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TRIPS AGREEMENT – INTELLECTUAL PROPERTY PROTECTION IN TRADE DURING PUBLIC HEALTH CRISES – ASEEM SRIVASTAVA

ABSTRACT

One of the most significant changes in international trade that brought the benefits of the same standardisation in the protection of patents was the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) but at the same time created some serious structural obstacles to universal health. The research paper examines the innate antagony between monopoly commercial rights of the intellectual property (IP) holders with the universal human right to health in the face of acute world-wide public health emergencies. Applying a doctrinal and analytical approach, the paper critically analyses the legal mechanism of TRIPS and its public health flexibilities, primarily compulsory licencing, parallel importation and, finally, the mechanisms affirmed in the 2001 Doha Declaration and the Article 31bis amendment. The paper shows that the current measures of safety, using detailed case analyses of both the HIV/AIDS epidemic and the COVID-19 pandemic, are simply not sufficient in a

structural, procedural, and political sense to address the issues of a modern, concurrent health crisis. The results indicate that bureaucratic inertia, non-disclosure of information (trade secrets) to the fast waivers, and general geopolitical deterrence are highly effective in halting that of the low- and middle-income states to obtain life-saving medical countermeasures. Finally, the 2022 WTO Ministerial Decision highlighted the failure of the international trade regime to be systemic in its approach of prioritising health equity to private monopolies. To address this imbalance, this paper suggests that the approach to take is a paradigm shift, i.e., introducing unilateral reforms like automatic legally binding IP waiver upon declared WHO pandemics, mandatory patenting of publicly funded research, and improving domestic patentability standards in the Global South to protect fair access to essential medicines.

1: Introduction

1.1 Background

The intersection of international trade, intellectual property (IP) rights, and global public health The paradigm of cross-border business transactions and intellectual property (IP) rights with world health is one of the most controversial concepts of the current international law. In 1994, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under the administration of the World Trade Organisation (WTO) made it a globally compliant standard of protection of intellectual property.[1] The TRIPS Agreement created a revolutionary change in the supply chain of medicine around the globe by ensuring possible 20 years life cycle of product and process patent in all areas of technological advancement, including pharmaceutical. Although the major goal of this framework is to motivate research, development,

[1] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.

and innovation through temporary commercial monopoly provided to creators, it too along has posed enduring challenges to the affordability, accessibility, and availability of life-saving medical technologies especially in low- and middle-income countries (LMICs).

This pent-up conflict between commercial rights of patenteers and the key human right to health, as guaranteed in Article 25 of the Universal Declaration of Human Rights[2] and Article 12 of the International Covenant on Economic, Social and Cultural Rights[3], is crucially exacerbated in periods of world health pandemics. The first major flash point was the HIV/AIDS epidemic of the late 1990s through the early 2000s which revealed the human catastrophe of high IP regimes at a time when critical antiretroviral therapies were out of reach to patients in the Global South. That emergency led to the 2001 Doha Declaration on

[2] Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III) (Dec. 10, 1948).
[3] International Covenant on Economic, Social and Cultural Rights art. 12, Dec. 16, 1966, 993 U.N.T.S. 3.

the TRIPS Agreement and Public Health[4], a historic consensus stating that the global IP regulations ought not to obstruct the measures made by the members of the WTO to safeguard the health of their citizens and foster the access to medicines to everyone. The Declaration made it clear that nations have rights to use flexibilities in TRIPS especially compulsory licencing and parallel importations when nations want to avoid monopolies on patents in times of national emergency.

Although such legal precautions exist, the recent COVID-19 pandemic unveiled the still-existing international IP regime systemic failures. The concentration of pharmaceutical organisations, over the raw materials and manufacturing expertise, and dominated by a small group as the virus was spreading around the world led to extreme vaccine inequity. This crisis gave rise to a new polarised controversy at the WTO, led by India

[4] World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (Nov. 20, 2001).

and South Africa, who demanded a total waiver of the TRIPS commitments in order to support the decentralised, generic manufacture of COVID-19 countermeasures. The negotiations and postponements thereof and the final watering down of the 2022 WTO Ministerial Decision[5] highlighted some terrible truths: the current TRIPS flexibilities are usually too procedurally-heavy, legally ambiguous, and even politically inept to be effective, rapid-response tools in the face of rapidly spreading pandemics. This study studies this important intersection, analysing the ways the TRIPS structure may regulate the dualism between medical protection and individual health today, and how the system might be restructured to guarantee equal medical access in an era of unrivalled vulnerabilities to global health.

1.2 Literature Review

The five key academic publications reviewed herein will support the theoretical and legal aspects of the

[5] World Trade Organization, Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/30, WT/L/1141 (June 17, 2022).

TRIPS Agreement and its role in the societal crisis of health.

1. *Liang, Warren. "The TRIPS Agreement: Protecting Innovation While Ensuring Access to Medicines" (2024).* [6]

Liang gives a background analysis of the duplicate role of TRIPS framework. He discusses that the agreement effectively incentivizes the pharmaceutical innovation process because it enables companies to recover research and development expenditure in addition to worsening the health inequality situations globally. The work by Liang evaluates critically the flexibilities inherent in TRIPS like compulsory licencing as theoretical solutions to close the divide between LMICs and the developed countries. He underlines how the Doha Declaration had a historical significance in reestablishing the primacy of public health over IP rights, and finally makes the conclusion that the TRIPS framework needs a

[6] Warren Liang, The TRIPS Agreement: Protecting Innovation While Ensuring Access to Medicines, 45 J. Int'l Econ. L. 112 (2024).

dynamic and constant assessment to keep vulnerable populations safe and not to put down the financial resources needed to be sustainably invested in the future development of medicine.

2. *Li, Zhanpeng, and Peng Guo. "Compulsory licensing of pharmaceuticals during public health crisis: a TRIPS framework analysis" (2024).*[7]

Li and Guo closely review the mechanics of the Article 31(b) of the TRIPS Agreement that allows the member states to waive the previous permission to use the patented inventions in situations of national emergence or in circumstances of extreme urgency. The authors consider the use of this tool in the context of the COVID-19 pandemic and compare the idea of mandatory licencing with the larger requirements of temporary waiver of IP. They consider that compulsory licencing is an essential tool, but the procedural complexity of the tool and constant risk

[7] Zhanpeng Li & Peng Guo, Compulsory Licensing of Pharmaceuticals During Public Health Crisis: A TRIPS Framework Analysis, 30 Med. L. Rev. 205 (2024).

of retaliation against trade is a constraint to its effectiveness. The authors propose that the reforms in the future should shift the priorities towards the access of the necessary medicines and against the regulation of prices and actively develop the local pharmaceutical production potential in developing states.

3. *Mercurio, Bryan, and Pratyush Nath Upreti. "From Necessity to Flexibility: A Reflection on the Negotiations for a TRIPS Waiver for Covid-19 Vaccines and Treatments" (2022).*[8]

This paper provides a critical backward look during the historic 2020 October proposal by India and South Africa to get a blanket TRIPS waiver. Mercurio and Upreti trace the development of the diplomatic talks through the prism of adopting a position of absolute necessity, to that of severe compromising flexibility, through the June 2022 WTO Ministerial Decision. The authors consider an impact of the changing situation surrounding the

[8] Bryan Mercurio & Pratyush Nath Upreti, From Necessity to Flexibility: A Reflection on the Negotiations for a TRIPS Waiver for Covid-19 Vaccines and Treatments, 25 J. Int'l Econ. L. 450 (2022).

availability of vaccines to shift the political wave of the waiver and achieve a final outcome document that addressed the need to relax current compulsory licencing policies and not to suspend intellectual property rights altogether. The article offers an important understanding of the geopolitical stalemate in which the response to crises in WTO is situated.

4. *Correa, Carlos M., and Nirmalya Syam. "The WTO TRIPS Decision on COVID-19 Vaccines: What is Needed to Implement it?" (2022).* [9]

The June 2022 WTO Ministerial Decision is critically deconstructed by Correa and Syam who claim that the resolution was a significantly watered-down form of the initial waiver proposal. As they point out, the ruling merely defered responsibility under Article 31(f) in terms of export bans, and most importantly, only to vaccines and not therapeutics and diagnostics. The authors give an extensive breakdown of the legal conditions and

[9] Carlos M. Correa & Nirmalya Syam, The WTO TRIPS Decision on COVID-19 Vaccines: What is Needed to Implement it?, 112 South Centre Pol'y Brief 1 (2022).

prerequisites place on developing countries who want to use this ruling. The research results of theirs display just how practical restrictions of the existing WTO consensus are harsh yet show how the bureaucratic pressures imposed upon states of enactment literally nullify the philosophy of the relief of the waiver in the form of humanitarian aid.

5. *Abbas, Muhammad Zaheer. "Twenty Years After Doha: An Analysis of the Use of the TRIPS Agreement's Public Health Flexibilities in India" (2022).* [10]

Abbas presents a serious empirical research on the way India has implemented the public health protections affirmed by the Doha Declaration within the past two decades. In the paper, an exclusive attention is given to the Indian distinct legislative translations of TRIPS flexibility, namely, under Section 3(d) of the Indian Patents Act designed to make it impossible to evergreen

[10] Muhammad Zaheer Abbas, Twenty Years After Doha: An Analysis of the Use of the TRIPS Agreement's Public Health Flexibilities in India, 12 Asian J. Int'l L. 180 (2022).

patents, that is formulated by introducing stringent requirements on the patentability of new forms of known substances. Moreover, Abbas examines the use of compulsory licencing by India in the history of its fight against high drug costs. This article is very topical because it puts into perspective the theoretical Uruguay WTO construction into the domestic law system of the pharmacy of the developing world.

1.3 Research Gap

Although the literature review directly reviews the theoretical basis of the Doha Declaration, the details of compulsory licencing, and particular instances such as the AIDS/HIV and COVID-19 crises, there is still an analytical gap. To a large extent, the available literature assesses these factors individually. Secular legal scholarship that summarises the systemic bottle necks of the procedures and the geopolitical fear that is a combination of all these makes the TRIPS flexibilities virtually sterile in cases of sudden global crisis. Moreover, although much has been

written on the subject of vaccine inequity, not enough attention has been given to the legal inability of the WTO system to properly accept therapeutics, diagnostics, and necessary manufacturing knowledge (trade secrets) into quick waiver schemes. This paper aims to fill this gap as far as not only the letter of the international IP law itself, but also its practical paralysis when it comes to dealing with a crisis is at stake but also suggest what can be deemed a unified and automatic waiver protocol in case of an impending pandemic in the future.

1.4 Research Questions

The central research questions used in this study are as follows:

1. How well do the current flexibilities of the TRIPS Agreement such as the Doha Declaration, Articles 31bis, balance the commercial rights of the owners of intellectual property with the fundamental right to health in case of global outbreak of any diseases?

2. Which are the particular procedural, legal, and geopolitical obstacles that have traditionally prevented the effective use of compulsory licencing and 2022 COVID-19 TRIPS Waiver by developing countries?
3. What changes should be made to the international trade regime and domestic patent regulations to allow automatic and rapid-response intellectual property waivers and technology transfers in the case of future WHO-declared pandemics?

1.5 Research Objectives

The major objectives of this study are:

1. To provide a critical examination of the international law system of the TRIPS Agreement in relation to pharmaceutical patents and exemptions of public health.
2. To assess the historical effectiveness and current failures of the Doha Declaration, Article 31bis and the 2022 WTO Ministerial

Decision in enabling equal access to life-saving medical technologies.

3. To determine the procedural and diplomatic bottlenecks at the international level of IP law that make the medical supply monopolies worse in times of crisis.
4. To recommend legally feasible and effective reforms at the multilateral (WTO) level as well as fundamental human rights level during health emergencies to improve harmonisation of the roles of international trade requirements with to the basic human rights.

1.6 Research Methodology

The research methodology mostly used in this study is a doctrinal and analytical research in law. It has drawn on a critical analysis of primary legal documents, such as international conventions (the TRIPS Agreement, the Paris Convention), WTO statements and Ministerial Decisions (the 2001 Doha Declaration and the 2022 TRIPS Decision), and domestic laws (such as the Indian Patents Act, 1970). Critical analysis of secondary sources, such

as journal articles, books, policy briefs, and reports issued by international organisations, such as the World Health Organisation (WHO), the WTO, and non-governmental organisations, such as Médecins Sans Frontières (MSF) are used as the supplements to the doctrinal approach. Through a comparative and evaluative approach, the study examines the text of the international trade law with respect to its actual socio-legal implications, particularly in determining the expressions of lapses in the law in terms of the overall obstacles to the realisation of public health in the Global South.

1.7 Scope of Study

This research study is limited within the boundaries of the international trade law, intellectual property rights and the management of severe health crises across the world in the global context. In its substantive aspects, the research is mainly concerned with the role of patents and protection of undisclosed information (trade secrets) as applied in the pharmaceutical,

vaccines, therapeutics, and diagnostics enterprise. Although the legal system examined is the international system, the key consideration of the practise evaluation and the case studies will emphasise significantly the impact on the low- and middle-income countries (LMICs). The research will make extensive use of legal and diplomatic stance of important developing countries, especially of India and South Africa as the locales to demonstrate the gap between the IP enforcement demands of the Global North and the demand of public health of the Global South.

1.8 Limitations of Study

This research is subject to several methodological and practical limitations. First, being a doctrinal and literature-based study, it relies exclusively on existing jurisprudence, publicly available WTO documents, and secondary academic data; it does not incorporate primary empirical field research, such as direct interviews with WTO delegates or pharmaceutical executives. Second, the geopolitical landscape regarding pandemic

preparedness and international trade is rapidly evolving in the post-COVID-19 era, meaning that ongoing WTO negotiations or newly proposed WHO pandemic treaties may alter state practices during the course of this study. Finally, due to constraints of length and focus, the study cannot provide a comprehensive jurisdictional analysis of the domestic patent regimes of all 164 WTO member states, necessitating a focused approach on key representative jurisdictions within the global pharmaceutical trade.

2: The Legal Framework: TRIPS and the Right to Health

2.1 The TRIPS Agreement and Pharmaceutical Patents

The accord on Trade-Related Aspects of Intellectual Property Rights (TRIPS) negotiated at the General Agreement on Tariffs and Trade (Uruguay Round) and implemented in 1995 is the broadest on intellectual property (IP) multilaterally. Before the TRIPS, the international IP regime, which was largely under the administration of the Paris Convention on the Protection of Industrial Property[11], gave sovereign states substantial freedom in deciding on the extent and on what is patentable. Lot of developing countries took advantage of this leniency to not protect pharmaceutical products under patents, but rather offer only process protection. This local strategy contributed to the development of strong generic pharmaceutical sectors that rationalised

[11] Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, revised at Stockholm July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305.

the price of necessary drugs and made them more accessible.

With the coming of the TRIPS Agreement, this picture changed radically, because minimum levels of IP protection were put on the same level of all the states that are members of the World Trade Organisation (WTO). Article 27.1[12] which requires patents to be made on any inventions of any type, be it a product or process are not in existence, inventive step is taken, and that is capable of industrial application, forms the corner stone of such standardisation in the context of the field of public health. More crucially, Article 27.1 does not allow any discrimination based on the location of invention, the area or technology and the imported or local products. This meant that drug patents had to be introduced by the members of WTO.

Also, Article 33 of the TRIPS Agreement[13] adopted the minimum terms of the patent as twenty years upon the application date, providing

[12] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27.1.
[13] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 33.

pharmaceutical inventors with the significant time-span of the market monopolisation. The rationalisation behind this strong protectionist strategy is rooted in theory within the need to incentivize the huge capital investment and risk of the research and development (R&D) of the Pharma industry. TRIPS framework proposes originators recover their investments and invest in the development of new products in the future by issuing a well-defined, legally guaranteed monopoly. Nevertheless, the real-life application of this regime has been the establishment of huge structural obstacles to the access to medicine. The legal powers of the donors in Article 28 [14]like the one that grants the holder of the patent the right to prevent any third party to make, use, offer to sell or actually sell, or import the patented product without permission is a de facto elimination of generic competition throughout the term of the patent, which regularly causes monopolistic prices, denying weak populations of low- and

[14] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 28.

middle-income countries access to the patented product.

2.2 Human Rights vs. Intellectual Property

The excessive application of pharmaceutical patents by the international trade law brings about an underlying normative and jurisprudential dispute with the international human rights system, namely, the core right to health. This conflict has been termed mostly as a conflict between individual and commercial trade advantages and general non-trade human rights.

The entitlement to the highest achievable standard of physical and mental health is firmly enshrined in the international law, which is most clearly expressed in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR).[15] The United Nations Committee on Economic, Social and Cultural Rights, in its General Comment No. 14[16], has made it clear that

[15] International Covenant on Economic, Social and Cultural Rights art. 12.
[16] U.N. Comm. on Econ., Soc. and Cultural Rts. (CESCR), General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000).

the right to health includes the availability, accessibility, acceptability and the quality (the AAAQ model) of operating public health and health-care facilities as well as goods, services and include, specifically, essential drugs. On the contrary, Article 15(1) (c) of the ICESCR[17] safeguards the moral and material interests that arise due to the production of scientific work, and it is known as the IP rights. The UN system clearly, however, draws a line between human rights, which are inherent and global, and the IP rights, which are transient, statutory monopolies devised as part of the state policy to fulfil a larger purpose to society.[18]

The tension between these regimes is acuted during the periods of the public health crises. Explicit patent monopolies have a direct negative effect on the aspects of right to health namely access i.e. economically (affordability) and physically (not reaching the right supplier)

[17] International Covenant on Economic, Social and Cultural Rights art. 15(1)(c).
[18] Holger P. Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicines (2007).

bottlenecks in supply chains. In order to balance this, domestic constitutional frameworks have the tendency to play the crucial role of providing the bridge. In a jurisdiction with transformative constitutions, the right to health is read in the basic right to life on a regular basis. As an example, the broad understanding of the right to life would necessarily include the right to life-saving medical care, and this would impose a positive burden on the state making sure that the international trade agreements do not violate the basic constitutional rights. This constitutional requirement is the need that countries should interpret and enforce the TRIPS Agreement in a way that would put the private IP monopolies under the larger laws of the common good of health, and should exercise legal flexibilities to meet their human rights commitments.

2.3 The Doha Declaration (2001)

In the late 1990s and early 2000s, the disastrous crash of the new TRIPS regime and an escalating global health crisis, the spread of HIV/AIDS,

occurred. Although there were highly effective antiretroviral (ARV) therapeutic treatments that have made HIV no longer to be a death sentence but a chronic condition that can be controlled in the Global North, the cost of using the drugs was very high; more than 10,000 dollars every year per patient was unaffordable to the large majority of patients in the Global South, especially those in Sub-Saharan Africa. When developing countries tried to introduce national policies to reach access to cheaper generic alternatives, they were under intensive pressure in foreign affairs, threat of trade sanctions and active litigation filed by global drug companies.

Moral outrage and public pressure led to the next stage in the moral outrage the 2001 WTO Ministerial Conference at Doha Qatar where the Declaration on the TRIPS Agreement and Public Health (the Doha Declaration) was adopted[19]. The Declaration is a breakthrough in international economic law since it provides a political and legal

[19] World Trade Organization, Declaration on the TRIPS Agreement and Public Health.

redress to the unbalance that the TRIPS Agreement developed.

The key part of the Declaration is expounded in paragraph 4[20] which openly states that the TRIPS Agreement does not and must not prohibit members to undertake actions aimed at protecting public health. It makes it clear that the Agreement can and must be interpreted and applied in a way that certifies WTO members the right to safeguard the health of the population and, in this specific instance, to further the interests of the population in gaining access to medicines. This is an essential interpretative requirement since it puts TRIPS in line with the provisions of the Vienna Convention on the Law of Treaties concerning the interpretation of subsequent agreements with regard to treaties.

Furthermore, Paragraph 5 of the Doha Declaration clarifies the specific "flexibilities" inherent within

[20] World Trade Organization, Declaration on the TRIPS Agreement and Public Health, para. 4.

the TRIPS Agreement.[21] It reaffirms the sovereign right of each member state to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. It also explicitly recognizes that each member has the right to determine what constitutes a "national emergency or other circumstances of extreme urgency," noting that public health crises—such as those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics—can represent such emergencies. By clarifying these flexibilities, the Doha Declaration sought to insulate developing nations from retaliatory trade practices when taking legitimate legislative or executive action to secure affordable medicines.

2.4 India's Patent Regime and the Global South

In order to completely understand how TRIPS flexibilities are applied in reality, the analysis of the patent regime of India could not be omitted. Until the Patents Act of 1970[22], which has since

[21] World Trade Organization, Declaration on the TRIPS Agreement and Public Health, para. 5.

[22] The Patents Act, 1970, No. 39, Acts of Parliament, 1970 (India).

been replaced by the Patents Act of 2005, India has only recognised process patent on pharmaceuticals. This strategic legislative decision triggered the development of a very competitive domestic pharmaceutical industry that was highly competitive and relied on reverse-engineering. Indian generic pharmaceutical firms could supply the typical ARV cobblage at less than a dollar a day by the time the HIV/AIDS crisis hit its apogee, and the nation became known as the pharmacy of the developing world because it has broken the patent monopolies in the west.

India, as a member of WTO, however, was supposed to change its product patent regime to be fully TRIPS compliant by the year 2005. [23]The dilemma was how to meet the international trade commitment and at the same time not to break up the generic industry that the Global South had depended on. The resultant Patents (Amendment) Act of 2005 is a testament to the art of flexibilities of TRIPS to provide a perfect balance between

[23] The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (India).

protection of IP on the one hand and the protection of strong public health on the other.

The most questioned mechanism to be implemented worldwide was the Section 3(d) of the Indian Patents Act which was intended to curb the evergreening concept- abusive practise of having pharmaceutical companies make small, insignificant changes to the drugs that already have a patent to obtain new patents and also create an artificial monopoly. Section 3(d) sets the rigorous edge of patentability that only the mere discovery of a novel form of an already known substance is not a patentable one unless it makes a significant improvement to the already known efficacy of that specific substance. This safeguard was hardened under the jurisprudential decision of the Supreme Court in the landmark case of Novartis AG v. Union of India Inc.[24] where the appeal of refusal to patent the cancer drug Glivec on the basis of meeting rigorous patent criteria

[24] Novartis AG v. Union of India, (2013) 6 S.C.C. 1 (India).

and patient access over reduced patent criteria on the secondary patents was upheld.

Also, the statutory system in India has a strong mechanism of compulsory licencing by use of Section 84 of the Patents Act. A compulsory licence can be issued at the expiry of three years to the granting of the patent, in case of failure to meet the reasonable needs of people, in the case where the invention covered by the patent is not commercially manufactured in the Indian territory, or in case it is not utilised reasonably. This was argued successfully in the Natco Pharma Ltd. v. Bayer Corporation[25] case where the Controller of Patents approved a domestic generic company licence to manufacture the patented kidney cancer treatment drug Nexavar thus saving the patient with the drug a substantial amount of money on a monthly drug expense.

The issue of the importance of domestic legal architectures is illustrated by the jurisprudential

[25] Natco Pharma Ltd. v. Bayer Corp., Compulsory License Application No. 1 of 2011, Controller of Patents, Mumbai (2012) (India).

and legislative manoeuvring of the TRIPS agreement in India. It shows that the macro-laying out of international treaties is not enough to give expression to the practical implementation of the right to health in crises, but requires to a great extent the strictness with which sovereign states apply the principles of constitutionality as well as flexibilities of statute to curtail the monopolistic excesses of the international trade law.

3: TRIPS Flexibilities and Mechanisms During Crises

3.1 Compulsory Licensing (Article 31)

Mandatory licencing is the most discussed and legally strong system of the TRIPS Agreement, which is aimed at excluding absolute monopoly of a patentee. A compulsory licence is set forth in Article 31[26] that a government may grant a third party (usually a generic drug manufacturer operating domestically) or a governmental agency the permission to utilise a patented invention without the direct permission of the patentee. This is arguably supposed to be an important safety valve where the exclusive rights granted by patents do not definitely override the public good, especially with regard to availability and affordability of important medicines.

The provision of Article 31, however, is extremely restricted in the provisions of a set of procedural requirements aimed at safeguarding the business

[26] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31.

interests of the patentee. Article 31(b)[27] requires that the proposed user must have made effort to secure the right holder permission of the right holder along reasonable terms and conditions on a commercial basis, and that having done so, his or her efforts must have failed within a reasonable timeframe. Only under the circumstances of a national emergency or other cases of extreme urgency a waiving of this prerequisite of prior negotiation by a member state is possible, as well as due to public non-commercial use. This concession becomes paramount in the situation of a threat to the health of the population as a quick delivery of diagnostics, vaccines, or therapeutics cannot spend the time on the long-term development of deals with companies.

Other powerful restrictions prevail in spite of this emergency waiver. Article 31(h)[28] demands that the owner of such a right must receive adequate remuneration in the situations of each case and

[27] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31(b).
[28] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31(h).

this should be based on the economic value of the authorization. The ambiguity in the meaning of what is considered as adequate remuneration is prone to lengthy lawsuits. Moreover, Article 31(c) narrows the licence scope and term to the purpose with which it was given and the Article 31(g)[29] requires the termination of the licence in case and when the conditions under which the licence was granted no longer exist, and are not likely to re-emerge.

Practically, the use of compulsory licencing by the developing countries is historically terribly geopolitically strained. In 2000s, the countries such as Thailand and Brazil were making threats or invoking compulsory licencing of HIV/AIDS and cardiovascular drugs, met with an prompt diplomatic response by the United States Trade Representative (USTR) with countries going to the Special 301 Watch List, and threats of generalised systems of preferences (GSP) in trade. As a result, where the legal framework of compulsory licencing

[29] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31(g).

clings to the international law, the reality of the structure is that its application entails enormous political assets. To most low- and middle-income countries (LMICs) the prospect of realisation of retaliatory trade measures and the risk of withdrawal of foreign direct investment is an effective deterrent mechanism leaving Article 31 a virtually impracticable but legally effective caution sign in all save the most extreme of most politically defensible situations.

3.2 Parallel Importation and Exhaustion of Rights

Parallel-importation is an important trade technology enabling any nation to legally, (legally) import a patented medication in another nation where it is more affordable, without the authorization of the patent holder in the state of importation. The law base to parallel importation in the international trade system lies on the doctrine of the exhaustion of rights. According to this doctrine, when a patent holder (or a party having the right to the patent) places a product

with a patented product on the market, they are exhausted of the right to ultimately exercise control over whether or not the particular product is further sold or distributed on the market.

Article 6 of the TRIPS Agreement[30] copes with this doctrine in so much that, without interfering with the provisions of non-discrimination (National Treatment and Most-Favoured-Nation treatment), anything contained in the Agreement shall not be invoked so as to solve the problem of the exhaustion of intellectual property rights in the context of dispute settlement in WTO.[31] This was an important go-slow to the developing countries at the Uruguay Round because it will retain the sovereignty of every member country to make its own decision on exhaustion.

Generally, it has three regimes of exhaustion namely national, regional and international. By virtue of national exhaustion, the copyright holder may only antecede the rights through sale of a

[30] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 6.
[31] Carlos M. Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement (2d ed. 2020).

product on the domestic territory; there will still be a ban on parallel importations. Regional exhaustion permits parallel imports of a certain set of countries (in the case of the European Union). The most beneficial to global public health is a case of international exhaustion because in this case, the rights of the patent owner are referred to as exhausted as soon as the product is sold in any part of the world. This was reiterated in the 2001 Doha declaration[32] where it is stated that the TRIPS Agreement does not in any way restrict any member in the right to draw its own exhaustion regime without question.

Parallel importation is an essential price-arbitration instrument in the context of a major health crisis of a population. To these pharmaceutical companies, it is very common to have a tiers pricing system where they are marketing the same type of medicine at an extremely wide range of prices in different national markets depending on the purchasing power of the

[32] World Trade Organization, Declaration on the TRIPS Agreement and Public Health.

locals or the tender that the government has bid. Through a regime of international exhaustion, a developing country that has a health crisis is able to avoid the domestic patent holder of a certain drug and import the same, legitimate drug that they already have invented in a neighbouring country that introduced the drug initially at a fraction of the cost.

The success of parallel imports however depends on the existence of a working international supply chain and prior presence of the drug in other markets. The process collapses during pandemic waves of pandemic fatality like COVID-19 which are already globalised. In a situation where the global demand simultaneously skyrockets and the supply, on the contrary, is strictly limited by the few patent-owning manufacturers, there are simply no cheaper, but available stocks, which can be imported. Accordingly, parallel importation is a very effective tool to deal with endemic diseases or localised epidemics where the global supply can be significantly large compared to the local demand,

but structurally it fails when dealing with an extinction wide, synchronous public health crisis where absolute global supply is the main bottleneck.[33]

3.3 The Article 31bis Amendment

The greatest structural constraint of standard compulsory licencing by the original TRIPS Agreement was written in Article 31(f).[34] It required that any necessity of licence issued must be predominantly intended the supply of the domestic market of the member that authorised such use. Although this clause was meant to safeguard international markets of the patent holder as well as stop diversion of trade, the legal provision was a fatal global paradox to the countries that had limited pharmaceutical production capacities, or those that had not had a capacity to produce pharmaceuticals. A nation with a critical shortage of the world community of public health yet with unsophisticated industrial basis to produce the

[33] Peter K. Yu, Intellectual Property and Information Wealth: Issues and Practices in the Digital Age (2007).
[34] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31(f).

drug locally would not have been legally allowed to import a generic copy produced under compulsory licence in another nation since the exporting nation would be contravening Article 31(f) prohibition which principally relates to the local state.

This was the flawiest point and has been known and commonly called the Paragraph 6 problem of the Doha Declaration[35] and this required a legal redress. After years of negotiation, the WTO General Council agreed in 2003 to a temporary waiver which was later converted into a permanent amendment to the TRIPS Agreement in 2005 taking effect in 2017. This amendment brought in Article 31bis[36] which established a specific legal avenue through which member states may deliver a compulsory licence specifically in the manufacturing and exportation of patent medications to legitimate importing nations that are in need.

[35] Brook K. Baker, Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration, 14 Ind. Int'l & Comp. L. Rev. 613 (2004).
[36] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31bis.

Article 31bis, as written, was celebrated as a victory of the humanitarian trade law. As a matter of fact, it has turned out to be a procedural maze. The process presupposes an unbelievable number of bureaucratic notifications and requirements. The importing nation has to make known to the WTO officially about the inability to produce the drug and the desired quantities in particular. The exporting nation then has to grant a similar compulsory licence which is strictly restricted to that quantity demanded. Moreover, to ensure that the generic drugs are not smuggled to the high-paying developed markets, the goods exported must be distinctly recognised either by use of special packaging, colour, or shape. Lastly, the exporting nation would have to enforce the requirement that the generic producer compensate the patentee with sufficient amount and this begs complicated issues regarding remuneration in such non-commercial, humanitarian environment.

The fact that Article 31bis is nearly not used at all proves the systemic failure of this article. Since the

first waiver came into existence in the previous twenty years, the mechanism has actually largely been applied to one case, the export of the HIV/AIDS drug Apo-Triavir of Canada (manufactured by generic pharmaceutical producer Apotex) to Rwanda in 2007.[37] It involved a number of years of legal wrangling, changes to regulations in Canada and complicated discussions, and, on a commercial level, it was proven to be so commercially untenable and procedurally exhausting that Apotex said it would probably never repeat the process in the system. The Rwandan case was a clear indication that Article 31bis is too bulky to allow the expedited transparent legal framework so badly needed in order to align swift, cross-border medical supply chains in the face of acute health emergencies that create a testing purpose.

[37] Duncan Matthews, Intellectual Property, Human Rights and Development: The Role of NGOs and Social Movements (2011).

3.4 Voluntary Licensing and Technology Transfer

Since compulsory licencing (on the one hand) and Article 31bis (on the other hand) are adversarial and procedurally complex, voluntary licencing (VL) and structured technology transfer is developing as a favourable, ostensibly collaborative alternative. A voluntary licence is the deal of allowing a patent holder to grant a third party (frequently a generic manufacturer in a developing country) permission to manufacture, sell, and sell the patented invention, usually in exchange of royalty and under some of the strict geographic and business terms.

At the institutional response, this mechanism has proved very effective by initiatives such as the Medicines Patent Pool (MPP) that is supported by the United Nations. The MPP makes agreements with original patent owners to collocate their IP, and then further licencing such rights to generic makers. This model has radically made treatments of HIV, Hepatitis C and tuberculosis more

accessible in the Global South. The MPP is made to work harmoniously without the diplomatic backlash of compulsory licencing but enables the speedy increase in generic manufacturing and technology transfer enabling generic companies to gain the requisite know-how to manufacture the complex formulations.

The very transfer of technology is an asserted goal of the TRIPS Agreement.[38] In article 7[39], emphasis is placed on the fact that the protection of IP must assist in the transfer and dissemination of technology to the benefit of both the users and the producers. Moreover, Article 66.2[40] clearly binds the members of the developed countries to give the incentives to their enterprises to facilitate the transfer of technology to the least-developed countries (LCDs) to make them build a solid and solid technological foundation.

Yet, voluntary licencing even during times of severe cases of public health has serious

[38] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 7.
[39] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 7.
[40] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 66.2.

shortcomings. Most importantly, it puts the entire control of global health on the hands of profit-driven institutions that are privately based. The holders of patent have the absolute right to choose whether or not to licence and most importantly where to sell licenced products. Traditionally, drug companies have been in the habit of not including the middle-income countries (MICs) within the physical scope of voluntary licences. Countries such as Brazil, South Africa, and India with large populations and high disease parameters but that are considered middle-income are usually excluded out of these agreements, and consequently, they have to pay extreme prices as monopolies and poorer states like their neighbours accept a cheap generic alternative.

This has been an innate drawback that was self-evident during the COVID-19 pandemic. The World Health Organisation initiated the programme called the COVID-19 Technology Access Pool (C-TAP) that leads to the voluntary sharing of intellectual property, knowledge, and data.

Nevertheless, major pharmaceutical firms did not pay much attention to C-TAP and instead encouraged bilateral voluntary licencing (like the one between AstraZeneca and the Serum Institute of India). These bilateral and opaque deals enabled originators to dominate global supply chains, limit technology flow of superior platforms (such as mRNA vaccinations), and give preference to profitable markets, which ultimately worsened the vaccine inequity, which characterised the pandemic reaction. In such a case therefore, though voluntary licencing is an instrumental tool in an endemic case, its discretionary character makes it inadequate as a main mechanism of promoting global equity in the process of countering an acute, universal health emergency.

4: Case Studies: Evaluating the Regime in Practice

The legal framework of the TRIPS Agreement and its flexibilities gives a balanced legal construction on paper. Nevertheless, the real effectiveness of any international legal regime is put prism through not in diplomatic vacuums, but at a time when an acute, real-life crisis occurs. In this chapter, the author shifts the shift of the analysis of the doctrine to the analysis of the practical assessment, questioning the two characteristic global health crises, such as the epidemic in the HIV/AIDS and COVID-19 epidemic. This chapter sheds light on the systemic bottlenecks that continue to push the justification of equitable allocation of life-saving medical technologies by disaggregating the legal, political and economic gambulures that defined the nature of such crises.

4.1 The HIV/AIDS Epidemic: The Catalyst for Legal Reform

The stress test of the newly-established TRIPS Agreement was at fault of the HIV / AIDS epidemic of the late 1990s and early 2000s. Although the Global North started treating the disease as a chronic issue in view of the introduction of the highly active antiretroviral therapy (HAART), the Global South, especially Sub-Saharan Africa, had an unmitigated disaster. The biggest obstacle was the cost: the cost of patented HAART regimens was estimated at around 10000-15000 a year per patient, a price which was in effect by a thousandfold that of the health spending of the affected developing countries per capita.

The South African legal epicentre of this crisis was the court. With a growing public health catastrophe threatening South Africa, in 1997 the South African government led by Nelson Mandela introduced the Medicines and Related Substances

Control Amendment Act.[41] Section 15C of this Act was meant to fundamentally open access to affordable medicines acquiring legal power to authorise parallel importation and compulsory licencing practicability exploiting flexibilities within TRIPS.

The Pharmaceutical industry in the world reacted forcefully and with coordination. Located in 1998, Pharmaceutical Research and Manufacturers of America (PhRMA) represented by a coalition of 39 multinationals pharmaceutical companies filed a high-profile suit against the South African government (commonly referred to as the Pretoria lawsuit).[42] The plaintiffs contended that South Africa had breached its duties by providing protection over the private property to the plaintiffs in the South Africa Constitution and the protection of privacy in the TRIPS Agreement. At the same time, immense pressure in the form of diplomatic pressure was experienced by the government of

[41] Medicines and Related Substances Control Amendment Act 90 of 1997 (S. Afr.).
[42] Pharm. Mfrs. Ass'n of S. Afr. v. President of the Republic of S. Afr., Case No. 4183/98 (High Court of South Africa, Transvaal Provincial Division, 1998).

South Africa with the country being listed on the USTR 301 Watch List as well as being threatened with deprivation of preferential trade benefits.

This rampant protection of intellectual property (IP) rights against millions of deaths to be prevented caused international furor. An intense public relations campaign led by international non-governmental organisations (NGOs) (with leading roles played by Medicins Sans Frontières (MSF) and Treatment Action Campaign (TAC))[43] portrayed the case as corporate profits over human lives. That changed in 2001 when an Indian generic pharmaceutical firm, Cipla, proposed a bio equivalent generic mixture of triple therapy ARV drugs at around $350 a year- a staggering 96% cheaper.

Faced with an unwinnable public relations disaster and mounting pressure from global civil society, the 39 pharmaceutical companies unconditionally withdrew their lawsuit in April

[43] Médecins Sans Frontières (MSF), Untangling the Web of Antiretroviral Price Reductions (18th ed. 2016).

2001.[44] This watershed moment was legally and politically transformative. It definitively proved that the baseline TRIPS framework was structurally incompatible with global health emergencies and demonstrated the lethal consequences of unmitigated patent monopolies. The fallout from the Pretoria lawsuit was the direct geopolitical catalyst that forced the WTO to convene later that year, resulting in the adoption of the Doha Declaration[45], which formally recognized the primacy of public health over strict IP enforcement.

4.2 The COVID-19 Pandemic and Vaccine Equity

The COVID-19 outbreak, in case it demonstrated the severe deficits of the post-Doha flexibility, was the manifestation of the fact that the original TRIPS framework was not as dangerous as the nouvelle avenue of crisis demonstrates itself currently. When the outbreak of a new coronavirus

[44] World Trade Organization, Declaration on the TRIPS Agreement and Public Health.
[45] Jakkrit Kuanpoth, Patents and Access to Medicines: The TRIPS Agreement and the Doha Declaration, 10 J. World Intell. Prop. 50 (2007).

affected all economies and healthcare systems worldwide, the scientific community has been doing an unparalleled amount of work, which led to the quick evolution of highly efficacious vaccines and therapeutics. But the further dissemination of these novelties was marked with excessive unfairness on a global level, commonly referred to as vaccine apartheid.[46]

4.2.1 Advanced Purchase Agreements and Monopoly Supply

It was the monopolisation of manufacture of vaccines by IP that was the key factor that encouraged the inequity. The owners of patents (like Pfizer-BioNTech and Moderna) not only had special privileges in respect to patents of the products but also the complicated manufacturing procedures and trade secrets that were essential in the production of mRNA vaccines. This meant that the world supply was artificially limited to that which the particular companies and the contract

[46] 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, LSE Legal Stud. Working Paper No. 06/2021 (2021).

manufacturers they selected would be able to supply. Advanced Purchase Agreements (APAs) were used by developed nations, which had enormous amounts of capital, to essentially carve off the vast majority of the estimated global supply ahead of the COVAX facility[47] an international initiative aimed at providing equitable global access to the vaccine, leaving the facility in a chronic state of dose shortage.

4.2.2 The India-South Africa TRIPS Waiver Proposal

In the year 2020 (October), India and South Africa presented a radical approach to the WTO TRIPS Council aimed at simplifying global manufacturing in the face of a rapidly spreading pandemic as it was clear that the method of standard compulsory licencing (operating on a sluggish country-by-country, patent-by-patent basis) was completely ineffective.

[47] Bryan Mercurio & Pratyush Nath Upreti, From Necessity to Flexibility: A Reflection on the Negotiations for a TRIPS Waiver for Covid-19 Vaccines and Treatments, 25 J. Int'l Econ. L. 450 (2022).

It was proposed that some of the provisions of the TRIPS Agreement that were to be waived temporarily are Section 1, 4, 5 and 7 of Part II[48], which address copyright, industrial designs, patents and protection of undisclosed information (trade secrets). This was aimed at eliminating any IP barriers that would discriminate against generic manufacturers across the world in the immediate reverse-engineering and production of COVID-19 diagnostic cases, therapeutics, and vaccines.

The proposal led to a sour and close to two year diplomatically frozen standoff. It had more than 100 developing countries and international health activists that claimed that during a global crisis,ipt rights should be set aside to decentralised production. On the other hand, the European Union, the United Kingdom and Switzerland (location of major pharmaceutical bases) vehemently opposed it. Opponents claimed that IP was the driver of the breakthrough of the rapid vaccine development and that waiving will not

[48] Agreement on Trade-Related Aspects of Intellectual Property Rights, Parts I-VII.

boost supply due to a reported absence of technological capacity in the Global South, supply chain congestion of raw materials, and quality control risks.

4.2.3 The 2022 WTO Ministerial Decision

WTO accepted the Ministerial Decision on the TRIPS Agreement at the 12th Ministerial Conference (MC12) in June 2022[49] after 20 months of painful delays, at which millions of lives were lost and the virus itself had changed several times.

Legal scholars and the health advocating groups were extremely critical of the ultimate move by the government as a mere farce. More importantly, it was not an extensive IP waiver. Rather, it just gave a specific definition and weak relief of the export limitations under Article 31(f) of compulsory licences. [50]The ruling had drastic restrictions:

[49] World Trade Organization, Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/30, WT/L/1141 (June 17, 2022).
[50] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31(f).

1. *Narrow Gap of Reach:* It was also limited to COVID-19 vaccines, specifically excluding all critical therapeutics and diagnostics (a decision on which was repeatedly postponed and eventually not realised).
2. *No Trade Secret Waiver:* It had not waived confidentiality of information which was not disclosed (Article 39).[51] In more complicated biologicals such as mRNA vaccines, patent is not as important as the unpatented manufacturing know-how. The right to legally produce the vaccine under compulsory licence without compelling the transfer of this technology is almost useless.
3. *Complex Procedural Conditions:* The decision imposed on developing countries trying to use it complex notification and anti-diversion conditions, which keeps the bureaucratic paralysis that is the hallmark of Article 31bis.[52]

[51] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 39.
[52] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31bis.

The Decision of 2022 was ultimately untimely and could not influence the direction of the pandemic, not mentioning that it did not provide ways to remove the fundamental legal and structural limitations that have hindered the prompt and decentralised manufacturing of medical countermeasures.

4.3 Systemic Bottlenecks: Why the Flexibilities Fail

Comparing the HIV/AIDS crisis and the COVID-19 crisis, one can see that there has been a steady tendency towards bottlenecks in the international IP regime. The flexibilities that the Doha Declaration advocates so much, which are compulsory licencing and Article 31bis[53], are constantly shown to be inadequate in emergencies of global scope, either due to the emergent conditions or simple because of the weaker state.

[53] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31bis.

4.3.1 Bureaucratic Inertia and Legal Complexity

The TRIPS flexibilities are implementationally exhausting, and procedurally burdensome in nature. The initiatives that have been described in Article 31 and 31bis [54]necessitate a product by product, country by country and frequently quantity by quantity strategy. In the case of a pandemic, one therapeutic or vaccine product might have dozens and possibly thousands of overlapping patents across jurisdictions (a so-called patent thicket). The aspirations of pushing through this legal maze in granting mandatory licences on all part of a medical product are bureaucratic unachievable to a majority of the developing countries that do not have large forces of specialty patent law firms. Diversity cannot deal with pandemics through legal negotiating in the long run, automatic and universal solutions are needed.[55]

[54] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31 & 31bis.
[55] Warren Liang, The TRIPS Agreement: Protecting Innovation While Ensuring Access to Medicines, 45 J. Int'l Econ. L. 112 (2024).

4.3.2 The Trade Secret "Black Hole"

Most modern drugs and especially biologics and mRNA technology are manufactured using sophisticated techniques depending on cell lineages, specialised and biological data. This is safeguarded under the TRIPS Agreement in the Articles 39 as undisclosed information (trade secrets). [56]Although government may grant a compulsory licence to supersede a patent, presently there is no operational mechanism across the international trade law to coerce the provision of the proprietary manufacturing knowledge, or to educate generic scientists, by a pharmaceutical company. In absence of this dynamic technology transfer, the granting of a patent waiver to a very complicated biologic is the same as issuing someone with the cover of a recipe book, minus the ingredients or recipe within it. This regulatory loophole makes traditional

[56] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 39.

flexibilities of patent more redundant in the contemporary world of biopharmaceuticals.[57]

4.3.3 Geopolitical Deterrence and Economic Retaliation

Lastly, political is not a legal bottleneck but it is most widespread. International trading system is based on deep power differentials. The corporate interests of the Global North strongly shaped the TRIPS Agreement, and these countries regularly apply extra-legal diplomatic instruments to bring about maximalist IP standards.[58]

As a developing country considers the use of a TRIPS flexibility, it has to strike a balance between domestic benefit to the public health and the fuzzy prospects of being retaliated against in the international market. There are such mechanisms as the US "Special 301" Report[59], which operates as a constant disincentive. The countries are afraid that the issuance of a compulsory licence

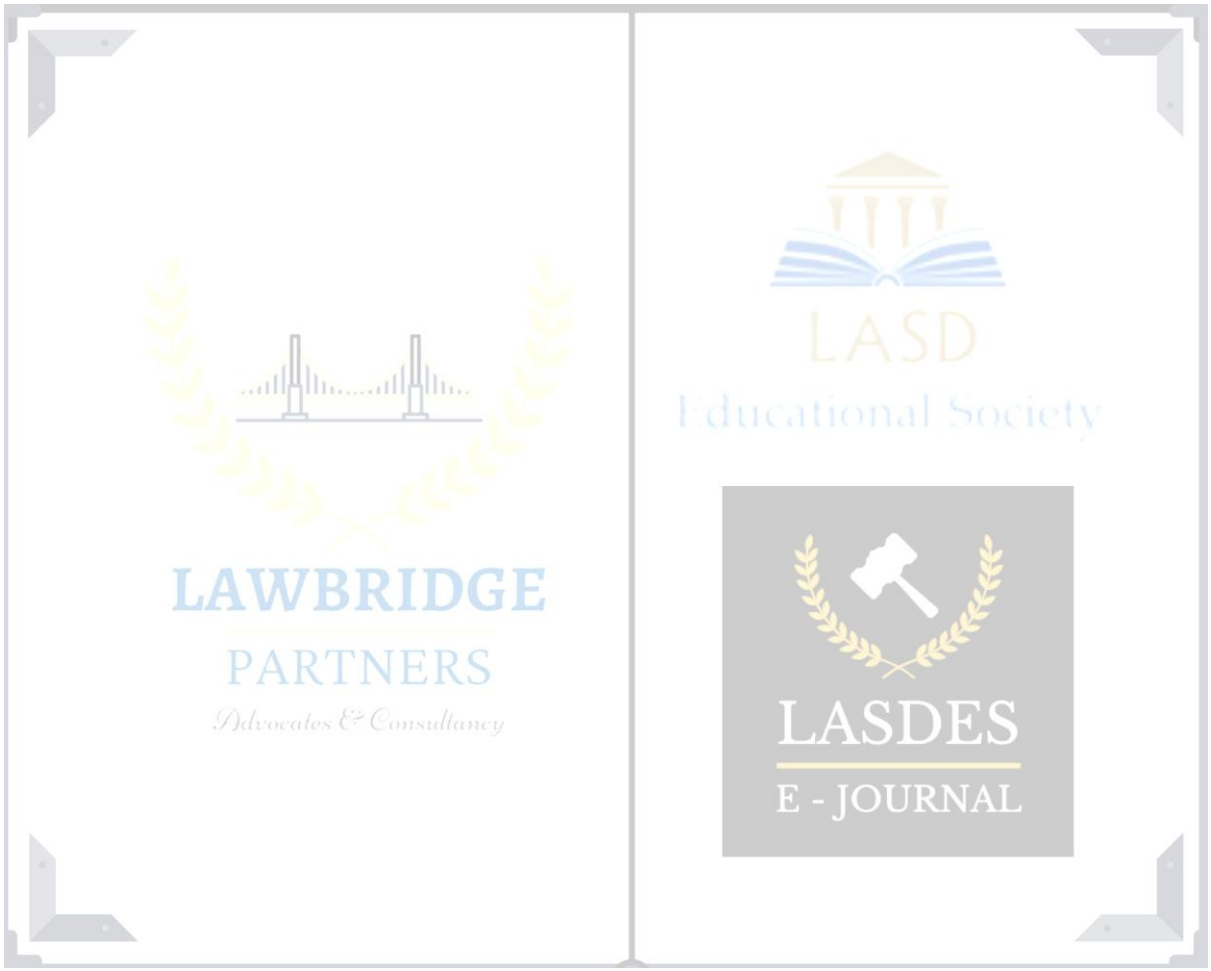
[57] Muhammad Zaheer Abbas, Twenty Years After Doha: An Analysis of the Use of the TRIPS Agreement's Public Health Flexibilities in India, 12 Asian J. Int'l L. 180 (2022).
[58] Susan K. Sell, TRIPS and the Access to Medicines Campaign, 20 Wis. Int'l L.J. 481 (2002).
[59] Brook K. Baker, Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration, 14 Ind. Int'l & Comp. L. Rev. 613 (2004).

will cause a country to be identified as an IP violator, causing it to lose foreign direct investment, preferential tariff treatment could be revoked (such as the Generalised System of Preferences) or even cause trade sanctions. This chill effect, sometimes referred to as TRIPS-plus enforcement, has the effect of guaranteeing that even in those instances in which a legal flexibility technically exists, sovereign countries are terrorised in their political capacity to utilise it.[60]

To sum it up, the case studies involving HIV/AIDS and COVID-19 integrated help to understand that the TRIPS regime is a rather efficient peacetime innovation mechanism that fails structurally during any public health crisis. The flexibilities that are currently in place are too narrow in the eyes of the law, are too procedurally bulky and politically untenable to offer the speed and decentralisation of medical response needed to

[60] Holger P. Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicines (2007).

achieve the universal right to health in the face of global crisis.



5: Conclusion and Suggestions

5.1 Concluding Remarks

This study aimed to investigate the acute conflict of the global intellectual property (IP) regime in the form of the TRIPS Agreement with the universal right to health in the case of global outbreaks of disease. By conducting doctrinal analysis of legal framework and critically assessing its application in the past, the main focus of the study was the answer to the central research questions, which is that the current TRIPS flexibilities are structurally, procedurally, and politically insufficient to address modern, synchronous global health emergencies.

In response to the first research question, the study AT proves that although the TRIPS Agreement is theoretically balanced between commercial innovation and public interest, they fail to balance each other when it comes to acute crises. Doha flexibilities such as compulsory licencing and parallel importation that are championed by the 2001 Doha Declaration had

initially been developed to deal with localised epidemics or market failure in peacetime. Their country-by-country, patent-by-patent approach is inherently incompatible with the responsiveness and population, as well as decentralisation needs of a fast-moving pandemic. Strict implementation of international trade and protection of the commercial liberty of IP holders has continued to override the very basic right of health, resulting in artificial supply restrictions and death through delays in low- and middle-income countries (LMICs).

On the second research question, the study mentions three distinct systemic impediments that freeze the realisation of TRIPS flexibilities. First is the bureaucratic apathy inbuilt in such mechanisms as Article 31bis. The outrageous cost of procedure to register generic medicines under a compulsory licence makes the route commercially infeasible and practically irrelevant. The second one is the regulatory blind spot of undisclosed information (trade secrets) under Article 39. With

the use of sophisticated biologicals and mRNA platforms becoming gradually vital in the field of modern medicine, the waivering of product patents cannot be achieved without the active and mandatory exchange of the manufacturing know-how. Lastly, the research provides an insight into the widespread geopolitical fear of deterrence that does not allow LMICs to apply available instruments of the law. The omnipresent sword of unilateral trade retribution, withdrawal of foreign investments and diplomatic coercion (are often led by developed countries nursing homephew pharmaceutical giants) have a chilling effect that negates the sovereign rights proclaimed at Doha.

The Final Ministerial Decision on the TRIPS Agreement; COVID-19 2022 at WTO is the final confirmation of these failures. The international trade regime showed that it cannot fix itself in case of a crisis by providing a highly diluted, vaccine-only waiver that came imminently too late without considering the most important disclosure of trade secrets. Finally, the existing system places the

sanctity of the privatised monopoly above the health security of the whole world, which needs to be reformed in detail.

5.2 Suggestions & Way Forward

In order to fill the severe gaps of this TRIPS regime and support the third research question, the suggested approach in this research includes multi-faceted solutions that comprise multilateral changes in the WTO organisation, as well as some strategic domestic policies in developing countries.

5.2.1 Multilateral Reforms at the WTO

- *Enacting An Automatic Pandemic Waiver Protocol:* The most urgent change that needs to be made is the creation of an automatic and legally-binding IP waiver that will take effect immediately once the World Health Organisation (WHO) declares a Public Health Emergency of International Concern (PHEIC). This protocol should avoid the formalities of the required consensus strikes of WTO talks in case of a crisis. Upon use, the waiver should

fully suspend the obligations under TRIPS with respect to patents, trade secrets and clinical data exclusivity, of all countermeasures, including vaccines, therapeutics, and diagnostics, that are related to medicine.

- *Mandatory Technology Transfer Of Publicly-Funded R&D:* Pandemic countermeasures are often developed and entirely underwritten by huge governmental infusions and advanced purchase deals. The WTO structure needs to be adjusted to allow that in case pharmaceutical innovations have been developed with the active support of a substantial amount of public money, the resultant IP and intellectual knowledge should be freely handed over to the initiatives such as the COVID-19 Technology Access Pool (C-TAP) organised by WHO or the Medicines Patent Pool (MPP). In such situation, voluntary licencing should be substituted with mandatory non exclusive global licencing.

- *Revamping Of Article 31bis:* The system of procedures in Paragraph 6 has to be uncoiled. The conditions of specific packaging, sending a particular quantity of goods, and pre-negotiating absolutely must be cancelled in case of known health crises. An efficient notification only mechanism should be facilitated through which those virtues with production level can produce and export life-saving generic medicines instantly to any country that is in acute shortage.

5.2.2 Domestic Policy Adjustments for Developing Nations

- *Strengthening the Patentability Criteria:* Developing countries should embrace the benefits of activities associated with TRIPS compliance of safeguarding the patent system to curb misuse of patent system. It is necessary to adopt stringent standards of patentability, which are based on the approach of Section 3(d) of the Indian Patents

Act to forestall the concept of evergreening, as well as propagation of secondary patents that artificially prolong monopolies in essential medicines.

- *Accelerated Domestic Compulsory Licencing Systems:* National patent legislations must be altered to comprise expedited administrative systems to grant compulsory licences on emergencies declared. These standards must avoid subjecting the company to long judicial processes or compulsory preceding negotiations with patentholders in order to enable domestic generic vendors to increase production as soon as the executive has approved.
- *Fostering South-South Cooperation and Regional Integration:* To counter the geopolitical deterrence and threats of trade retaliation from the Global North, developing nations must forge stronger regional alliances. By pooling regional manufacturing capacities,

harmonizing regional drug regulatory approvals, and presenting a unified diplomatic block at the WTO, the Global South can create a more resilient, decentralized pharmaceutical supply chain that is less vulnerable to the monopolistic pressures of multinational corporations.

In summation, the TRIPS Agreement must be reimagined not merely as a charter for trade protectionism, but as a flexible instrument capable of serving humanity. Until international trade law is subjugated to the supreme imperatives of human life and global health equity, the catastrophic inequities witnessed during the HIV/AIDS and COVID-19 crises will inevitably repeat themselves in the pandemics of the future.