, Gavi, the Vaccine Alliance, and the Coalition for Epidemic Preparedness Innovations (CEPI) are leading this international effort to guarantee that all nations, regardless of wealth, have fair access to COVID-19 vaccinations.[88] With an emphasis on health workers and high-risk groups, COVAX has negotiated partnerships with multiple vaccine producers to supply doses for up to 20 percent of the population in participating nations. Additionally, COVAX has created a system called the COVID-19 Technology Access Pool to encourage makers and developers of vaccines to freely share IPRs, technology.[89]

b) Vaccine Institute of Sabin

This non-profit organization works to discover and promote vaccinations against leishmaniasis, schistosomiasis, and hookworm, among other neglected tropical diseases (NTDs). In order to facilitate clinical trials and manufacturing, Sabin has embraced an open-source strategy to vaccine research, licensing its vaccine candidates to LMICs at no cost or at a reduced cost. Immunization prevents over 2.5 million child deaths annually worldwide, therefore vaccination initiatives in developing nations have been crucial in lowering neonatal mortality.[90] To improve the capability and sustainability of vaccine production in LMICs, Sabin also supports the

[87] Chattu et al., "Access to Medicines through Global Health Diplomacy."

[88] "COVAX," World Health Organization, accessed December 24, 2023, https://www.who.int/initiatives/act-accelerator/covax.

[89] Luiza Pinheiro Alves da Silva and Márcia Siqueira Rapini, "Suitability of Two WHO Research and Development Initiatives for COVID-19 to Promote Equitable Innovation: The Access to COVID-19 Tools Accelerator and COVID-19 Technology Access Pool," *Revista Panamericana de Salud Pública* 46 (November 8, 2022), doi:10.26633/RPSP.2022.194, accessed December 16, 2023.

[90] Amy Grenham and Tonya Villafana, "Vaccine Development and Trials in Low and Lower-Middle Income Countries: Key Issues, Advances and Future Opportunities," *Human Vaccines & Immunotherapeutics* 13, no. 9 (July 31, 2017): 2192–99, doi:10.1080/21645515.2017.1356495, accessed December 18, 2023.

creation of regional vaccine development networks, such as the Developing Countries Vaccine Manufacturers Network (DCVMN) and the African Vaccine Manufacturing Initiative (AVMI).[91]

c) Meningitis

The WHO and the nonprofit organization PATH collaborated to create and market a meningococcal meningitis vaccine, which is intended to prevent meningococcal meningitis, a fatal illness mostly affecting sub-Saharan Africa.[92] MVP collaborated with Serum Institute of India (SII), an Indian vaccine manufacturer, to create MenAfriVac, a conjugate vaccine that offers long-term protection against the disease for less than US$0.50 per dose. MVP also worked with SII to transfer the vaccine's IP rights and technology to the WHO, which then gave sublicenses to African producers so they could manufacture the vaccine there. MenAfriVac has therefore been administered to almost 300 million individuals across 26 African nations, and the incidence of meningitis has decreased by more than 90%.

These instances demonstrate that IP rights do not have to impede the development and availability of vaccines, provided that there is political will, a public-private partnership, and creative problem-solving techniques.

3.3.2 Underdeveloped Cases

IPRs have, however, occasionally impeded the creation and availability of vaccinations, particularly for illnesses with minimal market potential that primarily afflict LMICs. Among these are a few instances of:

a) HIV/AIDS

[91] Ganesh Kumraj et al., "Capacity Building for Vaccine Manufacturing Across Developing Countries: The Way Forward," *Human Vaccines & Immunotherapeutics* 18, no. 1 (2022), doi:10.1080/21645515.2021.2020529, accessed December 15, 2023.

[92] "Meningitis," World Health Organization, accessed December 24, 2023, https://www.who.int/teams/immunization-vaccines-and-biologicals/diseases/meningitis.

Despite decades of study and funding, HIV/AIDS is an incurable disease that has claimed the lives of over 35 million people globally, the majority of whom were living in low- and middle-income countries. The virus's complexity and diversity, which make it challenging to create a vaccine that can trigger a protective immune response, are some of the causes of this.[93] The absence of cooperation and coordination amongst the different parties involved in HIV vaccine research academic institutions, pharmaceutical corporations, governments, and civil society organizations, is another factor. Since these actors frequently have diverse interests and incentives for the ownership, distribution, and licensing of data, materials, and technologies linked to vaccines, IP rights have been a source of dispute and fragmentation among them. Access to current HIV/AIDS therapies and vaccinations, such as antiretroviral medications, which are frequently patented and too expensive for many people in LMICs, has also been hampered by IP rights.

b) Vaccination against tuberculosis

TB is an infectious disease that affects the lungs and other organs, and is one of the leading causes of death worldwide, especially in LMICs. The only available vaccine against TB, Bacille Calmette-Guérin (BCG), was developed in the early 20th century and has limited efficacy and duration of protection. There is an urgent need for a new and improved TB vaccine, but the development of such a vaccine has been hampered by several factors, including IPRs. IPRs have created challenges for accessing and sharing biological materials, such as TB strains and animal models, that are essential for vaccine research. IPRs have also discouraged the participation and investment of private sector actors, such as pharmaceutical companies, in TB vaccine development, due to the low profitability and high risk of the TB vaccine market.

[93] Wajeeha Bilal Marfani et al., "The Rise in HIV Cases in Pakistan: Prospective Implications and Approaches," *Annals of Medicine and Surgery* 81 (August 24, 2022): 104492, doi:10.1016/j.amsu.2022.104492, accessed December 19, 2023.

Furthermore, IPRs have raised concerns about the affordability and availability of new TB vaccines, especially for LMICs, where most of the TB burden lies.

c) Hepatitis C virus

HCV is a viral infection that affects the liver and can cause chronic liver disease, cirrhosis, and liver cancer. It is estimated that more than 70 million people are infected with HCV worldwide, mostly in LMICs. There is no vaccine against HCV, although there are effective treatments, such as direct-acting antivirals (DAAs), that can cure the infection.[94] However, the development of a HCV vaccine has faced several obstacles, including IPRs. IPRs have limited the access and affordability of DAAs, which are patented and priced at exorbitant levels, making them inaccessible for many people in LMICs. IPRs have also reduced the incentive and interest of pharmaceutical companies to invest in HCV vaccine research, as they perceive the market to be shrinking and unprofitable due to the availability of DAAs. Moreover, IPRs have created difficulties for collaborating and sharing information and technologies among HCV vaccine researchers, who often work in silos and compete for funding and recognition.

In addition to vaccinations, the COVID-19 pandemic has raised the need and demand for other therapies such oxygen therapy, ventilators, monoclonal antibodies, and antiviral medications.[95] Nevertheless, different parts of the world do not have equal access to these therapies, and IP laws contribute to or exacerbate these differences. There are disparities in access due to intellectual property laws, IP laws may impact COVID-19 treatment access in a number of ways, including:

a) Restricting the accessibility and cost of patented therapies, particularly for low- and middle-income countries (LMICs), where the cost of certain treatments may

[94] "Hepatitis C," accessed December 24, 2023, https://www.who.int/news-room/fact-sheets/detail/hepatitis-c.

[95] Laila Rahmah et al., "Oral Antiviral Treatments for COVID-19: Opportunities and Challenges," *Pharmacological Reports* 74, no. 6 (2022): 1255–78, doi:10.1007/s43440-022-00388-7, accessed December 21, 2023.

be unaffordable or the supply may be inadequate or untimely. For instance, Gilead Sciences, a US-based business, is the patent holder of remdesivir, an antiviral medication that has been approved for use in several countries' emergency rooms. The medication costs US$2340 per treatment course in developed nations and US$560 in low-and middle-income countries. Remdesivir is still out of reach for many individuals in LMICs, despite the price reduction, and Gilead has come under fire for its exclusive and limited licensing deals with generic producers, which prevent the medication from being available in many nations.[96]

b) Limiting the exchange and transfer of knowledge and know-how for the creation and manufacturing of treatments, particularly for LMICs where local manufacturing capacity and expertise may be inadequate or undeveloped. For instance, producing monoclonal antibodies, which are artificial proteins that can neutralize the virus, is difficult, expensive, and requires certain knowledge and equipment.[97] IP laws may make it difficult for LMICs to obtain the knowledge and resources required to manufacture these medicines domestically, forcing them to rely on imports from wealthy nations that may be restricted or given preference for domestic use.

c) Discouraging the development of novel and alternative treatments, particularly for LMICs, where the prospect for commercial acceptance and financial return on investment may be limited or unclear. For instance, ivermectin, an anti-parasitic medication that has been extensively utilized in LMICs to treat

[96] "Remdesivir," *COVID-19 Treatment Guidelines* (blog), accessed December 24, 2023, https://www.covid19treatmentguidelines.nih.gov/therapies/antivirals-including-antibody-products/remdesivir/.

[97] Giuseppe Pantaleo et al., "Antibodies to Combat Viral Infections: Development Strategies and Progress," *Nature Reviews Drug Discovery* 21, no. 9 (September 2022): 676–96, doi:10.1038/s41573-022-00495-3, accessed December 19, 2023.

neglected tropical diseases, has been suggested as a possible COVID-19 treatment, based on some initial research.[98] To validate its involvement in COVID-19 treatment, more clinical trials are required as the data for its safety and efficacy is still equivocal. IP laws have the potential to discourage pharmaceutical corporations and researchers from funding and participating in these kinds of studies, particularly when it comes to generic or off-patent medications with little to no market value, like ivermectin.

These illustrations demonstrate how IP regulations have the potential to exacerbate or cause regional differences in COVID-19 treatment access, undermining both the right to health and the idea of health equity.

To alleviate the inequities in treatment access, the proposed waiver of intellectual property rights for COVID-19 associated technologies would enable additional nations, particularly low- and middle-income countries, to manufacture and import these therapies without being restricted by IP laws.[99] The waiver is still being negotiated at the WTO, though, and several developed nations and pharmaceutical industry associations are against it. They claim the waiver is harmful to public health and innovation, or that it is unnecessary. Because it depends on so many variables, including the waiver's implementation, duration, and scope as well as the availability of additional resources and capacities for treatment development and production, it is challenging to evaluate how the waiver will affect patients' access to therapies.

On the other hand, we can compare, at best, select regions with and without the waiver, or with varying degrees of IP protection, for specific COVID-19 therapies based on the web search results. As an illustration:

[98] Maria Popp et al., "Ivermectin for Preventing and Treating COVID-19," *The Cochrane Database of Systematic Reviews* 7, no. 7 (July 28, 2021), doi:10.1002/14651858.CD015017.pub2, accessed December 15, 2023.

[99] Amin and Kesselheim, "A Global Intellectual Property Waiver Is Still Needed to Address the Inequities of COVID-19 and Future Pandemic Preparedness."

a) Remdesivir is a medication that can be produced and exported in greater numbers and at lower costs in regions with compulsory licenses or waivers, like Egypt, Bangladesh, and India, than in regions without such protection or waivers, like the US, the EU, and Japan. Remdesivir's use and demand, however, have decreased in some areas as a result of the introduction of novel variations, the accessibility of vaccinations, and the absence of conclusive proof of its therapeutic benefit.

b) Regions lacking waivers or possessing patent protection, like the US, UK, and Canada, have been able to obtain substantial quantities of monoclonal antibodies from the original manufacturers, including Regeneron, Eli Lilly, and GlaxoSmithKline, and have approved their use for high-risk patients in an emergency. However, because to the low worldwide supply, high costs, and technological obstacles in producing them domestically, countries like Brazil, South Africa, and India that have waivers or have less IP protection have had difficulty gaining access to these treatments.[100]

c) Based on their own regulatory decisions, clinical guidelines, and local evidence, countries like India, Peru, and Bolivia that have less IP protection or have waivers have been able to distribute and utilize ivermectin broadly for the treatment or prevention of COVID-19.[101] Nevertheless, because there is a lack of solid evidence from numerous, high-caliber trials and because the WHO and other health authorities have issued warnings, countries without the waiver or with stronger intellectual property protection, like the US, the UK, and the EU, have been more circumspect and restrictive in their use of this medication.

[100] Chattu et al., "Access to Medicines through Global Health Diplomacy."

[101] José Antonio Requejo Domínguez, Dolores Mino-León, and Veronika J Wirtz, "Quality of Clinical Evidence and Political Justifications of Ivermectin Mass Distribution of COVID-19 Kits in Eight Latin American Countries," *BMJ Global Health* 8, no. 5 (May 23, 2023), doi:10.1136/bmjgh-2022-010962, accessed December 17, 2023.

These examples demonstrate how, depending on the nature, accessibility, and supporting data of the COVID-19 treatments as well as the political, social, and economic variables influencing their use and access, the waiver of intellectual property rights for those treatments may have varying impacts on various geographical areas. Because of this, a thorough and detailed analysis of the waiver's effects is required, taking into account the various, changing situations and needs of various locations.

3.4 Conclusion

To sum up, it can be stated that the challenges and tensions that exist between promoting public health and protecting intellectual property rights (IPRs), particularly with regard to the production and accessibility of vaccines, have been brought to light by the COVID-19 pandemic. This chapter has covered a critical analysis of the intellectual waiver framework, IP waiver, and the implications of vaccine development for various geographic and demographic groups. We have discovered that the TRIPS agreement, which permits certain safeguards and flexibilities for public health emergencies, including parallel imports and mandatory licensing, forms the basis of the framework pertaining to intellectual waivers. To address the urgent and worldwide needs of the pandemic, these processes are frequently insufficient, ineffectual, or impracticable. As a result, several WTO members have proposed a temporary waiver of intellectual property rights (IPRs) for COVID-19-related technology.

The rationale and interests of certain developed nations and pharmaceutical industry groups, who oppose the waiver on the grounds that it is needless, ineffectual, or detrimental to innovation and public health, constitute the foundation for the exceptions to IP waiver. They contend that the waiver would reduce the benefits and incentives for research and development, complicate matters legally and technically, and jeopardize the goods' quality and safety. The impact of vaccine development is based on case studies and illustrations of how intellectual property rights (IPRs) have affected vaccination accessibility and cost, particularly for

vulnerable populations of low and middle-income countries (LMICs). It has been demonstrated that intellectual property rights (IPRs) have the potential to exacerbate or cause inequities in vaccine access, thereby, undermining the principles of health equity and the right to health. It is found that depending on the nature, extent, and length of IP protection and enforcement, intellectual property rights (IPRs) can help in the development of novel or improved vaccinations. As this chapter has demonstrated, the question of intellectual waivers for COVID-19 vaccinations is complicated and contentious, involving a wide range of parties, interests, and point of views. It has also demonstrated the issue's substantial long- and short-term effects on the pharmaceutical industries and the state of world health. Because of this, a thorough and nuanced study of the waiver's costs and advantages is required, taking into account the various dynamic situations which are to be dealt with and the needs of various nations and regions in the access to the vaccinations.

Chapter 4: Conclusions and Recommendations

Beyond patent waivers, donations to COVAX, the capability of countries to distribute doses and manufacturers' capacity levels are all paramount in ensuring equitable vaccine administration. When the international patent waiver over the COVID-19 vaccinations was suggested in 2020, global production skyrocketed, prompting various countries and organizations to prioritize the fair distribution of vaccines.

In 2021, the WHO boldly declared that with global vaccine production at one and a half billion doses per month, provided they are distributed equitably, its aim of vaccinating 70% of the world's population by mid-2022 is realistic. This statement contends that the issue is not a lack of supplies, but rather one of determining their proper distribution. WTO Director General, Ngozi Okonjo-Iweala has discussed the complexities of amplifying and diversifying vaccine production. She points out that Pfizer's vaccines include 280 components which are being produced at 86 sites in 19 countries. This makes it difficult for the release of intellectual property rights to have a substantial effect without sharing technical know-how and time investment toward ramping up manufacturing efforts.[102]

Despite having sufficient vaccine production, the Organization for Economic Cooperation and Development (OECD) has cautioned that vaccination campaigns in lower-income countries would likely face several obstacles during the roll out phase. For instance, due to a lower number of health workers per capita within low-income states, their capacity to rapidly deploy an immunization campaign is restricted. Vaccines must be refrigerated to remain effective, which greatly complicates the process in areas with limited access to electricity or locations that are more rural. The Covid-19 pandemic has already impaired the success of immunization programs and exposed gaps in healthcare infrastructure, making it difficult to

[102] Barnes-Weise, Rutschman, and Adler, "Assessment of the Proposed Intellectual Property Waiver as a Mechanism to Address the COVID-19 Vaccine Scarcity Problem."

prioritize other areas. One of the reasons for the limited ability to quickly implement vaccination campaigns in low-income nations is the lack of sufficient healthcare personnel. The requirement for cold chain infrastructure, especially in regions with limited electrical availability or in remote areas, gives rise to difficulties in storage and distribution. The epidemic has also disrupted routine immunization programs, exacerbating pre-existing deficiencies in health systems such as insufficient finance and shortages of medical equipment. This combined with existing weaknesses in health systems could spell a disaster for vulnerable populations.

Proposed by certain WTO members and approved for vaccines at MC12, the waiver of IP rights for COVID-19 vaccination and associated technology could have profound short and long-term effects on the pharmaceutical industry and global health conditions. Aspects of the pharmaceutical innovation system and the public health in response to the pandemic may benefit or suffer from the waiver, depending upon its scope, duration, and implementation, as well as the availability of other resources and capacities for the development and production of vaccines, diagnostics, and therapeutics. The pharmaceutical industries may be impacted by the waiver of IP rights in a number of ways, including:

a) Reorienting pharmaceutical companies' and researchers' motivations and interests to support and carry out R&D for COVID-19 and other diseases, particularly those that primarily impact low and middle-income countries and have limited commercial prospects. The waiver may lessen the IP-based business model of profitability and uniqueness, which would deter private sector players from contributing to and participating in the innovation process. As an alternative, the waiver might encourage the establishment of complementary or alternative models that could improve cooperation and knowledge sharing amongst many stakeholders through open innovation,

public-private partnerships, and social entrepreneurship. These models would give priority to fostering collaboration and facilitating the flow of knowledge among different stakeholders in the healthcare industry. In order to improve collaboration and the exchange of information, it is possible to build alternative approaches instead of exclusively depending on the conventional IP-based business model. This has the potential to result in more streamlined research and development processes, improved allocation of resources, and expedited progress in the creation of medicines. Some other models that can be considered are open innovation, public-private partnerships, and social entrepreneurship. These approaches strive to provide a more comprehensive approach to innovation and tackle the healthcare requirements of marginalized communities.

b) Enabling more nations to manufacture and import COVID-19-related technologies without being restricted by IP laws. This shall thus, be raising the technologies' accessibility and affordability, particularly for LMICs. The waiver may make to it easier spread and transfer the technological advancements, which would allow supply chains and manufacturing capacity to diversify and grow. The waiver, however, may also make it more difficult to guarantee the items' efficacy, safety, and quality and shall also have an impact on their distribution and allocation in accordance with regional needs and demands.

c) The impact on the equilibrium and consistency of the international IP system and the rules-based trading system by establishing a precedent and a process for the waiver of IP rights in the event of a public health emergency or other extraordinary situations. The waiver might weaken WTO member confidence and cooperation by undermining the TRIPS agreement's and the WTO's

legitimacy and efficacy. As an alternative, the waiver might increase the TRIPS agreement's and the WTO's adaptability and flexibility. This would encourage discussion and debate among WTO members about how to enhance and modify the trade and intellectual property rights to better serve the public interest.

It will be necessary to carefully monitor and assess the results and ramifications of the waiver, which can be conducted by the concerned governmental authorities, WTO as well as NGOs. It is because these modifications may have varying effects on the various actors and geographical areas involved in the pharmaceutical landscapes.

The following long-term impacts on the state of world health could result from the waiver of IP rights:

a) It will help lowering the obstacles and inequities brought about by IP laws and other variables in order to improve the equity and access of health care and health technologies for LMICs and disadvantaged populations. The waiver could improve the health and well-being of millions of people affected by COVID-19 and other such diseases by advancing the attainment of the right to access the medicines and the principle of health equity. The waiver, however, may also bring with it new risks and challenges for the health systems and health governance of various nations, including the management and coordination of the supply and demand of products, the regulation and monitoring of product quality and safety, and the promotion and protection of peoples' rights of health.
b) It shall, by increasing the availability and diversity of health technology and fostering collaboration and coordination among health actors will help to improve the preparation and resilience of the international health community. It shall also help the international health institutions to address present and future health emergencies. The waiver could assist in limiting and controlling the

pandemic and stopping the additional deaths and damage by facilitating the research. It might also help through the distribution of efficient and reasonably priced vaccinations, diagnostics, and treatments for COVID-19 and its variations. The waiver may also encourage the exchange of best practices and lessons discovered during the COVID-19 pandemic, which would enhance the WHO, WIPO, WTO, and other health organizations' capacity to meet the demands and problems in the present times and to be prepared for such situations that might arise in the future.

c) It shall help influencing the development and investigation of novel or alternative health technologies and remedies by posing fresh challenges and opportunities for the progress of science and technology. The waiver may encourage the creation and sharing of new information and technology, which would hasten the development of fresh or enhanced COVID-19 and other illness treatments, diagnostic tools, and vaccines. However, by introducing ambiguities, complications for IP protection and enforcement, R&D financing, ethical and social consequences of the health innovations, the waiver may have an impact on the sustainability and quality of the innovation and research process.

Besides having many advantages, there are some other things that need to be considered which include the complications, social consequences and impacts on innovation and research process. Thus, it is necessary to carefully weigh the advantages and disadvantages of the waiver because these impacts may have varying consequences on various facets and dimensions of the global health scenario. COVAX and global access to vaccines dive deeper into the struggles associated with vaccine distribution. Even though the adoption of the TRIPS Waiver may reduce vaccine inequality to some extent, it is not a complete solution for this entire crisis.

Thanks to the successful resolution of production obstacles, global vaccine shortages have now been alleviated. Surprisingly, some nations even have an abundance of vaccines that end up going to waste. The issue isn't just that vaccines are not distributed equally, but rather the great disparity between wealthy countries and poorer ones. To ensure the equitable dispensation of vaccines, we must empower developing countries, by technology transfer, with the capability for self-sufficiency in vaccine production. One of the examples of initiative taken for the sake of knowledge transfer in case of COVID-19 is Covid-19 technology Access Pool (CTAP) which was developed to share the technological advancements in the treatment by the nations in order to overcome and reduce the impact of deadly Corona virus.

As nations grapple with fresh outbreaks of the virus and combat novel variants, there are further measures that can be taken to preserve lives around the world. While it is uncertain how many more lives could have been saved if the TRIPS Waiver had been adopted sooner, one thing is certain: developing nations, like Pakistan, have not gotten the access to COVID-19 vaccines they deserve. Unfortunately, the same disparities in vaccine distribution have been repeated with the newest Novavax dose. Despite already having their hands full with vaccines, wealthier countries are acquiring the Novavax vaccine before poorer nations do, which is ironic considering how appropriate it is for developing countries due to its convenience in terms of storage and transportation. It is unfortunately too late for some, yet there is still time to stop this tragedy from happening again.

The TRIPS Waiver is not enough and more progressive steps must be taken. To this point, we have been overly preoccupied with patents, from the Doha Declaration to the TRIPS Waiver. Unfortunately, however, they have failed to capture all of the nuances involved in this situation. By waiving patents or granting compulsory licensing, countries in the developing world can make use of existing pharmaceutical patents; however, this does not give these nations the necessary skills and ability to manufacture drugs necessary to battle the deadly

disease. A sound technology transfer and data-sharing infrastructure should be established to guarantee that all emerging countries have equitable access to COVID-19 vaccines and medicines, unlike the WHO's CTAP which is dependent on pharmaceutical companies' "kindness". Unfortunately, it appears that any further progress in the negotiation of a TRIPS Waiver will be hindered by the conflicting desires between developed and developing countries.

To fulfil the dreams of providing good health and access to medicine for all human beings as stated in the Universal Declaration of Human Rights (UDHR) and ICESCR, it is essential that we critically review how intellectual property rights intersect with public health protection. A few years ago, the Doha Development Round of trade negotiations pledged to prioritize developing countries' needs in international trade talks. Nevertheless, regrettably, WTO members have not kept their promise and have also not fulfilled the necessary pro-development changes. The Doha Declaration has been proven correct in its prognostication: “The poorest in developing countries are unable to access affordable medicine because members have failed to clarify ambiguities between the need for governments to protect public health on one hand and on the other to protect the intellectual property rights of pharmaceutical companies.” It may be the right time to change the existing framework through the consensus of member states at WTO and achieve more. It might be time to revolutionize the existing legal framework developed through the TRIPS framework to achieve more rewards from innovation in medicines while still providing fair distributive access to them

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