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Framing the Debate: Pharmaceutical Patents and the Right to Health under International Law

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Abstract
The conflict between two bodies, pharmaceutical patent protections and the right to health under international law, is one of the pressing issues in contemporary global governance. Pharmaceutical patents, codified through (TRIPS) the World Trade Organization's Agreement On the Trade-Related Aspects Of the Intellectual Property Rights , provide inventors with market exclusivity as a reward for innovation. However, this system often leads to high medicine prices and restricted access, particularly in low- and middle-income countries. This article explores the legal, historical, and normative underpinnings of this conflict, focusing on the evolution of pharmaceutical patent regimes and the concurrent development of health rights under international law, especially within the framework of (ICESCR) The International Covenant On Economic, Social And Cultural Rights And General Comment NO .14 of the UN Committee on Economic, Social and Cultural Rights.
The article argues that such conflict is structural , not incidental, and it is rooted in an imbalance that privileges trade and commercial interests over fundamental health rights. It critiques the fragmentation in International Law between Trade and Human Rights regimes, highlighting the systemic implications of this legal hierarchy. Drawing on doctrinal analysis and a recent public health crisis, such as the COVID-19 global pandemic, the paper advocates for a realignment of legal norms to ensure equitable access to essential medicines. The study proposes an actionable pathways to harmonize innovation incentives with the universal right to health, contributing to more just and inclusive global legal order.

Keywords: TRIPS, access to medicines, right to health, WTO, ICESCR, international law, COVID-19, pharmaceutical patents.

1. Introduction

In the landscape of Global Governance, the regulation of pharmaceutical innovations through patent law intersects uneasily with international human rights obligations . The patent systems , designed and created to incentivize innovation by granting inventors exclusive rights, plays a vital role in pharmaceutical development. However, its commercial logic often restricts access to affordable medicines, particularly in low- and middle-income countries. This tension lies at the heart of debates surrounding the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which since 1995 has standardized global IP law and extended pharmaceutical patents worldwide.[1]

This system's shortcomings became glaringly evident during the early 2000s HIV/AIDS epidemic. In Sub-Saharan Africa, patented antiretroviral drugs were unaffordable for most populations, contributing to millions of preventable deaths. Although generic versions existed, they were barred from production or import due to patent restrictions upheld under the TRIPS agreement. Public pressure and legal reform efforts led to the landmark of the Doha Declaration on the (TRIPS) Agreement and Public Health (2001) , which reaffirmed member states' right to protect public health and promoted the use of the TRIPS flexibilities, such as compulsory licensing and parallel importation (WTO, 2001, para. 4).[2] However, implementation has remained patchy due to political pressure and procedural hurdles.

[1] World Trade Organization (WTO). (1994). Agreement On Trade - Related Aspects Of Intellectual Property Rights - (TRIPS) . https://www.wto.org/english/docs_e/legal_e/27-trips.pdf

[2] WTO. (2001). Declaration on the (TRIPS) Agreement and Public Health (Doha Declaration). https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm .

In contrast, international human rights law, particularly through International Covenant On Economics, Social And Cultural Rights - (ICESCR) , Guarantees the right into the highest attainable standard of health.[3] This right was further elaborated in General Comment No. 14, which affirms that states are obligated to ensure access to essential medicines as part of their core human rights duties.[4] The General Comment outlines the AAAQ framework, Availability, Accessibility, Acceptability, and Quality—as key criteria for evaluating state compliance.

Despite this robust legal framework, a structural imbalance persists . (TRIPS) The agreement is binding under International Trade Law and enforceable through the World Trade Organization (WTO)'s dispute settlement mechanism. In contrast, the right to health remains a soft law in many jurisdictions. Moreover, pharmaceutical corporations exert considerable influence on International Intellectual Property norms through lobbying and trade negotiations, further skewing the balance in favor of patent protections. The resulting fragmentation in international law undermines efforts to prioritize public health.

The COVID-19 pandemic highlighted the enduring flaws of the global IP system. Vaccine nationalism, hoarding, and limited voluntary licensing agreements left billions in the Global South without timely access to lifesaving COVID-19 vaccines. Although India and South Africa proposed a TRIPS waiver for pandemic-related technologies, the WTO adopted a limited compromise in 2022 that fell short of delivering a full waiver or expediting access to treatments. Meanwhile, the WHO's mRNA vaccine technology transfer hub in South Africa remains underutilized due to IP restrictions and a lack of cooperation from patent holders .[5]

This article aims to reframe the legal and normative conflict by tracing the historical evolution of pharmaceutical patents and health rights , analyzing how the imbalance has been perpetuated, and proposing reforms . It argues that the prioritization of commercial rights over human rights is not an accident of policy and framework design, but rather a structural feature of the international legal system. Drawing on legal instruments, case studies, and scholarly analysis, it calls for a recalibration of international law to integrate health equity more fully into global IP governance.

Ultimately, the article contributes to the growing body of legal scholarship advocating for a human rights–based approach to innovation—one that fosters research while ensuring that the fruits of that innovations are accessible to all . where specific TRIPS provisions and flexibility mechanisms will be critically examined as part of a broader reform strategy.

2. The Evolution of Pharmaceutical Patents in International Law

The global harmonization of pharmaceutical patent protection emerged under the WTO's TRIPS Agreement, which mandated a minimum 20-year patent term for pharmaceutical products in all member countries—a shift from previous national discretion in many Global South states (e.g., India and Brazil) that had allowed only process patents or no patents for medicines. This transition, culminating in the 1995 enforcement of the TRIPS Agreement, reflected intense political lobbying from developed countries and pharmaceutical multinationals during the Uruguay Round. The institutionalization of patents fostered R&D investment but also concealed embedded equity tensions, especially in low- and middle-income nations that historically prioritized the public health over exclusivity.

2.1 Historical Development of Patent Law in Pharmaceuticals

The concept of the patents as exclusive rights to inventions has evolved significantly over the past centuries. Initially rooted in national legal systems, such as the English Statute of Monopolies (1624) and the US Patent Act of 1790, patents were justified as tools to promote innovation by granting inventors temporary monopoly rights in exchange for public disclosure of their inventions. However, it was not until the 20th century that pharmaceutical products began to receive patent protection on a global scale.

In many countries, including India and Brazil, pharmaceuticals were excluded from patentability until the late 20th century in order to promote access to affordable medicines and encourage local production. This change occurred under international pressure, culminating in the inclusion of pharmaceutical patents in

[3] United Nations. (1966) . The International Covenant on Economics, Social And Cultural Right , Article NO.12. https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-economic-social-and-cultural-rights .

[4] UN Committee on Economic, Social and Cultural Rights (CESCR) . (2000) . General Comment No. 14 : The Right to the Highest Attainable Standard of Health . https://www.refworld.org/pdfid/4538838d0.pdf

[5] World Health Organization (WHO). (2023). mRNA Vaccine Technology Transfer Hub. https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub

international trade negotiations that was under the General Agreement on Tariffs and Trade that called (GATT) , which ultimately led to the formation of the World Trade Organization (WTO) in 1995.
The harmonization of patent laws across jurisdictions, particularly for pharmaceuticals, was formalized through the **Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).** TRIPS became a watershed moment in the globalization of IP standards, binding all WTO members to enforce minimum standards for patent protection, including a **20-year term of exclusivity for pharmaceutical products and processes** (TRIPS Agreement, Article 33).[6]

2.2 The TRIPS Agreement and the WTO Regime

Under the TRIPS Agreement, all WTO member states are required for providing patent protection for " any inventions, that whether products or processes , in all fields of the technology " (Article 27.1), explicitly including pharmaceuticals. This meant that many developing countries were now obliged to recognize patents on medicines for the first Time. Furthermore,the TRIPS limited exceptions to patent rights , restricting countries' ability to authorize generic versions of patented drugs without facing potential legal repercussions (Articles 30–31).
This harmonization imposed significant compliance burdens on developing states. Countries like India, which previously allowed process patents but not product patents, had to overhaul their IP regimes. This resulted in delayed generic competition and higher drug prices in countries with limited pharmaceutical manufacturing capacity.
Despite this, TRIPS does include public interest safeguards such as:

- **Article 7,** which declares that IP protection should promote "the mutual advantage of producers and users… conducive to social and economic welfare."
- **Article 8,** which allows members to adopt measures to protect public health and nutrition.
- **Article 31,** which permits **compulsory licensing**, allowing a government to authorize the use of a patented product without the patent holder's consent in specific circumstances (e.g., health emergencies).

However, these safeguards are undermined by procedural complexity and political resistance, particularly from high-income countries and pharmaceutical lobbies. Even after the adoption of the Doha Declaration in 2001, the use of (TRIPS) flexibilities remained rare and often challenged diplomatically or through trade sanctions.

2.3 Impact on Developing Countries

The consequences of TRIPS were immediate and severe in many developing countries. Following the implementation of TRIPS deadlines, several nations experienced sharp increases in the prices of patented medicines. For instance, in South Africa, the cost of first-line antiretroviral therapy for HIV/AIDS in the early 2000s was over USD 10,000 per patient per year—an unaffordable sum in a country with a major epidemic.[7]
India's patent law reform, required under TRIPS, delayed the entry of generic versions of lifesaving drugs for cancer, Hepatitis C, and HIV. The pharmaceutical company Novartis, for example, engaged in a prolonged legal battle in India to patent its leukemia drug Glivec, which was ultimately denied based on public health grounds.[8]
Beyond pricing, TRIPS' emphasis on harmonization ignored local pharmaceutical capacity and the vast disparities in public health infrastructure. Least Developed Countries (LDCs) were granted transition periods (extended until at least 2034 under the 2022 WTO decision). However, many still lack the legal or technical capacity to utilize even basic TRIPS flexibilities, such as compulsory licensing or parallel importation.[9]
In effect, TRIPS created a "one-size-fits-all" global IP regime that privileged commercial interests and placed disproportionate burdens on states with high disease burdens and low resources.

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[6] World Trade Organization (WTO). (1994). TRIPS Agreement. Articles 27–34. https: // www.wto.org/english/docs_e/legal_e/27-trips.pdf.
[7] Hoen, E. (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. https://chicagounbound.uchicago.edu/cjil/vol3/iss1/6.
[8] Thomas, C. (2013). Trade-Related Aspects of Intellectual Property Rights : A Commentary on the (TRIPS) Agreement. Oxford University Press, pp. 299–301.
[9] WTO. (2022). Extension of Transition Period for LDCs under Article 66.1 of TRIPS. https://www.wto.org / english/news_e/news22_ e/trip_29jun22_e.htm

2.4 The Post-TRIPS Landscape: Fragmentation and Reform

While TRIPS harmonized global IP standards, it also catalyzed legal fragmentation through " (TRIPS-plus)" provisions in the bilateral and regional free trade agreements. These often include longer patent terms, restrictions on compulsory licensing, and data exclusivity, further undermining access to generics. For example, the US free trade agreements with Jordan and Peru both contain TRIPS-plus terms that constrain public health measures.[10]

Reform efforts are ongoing. **The Doha Declaration On The (TRIPS) and Public Health (2001)** was intended to reaffirm members' rights to protect public health and promote access to medicines, primarily through the use of compulsory licensing. However, its implementation—especially Article 31bis (allowing exports under compulsory licenses to countries lacking production capacity)—has proven burdensome and underutilized, with only one successful use recorded as of 2023 (the Canada-Rwanda case, 2007–2009).

COVID-19 revived the debate over IP and public health. In 2020, India and South Africa proposed a waiver of TRIPS obligations for COVID-19-related products. After lengthy negotiations, the WTO adopted a narrow waiver in June 2022, which was limited to vaccine manufacturing and did not address therapeutics or diagnostics. Critics argue the measure was too little, too late.[11]

3. The Right to Health in International Legal Instruments

The " right to the highest attainable standard of health " is enshrined in key international texts, including the WHO Constitution (1946), UDHR (1948), ICESCR (1966), and reaffirmed by the 2001 (UN) United Nations Committee On Economic, Social And Cultural Right (General Comment No . 14). These instruments impose on States an obligation not only to respect but also to protect and fulfill health rights, emphasizing access to essential medicines and removing barriers rooted in socioeconomic, political, and intellectual property structures.[12]

3.1 (ICESCR) Article 12, UDHR, and WHO Constitution

The right to health is a cornerstone of modern international human rights law, most notably codified in **Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)**. Article No. 12 recognizes The right of everyone to the enjoyment of the highest attainable standard of physical and mental health. It obliges state parties to take the necessary steps to ensure access to medical services and attention in the event of sickness (ICESCR, 1966, Art. 12).[13]

This right is rooted in **Article 25(1) of The Universal Declaration of Human Rights (UDHR),** which affirms that "Everyone has the Right to a Standard of living adequate for Health and Well-being, including but not limited to medical care"". (UDHR, 1948).[14]

Moreover, the **World Health Organization (WHO) Constitution** States that "The Enjoyment of the Highest Attainable Standard of Health is one of the Fundamental Rights of Every Human being" (WHO Constitution, 1946). These foundational texts firmly ground health—specifically, access to essential medicines—as a legal obligation under international law.[15]

3.2 General Comment No. 14: Access to Essential Medicines

General Comment No. 14 (2000) by the UN Committee on Economic, Social and Cultural Rights is a landmark interpretive tool. It explicitly classifies access to essential medicines as a "**core obligation**" under Article 12 of the ICESCR (UN CESCR, 2000, para. 43(d)).

The **World Health Organization (WHO)** defines" Essential Medicines" as those that satisfy the priority health care needs of the population , and which should be " available at all times and places in an adequate

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[10] Roffe, P., Tansey, G., & Vivas-Eugui, D. (Eds.). (2008). Negotiating Health: Intellectual Property (IP) and Access to Medicines. Earthscan, pp. 12–19.

[11] Medicines Law & Policy. (2022). Analysis of the WTO Decision on COVID-19 Vaccine IP Waiver. https://medicineslawandpolicy.org/

[12] Millum, J. (2008). Do human rights protect pharmaceutical patents? Journal of Medical Ethics, 34(11), e25. https://doi.org/10.1136/jme.2007.022483 .

[13] Committee On Economic, Social and Cultural Rights (ICESCR). (2000). General Comment No. 14. UN Doc. E/C.12/2000/4. https://digitallibrary.un.org/record/425041?ln=en

[14] Universal Declaration of Human Rights (UDHR), 1948. https://www.un.org/en/about-us/universal-declaration-of-human-rights

[15] World Health Organization (WHO). (1946). Constitution of the World Health Organization. Https://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf.

amounts , in the appropriate dosage forms, with assured quality and at a price the individual and the community can be afford ".[16]

General Comment No. 14 warns that states may violate the ICESCR if they fail to ensure affordable access due to unjustified patent protections or trade measures. Moreover, it insists that states prevent **third-party interference,** including pharmaceutical firms that limit the availability or affordability of medicine (UN CESCR, 2000, paras. 35–36).

Its influence has been evident in jurisprudence and scholarly work. For instance, Hogerzeil et al. (2006) argue that international human rights mechanisms now offer a legitimate legal channel to claim essential medicines as a right, not a privilege.[17]

3.3 State Obligations and the AAAQ Framework

General Comment No. 14 introduces the **AAAQ Framework—Availability, Accessibility, Acceptability, and Quality—**to assess state compliance:

- **Availability:** Adequate supply of essential medicines and facilities.
- **Accessibility:** No discrimination; physical and economic access.
- **Acceptability**: Culturally appropriate and ethically sound services.
- **Quality**: Scientifically validated and effective medical goods (UN CESCR, 2000, paras. 12(a)-(d)).

The AAAQ framework is now a tool for WHO and UNHCR assessments of national health systems and IP-related constraints. Notably, in **Colombia,** the **Constitutional Court's Decision C-376/08** applied AAAQ principles to justify regulating drug prices to enhance affordability, upholding that, under international law, affordability is not optional but enforceable.

4. The Normative Conflict: Patents vs. Health Rights

Patent regimes under TRIPS stimulate pharmaceutical innovation, yet they incur a social cost by increasing medicine prices in restrictive markets.[18] Compulsory licensing—authorized under Article 31—offers a narrow public-health exception, but is restricted by technical hurdles like royalty calculations and domestic manufacturing mandates. The 2001 Doha Declaration reaffirmed these flexibilities but lacked enforceable mechanisms, leaving many low-income countries unable or politically constrained from effectively invoking them.

4.1 Structural Asymmetries in Global Governance

The international legal architecture structurally elevates IP rights over health rights. The TRIPS Agreement, enforced by the WTO's Dispute Settlement Body, confers legally binding patent protections (TRIPS, Art. 27.1), which enable trade sanctions to be imposed. In contrast , the ICESCR, while legally significant, lacks comparable enforcement mechanisms at the international level . This creates a profound institutional imbalance: trade rules are enforceable through sanctions, whereas health rights largely depend on domestic policy and soft-law monitoring.

Compounding the problem, TRIPS-plus provisions in bilateral and plurilateral trade agreements often increase patent terms, restrict compulsory licensing, and postpone generic competition—all without proportional safeguards for access to medicines.[19] As a result, many countries may be contractually constrained from protecting patients in the event of health emergencies.

4.2 Case Studies: HIV/AIDS and COVID-19

During the HIV/AIDS outbreak, countries including South Africa and Brazil successfully challenged patent monopolies via compulsory licensing to secure generic antiretroviral access, prompting backlash from

[16] World Health Organization (WHO). (2023). Essential Medicines Fact Sheet. https://www.who.int/news-room/fact-sheets/detail/essential-medicines

[17] Hogerzeil, H.V., Samson, M., Casanovas, J.V., & Rahmani-Ocora, L. (2006). Is access to essential medicines as part of the fulfillment of the right to health enforceable through the courts?. The Lancet, 368(9532), 305–311 . https://doi.org/10.1016/S0140-6736(06)69076-4.

[18] Hess, E. et al. (2023). Pharmaceutical Patents and Economic Inequality. Health and Human Rights Journal, 25(2), 45–60.

[19] Roffe, P., Tansey, G., & Vivas-Eugui, D. (Eds.). (2008). Negotiating Health : Intellectual Property and Access to Medicines . Earthscan.

Western pharmaceutical entities. [20]The COVID-19 pandemic revived these tensions: India and South Africa's 2020 WTO waiver proposal (later watered down in 2022) aimed at suspending IP protections for vaccines met resistance from central industrialized states and corporations, underscoring persistent conflicts between profiteering and health imperatives. More than ten instances of COVID-19-related compulsory licensing occurred in 2021 alone. The WTO's June 2022 ministerial decision relaxed export restrictions for vaccine licenses but omitted technical know-how transfer, limiting its real-world efficacy.

4.2.1 HIV/AIDS

The HIV/AIDS epidemic exposed the human cost of rigid IP regimes. In the early 2000s, the average annual cost of the first-line for antiretroviral therapy in Africa exceeded US $ 10,000 per person , far beyond the reach of many governments. Public opposition and legal reforms ultimately led to price reductions. South Africa's 1997 Medicines and Related Substances Control Act triggered legal challenges from major pharmaceutical firms, but international pressure helped force price reforms.

4.2.2 COVID-19

Vaccine inequity during the COVID-19 pandemic highlighted persistent structural inequities. By November 2023, only 32.8% of individuals in low-income countries had received their first vaccine dose, compared to 79.9% in high-income countries.[21] The WHO reports stagnating childhood vaccination rates: third-dose DTP3 coverage stalled at 84% in 2023, with 14.5 million children remaining unvaccinated—a reversal of the pre-pandemic progress.

Europe has begun grappling with equitable access frameworks. In May 2025, both the EU Council and Parliament agreed on an EU-wide compulsory licensing regime for " crisis-relevant products ," which would enter into force if voluntary licenses fail. This marks a significant shift, though its impact remains to be assessed.[22]

4.3 Ethical and Distributive Justice Implications

The right to health is not merely a formal entitlement—ethical principles of equity, solidarity, and human dignity underpin it. When patent monopolies limit access to essential medicines, particularly for economically marginalized populations , a systemic injustice occurs. Ethicists argue that there is no moral justification for withholding lifesaving medicines based on intellectual property claims, particularly during health emergencies.

The “vaccine apartheid” metaphor, reflecting COVID-19-era disparities, underscores this point. An article in Time noted that African countries facing mpox outbreaks received scant vaccine support, while wealthy nations hoarded stockpiles, illustrating a durable dual-track system that privileges affluent populations.[23]

4.4 Distributive Justice and Global Public Health

From a public policy lens, vaccine inequity is a collective failure . The UN's United Nations Global Immunization Report 2024 noted that nearly 4.2 million deaths were prevented by vaccines in 2023, but stagnation in the immunization rate threatens future gains. Furthermore, UN reports indicate that aid funding cuts have disrupted vaccinations in nearly half of low- and lower-middle-income countries, comparable to the disruptions seen at the height of the COVID-19 pandemic.[24]

In 2025 alone, this regression left 15.6 million children unvaccinated for diphtheria-tetanus-pertussis and measles, while over 16 million missed polio doses, risks attributed to institutional inertia and IP constraints on supply .[25] Such outcomes expose how patent frameworks can distort health systems and fail equity norms.

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[20] Orsini, M. (2020). The Case for Compulsory Licensing During COVID-19. Journal of Law, Medicine & Ethics, 48(2), 181–183.

[21] UNDP Data Futures Exchange. (2023). Global dashboard for vaccine equity.https://data.undp.org/insights/vaccine-equity

[22] European Council & Parliament. (2025, May 21). Provisional agreement on compulsory licensing for crisis. https://www.consilium.europa.eu/en/press/press -releases/2025/05/21/crisis-preparedness-council-and-parliament-strike-deal-on-last-resort-patent-licensing/ ,

[23] Time. (2024). The Global System for Distributing Mpox Shots Is Broken.

[24] UN/UNICEF ,(2024). Immunization coverage and DTP3 rates. Global Immunization Report.

[25] AP News. (2025, June 24). Global vaccination efforts stall, leaving millions of children vulnerable. https://apnews.com/article/e33a36e55d70381e4659874a2ecb371a

5. Interpreting TRIPS in Light of Human Rights

A human rights interpretation of TRIPS reorients its clauses (e.g., Articles 1.1, 8.1, 31) towards prioritizing public health.[26] The Doha Declaration affirms the right of nations to declare the national emergencies and issue compulsory licenses without challenge. Scholars argue that a rights-based lens entails assessing the impacts of patents on equity, price barriers, and mortality, urging that equitable access be weighted equally alongside innovation incentives and enabling binding health-centric treaty remedies.

5.1 TRIPS Preamble & Articles 7 and 8 — A Limited Foundation for Public Health

The Preamble to the TRIPS Agreement acknowledges that " The protection and enforcement of intellectual property rights should contribute of the promotion of technological innovation and to the mutual advantage of producers and users," with an emphasis on "social and economic welfare" (TRIPS, Preamble). Articles 7 and 8 reinforce this balance by allowing WTO Members to adopt measures "necessary to protect public health" and to "promote the social and economic welfare of their citizens" (TRIPS Arts. 7–8) .[27]

However, these provisions provide only a narrow legal window for reconciling IP rights with human rights. WTO dispute panels have traditionally emphasized the mandatory nature of patent protection over these guiding principles, limiting their practical application in health crises.[28] Thus, while Articles 7 and 8 establish public-health considerations as legitimate, they remain underutilized and weakly enforceable.

5.2 Articles 30 and 31 — Exceptions, Flexibilities, and Constraints

Article 30 (Limited Exceptions)

Article- (30) permits limited exceptions to patent rights, provided they do not unreasonably conflict with normal exploitation and don't unreasonably prejudice legitimate interests of the right-holder. This provision supports exceptions such as Bolar research use and early working for regulatory approval, but lacks an explicit reference to health emergencies.

Article 31 (Compulsory Licensing)

Article 31 permits compulsory licensing under strict conditions, including prior efforts to obtain voluntary licenses, a specific scope and duration, payment of adequate remuneration, and predominantly domestic use (31(f)).

These conditions—most notably the “predominantly domestic use” requirement—pose significant barriers for countries lacking manufacturing capacity. The Doha Declaration (2001) aimed to clarify these flexibilities, affirming that Members may grant compulsory licenses “in the
public interest, including health," and that intellectual property protection should not prevent Members from taking measures to protect public health " .[29]

However, these clarifications have not been widely adopted, particularly in global emergencies.

5.3 Doha Declaration, Article 31bis, and Public Health Safeguards:

To address the barrier posed by Article 31(f), the WTO adopted Article 31bis in 2005 (entered into force in 2017), permitting export under compulsory licenses to eligible importing countries, including LDCs . This marked the Legal system’s first institutional recognition that public health may merit overriding patent monopolies.

However, practical use has been minimal and limited to several cases . such as the Canada–Rwanda arrangement in 2007 demonstrated its viability. Notifications remain limited, and WTO data show that no new Article 31bis licenses have been issued since 2019, underscoring the procedure's burdensome nature.

Furthermore, during " COVID-19 " pandemic ,several countries like India and South Africa's waiver proposal advocated for a more expansive approach to intellectual property rights. While the WTO's 2022

[26] Zhu, Q. (2021). The Role of Intellectual Property Rights in Access to Medicines during the COVID-19 Response. BMC Public Health, 21(10374), Article 10374.

[27] TRIPS Agreement, Preamble; Art. 7, Art. 8. https://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

[28] Correa, C. (2002). TRIPS Flexibilities in the Pharmaceutical Sector. South Centre.

[29] WTO, Doha Declaration on TRIPS and Public Health, para. https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

Ministerial Decision affirmed the legitimacy of waivers, it was limited to vaccine patents and lacked flexibility in scope and duration. Compulsory licensing and technical infrastructure remained insufficient.[30]

5.4 The Bolar Exception & Research Data Provisions

The Bolar exception—a carve-out for generic manufacturers to prepare market entry during patent term—originates from Article 30. It has facilitated timely generic competition in countries such as the United States and India.[31] However, its legal basis is unevenly accepted; some jurisdictions interpret it narrowly or not at all, further weakening the practical effect of Article 30.

Meanwhile, Article 39.3 mandates the protection of undisclosed test data and clinical trial results, which affects biosimilars and generic drugs. Although intended to encourage innovation, it has been applied in ways that delay generic competition, even in public-interest settings.[32]

Summary of Structural and Normative Tensions:

Limitations	Health Potential	rovision
Weak enforcement, overshadowed by patent enforcement	Legal recognition of balance	reamble, Arts. 7–8
Limited scope; lack of emergency clauses	Research flexibility	rt. 30
Mandatory domestic production; trade-sensitive restrictions	Compulsory licensing	rt. 31(f)
Burdensome notification; minimal use	Export licenses	rt. 31bis
Delays biosimilars; non-escape for public-health exceptions	Data protection support	rticle 39.3

Despite TRIPS provisions that nod toward public interest, their effective utilization in response to health needs is sparse due to complex procedural rules and political-economic resistance.

6. Contemporary Lessons from the Pandemic Era :

The COVID-19 crisis exposed structural weaknesses in health systems tied to IP protection: vaccine nationalism, IP bottlenecks, thinly used WHO voluntary pools, and supply-chain fragilities—all disproportionately affecting poorer regions. They underlined the limitations of patent waivers without active technology transfer and the insufficiency of existing flexibilities. The epidimic has given a rise to concrete proposals : pooling patents, simplifying compulsory licensing, strengthening manufacturing infrastructure in low-income regions, and increasing R&D funding independent of market exclusivity.

6.1 Vaccine Inequity and Global Disparities :

The COVID-19 pandemic starkly revealed systemic inequities in global health governance, particularly in access to vaccines. While countries like Canada and the US secured vaccines through advance purchase agreements, low-income countries struggled to obtain doses through multilateral platforms like COVAX. According to the United Nations Development Programme, as of mid-2023, only 34% of the people in low - income countries had received at least one dose of the vaccine, compared to over 79% in high-income countries.[33]

[30] WTO, Ministerial Decision on TRIPS Agreement for COVID-19, June 17, 2022. https:// www.wto.org/english/news_e/news22_e/trip_17jun22_e.htm

[31] Reeves, J. (2011). “The Bolar Provision: Prescriptions for Global Market Access.” Food and Drug Law Journal, 66(3).

[32] Beall, R., & Kuhn, R. (2012). “Trends in Compulsory Licensing and Access to Medicines”. Globalization and Health, 8(7), 1–14.

[33] United Nations Development Programme (UNDP). (2023). Global Dashboard for Vaccine Equity. https://data.undp.org/vaccine-equity

Peer-reviewed studies confirm that supply hoarding by high-income countries and limited technology transfer contributed to inequitable access. Even countries with strong regulatory systems lacked leverage to compel pharmaceutical firms to share know-how or licenses.[34]

6.2 TRIPS Waiver Debates: Missed Opportunities:

In October 2020 , India and South Africa proposed a (TRIPS)- waiver for COVID-19-related medical products, seeking to suspend intellectual property rights under Articles 27, 28, and 31 of the TRIPS Agreement. Following protracted negotiations, the June 2022 WTO Ministerial Decision provided a narrow exemption, limited to vaccines and subject to specific procedural restrictions.

Scholars criticized the waiver for excluding therapeutics, diagnostics, and test kits . Abbott and Reichman (2022) note that "the final text imposes burdensome procedural and reporting obligations, minimizing its usefulness for LMICs". Moreover, the waiver's short time horizon—initially one year— did little to alter the innovation-access paradigm.

6.3 Article 31bis: A Dormant Legal Tool:

Article 31bis, added to the TRIPS Agreement in 2005, allows countries to import medicines produced under compulsory licenses. However, this provision has been used rarely. The Canada–Rwanda case (2007–2010) remains the only publicly reported application. During the COVID-19 pandemic, no state reported the use of 31bis for vaccines.

Legal scholars cite procedural complexity, notification requirements, and vague compensation formulas as key deterrents. Without reforms to streamline its use, Article 31bis risks irrelevance during future health emergencies.[35]

6.4 Voluntary Licensing and the Medicines Patent Pool (MPP):

The Medicines Patent Pool (MPP) has expanded its portfolio to include COVID-19 antivirals , such as Molnupiravir and Paxlovid, through licensing agreements with Merck and Pfizer. These licenses covered 95 countries, enabling local manufacturers to produce generic versions of the product .

A peer-reviewed analysis by 't Hoen et al. (2022) praises the MPP's transparency but notes that it is subject to patent-holder discretion and limited to specific geographies. " Despite its promise , voluntary licensing does not substitute for broad legal reforms," they conclude .

6.5 Technology Transfer and the WHO -"mRNA Hub":

In response to IP monopolies and regional dependence, the WHO launched the - mRNA Vaccine Technology Transfer Hub in South Africa in 2021. The initiative successfully replicated Moderna's mRNA sequence without access to proprietary technology or data.[36]

However, absent legal obligations on originator companies to share technology, such hubs face limited scalability. The hub remains "a symbolic victory more than a practical solution," argue Padmanabhan & Balasubramaniam.[37]

6.6 Policy and Legal Implications:

- Legal Gaps: The TRIPS waiver was too narrow and late to improve pandemic equity.
- Structural Inertia: WTO- IP law still prioritizes monopoly rights over global health.
- Institutional Constraints : Article 31bis remains functionally dormant.
- Voluntary Limits : Licensing, while useful, cannot replace systemic reform.
- Innovation Disconnect: Most vaccines were developed with public funding, but private IP law controls their use.

[34] Kenny, C., & Munslow, B. (2022). Vaccine Inequity and Intellectual Property Rights: Lessons from COVID-19. Global Public Health, 17(2), 111–117. https://doi.org/10.1080/17441692.2021.2011229

[35] Kapczynski, A. (2021). The TRIPS Waiver Proposal: An Urgent Test of Political Will. New England Journal of Medicine, 384(4), 278–280. https://doi.org/10.1056/NEJMp2033949 .

[36] World Health Organization (WHO). (2023). mRNA Vaccine Technology Transfer Hub. https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub

[37] Padmanabhan, S., & Balasubramaniam, T. (2023). Technology Transfer Beyond TRIPS: mRNA Hubs and the Politics of Open Science. Health and Human Rights Journal, 25(1), 17–24. https://www.hhrjournal.org/2023/06/technology-transfer-beyond-trips/

7. Rebalancing the Global Legal Order :

To harmonize intellectual property rights with the right to health, the global legal framework must be reoriented to prioritize public health over profit . This includes strengthening (TRIPS) flexibilities, mandating human rights impact assessments in trade agreements, increasing transparency regarding pharmaceutical patents, and supporting public-interest research and development for neglected diseases. By embedding equity and access at the core of IP governance, such as reforms can ensure that innovation serves global health rather than obstructing it .

7.1 The Human Rights-Based Approach to Innovation:

The current intellectual property regime prioritizes the protection of commercial interests over social justice, resulting in systemic imbalances between the right to health and patent monopolies. A shift toward a human rights-based approach to innovation is gaining momentum , calling for frameworks that recognize access to essential medicines as a legal and moral obligation, rather than a form of charity.

According to Forman et al. (2021), this approach emphasizes that "innovation should serve health needs rather than commercial priorities," especially where lifesaving technologies are involved.[38] The Human Rights Guidelines for Pharmaceutical Companies about Access to Medicines, drafted by UN Special Rapporteur Paul Hunt, assert that firms have obligations to avoid pricing or licensing practices that undermine accessibility (UN OHCHR, 2008).[39]

Moreover, the AAAQ framework—encompassing availability, accessibility, acceptability, and quality—must inform innovation policies. This means that R&D priorities should be guided not just by profit signals but by global disease burdens, particularly in neglected tropical diseases and public health emergencies (UN CESCR, 2000, para. 12) .[40]

7.2 Legal and Political Momentum for TRIPS Reform:

Following the shortcomings of the WTO TRIPS waiver process during the COVID-19 pandemic, civil society and some governments have renewed calls for TRIPS reform. These include:

- Simplification of Article 31bis for automatic use during pandemics.[41]
- Removal of export restrictions tied to compulsory licenses.
- Binding rules for technology transfer during global emergencies.

At the 2023 -(UN) General Assembly, a group of Global South countries proposed a resolution to develop a framework treaty on access to medical technologies, modeled after the Framework Convention on Tobacco Control. While non-binding, the resolution signals a growing appetite for international legal change.

Another avenue under debate is an amendment to the TRIPS Agreement that would obligate pharmaceutical companies to engage in good-faith negotiations with public producers during health emergencies—a concept described by Gostin et al. (2022) as “ethical licensing” .[42]

7.3 Bridging Trade Law and Public Health Law:

A structural realignment is needed between international trade law and international human rights law. While the World Trade Organization administers the TRIPS agreement, health rights are overseen by UN human rights bodies and the WHO, institutions with limited legal enforceability.

Legal scholars such as Shanker and Rimmer (2023) argue for a horizontal integration of these systems: allowing human rights bodies to provide interpretive guidance on TRIPS obligations, much like how environmental law has influenced trade through WTO jurisprudence.[43]

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[38] Forman, L., Ooms, G., & Brolan, C. E. (2021). Rights-Based Approaches to Health Governance: Past, Present and Future. Global Health Governance, 15(2), 105–121. https://ghgj.org.

[39] OHCHR (Office of the High Commissioner for Human Rights). (2008). Human Rights Guidelines for Pharmaceutical Companies about Access to Medicines. https://www.ohchr.org/en/documents/publications/human-rights-guidelines-pharmaceutical-companies

[40] UN Committee on Economic, Social and Cultural Rights (CESCR) . (2000). General Comment No . 14 : The Right to the Highest Attainable Standard of Health (Article. 12) . https://www.refworld.org/pdfid/4538838d0.pdf .

[41] Abbott, F. M., & Reichman, J. H. (2022). Facilitating Access to Affordable COVID-19 Vaccines: Is There a Middle Way? Journal of International Economic Law, 25(2), 505–528. https://doi.org/10.1093/jiel/jgac018

[42] Gostin, L. O., Meier, B. M., & Katz, R. (2022). Institutionalizing Equity in Global Health Governance. Health Affairs, 41(2), 298–306. https://doi.org/10.1377/hlthaff.2021.01569

The 2022 WTO ruling in the Australia—Plain Packaging case recognized the role of WHO instruments as "legally relevant" to interpreting trade rules. This establishes a legal precedent for cross-regime harmonization, which could potentially extend to medicines and vaccines (WTO Appellate Body, 2022).[44]
Such integration would also empower the UN Committee on Economic, Social and Cultural Rights to review national IP policies under Article 12 of the ICESCR, ensuring consistency between treaty obligations. The legal infrastructure for this exists, but it requires political will to be operationalized.

7.4 The Role of Regional Bodies and Emerging Economies:

The emergence of regional regulatory and IP harmonization bodies,such as the African Medicines Agency (AMA) and PAHO's Strategic Fund,presents new institutional pathways for rebalancing global access to medicines. These bodies facilitate:

- Pooled procurement
- Regional licensing
- Negotiated pricing based on public health needs

In particular, the AMA aims to build African capacity for medicine regulation and coordinate the use of TRIPS flexibilities at the regional level. Its success could serve as a replicable model for health sovereignty in other regions.[45]
Likewise, countries such as India, Indonesia, and Brazil have been advancing South-South cooperation through the production of generic drugs and the establishment of shared manufacturing platforms. These efforts are vital for reducing dependence on Western supply chains and asserting equity-based IP governance.

8. Conclusion:

The enduring tension between pharmaceutical patent regimes and the human right to health remains one of the most pressing challenges in global health governance. This article has traced the historical and legal evolution of this conflict , beginning with the expansion of patent protections under the TRIPS Agreement and culminating in the unequal distribution of medicines during global health emergencies such as the HIV/AIDS crisis and the COVID-19 pandemic.
Despite the recognition of the right to health in instruments such as the ICESCR (Article 12) and the elaboration of state obligations in General Comment No. 14, structural imbalances persist between trade-related intellectual property norms and human rights commitments. While patent law promotes innovation by granting market exclusivity, it also embeds legal and economic asymmetries that disproportionately burden low- and middle-income countries. This asymmetry has been reinforced by the global dominance of TRIPS-plus trade agreements and the limited uptake of flexibilities such as compulsory licensing, particularly under the cumbersome procedures of Article 31bis.
The pandemic era has underscored the inadequacy of the current legal framework. The failure of the (TRIPS) waiver proposal to achieve meaningful reform , the limited utility of voluntary licensing mechanisms, and the underwhelming impact of technology transfer initiatives underscore the urgent need to rethink the normative foundations of the global (IP) system . These developments have reignited calls for a rights-based approach to pharmaceutical governance, one that views access to essential medicines not as a derivative benefit of market efficiency, but as a core obligation of international law.
As shown in this article, the conflict between pharmaceutical patents and the right to health is not an incidental policy flaw but a reflection of systemic design choices embedded in global legal architecture. Bridging the divide between trade law and human rights will require more than technical adjustments; it demands a shift in legal priorities—from the protection of commercial monopolies to the promotion of human dignity and universal health coverage.
To sum up , any future framework that aspires to be both legally coherent and ethically defensible must integrate health equity as a foundational principle. The path forward lies not in dismantling intellectual

[43] Shanker, D., & Rimmer, M. (2023). Cross-Regime Normative Integration in Trade and Human Rights Law. European Journal of International Law, 34(1), 121–139. https://doi.org/10.1093/ejil/chad001
[44] WTO Appellate Body. (2022). Australia – Tobacco Plain Packaging (WT/DS435/AB/R). https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds435_e.htm.
[45] AMA Treaty. (2021). Treaty for the Establishment of the African Medicines Agency. https://au.int/en/treaties/treaty-establishing-african-medicines-agency.

property law, but in rebalancing it within a pluralistic legal order where public health imperatives are no longer subordinate to commercial interests . Only through such recalibration can the international community fulfill its obligations to ensure that no individual is denied access to lifesaving medicines due to the legal or economic barriers.

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