# TRIPS AGREEMENT WAIVER- IMPACT ON DRUG DEVELOPMENT AND HUMAN RIGHTS ANALYSIS

Kirti Anand, Academician, LLM (Intellectual Property and Trade Law), Christ (Deemed to be University), Delhi NCR

**ABSTRACT**

The TRIPS waiver, initially focused on COVID-19 vaccines, should indeed extend to medical treatments to enhance global health equity and access to essential medicines. This extension is crucial for addressing the broader public health needs, particularly in developing countries. India already suffered a pandemic which caused a lot of disruption to the population of the country hence to not suffer further, provisions as to extend its applicability to life-saving generic medicines to address global health challenges like cancer, diabetes, and cardiovascular diseases. While this proposal aims to provide broader access to critical medicines, it faces significant challenges. One major concern is the lack of local manufacturing infrastructure in many low- and middle-income countries, which hinders the ability to produce vaccines and treatments, even with relaxed IP restrictions. The 2022 WTO decision partially addressed this by offering a limited waiver for vaccines, but it did not extend to diagnostics or treatments, exposing a critical gap in global health access.

Furthermore, the temporary nature of the waiver raises concerns about long-term sustainability. Without a permanent framework for addressing health inequities, access to affordable medicines may remain constrained, especially post-pandemic. Global IP laws continue to limit the widespread availability of essential medicines, reinforcing disparities, especially in poorer regions. To resolve these issues, a more expansive and permanent waiver is needed, including effective technology transfer to empower developing nations to produce and distribute medicines independently. In conclusion, a more comprehensive TRIPS waiver could balance intellectual property rights with the urgent need for equitable access to essential medicines, which should be regarded as a fundamental human right. More research is required to assess how this broader approach could meet global health needs while promoting sustainable, long-term solutions.

Keywords: Pharmaceuticals, innovation, affordability, life-saving medicines

**Statement of the Problem**:

The lack of strong TRIPS Agreement waiver laws in India raises significant concerns about the availability of generic drugs, particularly essential and life-saving medicines and treatments. This gap limits access to affordable healthcare, human lives and poses economic risks to India's pharmaceutical industry, especially in the generics sector. Additionally, the absence of a comprehensive TRIPS waiver could lead to barriers in technology transfer and predatory pricing practices that worsen health inequities. The recent inclusion of the TRIPS waiver in the WHO pandemic treaty highlights the urgent need to consider extending it to encompass treatments and medical diagnostics for non-communicable diseases, ensuring a more comprehensive response to public health challenges.

**Research Questions**

1. Whether the absence of strong TRIPS Agreement waiver laws in India affect the availability of generic drugs, particularly for life-saving and essential medicines?

2. How would the absence of the TRIPS waiver impact India's generic pharmaceutical industry, particularly in terms of drug pricing and the potential for predatory pricing by patent-holding pharmaceutical companies?

3. Whether the TRIPS waiver should extend it validity to medical products like treatment and diagnostics as it is only limited to vaccine development at time of covid-19?

**Research Objectives**

- To analyze the impact of the absence of strong TRIPS Agreement waiver laws in India on the availability of generic drugs, particularly life-saving and essential medicines.

- To assess how the absence of a TRIPS waiver would raise drug prices in India by limiting generic production and enabling monopoly pricing by patent-holding firms. The study will examine predatory pricing risks and explore regulatory measures to ensure drug affordability.

- To explore the necessity of extending the TRIPS waiver's scope to include treatments and diagnostics in addition to vaccines.

## Research Methodology

### 1. Research Design:

The research will adopt a doctrinal methodology to analyse and interpret legal principles, statutes, case laws, international agreements, and academic literature relevant to TRIPS Agreement Waiver in India and globally. The goal is to critically assess India's legal framework compared to global standards of South Africa and developed countries, examine its compliance with international obligations, and explore the potential legal and economic implications of introducing stronger TRIPS Agreement Waiver provisions.

### 2. Identifying Legal and Policy Gaps:

- Evaluate the gaps in India's current legal framework concerning TRIPS Agreement Waiver and public health, as identified through the review of primary and secondary sources.

- Propose legal reforms and policy measures based on the analysis of India's legal obligations under international agreements, public health concerns, and the need for pharmaceutical innovation.

## Chapter 1

## INTRODUCTION

In advocating for the TRIPS waiver, India aims to address critical healthcare needs, promote equitable access to essential medicines, and reinforce the fundamental right to health. Given its robust pharmaceutical sector and longstanding commitment to affordable healthcare, India is uniquely positioned to lead the global call for a more flexible IP framework during public health crises. The TRIPS waiver would empower India to fulfil its role as a key player in global health, ensuring that life-saving medicines are accessible to all, especially during times of crisis.

India's support for a TRIPS waiver is driven by its commitment to ensuring equitable access to

life-saving medicines and addressing global health inequities, especially during public health crises. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, administered by the World Trade Organization (WTO), establishes a global framework for intellectual property protection, including patents on pharmaceuticals. While these protections are intended to incentivize innovation, they also create monopolies that often limit access to affordable medicines in developing nations, including India. The waiver, proposed by India and South Africa in 2020, seeks to temporarily suspend certain IP protections, particularly for vaccines, treatments, and diagnostics during emergencies, allowing countries to produce or import generic versions without facing legal repercussions.

India's pharmaceutical industry plays a crucial role in the global healthcare ecosystem. Known as the "pharmacy of the world," it supplies affordable generic medicines to many low- and middle-income countries. However, the stringent patent protections under TRIPS prevent India from fully utilizing its manufacturing capacity, particularly during public health emergencies like the COVID-19 pandemic. During the pandemic, wealthier nations secured the majority of vaccine supplies, leaving developing countries struggling to obtain the doses they needed. The TRIPS waiver would allow India to bypass patent restrictions and ramp up the production of vaccines, treatments, and diagnostics, ensuring that low-cost alternatives are available not only to its population but to other nations reliant on affordable medicines.

The COVID-19 crisis highlighted the inequities in global healthcare access, particularly the way patent protections can hinder timely access to essential medical products. Despite having the capacity to produce vaccines and treatments, India and other developing nations were restricted by the patents held by pharmaceutical companies in developed countries. The TRIPS waiver would enable India to produce generic versions of these products without the fear of infringing on patents, thus speeding up the process of making life-saving medicines available at a lower cost. This is crucial not only for addressing the immediate crisis but also for building long-term resilience in India's healthcare system by reducing dependency on expensive imports.

One of the core arguments in favour of the TRIPS waiver is its alignment with the right to health, which is recognized as a fundamental human right in international law. In India, millions of people struggle to access affordable healthcare, and the high cost of patented medicines further exacerbates this issue. The TRIPS waiver would prioritize public health over

corporate profits, ensuring that essential medicines are accessible to those in need. By removing the barriers posed by patents, India can uphold the right to health and protect its citizens from the negative consequences of monopolistic pricing on critical drugs and vaccines. Furthermore, the TRIPS waiver aligns with India's humanitarian values and its role as a global leader in advocating for equitable healthcare access. India's push for the waiver reflects a broader commitment to promoting health justice and reducing the disparities in access to medicines between rich and poor countries. By leading the global call for more flexible IP regimes during health emergencies, India can position itself as a champion of public health and global solidarity, advocating for a more just and equitable healthcare system.

## Chapter 2

## Literature review

1. **Erfani, P. (2021, August 3). Intellectual property waiver for COVID-19 vaccines will advance global health equity. BMJ, 374.**

   Summary: The introduction sets the stage for a discussion on the potential benefits of the waiver, including increased vaccine supply, reduced costs, and improved health outcomes in underserved regions. The authors aim to persuade policymakers and stakeholders of the importance of this waiver in advancing global health equity and ensuring that the world can effectively combat COVID-19.

   Key Finding: the paper highlights the importance of a temporary intellectual property waiver for COVID-19 vaccines in increasing supply, promoting equitable access, and advancing global health equity.

   Research Gap: empirical data is needed to assess how such waivers could influence vaccine production capabilities and ultimately affect herd immunity on a global scale.

2. **Hassan, F. (2021, August 16). Profiteering from vaccine inequity: A crime against humanity. BMJ, 374.**

   Summary: Authors emphasize the moral obligation of wealthier nations and pharmaceutical companies to ensure fair distribution of vaccines. They argue that

failing to address these inequities constitutes a crime against humanity, as it directly impacts the lives of millions who are unable to access vaccines.

Key Findings: the key findings of the paper revolve around the critical issues of vaccine inequity, its public health implications, ethical concerns regarding profit motives, and the urgent need for global responsibility and systemic change to ensure equitable vaccine distribution.

Research Gap: While the paper discusses the immediate consequences of unequal vaccine distribution, there is a need for more extensive studies that track the health impacts over time, particularly in low-income countries.

3. **Subhan, J. (2020). Scrutinized: The TRIPS agreement and public health. McGill Journal of Medicine, 9(2), 152-159. https://doi.org/10.26443/mjm.v9i2.445**

Summary: The TRIPS agreement, established by the World Trade Organization (WTO) in 1994, aims to standardize intellectual property protection across member nations. However, it has faced criticism for overly stringent protections that hinder access to essential medications in developing countries.

Key Findings: author emphasizes that addressing the public health crisis in developing nations requires unprecedented levels of international cooperation and empathy, alongside necessary legislative reforms a lack of longitudinal studies that assess the health outcomes in developing nations before and after the implementation of TRIPS-related policies. Such studies could help in understanding the real-world impact of intellectual property laws on public health the TRIPS agreement.

Research Gap: A lack of longitudinal studies that assess the health outcomes in developing nations before and after the implementation of TRIPS-related policies. Such studies could help in understanding the real-world impact of intellectual property laws on public health.

4. **Borges, C. (2023, March 15). TRIPS waivers and pharmaceutical innovation. Centre for strategic and international studies.**

**https://www.csis.org/analysis/trips-waivers-and-pharmaceutical-innovation**

Summary: The WTO is currently considering if the waiver should be expanded to include the production and supply of COVID-19 diagnostics and therapeutics. This would cover a broad category of products, including products utilized for diseases and conditions beyond COVID-19.

Key Findings: Expanding the TRIPS waiver to therapeutics will disincentivize the creation of new COVID-19 treatments. Biopharmaceutical research is expensive and risky—the R&D process for new drugs costs close to $1 billion on average, and only 12 percent of drugs which enter clinical trials are ultimately approved for use. Companies will simply not invest in creating new therapeutics if they will lose ownership of their IP should their huge and risky investment prove fruitful.

Research Gap: Less innovation in the pharmaceutical industry means fewer vaccines and drugs in the future, leaving the United States and other nations less prepared for future pandemics and other health emergencies.

5. **Kohler, J., & Tailor, L. (2022). An analysis of TRIPS waiver discourse among WTO members, civil society organizations, and pharmaceutical industry stakeholders. Health and Human Rights Journal, 24(2), 159-175.**

Summary: A TRIPS waiver enables states to uphold their international human rights obligations. Many civil society organizations emphasized the role of a TRIPS waiver in ensuring equal access to critical health technologies consistent with the human rights to health, to receiving and imparting information, to education, to participating in cultural life, and to equally benefitting from scientific progress.

Key Findings: A TRIPS waiver is a tool consistent with promoting the human right to health. Several WTO members highlighted the sharp inequities among high-income and low-income countries regarding access to COVID-19 vaccines.

Research Gap: A TRIPS waiver for just vaccines is insufficient. Several supporting members emphasized the importance of including all relevant health technologies—rather than just vaccines—within the scope of the waiver.

6. **Butchard,P. (2024, May 16). What is the proposed WHO Pandemic Preparedness Treaty? House of Commons Library, UK Parliament.**

**https://commonslibrary.parliament.uk/research-briefings/what-is-the-proposed-who-pandemic-preparedness-treaty**/

Summary: The article noted that the world would face other pandemics and major health emergencies in the future and said no state or multilateral agency can address these threats alone. The article stressed that: We must be better prepared to predict, prevent, detect, assess and effectively respond to pandemics in a highly co-ordinated fashion. The Covid19 pandemic has been a stark and painful reminder that nobody is safe until everyone is safe. With that, the leaders committed to "ensuring universal and equitable access to safe, efficacious and affordable vaccines, medicines and diagnostics for this and future pandemics." They said the world needed capacity to develop, manufacture, and deploy vaccines quickly in response to such threats, as well as doing more to "promote global access" to vaccines.

Key Findings: The main goal of this treaty would be to foster an all of government and all of society approach, strengthening national, regional and global capacities and resilience to future pandemics. This includes greatly enhancing international co-operation to improve, for example, alert systems, data-sharing, research and local, regional and global production and distribution of medical and public health counter-measures such as vaccines, medicines, diagnostics and personal protective equipment.

Research Gap: There is requirement of Legal basis for international responses to "public health emergencies of international concern", the regulations therein are relevant to the development of the pandemic preparedness treaty.

7. **Public Health on Call. (2024, August 12). Why we are still waiting for a pandemic treaty: The pandemic treaty deadline has passed, but the need for it hasn't. Johns Hopkins Bloomberg School of Public Health.**

Summary: One thing to reflect on is a large reason why this imbalance exists. High-income countries have these financial and technical resources because of long histories of colonialism and slavery. These are entrenched inequities. There's a historical dynamic at play: Global South countries have been subjected to scientific extra activism, where high-income countries' researchers have come in, isolated pathogens,

taken them out of the country, and then used them to produce vaccines, diagnostics, and therapeutics.

Key Findings: We see pathogen access and benefit sharing as a big issue in the treaty. High-income countries need to get access to pathogens in order to create vaccines, diagnostics, and therapeutics, and they've pushed lower-income countries to provide that without agreeing to equitably share the benefits that arise from the use.

Research Gap: Even with the pandemic treaty agreement approved it is important to rebuild norms and trust between countries, expected standards of behaviour countries and institutions like the WHO.

8. **Moon, S. (2024, July 17). Pandemic agreement talks resume with global equity at stake. Global Health Centre, Graduate Institute of InternationalandDevelopmentStudies. https://www.thinkglobalhealth.org/article/pandemic-agreement-talks-resume-global-equity-stake**

Summary: WHO member states also agreed to establish a coordinating financial mechanism that will operate under the amended IHR and the pandemic agreement. The mechanism seeks to improve the coherence, transparency, and efficiency of financial flows and to support countries' access to financing. International pandemic funding comes from many sources, including national aid agencies, development banks, global health initiatives, multilateral institutions, and nongovernmental organizations. But such funding is disjointed, uncoordinated, and nearly impossible to track. Improving the efficiency of financing through the coordinating financial mechanism is critical given that the total envelope of development assistance for health is likely to decline in coming years.

Key Findings: The unresolved issues concern access to and control of health products. Given that the Pandemic Agreement negotiations are the first major effort to achieve better access to health products in a binding treaty, it is no surprise that consensus has been elusive. But credible, reliable solutions for access have to be found if the Pandemic Agreement is to make good on the promise of more equitable pandemic governance.

Research Gap: A strong, effective pandemic agreement is still needed for a safer, fairer world.

9. **Ministry of Commerce and Industry. (2022, June). WTO ministerial conference and India's advocacy for expanded TRIPS waiver.**

   Summary: TRIPS waiver and India's continued efforts to expand its scope to include treatments and diagnostics. India's push for more inclusive global health measures is highlighted as part of its ongoing advocacy for equitable access to essential medicines.

   Key Findings: India's continued push for an expanded waiver stems from the need to provide equitable access to life-saving medicines for low- and middle-income countries, many of which were excluded from rapid vaccine access during the pandemic.

   Research Gap: How can developing countries overcome manufacturing challenges to fully utilize the TRIPS waiver for both vaccines and treatments?

10. **Dhar, B., & Gopakumar, K. M. (2020). *Towards more affordable medicine: A proposal to waive certain obligations from the Agreement on TRIPS.* ARTNeT Working Paper Series, No. 200. Asia-Pacific Research and Training Network on Trade (ART Net), Bangkok.**

    Summary**:** This paper discusses the need to waive specific obligations under the TRIPS Agreement to enhance the accessibility of medicines examining the proposal made by India and South African (2020) which sought to suspend IP protections on medical products in a crisis like a pandemic highlighting how patents, trade secrets and data exclusivity restrict productions and affordability of medicines and to overcome these barriers.

    Key Features: There is a requirement to address the public health needs as the existing TRIPS flexibilities are too slow and complex. (compulsory licensing)

    Research Gap: Long-term reforms are required beyond COVID-19, further research on TRIPS Waiver is to be extended to other global health emergencies for eg. Cancer patients and diseases.

11. **Lex Orbis. (2022, August 24). India - TRIPS and international pressure on high income countries to accept TRIPS waiver. Lex Orbis, Intellectual Property AttorneyandAdvocates.https://www.asiaiplaw.com/article/trips-and-international-pressure-on-high-income-countries-to-accept-trips-waiver**

Summary: The article highlights India's leadership in advocating for a TRIPS waiver to address global inequalities in accessing COVID-19 vaccines, treatments, and diagnostics. India emphasizes the need for high-income countries to support this waiver to ensure equitable access in low- and middle-income nations, particularly during health crises.

Key Findings: India's push targets reducing IP restrictions to ensure wider global access to essential medical technologies. High-income countries, especially in the EU, have resisted the waiver, citing innovation concerns.

Research Gap: How can international consensus on IP waivers be reached to balance innovation with global health equity?

12. **Gorskii, M. A. (2022). Protecting public health through technology transfer: The unfulfilled promise of the TRIPS Agreement. DOAJ, 24(2), 211-214.**

Summary: The paper outlines the TRIPS Agreement's role in harmonizing global intellectual property laws and its implications for public health, particularly in developing countries. It highlights the ongoing challenges in accessing essential medicines and argues that the TRIPS Agreement has not effectively facilitated technology transfer, which was intended to enable the production of generic medicines. As a result, many low-income populations lack access to life-saving treatments. The authors call for a re-evaluation of the TRIPS Agreement to ensure that intellectual property rights do not hinder access to essential health technologies and medicines.

Key Findings: The TRIPS Agreement has established a global standard for intellectual property rights, which helps to create a more predictable and stable environment for international trade. This standardization can encourage investment in research and development, particularly in the pharmaceutical sector, as companies are more likely to invest in innovation when their intellectual property is protected.

Research Gap: The research gap highlighted in the paper revolves around the insufficient exploration of how the TRIPS Agreement can be effectively reformed to enhance technology transfer and access to medicines in developing countries.

13. **Perehudoff, K., ’t Hoen, E., Mara, K., Balasubramaniam, T., Abbott, F. M., & Bake, B. K. (2022). A pandemic treaty for equitable global access to medical countermeasures: Seven recommendations for sharing intellectual property, know-how and technology. BMJ Global Health, 7(7), e009709. https://doi.org/10.1136/bmjgh-2022-009709**

Summary: The COVID-19 pandemic has highlighted significant flaws in current international health and intellectual property (IP) laws, which fail to provide equitable access to medical countermeasures. In December 2021, the World Health Organization (WHO) Member States began negotiations for a new international instrument, often referred to as a "pandemic treaty." This treaty aims to address the inequities in access to medical countermeasures and promote a more collaborative global health governance framework. The proposed pandemic treaty represents a critical opportunity to reform global health governance, ensuring that future pandemics are met with a more equitable and effective response, ultimately benefiting all nations.

Key Findings: The paper identifies that the COVID-19 pandemic has revealed significant inequities in access to medical countermeasures due to inadequate international health and intellectual property laws. It emphasizes the need for a pandemic treaty to facilitate equitable access by promoting technology transfer and ensuring that public funding leads to shared knowledge and resources. The treaty represents a crucial opportunity to reform global health governance for better preparedness in future pandemics.

Research Gap: The paper identifies a gap in effective technology transfer mechanisms and intellectual property sharing during health crises, particularly affecting low- and middle-income countries. This inadequacy hinders equitable access to medical countermeasures, which the proposed pandemic treaty seeks to rectify.

## CHAPTER 3:

## TRIPS Waiver and Its Impact on Access to Medicines in India

### 3.1 TRIPS and Access to Medicines

TRIPS introduced comprehensive IP standards, granting pharmaceutical companies exclusive rights over the manufacture and sale of new drugs for a set period. While these protections were meant to incentivize innovation, they also enabled monopolistic pricing structures that disproportionately affected LMICs (Hoen, 2003)[1].

India's generic pharmaceutical sector has played a crucial role in improving access to medicines. The Indian Pharmaceutical Alliance (IPA) reports that India meets 50% of global vaccine demand and accounts for 40% of generic exports. Notably, Indian companies supply around 80% of antiretroviral drugs for HIV/AIDS treatment in LMICs (World Health Organization [WHO], 2020)[2]. Despite this, patented drugs often remain unaffordable—costing up to 20 times more than generics.

To address these inequities, the Doha Declaration on the TRIPS Agreement and Public Health (2001) affirmed that TRIPS should not prevent countries from protecting public health. It emphasized the rights of WTO members to use flexibilities such as compulsory licensing and parallel importing to improve access (WTO, 2001)[3]. However, the real-world use of these flexibilities remains limited due to legal, political, and economic pressures (Hoen, 2003).

During health emergencies, the limitations of TRIPS are magnified. While compulsory licensing is a legally recognized option, many countries face diplomatic pressure or threats of trade sanctions when attempting to use it, undermining its effectiveness. Furthermore, many developing countries lack the technical capacity to produce medicines locally even when IP restrictions are waived, resulting in structural dependency on external suppliers.

Patent evergreening further obstructs access. Pharmaceutical firms often make incremental

[1] Hoen, E. 't. (2003). TRIPS, pharmaceutical patents, and access to essential medicines: A long way from Seattle to Doha. *Chicago Journal of International Law, 3*(1), 27–46.
[2] World Health Organization. (2020). *The Indian pharmaceutical industry: Global leader in generics*.
[3] World Trade Organization. (2001). *Declaration on the TRIPS Agreement and Public Health*.

changes to existing drugs to extend patent life, thereby delaying the entry of affordable generics. TRIPS does not explicitly prohibit this practice, and in the absence of stringent patentability criteria, it is widely exploited.

The right to health, recognized under international human rights instruments like the International Covenant on Economic, Social and Cultural Rights (ICESCR), further challenges the legitimacy of strict IP protections that hinder access to essential medicines. A human right–based interpretation of TRIPS would prioritize public health over commercial interests during emergencies.

Civil society organizations and health advocacy groups, including Médecins Sans Frontières (MSF) and the South Centre, have long argued that the TRIPS regime privileges multinational pharmaceutical corporations at the expense of vulnerable populations. Their campaigns have called for a reinterpretation of TRIPS through a development-centric and equity-driven lens.

### 3.2 The COVID-19 TRIPS Waiver Proposal

The COVID-19 pandemic sparked calls for greater IP flexibility to ensure equitable access to vaccines, diagnostics, and therapeutics. In October 2020, India and South Africa submitted a joint proposal to the WTO for a temporary waiver of specific TRIPS provisions to enable countries to bypass patent protections and increase production capacity without legal obstacles (WTO, 2020).

This proposal garnered significant support from LMICs and international health organizations. Advocates argued that IP waivers would facilitate technology transfer and scale up production, thereby reducing the disparities in vaccine distribution (Gopakumar & Hanna, 2022)[4]. However, the proposal faced opposition from several high-income countries and pharmaceutical firms who expressed concerns about weakening innovation incentives (Feldman, 2022)[5].

Critics of the opposition pointed out that the research and development (R&D) behind several COVID-19 vaccines, such as those by Moderna and Oxford-AstraZeneca, was publicly funded.

[4] Gopakumar, K. M., & Hanna, T. (2022). *TRIPS waiver proposal: A South-South cooperation perspective on pandemic response*. *South Centre Research Paper* (161).
[5] Feldman, R. (2022). *The COVID vaccine patents: Innovation vs. access*. *Journal of Law and the Biosciences, 9*(1), 1–22.

As such, the exclusive rights granted under TRIPS failed to reflect the collaborative and public-interest nature of vaccine development.

In 2021, the United States expressed support for a limited version of the waiver, focusing on vaccines. However, the European Union, United Kingdom, and Switzerland remained opposed, arguing that technology transfer and capacity building, not IP, were the primary barriers to equitable access.

After extended negotiations, a diluted version of the waiver was adopted at the WTO's 12th Ministerial Conference (MC12) in June 2022. The final agreement applied only to vaccines, excluding treatments, diagnostics, and other critical forms of IP, such as trade secrets, which are vital for biologics production. Many public health experts criticized the waiver as a missed opportunity to ensure global equity in pandemic response.

India played a key role in keeping the waiver on the WTO's agenda, leveraging its pharmaceutical capacity and global diplomatic engagement. Companies like the Serum Institute of India and Bharat Biotech were instrumental in supplying vaccines to LMICs through initiatives like COVAX. India's history of generic manufacturing and its policy stance on TRIPS flexibilities positioned it as a leader in promoting global health equity.

Though the final waiver fell short of its original intent, it reignited global discussions on reforming TRIPS. Advocates now call for automatic IP waivers during future health emergencies to avoid delays, vaccine nationalism, and IP-driven access barriers. India remains a prominent voice in these debates, promoting a more balanced IP regime that aligns innovation with global health needs.

### 3.3 India's Role in Generic Drug Manufacturing

India has long been known as a top producer of medicines that are generic, thus it is called "pharmacy of the world." This nation's drug sector has been key when supplying cheap drugs to LMICs, more so for diseases like HIV/AIDS (Chaudhuri, 2005)[6]. The TRIPS waiver proposal presented some opportunity for India toward leveraging its manufacturing capabilities

[6] Chaudhuri, S. (2005). *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries*. Oxford University Press.

for production of COVID-19 vaccines plus therapeutics without some constraints on patent protections.

Through using of the waiver, Indian manufacturers could possibly increase some global supply for COVID-19-related medical products, contributing to a more equal accessibility. However, particular challenges such as technology transfer, scaling up of production, and ensuring compliance with international quality standards still remain important hurdles (Sampat & Shadlen, 2021)[7]. India's generic market has been vital to ensuring of affordability for important medicines. Per WHO, India makes 60% of global vaccines and gives 80% of antiretroviral drugs (World Health Organization [WHO], 2021)[8]. By using of the waiver, Indian manufacturers could increase into the global supply of COVID-19-related medical products, contributing with more equal accessibility. However, challenges such as technology transfer and scaling up production remain hurdles. Ensuring compliance with international quality standards remains a hurdle.

For instance, back in 2021, India was then able to rapidly scale up production of the Covishield vaccine after receiving technology transfer from AstraZeneca and Oxford University (Kramer, 2021)[9]. Even so, scaling up production in LMICs remains quite a challenge, and this waiver alone may not fully address most issues related to manufacturing infrastructure. India's dedication to the balancing of intellectual property protection with public health has been reflected in its use of compulsory licensing. The landmark case from *Natco Pharma Ltd. vs. Bayer Corporation* (2012) marked India's initial compulsory license. This action allowed Natco to produce a generic version of Bayer's cancer drug Nexavar at a fraction of cost. This case highlighted India's willingness to prioritize both affordability and accessibility, setting an example for other countries navigating the constraints of the TRIPS regime (Basheer, 2012)[10].

In the context of global health emergencies like the COVID-19 pandemic, India's role became still more pronounced. Indian firms like Serum Institute of India, Bharat Biotech, and Cipla were instrumental in scaling up production as well as distribution of vaccines, oxygen concentrators, as well as necessary medicines, often in partnership with global institutions like

[7] Sampat, B. N., & Shadlen, K. C. (2021). The COVID-19 innovation system. *Health Affairs*, 40(3), 400–409.
[8] World Health Organization. (2021). *India's contribution to global vaccine production*.
[9] Kramer, A. (2021). Covishield and India's vaccine drive. *The New York Times*.
[10] Basheer, S. (2012). India's first compulsory license: Natco vs. Bayer. *SpicyIP*.

Gavi as well as the COVAX Facility (Dhar, 2021)[11]. India's proactive stance, inclusive of its proposal (with South Africa) in favour of a TRIPS waiver at the WTO, reflects a long-standing commitment for equitable healthcare access.

India still faces issues despite such gains, most notably due to pressure for stronger IP protection. Free Trade Agreements (FTAs) like EU ones include TRIPS-plus provisions like data exclusivity and patent extensions, which could curtail the nation's ability to make generics (Kumar, 2020)[12]. The Indian government has, from, however, resisted such provisions to safeguard into its public health priorities.

India's pharmaceutical success is also deeply tied with its domestic policy ecosystem, including a skilled workforce, government support for R&D, and public-private collaborations. Initiatives such as Pharma Vision 2020 as well as Make in India have sought to strengthen the industry's global competitiveness (Ministry of Chemicals and Fertilizers, 2017). Initiatives ensure a continued focus on health security plus affordability.

India has leadership in south-south cooperation. It has reinforced its position as a champion in global health equity through aid. Indian pharma companies have enabled access through exports as well as through voluntary licensing, which allows local production in Africa and Latin America (Chaturvedi & Thorsteinsdóttir, 2021)[13].

### 3.4 Expanding the TRIPS Waiver Beyond COVID-19

The discussions surrounding the TRIPS waiver have also set off debates over its applicability for other public health challenges. Advocates suggest that extending of similar flexibilities to treatments for non-communicable diseases (NCDs) and illnesses exacerbated via ecological factors could improve access to important medicines in LMICs (Baker, 2022)[14]. For instance, diseases linked to air pollution, such as respiratory ailments, disproportionately affect populations in developing countries, in which access to treatments affordable is often limited.

[11] Dhar, B. (2021). India's role in equitable access to COVID-19 vaccines. *Economic & Political Weekly*, 56(5), 15–17.
[12] Kumar, N. (2020). India's stance on TRIPS-Plus provisions in FTAs. *Journal of Intellectual Property Rights*, 25(2), 103–112.
[13] Chaturvedi, S., & Thorsteinsdóttir, H. (2021). *India's South–South Cooperation in Health*. Springer.
[14] Baker, B. (2022). *Extending the TRIPS waiver to essential medicines beyond COVID-19*. Health Policy Watch.

To expand the scope of the TRIPS waiver could allow for production and distribution of generic versions of patented drugs, likely lowering costs and increasing availability. However, such a move still would require some mindful deliberation in light of the balance between incentivizing pharmaceutical innovation as well as addressing public health needs (Gostin & McCabe, 2022)[15]. For example, the World Health Organization (WHO) estimates that 71% of global deaths are caused by NCDs. These include cardiovascular diseases as well as diabetes, which air pollution often exacerbates. These diseases considerably affect most populations in developing countries. The access to affordable treatments there is frequently limited. Broadening TRIPS waiver scope might ease output and supply of copycat forms of branded medicines, perhaps cutting costs and increasing access.

A study from the Lancet Commission on Pollution and Health (2017) found that 9 million deaths do occur annually due to all pollution-related diseases (Landrigan et al., 2018)[16]. A number of these conditions could be treated with medicines. These must be generic medicines if patent protections were waived or reduced. This shows a need to check the waiver's use for key world health ills besides COVID-19. Extending such TRIPS waiver to other public health emergencies and important medicines beyond COVID-19 has surely become a pressing global concern. Diseases like tuberculosis, HIV/AIDS, malaria, hepatitis C, also cancer still cause important morbidity and mortality, particularly in the Global South, where access to patented treatments stays restricted due to elevated costs and monopolies.

Many of these conditions are treatable as well as manageable with existing drugs, but pricing and IP barriers often keep them out of reach. India, in conjunction with South Africa with countless other nations, has argued for the institutionalization of the TRIPS waiver.

Countless health and development experts argue that the pandemic should act as a turning point to reform the global IP regime toward a more equity-based, health-centred model. This includes ensuring full open access to publicly funded research, promoting global technology pooling mechanisms like the WHO's COVID-19 Technology Access Pool (C-TAP), and promoting local production capacities in low- and middle-income countries (Correa, 2021).

[15] Gostin, L. O., & McCabe, H. A. (2022). The case for a global pandemic treaty. *JAMA*, 327(3), 203–204.
[16] Landrigan, P. J., et al. (2018). The Lancet Commission on Pollution and Health. *The Lancet*, 391(10119), 462–512.

Expanding TRIPS waivers past COVID-19 concerns more than just one virus or one pandemic: it concerns building a strong, fair, plus inclusive public health structure which responds to future global health crises, for example, non-contagious plus ignored tropical illnesses. India's guidance in this field stays vital, not only as a key vendor of cheap generics but as a moral and planned voice pushing for health equity and progress without barriers.

## Chapter 4:

## TRIPS Waiver and Predatory Pricing: Market Dynamics and Barriers to Generic Entry

The global health crisis precipitated by the COVID-19 pandemic has intensified discussions surrounding intellectual property (IP) rights, particularly those enshrined in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. A central concern has been the capacity of developing nations to ensure timely and equitable access to life-saving treatments and vaccines. This chapter examines how the absence of a TRIPS waiver can contribute to predatory pricing practices within the pharmaceutical industry and restrict the entry of generic drugs, thereby compromising public health objectives. It further analyses the potential of the TRIPS waiver to counteract such practices by fostering increased market competition.

### 4.1 Predatory Pricing in the Pharmaceutical Sector

Predatory pricing is a well-documented anti-competitive strategy wherein dominant firms deliberately lower their product prices, often below production costs, with the intent to eliminate or marginalize existing competitors and deter potential market entrants. Once competition is sufficiently weakened or eliminated, these firms often increase prices to recoup losses and exploit their monopolistic position[17]. While predatory pricing has been widely studied in sectors such as retail and telecommunications, its implications for the pharmaceutical industry are particularly concerning due to the life-saving nature of its products and the ethical imperatives for access and affordability.

In the pharmaceutical sector, predatory pricing does not always manifest solely through price-cutting. Instead, it often involves maintaining prohibitively high prices for patented medicines in the absence of competition, while simultaneously engaging in practices that prevent or delay

[17] Greenbaum, J. L. (2008). *TRIPS and Public Health: Solutions for Ensuring Global Access to Essential AIDS Medication in the Wake of Paragraph 6 Waiver*. *Journal of Contemporary Health Law and Policy*, 25, 142–173.

the entry of lower-cost generic alternatives. These practices include strategic litigation, the creation of patent thickets, and the 'evergreening' of patents[18]. In this context, predatory pricing includes broader exclusionary conduct that manipulates market conditions to retain dominance.

The impact of such pricing strategies is felt most acutely in low- and middle-income countries (LMICs), where public healthcare systems are often underfunded and large segments of the population rely on affordable medications. Strong patent protections hinder generic competition, allowing medicine prices to escalate beyond the reach of patients and governments[19]. For example, in the early 2000s, prices of HIV antiretroviral therapies were kept exorbitantly high by patent-holding multinational pharmaceutical companies, leading to millions of preventable deaths in developing countries[6]. It was only after sustained advocacy and the entry of generic manufacturers, such as Cipla in India, that prices decreased significantly, saving countless lives[7].

The TRIPS Agreement, while providing global standards for intellectual property protection, does not sufficiently address or prohibit monopolistic or anti-competitive pricing behaviour. Although Article 8 of the TRIPS Agreement allows WTO members to adopt measures necessary to protect public health and prevent the abuse of intellectual property rights[20], the absence of specific language targeting predatory pricing weakens the utility of these provisions. Additionally, the capacity to enforce competition laws varies significantly across countries, undermining the ability to curb such practices in jurisdictions without strong regulatory frameworks[21].

The COVID-19 pandemic served as a stark reminder of global health inequities arising from pricing models. Pharmaceutical companies that developed COVID-19 vaccines and treatments using substantial public funding-maintained exclusivity and set high prices, often prioritizing high-income countries. This model, though lawful under TRIPS, created substantial barriers to vaccine access in LMICs, exacerbating the pandemic's impact in vulnerable regions. These

[18] Lehman, B. (2003). *The Pharmaceutical Industry and the Patent System*. International Intellectual Property Institute

[19] Ibrahim, B. (2003). *Implications of WTO-TRIPS Agreement from a National Innovation Systems Perspective*. The School of Public Policy and Administration.

[20] World Trade Organization. (1994). *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*, Article 8.

[21] Hu, W. (2020). *Compulsory Licensing and Access to Future COVID-19 Vaccines*. Centre for European Policy Studies.

outcomes reignited calls for reassessing the balance between IP protection and public health, especially in emergencies.

It is within this landscape that discussions around the TRIPS waiver gained importance. By suspending certain IP rights for COVID-19-related medical products, the waiver aims to dismantle the structural enablers of predatory pricing, allowing for greater generic competition and more equitable access[22]. However, the limited scope of the waiver adopted by the WTO in June 2022 failed to address broader pricing and access challenges. A more comprehensive waiver covering treatments and diagnostics is necessary to counter monopolistic practices and improve global health equity.

### 4.2 Monopolistic Pricing and Barriers to Entry

Monopolistic pricing in the pharmaceutical industry arises from the exclusive rights granted under intellectual property regimes such as the TRIPS Agreement. These rights allow originator firms to enjoy market exclusivity for a minimum of 20 years, enabling them to set prices with minimal competitive constraint[23]. While this framework aims to incentivize innovation and reward investment in research and development, its practical outcome has often been high medicine prices, limited access for patients—particularly in low- and middle-income countries (LMICs)—and significant entry barriers for generic manufacturers[24].

Pharmaceutical companies frequently employ various strategies to maintain exclusivity beyond the expiration of a patent. One such strategy is evergreening, where minor modifications to existing drugs—such as changes in dosage, delivery mechanisms, or combinations with other active ingredients—are patented to extend exclusivity beyond the original patent term. These secondary patents often lack substantial therapeutic advancement but still prevent the entry of generic competitors, sustaining inflated prices. Generic manufacturers are deterred by the high cost and complexity of challenging such patents through litigation.

A related tactic involves the creation of patent thickets—dense webs of overlapping patents around a single drug. These thickets form a legal minefield, making it exceedingly difficult for

[22] Ranjan, P. (2021). *The Case for Waiving Intellectual Property Protection for COVID-19 Vaccines*. Observer Research Foundation.
[23] Love, J. (2003). *The Role of Intellectual Property in Access to Medicines*. WHO Commission on Intellectual Property Rights.
[24]Reichman, J. H. (2009). *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*. *Journal of Law, Medicine & Ethics*, 37(2), 247–263.

generic companies to navigate entry without risking infringement suits[25]. Even when a primary patent expires, secondary patents covering manufacturing processes or chemical intermediates can be used to initiate legal challenges and delay generic approvals[6]. As a result, one of the most effective tools for driving down prices—generic competition—is systematically delayed or suppressed.

Moreover, data exclusivity provisions, often enshrined in bilateral free trade agreements or national legislation under TRIPS-Plus regimes, create an additional barrier. These rules prohibit regulatory authorities from relying on clinical trial data submitted by the originator to approve generic equivalents for a certain period, even when patent protection has lapsed. In practice, data exclusivity obstructs the introduction of affordable generics, thereby sustaining monopolistic pricing and limiting timely access to essential medicines in resource-constrained settings[26].

These barriers—legal, technical, and economic—are especially burdensome for small and medium-sized pharmaceutical firms. The cost of litigation, the risk of injunctions, and the uncertainty surrounding regulatory approvals discourage new entrants. Even when willing to challenge dubious patents or navigate complex regulatory systems, the required time and financial investment can be prohibitive[9]. Thus, monopolistic pricing is not merely a legal artifact—it is structurally enforced through mechanisms that raise the cost and complexity of competition.

These structural barriers have critical implications for global health, especially in LMICs. For instance, the cancer drug imatinib (marketed as *Glivec* by Novartis) was initially priced at unaffordable levels in India. It was only after a prolonged legal battle that the Indian Patent Office denied Novartis's patent under Section 3(d) of the Patents Act—citing lack of enhanced therapeutic efficacy—that an affordable generic version became available. The *Glivec* case exemplifies how unregulated pricing and IP enforcement can deprive patients of access to life-saving drugs, even in jurisdictions with progressive patent frameworks.

While Articles 7 and 8 of the TRIPS Agreement acknowledge the need to balance rights with public health obligations, the Agreement lacks robust provisions to directly address

[25] I-MAK. (2018). *Overparented, overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving Up Drug Prices*.
[26] UNDP. (2013). *The Role of Data Exclusivity in Delaying Generic Entry: Implications for Public Health*.

monopolistic behaviour. Further compounding the issue, TRIPS permits member states to adopt stronger IP protections through additional trade agreements, thereby creating a global regime where pharmaceutical giants wield disproportionate control over drug pricing and availability.

The TRIPS waiver proposal thus aims to address some of these structural inequities by temporarily suspending IP obligations related to COVID-19 medical products. Although the 2022 waiver was limited to vaccines and excluded therapeutics and diagnostics, expanding it could disrupt monopolistic control and facilitate the entry of generic manufacturers[27]. In doing so, the waiver would not only lower prices but also pave the way for more equitable access to essential medicines during global health emergencies.

### 4.3 Legal Analysis and Case Study

The enforcement of pharmaceutical patents under the TRIPS regime often creates structural barriers to generic competition, thereby limiting access to affordable medicines. TRIPS provides minimum standards for IP protection and includes flexibilities—such as compulsory licensing and strict patentability standards—that countries may use for public health. However, in practice, the exercise of these flexibilities is often curtailed by litigation, trade pressures, and procedural complexities[28].

**Case Study 1: Novartis AG v. Union of India (2013)**

A landmark case that exemplifies the tension between monopolistic pricing, patent protections, and access to affordable medicines is *Novartis AG v. Union of India* (2013) 6 SCC 1. This case revolved around Novartis's attempt to secure a patent in India for the beta crystalline form of imatinib mesylate, marketed internationally as Glivec, a life-saving drug used to treat chronic myeloid leukemia (CML) and other cancers.

Novartis's application was rejected by the Indian Patent Office under Section 3(d) of the Indian Patents Act, 1970. This section prohibits patents for new forms of known substances unless they demonstrate "enhanced efficacy."[29] The Supreme Court upheld this rejection, holding that

[27] WTO. (2022). Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/30
[28] Basheer, S., & Reddy, T. (2008). *The 'Efficacy' of Indian Patent Law: Ironing out the Creases in Section 3(d)*. *Indian Journal of Law and Technology*, 2(1), 19–51
[29] Indian Patents Act, 1970, Section 3(d).

the new form did not exhibit therapeutic efficacy sufficient for patent protection. The Court emphasized that Section 3(d) functions as a public interest safeguard against evergreening and unjustified monopolies.

This ruling had several significant implications:

- **Access to more affordable medicine**: After the judgment, Indian generic companies were permitted to manufacture and sell imatinib at a fraction of the original cost—from INR 120,000/month to around INR 8,000/month.

- **Global health impact**: The availability of generics helped Indian patients and supported international treatment efforts in other developing nations.

- **TRIPS interpretation**: The judgment demonstrated that TRIPS-compliant domestic legislation may include public health safeguards like Section 3(d).[30]

This case serves as a powerful legal precedent, underscoring the importance of domestic legislation designed to promote access to medicines. It also bolsters the case for broader TRIPS waivers by affirming national autonomy in IP implementation aligned with public health needs.

**Case Study 2: Gilead Sciences, Inc. v. Natco Pharma Ltd. (2016, Indian Patent Office)**

In 2015, Natco Pharma opposed Gilead's patent application for Sofosbuvir, a groundbreaking Hepatitis C drug, under Section 25(1) of the Indian Patents Act. Natco argued that the compound lacked novelty and an inventive step, qualifying it as merely a new form of a known substance.The Patent Office upheld this argument, rejecting Gilead's application based on Section 3(d).[31]

Key outcomes of this case included:

1. **Access to Medicines**: Indian manufacturers could now produce and distribute generic versions of Sofosbuvir, significantly lowering treatment costs.

2. **TRIPS Flexibility in Action**: It demonstrated how Indian law utilizes Section 3(d) as

[30] Doha Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference, 2001.
[31] MSF Access Campaign. (2016). Sofosbuvir Patent Oppositions: Fighting for Affordable Hepatitis C Treatment.

a TRIPS-compliant tool to promote public health.

The case affirmed India's resolve to resist unjustified patent monopolies and preserve access through legal mechanisms.

### 4.4 Anticompetitive Practices and Regulatory Loopholes

Pharmaceutical giants often employ tactics to prolong market dominance, including patent evergreening, where minor modifications to a drug lead to new patent filings, extending exclusivity periods (Baker, 2020). Other tactics include pay-for-delay agreements, where originator companies compensate generic producers to postpone market entry (Cohen & Gurkewitz, 2022)[32].

The lack of a robust waiver process enables these strategies. Even voluntary licensing often comes with restrictive terms, such as limitations on technology transfer, caps on production quantity, or exclusion of middle-income countries, thereby maintaining monopolistic control over essential medicines (MSF, 2022; KEI, 2022).

### 4.5 Market Dynamics and the Economic Consequences of a Delayed Waiver

The pharmaceutical market lies at the intersection of public health needs and private profit. Intellectual property rights, particularly under the TRIPS Agreement, significantly shape market dynamics. Delays in implementing TRIPS waivers—or limited waivers—cause market distortions that disproportionately affect LMICs, contributing to supply bottlenecks, monopolistic control, and excessive pricing, thereby worsening health disparities (WHO, 2022).

#### 4.5.1 Extended Monopoly Pricing and Lack of Competitive Pressure

Pharmaceutical companies with TRIPS-based patents maintain exclusive rights over manufacturing and sales of new medicines. This power allows price control, especially in countries with weak price regulation frameworks. Delays in TRIPS waivers reinforce such periods of exclusivity, preventing capable generic manufacturers from producing alternatives

[32] Cohen, J. C., & Gurkewitz, S. (2022). Delaying competition: Pay-for-delay settlements in pharmaceutical markets. *Journal of Law and Health Policy*, 18(2), 123–138.

(Correa, 2022).

A lack of competition removes any market pressure for price reduction. For instance, Remdesivir, an antiviral used during the COVID-19 pandemic, was priced around $3,000 in the U.S. for a five-day course. In contrast, Indian generic versions were sold for under $50 once licensing was permitted (Oxfam, 2021). The delay in establishing a globally coordinated TRIPS waiver prolonged such pricing gaps and restricted access in countries without compulsory licensing frameworks.

### 4.5.2 Reduced Incentive for Local Manufacturing and Capacity Building

One of the goals of the TRIPS waiver is to let nations build or grow their own medicine output without dread of IP violation. However, in the absence of any timely waiver, the legal uncertainty surrounding potential patent violations deters investment in local manufacturing infrastructure. This specially affects middle-income countries, such as Brazil, South Africa, and Thailand, that have certain manufacturing capacities; they are unable to deploy those capacities fully due to patent restrictions.

Furthermore, multinational pharmaceutical companies may go on to exploit this dependency through the offering of selective voluntary licenses that come with stringent conditions, thereby consolidating their dominance[33]. This practice hampers growth of pharmaceutical industries; it also prevents the emergence of manufacturing hubs that are regional, as these are vital for health security that is long-term as well as preparedness for a pandemic.

### 4.5.3 Strategic Stockpiling and Supply Chain Manipulation

One of the goals of the TRIPS waiver is to let nations build or grow their own medicine output without dread of IP violation. However, in the absence of any timely waiver, the legal uncertainty surrounding potential patent violations deters investment in local manufacturing infrastructure. This especially affects middle-income countries, such as Brazil, South Africa, and Thailand, that have certain manufacturing capacities; they are unable to deploy those capacities fully due to patent restrictions

[33] Thambisetty, S., McMahon, A., McDonagh, L., Kang, H., & Dutfield, G. (2021). *The TRIPS intellectual property waiver proposal: Creating the right incentives in patent law and politics to end the COVID-19 pandemic*. LSE Legal Studies Working Paper.

In market terms, this shows demand-side distortion, where price is not dictated at all by supply-demand equilibrium but by complete monopolistic control. The hoarding of supplies, along with scarce production rights, escalates the problem of vaccine nationalism, deepening global inequalities.

### 4.5.4 Inhibited Technological Collaboration and Innovation Sharing

The delay for implementing the waiver also discourages open innovation for knowledge transfer, both of which are important for tackling global health emergencies. Pharmaceutical firms are somewhat disincentivized from ever participating in collaborative research initiatives, such as the WHO's COVID-19 Technology Access Pool (C-TAP), which truly aims to share IP, data, and even know-how.

In the absence of a waiver, the risk that legal repercussions under TRIPS dissuades universities and research institutions and then biotech companies from entering into collaborative agreements with manufacturers located in the Global South. This engenders information silos as well as technical inequality. It slows the global response to health emergencies, also denying many countries the tools for self-reliance.

## 4.6 Conclusion

In conclusion, the TRIPS Waiver is truly not just a temporary legal exception—it can represent a calculated and moral imperative in order to recalibrate global access for life-saving medicines. By somewhat relaxing stringent patent obligations, this waiver enables many countries—particularly most of those within the Global South—to fully activate compulsory licensing, support more generic competition, and foster mostly affordable domestic manufacturing. This, in turn, directly challenges monopolistic behaviour, curbs predatory pricing, in addition to restoring a competitive pharmaceutical landscape grounded in public interest.

The waiver holds transformative potential in realigning the intellectual property regime with human rights obligations. This is especially so for the right to health enshrined under international legal frameworks such as the International Covenant on Economic, Social, and Cultural Rights (ICESCR). It signals a move towards a more equitable as well as need-based approach to global health governance—one that prioritizes several lives over some profits.

Notably, the TRIPS Waiver also encourages innovation through collaboration, not isolation. It invites both public-private partnerships and open licensing initiatives with shared research, all of which are key for new treatments that lack barriers. However, its success is contingent upon global cooperation, on political will, and on a commitment to addressing structural inequalities in pharmaceutical production and in distribution.

Ultimately, as the world continues to confront several health emergencies, present and future, the TRIPS Waiver stands out. It stands out as an important mechanism to ensure timely access, prevent exploitative pricing, and restore the core principle of equity in drug development. Its considerate implementation can shift the IP model from only a purely proprietary model to one supporting global health solidarity plus sustainable innovation.

India emerges out as one calculated pharmaceutical producer that has effectively used certain TRIPS flexibilities to balance IP rights with particular public health needs. Its specially proactive legal framework, including Section 3(d) and also compulsory licensing, enabled a production of more affordable generics for both domestic and further global markets. However, geopolitical pressure from high-income countries with reliance on imported active pharmaceutical ingredients (APIs) remain pressing challenges.

As a whole, these same case studies show that the complete absence of a thorough TRIPS waiver perpetuates total global inequities in medicine access, particularly in the Global South. The pandemic exposed the limitations of voluntary licensing as well as charity-based distribution plus market monopolies in addressing urgent healthcare needs. A broader and fully binding TRIPS waiver would empower countries to bypass certain IP barriers, foster overall local manufacturing, and ease technology transfer without any fear of retaliation or even trade sanctions.

Going forward, global health governance must prioritize legal and policy frameworks that support thorough access to medicines—not simply during pandemics, but as a permanent feature of international IP law. For that, the experiences of India, South Africa, and also the contradictions in U.S. policy, can offer critical lessons for the need for a rebalance of the TRIPS regime in favour of health justice.

# CHAPTER 5:

# CONCLUSION AND RECOMMENDATIONS

## 5.1 Summary of Key Findings

This dissertation has closely analysed global medicines access and the connection between intellectual property rights per the TRIPS Agreement, especially during the COVID-19 pandemic. IP rights are conventionally justified as being drivers of innovation, the study stressed, but that in emergency situations they often serve as barriers preventing the access in a timely manner to life-saving technologies.

In the discourse that is around global health equity, a watershed moment was that of the TRIPS waiver proposal by India and South Africa in 2020. The broader structural inequalities within the IP regime, along with the inadequacy of existing TRIPS flexibilities, were exposed in time. More than 100 countries and civil society considerably supported the waiver. However, in June of 2022, that final WTO Ministerial Decision narrowly applied such a waiver solely to COVID-19 vaccines, thereby excluding diagnostics as well as therapeutics since they remain equally critical for managing pandemics.

## 5.2 The Omission of Diagnostics and Therapeutics

The decision of excluding diagnostics and therapeutics means the final TRIPS waiver is unsound scientifically and also indefensible ethically. In order to effectively manage any pandemic, we need to have an approach that prevents by way of vaccines, detects through diagnostics, and treats by using therapeutics. For identifying as well as isolating cases, we require some diagnostics, as to manage health system burdens as well as reduce mortality, several therapeutics remain critical.

Disease surveillance as well as containment were indeed limited because many low- and middle-income countries (LMICs) struggled to scale up testing without any access to patented diagnostics. Patent protections, high prices, and also limited voluntary licensing made treatments such as Paxlovid and Remdesivir inaccessible in much of the Global South too.

Trade secrets and regulatory exclusivity can block or delay generics production even when patents are circumvented, furthermore frequently overlooked. Global solidarity fails because

of this exclusion, and that contradicts the principle of health as being a human right. Therefore, future global responses that are addressing each part of the health technologies have to be holistic in nature.

### 5.3 Conclusion: Reconciling IP and Global Health Equity

The core of the global IP system was exposed to have a certain ethical crisis because of the pandemic. Certain life-saving innovations have remained concentrated within the hands of a few multinational corporations since they were developed with public funding, and this highlights a tension between market-based IP incentives and human rights obligations.

The TRIPS waiver debate must not be seen as an exception but as a point at which it inflects. Innovation is just not assaulted in terms of a realistic and rights-based solution, like in terms of a time-bound waiver for health emergencies. Indeed, evidence does suggest open collaboration and R&D publicly funded played a role in COVID-19 innovation. Exclusive IP rights, on the other hand, played a more limited role.

IP as well as health equity must be reconciled going forward by fully embracing legal adaptability along with international cooperation. To reconcile, different innovation models must unlink R&D costs and final pricing. The right to health must be mainstreamed into all of global trade and IP policymaking with binding commitments for people that are prioritized over patents.

### 5.4 Recommendations

1. Diagnostics as well as Therapeutics Should each Be Covered under the TRIPS Waiver

   Diagnostic tests and also therapeutic medicines must be included in the waiver's extension as well. These important resources are key for reducing and managing pandemics. The expansion shall allow for broader technology sharing as well as local production. It should cover various forms of IP, including patents, trade secrets, and regulatory data protection.

2. Compulsory Licensing under Articles 31 and 31bis must be Somewhat Simplified and Further Strengthened.

The existing mandatory licensing scheme requires simplification. Health emergencies should waive procedures such as the export conditions and the notifications as well as prior negotiations. With global support mechanisms, countries could be empowered by a model compulsory license template to act decisively without fear of retaliation.

**3.** A Pandemic IP Exception Mechanism should be institutionalized by design.

The TRIPS Agreement should have such a permanent "Pandemic IP Waiver Protocol" added to it, and it is triggered automatically at the time that WHO declares a global health emergency. These clear guidelines for tech transfer and licensing should be established by this mechanism which waives TRIPS enforcement obligations and includes pre-negotiated terms.

**4.** Several Alternative R&D Models are promoted.

Policymakers should invest within prize funds, throughout open-source research, and into "delinkage" models. These models reward innovation, and they do so devoid of reliance upon exclusive rights. The Drugs for Neglected Diseases initiative (DNDI) and the Medicines Patent Pool have shown that equitable innovation is both possible and effective.

**5.** Innovation that is publicly funded must ensure a degree of transparency.

Assured access needs to come in conjunction with publicly funded R&D. Open-access publishing, plus data sharing, along with non-exclusive licensing, should be mandated within the contracts. This transparency curtails profiteers and makes sure taxpayers do not pay in duplicate—to develop and then to access.

**6.** Manufacturing in a local way and also technology transfer should be encouraged here.

Vaccines, diagnostics, and treatments need to be produced via Global South empowerment. Developed countries must fulfil their Article 66.2 obligations through funding, through training, and patent pool contributions, thereby providing support to tech transfer. Decentralized production is something that needs regional hubs for it.

**7.** Address equity gaps. Disparities, both regional and gendered, must be addressed.

Equity assessments must have to integrate IP policies, along with future waiver mechanisms. Specific healthcare access barriers are faced by women, rural populations, and marginalized groups. Prioritizing a number of intersectional strategies such as mobile diagnostics, community outreach, and also gender-inclusive policies is certainly important.

8. In IP policy-making, it is key to embed human rights impact assessments.

   Those in charge must judge all issues tied to IP, most notably amid crises. Such assessments do evaluate as to whether these kinds of decisions do comply with international human rights obligations by way of Human Rights Impact Assessments (HRIAs). TRIPS implementation does align with both the Sustainable Development Goals and international covenants on cultural, social, and economic rights.

### 5.5 Final Reflections

The COVID-19 pandemic was not purely just a health emergency but rather a litmus test for the whole world's dedication to equity, to justice, and to international cooperation. A deep contradiction lay at the heart within this crisis: some of the deepest inequalities in access accompanied the most advanced scientific breakthroughs in human history. Intellectual property rights were designed for rewarding innovation as well. Such rights turned into instruments of exclusion however, eventually costing lives, increasing disparities, and postponing access.

Countries such as India and South Africa championed the TRIPS waiver proposal. It was representative of a bold call so as to reimagine just how global health is to be governed. The primacy of monopolistic control was questioned during certain times when human lives hung in the balance. The definite WTO decision eventually fell short, not including diagnostics and therapeutics, yet it ignited a critical conversation about the limitations upon our existing legal frameworks and the need to embed solidarity into the architecture within global trade.

This reflects greater than merely past events; it calls upon people toward action. We risk repeating the same exact injustices in the time of future crises if we keep on treating health as if it's a commodity not as if it's a public good. Our legal systems must be ready to respond to that end with that speed, with compassion, and with fairness because emergencies will in fact

return whether as emerging diseases, or climate-related disasters, or as pandemics.

Its alignment alongside public purpose is regarding transformation of the global IP regime, not innovation dismantling. To ensure benefits from scientific progress fully reach all people, it means regardless of geography, income level, or social status. The genuine innovation within the 21st century will reside in the molecules that we develop. It also will exist within each of the systems that we are building for purposes of sharing all molecules.

The story does not end with the TRIPS waiver ultimately. The move from exclusion to inclusion, competition to cooperation, and profit-centric models to people-centered systems is starting. Clearly, the global community faces such a challenge: to create policy and also legal frameworks that reflect all of our shared humanity.

Therefore, the question that defines for us is not just whether we can afford to suspend intellectual property rights in such a crisis—but also whether we can afford the human cost if ever we do not.