THE REALISATION OF THE RIGHT TO HEALTH IS HEAVILY DEPENDENT ON THE LEGAL FRAMEWORK APPLIED FOR THE PRODUCTION AND DISTRIBUTION OF MEDICINES, INCLUDING INTELLECTUAL PROPERTY RIGHTS

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ABSTRACT

The paper critically examines how intellectual property rights, especially patents on medicines, clash with the right to health under Article 12 of the ICESCR, making essential drugs unaffordable for millions in low- and middle-income countries. It highlights historical tensions—from the AIDS crisis to COVID-19 "vaccine apartheid"—where patent monopolies drove sky-high prices, despite TRIPS flexibilities like compulsory licensing and parallel imports affirmed in the 2001 Doha Declaration. Through case studies like India's Novartis ruling and South Africa's pharma lawsuit, plus critiques of EU TRIPS-plus deals and corporate profiteering, the analysis urges reforms: robust use of licensing, delinking R&D from profits via public funding, and treating health tech as global commons to prioritize equity over commerce.

INTRODUCTION

The right to the "highest attainable standard of physical and mental health," codified in Article 12(1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR)[1], obligates states to provide universal access to medicines. The achievement of this right is, nevertheless, inherently interconnected with the international legal frameworks for intellectual property (IP) rights, specifically patents. Patents, which were intended to promote pharma innovation by granting temporary monopolies, inevitably conflict with the need to make medicines affordable and accessible. That conflict is central to an urgent human rights challenge: How do governments balance IP rights protection with their international law obligations to realize the right to health?

The Conflict Between IP Rights and Health Equity:

The WTO TRIPS Agreement mandates 20-year patents on medicines[2]. Patents induce innovation, but they also permit drug firms to charge astronomical prices, rendering cures inaccessible to millions, especially in middle- and low-income nations. In the AIDS pandemic, patented antiretroviral treatment costed more than $10,000 per year per patient, resulting in unnecessary deaths in sub-Saharan Africa until generic competition reduced the price by 99%. The COVID-19 pandemic revealed vaccine inequity, exacerbated by patent protection, which resulted in billions in the Global South being unprotected while affluent countries hoarded supplies.

General Comment No. 14 underscores the need for governments to guarantee the availability, accessibility, acceptability, (3As) and quality of health products and services as stipulated in Article 12(1) of the ICESCR[3]. Nonetheless, inflexible patent systems that prioritize corporate profit over public health undermine these criteria. The ICESCR identifies access to essential drugs as an irreversible core obligation (para. 43(d))[4] that states must uphold even in the face of resource constraints.

This obligation provokes questions about intellectual property regimes' conformity with human rights and whether they can reinforce systemic imbalances. This tension can be mitigated by international law.

Countries can prioritize health over intellectual property by using forced licensing (generic production without permission of patent holders) or parallel imports, according to the 2001 Doha Declaration on

[1] International Covenant on Economic, Social, and Cultural Rights, 1966, Article 12 (1).
[2] Information and Media Relations Division (2003). *TRIPS and pharmaceutical patents. https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_e.pdf*
[3] *CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) (2000) Document E/C. 12/2000/4. https://www.ohchr.org/sites/default/files/Documents/Issues/Women/WRGS/Health/GC14.pdf*
[4] *CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) (2000) Document E/C. 12/2000/4. https://www.ohchr.org/sites/default/files/Documents/Issues/Women/WRGS/Health/GC14.pdf*

TRIPS and Public Health. South Africa, India, and Brazil have used these flexibilities to expand the availability of HIV/AIDS and hepatitis C medicines[5]. Their use remains occasional. Poor countries have been avoiding these measures due to political pressure from wealthy nations, trade disputes, and a lack of technological capabilities. Existing free trade agreements include sometimes "TRIPS-plus" clauses that extend the patent duration or restrict compulsory licensing, further denying access. State Responsibilities and Article 12(1) of the ICESCR requires governments to respect, protect, and fulfill health rights[6].

LEGAL FRAMEWORK

Parallel Imports:

Parallel imports are a significant way of enhancing access to low-cost medicines under the doctrine of "exhaustion of rights"[7]. Under this doctrine, once a patented product is legally sold in one country, the patent holder's rights are "exhausted," and the product can be imported into another country without the patent holder's consent. This avoids monopoly prices, especially for developing nations where patented drugs are very costly. An example is that parallel imports can be essential when generic versions made under compulsory licenses in exporting nations are imported to address essential public health concerns[8]. The legality of parallel imports, however, depends on domestic law, which differs extensively. Others, driven by TRIPS-plus measures in FTAs, closed off parallel imports to safeguard patent holders, thus compromising affordability—a flagrant contravention of Article 12(1) of the ICESCR, which ensures non-discriminatory access to health resources[9]. Additionally, ongoing disputes about the potential infringement of TRIPS by the importation of products manufactured under compulsory licensing result in legal ambiguities that deter states from using this flexibility[10]. This uncertainty reflects the overarching conflict between intellectual property regimes and the right to health, as stringent interpretations of TRIPS may exacerbate systematic disparities in access to medications.

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[5] Forman, L. (2011) 'An elementary consideration of humanity? Linking trade-related intellectual property rights to the human right to health in international law,' *The Journal of World Intellectual Property,* 14(2), pp. 155-175. https://doi.org/10.1111/j.1747-1796.2010.00413.x

[6] *CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) (2000) Document E/C. 12/2000/4. https://www.ohchr.org/sites/default/files/Documents/Issues/Women/WRGS/Health/GC14.pdf*

[7] Correa, C.M., and South Centre (2020). *Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents.* https://ipaccessmeds.southcentre.int/.

[8] Correa, C.M., and South Centre (2020). *Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents.* https://ipaccessmeds.southcentre.int/.

[9] Correa, C.M., and South Centre (2020). *Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents.* https://ipaccessmeds.southcentre.int/.

[10] Correa, C.M., and South Centre (2020). *Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents.* https://ipaccessmeds.southcentre.int/.

Compulsory Licensing (CLs):

CLs are a gateway to TRIPS flexibilities for responding to public health emergencies. CLs allow governments to authorize third-party production or importation of patented pharmaceuticals without the patent owner's agreement, subject to the payment of "adequate remuneration." The Doha Declaration expressly reaffirms states' sovereign right to set grounds for CLs, such as national emergencies, epidemics, or anti-competitive practices. The main procedural issues are the determination of pertinent patents, made difficult by "evergreening" practices (multiple patents on trivial drug modifications) and defective patent databases[11]. For instance, the pharmaceutical industry frequently submits multiple patents on one product (e.g., forms, salts), thus building a "patent thicket" deterring generic competition[12]. Additionally, pre-negotiation terms with patent holders—unless waived in emergencies—can delay access to life-saving medicines, contrary to states' immediate obligation under Article 12(1) ICESCR to provide timely health services.[13] Data exclusivity legislation prevents generic producers from utilizing clinical trial data to gain marketing approval even when patents lapse or CLs are issued, further delaying affordable access.[14] Case examples like the Colombian effort to license a CL for leukemia medication imatinib show political coercion by patent-holding governments and corporations to reject CLs, demonstrating structural imbalance in global IP governance.[15]

Doha Declaration and TRIPS Flexibilities:

The Doha Declaration (2001)[16] significantly reaffirms public health priorities in opposition to stringent intellectual property rights.[17] It indicates that TRIPS must be read to guarantee medication access, primarily via compulsory licenses and parallel imports. The Declaration facilitated the 2003 WTO Decision (included as Article 31bis of TRIPS), which permits nations lacking pharmaceutical production capacity to import generics under compulsory licenses, addressing disparities in HIV/AIDS treatment.[18] The Doha Declaration highlights that the mechanism is essential for least-developed

[11] Correa, C.M., and South Centre (2020). *Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents.* https://ipaccessmeds.southcentre.int/.
[12] Correa, C.M., and South Centre (2020). *Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents.* https://ipaccessmeds.southcentre.int/.
[13] Correa, C.M., and South Centre (2020). *Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents.* https://ipaccessmeds.southcentre.int/.
[14] Correa, C.M., and South Centre (2020). *Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents.* https://ipaccessmeds.southcentre.int/.
[15] Correa, C.M., and South Centre (2020). *Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents.* https://ipaccessmeds.southcentre.int/.
[16] WORLD TRADE ORGANIZATION (2001) *DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH, MINISTERIAL CONFERENCE.*
https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf.
[17] World Health Organization (2008) *Global strategy and plan of action on public health, innovation, and intellectual property, SIXTY-FIRST WORLD HEALTH ASSEMBLY.*
https://apps.who.int/gb/ebwha/pdf_files/a61/a61_r21-en.pdf
[18] Musungu, S.F. *et al.* (2006) *THE USE OF FLEXIBILITIES IN TRIPS BY DEVELOPING COUNTRIES: CAN*

countries (LDCs), which are not required to apply pharmaceutical patents until 2033. Nonetheless, the complexity of the system—notification obligations to the WTO and export quantity limitations—has restricted its utilization, with no more than a few nations (e.g., Rwanda, Canada) applying it. The COVID-19 pandemic laid bare vulnerabilities in relying on voluntary licenses or donor-influenced measures since high-income nations cornered the vaccine supply, subjecting LMICs (low- and middle-income countries) to delayed COVAX efforts. The Doha framework remains underutilized due to political resistance and technical hurdles, which erodes its potential to balance IP systems with the right to health.[19]

CASE STUDIES

India:

Novartis AG v. Union of India, a 2013[20] Indian Supreme Court lawsuit, attempted to patent Glivec, the beta crystalline version of imatinib mesylate. The Indian Patent Office rejected the application on Section 3(d) of the Indian Patents Act, which prohibits patenting new forms of recognized substances without "significantly enhanced efficacy".

Section 3(d) of India's Patents Act outlaws "evergreening," when pharma corporations preserve patent monopolies by constantly changing popular drugs. The court specifically defined "efficacy" as therapeutic efficacy, requiring clinical proof that the new variety is healthier. Because Novartis merely evaluated bioavailability, it could not establish the beta crystalline form improved patient outcomes.[21] While maintaining the patent refusal, the court allowed generic manufacturers to develop cheaper imatinib, cutting its monthly price from 2,500 to 150.[22] This allowed disadvantaged people to acquire life-saving medicine, directly benefiting Article 12(1) of the ICESCR. India's use of Section 3(d) shows the Doha Declaration's recognition that TRIPS must be read to improve public health.[23]

The court repeated the ICESCR's demand to prevent healthcare discrimination by banning IP regimes' pharmaceutical access restrictions. India showed that poor governments may utilize TRIPS flexibilities to prevent patent abuse while preserving international trade standards by prioritizing public health

THEY PROMOTE ACCESS TO MEDICINES? South Centre. https://www.southcentre.org.

[19] *WTO | intellectual property (TRIPS) – TRIPS and public health.* https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm.

[20] UNCTAD's Intellectual Property Unit (2013) *Novartis AG v. Union of India & Others, Supreme Court of India.* https://unctad.org/ippcaselaw/sites/default/files/ippcaselaw/2020-12/Novartis%20AG%20v.%20Union%20of%20India%20%26%20Others%20Indian%20Supreme%20Court%202013_0.pdf.

[21] Bonadio, E. 'Compulsory Licensing of Patents: the Bayer-Natco Case,' *European Intellectual Property Review,* 34(10), pp. 719-728.

[22] *Ibid.*

[23] WORLD TRADE ORGANIZATION (2001) *DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH, MINISTERIAL CONFERENCE.*

above corporate profits. The case also made India the "pharmacy of the Global South," since Indian generic imatinib clones helped local patients and LMICs that sought inexpensive pharmaceuticals. Novartis' strong patentability requirements were adopted by LMICs including Argentina and the Philippines.[24]

South Africa:

The 2001 South African court dispute[25] between the government and 39 global pharmaceutical corporations shows how IP rights, such as patents, clash with Article 12(1) of the ICESCR's right to health. The HIV/AIDS epidemic in South Africa infected approximately 4.5 million individuals, and patented antiretroviral (ARV) medications cost 4–12 times more than generics. The 1997 Medicines Act addressed this disparity with parallel imports, generic replacement, and cost transparency. The Pharmaceutical Manufacturers Association (PMA) sued the government, saying the Act breached its TRIPS patent rights and South Africa's constitutional property rights.[26]

South Africa in return said that the Medicines Act would help poor people. The Treatment Action Campaign (TAC) featured HIV/AIDS sufferers' declarations as amicus curiae, including Vernon Ogle, who had to choose between ARVs (R1,200/month) and feeding his family on R500/fortnight. The affidavits indicated how patent-enforced pricing rendered drugs costly, violating the ICESCR's (3As) availability, accessibility, and affordability prohibitions.

In public health emergencies, TRIPS allows compelled licensing and parallel imports. South Africa's Medicines Act wanted flexibility, on the other hand, Pharma companies asserted that Clause 15c of the Act gave "arbitrary powers" to overturn patents, infringing TRIPS and constitutional property rights.[27] Their legal goal was to weaken TRIPS' public health safeguards and make patents absolute. Merck and Pfizer developed $1,000/year triple ARVs in response to popular outcry. Disease-specific, conditional, and unsustainable. Pfizer's fluconazole gift was related to patent expiry, whereas Abbott Laboratories' reductions were due to generic import limitations. These policies prioritized market control over systemic transformation. whereas, Cipla and Aurobindo, Indian generics, offered triple therapy for $295/year, far below corporate expenses, illustrating compulsory licensing's revolutionary potential.[28]

Despite firm discounts, South Africa's annual pharmaceutical budget couldn't treat HIV-positive persons. Treating 700,000 people at 1,000/year in Brazil would cost 700 million—three times the

[24] Bonadio, E. 'Compulsory Licensing of Patents: the Bayer-Natco Case,' *European Intellectual Property Review,* 34(10), pp. 719-728.
[25] Oxfam (2001) *Oxfam Update on South African Court Case South Africa vs. the Drug Giants.*
[26] Oxfam (2001) *Oxfam Update on South African Court Case South Africa vs. the Drug Giants*
[27] State President (2017) *MEDICINES AND RELATED SUBSTANCES ACT, Government Gazette.*
[28] Oxfam (2001) *Oxfam Update on South African Court Case South Africa vs. the Drug Giants*

medicine budget. Generic imports under mandatory license ($295/year) would save 70% but need huge foreign assistance to avoid diverting resources from Tuberculosis.[29] The move prohibited poor nations from using TRIPS flexibilities. The EU and U.S. pushed "TRIPS-plus" measures in bilateral trade agreements after pharmaceutical industry lobbying.

After a global uproar, drug corporations dropped the litigation in April 2001.[30] The court affirmed governments' need to balance IP and health rights utilizing TRIPS public health flexibilities. South Africa's success inspired global health campaigns and the 2001 Doha Declaration, which codified TRIPS' public health criteria. Least-developed countries' TRIPS transition periods are short, whereas richer ones resist medical patent modifications. This case highlights how absolute IP regimes place commercial interests before human rights, harming health.

CORPORATE POWER

EU trading away

In addition to WTO TRIPS, EU free trade agreements with less affluent nations have promoted TRIPS-plus intellectual property legislation. Exclusive data and protection certificates may inhibit generic competition for a duration of 11 years. Subsequent analyses of the EU-Colombia Free Trade Agreement may forecast a $620 million escalation in pharmaceutical expenditures by 2030, adversely affecting the impoverished population.[31] This contravenes Article 12(1) of the ICESCR, which requires government provision of pharmaceuticals.

The EU used bilateral pressure to deter developing nations from using TRIPS flexibilities such as compulsory licensing, which reduced medical expenses. The European Union said that Thailand's authorization of generic HIV and cancer medications may jeopardize public health. These practices contravene the Doha Declaration on TRIPS and Public Health. The resistance from the EU hinders needy nations from fulfilling their ICESCR obligation to provide fair access to healthcare.

On the other hand, Border agents may convey generic medications authorized in both nations in accordance with EU customs regulation 1383/2003.[32] Dutch and German authorities confiscated HIV drugs destined for Nigeria and Brazil due to infringement of EU patents.[33] Seizures impede generic

[29] Oxfam (2001) *Oxfam Update on South African Court Case South Africa vs. the Drug Giants*
[30] Sibbald, B. (2001) *Drug giants drop suit against South Africa drug law.* https://pmc.ncbi.nlm.nih.gov/articles/PMC81124/.
[31] Oxfam International and Health Action International (2009) *Trading Away Access to Medicines: How the European Union's Trade Agenda Has Taken a Wrong Turn.* https://www.haiweb.org
[32] *Regulation – 1383/2003 – EN – EUR-LEX.* https://eur-lex.europa.eu/eli/reg/2003/1383/oj/eng
[33] *Brazil, India denounce Dutch generic drug seizure* (2009). https://www.reuters.com/article/business/change-suite/brazil-india-denounce-dutch-generic-drug-seizure-idUSTRE50T27O/

manufacturers and supply chains from providing crucial medications to those in need, violating Article 12(1).

Price restrictions and generic substitutions enable the EU to provide affordable medications domestically while constraining intellectual property rights internationally. The European Commission's antitrust investigations indicate that EU pharmaceutical companies have influenced developing countries to implement IP regulations that foster generic competition via exploitative patent practices.[34] This illustrates the contradictory standards of the EU and Double standards contravene the non-discrimination provisions of the ICESCR regarding healthcare.

The EU's R&D efforts concerning diseases prevalent in underdeveloped nations are insufficient. Despite the Innovative Medicines Initiative (IMI) promoting cost-effective pharmaceuticals, just 1% of new drugs address neglected diseases such as tuberculosis.[35] The EU has rejected the WHO's patent pool and prize fund initiatives aimed at dissociating R&D costs from pharmaceutical prices. This neglect violates the ICESCR's stipulation about the "prevention, treatment, and control of epidemics" (Article 12(2)(c)) and sustains treatment inequities.

The EU dismisses the WHO-led Global Strategy and Plan of Action on Public Health, Innovation, and IP, which emphasizes public health above IP rights. The EU rejected the reiteration of the Doha Declaration and the restriction of TRIPS flexibilities for middle-income countries.[36] This suggestion emphasizes economic concerns above the ICESCR's stipulation of "the right of everyone to the enjoyment of the highest attainable standard of health" for the underprivileged.

The Great Vaccine Robbery: A Systemic Exploitation of Global Health Equity

The COVID-19 pandemic highlighted how vaccine manufacturers profited from life-saving vaccines developed with extraordinary public funding, resulting in global inequity. "The Great Vaccine Robbery" illustrates how IP monopolies enabled Pfizer/BioNTech and Moderna to commercialize publicly supported research at exorbitant prices, therefore excluding low- and middle-income countries at a crucial period. Moderna's mRNA vaccine was priced at 4 to 13 times its production cost, whereas Pfizer's vaccine had a manufacturing cost of 1.18 per dosage

[34] Oxfam International and Health Action International (2009) *Trading Away Access to Medicines: How the European Union's Trade Agenda Has Taken a Wrong Turn.* https://www.haiweb.org
[35] The Innovative Medicines Initiative (IMI) (2008) *The Innovative Medicines Initiative (IMI) continues into the next phase.* https://www.ihi.europa.eu/sites/default/files/uploads/documents/news-events/press-releases/press-release-17072008_en.pdf
[36] Oxfam International and Health Action International (2009) *Trading Away Access to Medicines: How the European Union's Trade Agenda Has Taken a Wrong Turn.* https://www.haiweb.org

but was marketed for 28.[37] Colombia and South Africa spent millions for 20 million pills and 177 million doses, respectively.[38] This funding may have been used for healthcare or poverty reduction initiatives. These tactics clearly contravene Article 12(1) of the ICESCR.

Vaccine monopolies have engendered "vaccine apartheid" by stockpiling doses to inoculate low- and middle-income countries several times.[39] By mid-2021, less than 1% of low-income countries had received a single vaccine[40], but the G7 nations were almost fully vaccinated. Pfizer/BioNTech allocated 8% to LMICs, whereas Moderna allocated 7%. Hoarding impeded the protection of billions and fostered lethal mutations, jeopardizing global health.[41] Governments violated the ICESCR's global cooperation mandate by failing to provide immunizations equitably. COVAX, which promised equitable global access, had institutionally failed.

COVAX procured immunizations for 23% of the low- and middle-income country population for 5 to 20 times the anticipated manufacturing cost instead of addressing corporate monopolies.[42] The absence of input from low- and middle-income countries in decision-making has perpetuated the unaffordability of pneumococcal vaccines, which are dominated by pharmaceutical duopolies for a decade. COVAX placed profit above public health due to insufficient cost transparency and equitable distribution. This evasion of accountability indicates an institutional hesitance to prioritize human rights above profit. Public health funds were squandered when Pfizer/BioNTech and Moderna spent $19.3 billion on pandemic creation in 2021.[43] The EU allocated €31 billion for mRNA vaccines, or 19% of its budget, to reveal public R&D fraud. Capitalizing on life-saving technology rather than global public goods demonstrated moral bankruptcy and redirected financing from essential health infrastructure.

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[37] Marriott, A., Maitland, A., and The People's Vaccine Alliance (2021) *The great vaccine robbery, policy brief.* https://webassets.oxfamamerica.org/media/documents/The_Great_Vaccine_Robbery_Policy_Brief.pdf?_gl=1*vhzenx*_ga*MjI3NDExNDAzLjE2NjU2Njg4MzE.*_ga_R58YETD6XK*MTY2NjM0MTgzNS41LjAuMTY2NjM0MjA4OC42MC4wLjA

[38] *Ibid.*

[39] *Ibid.*

[40] Vaccination data from Our World in Data as of 27th July 2021; population data from the UN.

[41] Analysis by People's Vaccine Alliance using data from Airfinity https://www.airfinity.com/

[42] *COVAX Global Supply Forecast* (2021). https://www.gavi.org/sites/default/files/covid/covax/COVAX-Supply-Forecast.pdf

[43] Marriott, A., Maitland, A., and The People's Vaccine Alliance (2021) *The great vaccine robbery, policy brief.* https://webassets.oxfamamerica.org/media/documents/The_Great_Vaccine_Robbery_Policy_Brief.pdf?_gl=1*vhzenx*_ga*MjI3NDExNDAzLjE2NjU2Njg4MzE.*_ga_R58YETD6XK*MTY2NjM0MTgzNS41LjAuMTY2NjM0MjA4OC42MC4wLjA

SOLUTION

The COVID-19 pandemic laid bare the structural inequities embedded within global health governance, where IP regimes, corporate monopolies, and profit-driven R&D models systematically exclude low- and middle-income countries (LMICs) from accessing lifesaving health technologies.[44] Compulsory licensing emerges as a critical mechanism to address these inequities, yet its necessity underscores a broader systemic failure. During the pandemic, IP barriers extended beyond vaccines to diagnostics and treatments, with monopolies on monoclonal antibodies (mAbs) like casirivimab/imdevimab pricing therapies at $820 in India and $2,100 in the U.S., far beyond the reach of LMIC health systems.[45] Such pricing, enforced by patents held by corporations like Regeneron and Roche, not only contravenes the ICESCR obligation to ensure the "highest attainable standard of health" but perpetuates a cycle of exclusion where marginalized populations in LMICs face structural discrimination in accessing care.

The inability to procure WHO-recommended therapies like tocilizumab, coupled with supply shortages that left LMICs—home to 48% of global COVID-19 cases—with only 0.4% of treatments, exemplifies how IP regimes prioritize profit over public health.[46] Temporary suspensions of IP barriers through a TRIPS waiver, facilitated by CLs, could have enabled decentralized production in regional hubs like India's generic pharmaceutical sector, scaling access to antivirals like molnupiravir and Paxlovid. However, the refusal of high-income countries to endorse such measures reveals a fatal contradiction: while international law obligates states to prioritize vulnerable groups under General Comment No. 14, existing frameworks perpetuate a system where access to health technologies remains contingent on market dynamics rather than human rights.

The limitations of CLs, however, cannot be resolved without addressing the root cause of inequity: a profit-centric R&D model that neglects diseases disproportionately affecting LMICs.[47] Public funding reforms are essential to delink innovation from monopolistic pricing, ensuring that R&D serves public health rather than corporate interests. Tuberculosis, malaria, and neglected tropical diseases—ailments with minimal commercial viability—remain underfunded, as pharmaceutical firms prioritize lucrative markets. The delinkage approach, which proposes funding R&D through public grants or collective

[44] Medicins Sans Frontieres Access Campaign (2003) '*3 reasons why we need a Waiver on monopolies of ALL COVID-19 medical tools*'. https://msfaccess.org/3-reasons-why-we-need-waiver-monopolies-all-covid-19-medical-tools.
[45] Hoen, E. (2016) *PRIVATE PATENTS AND PUBLIC HEALTH.* Health Action International. https://www.accesstomedicines.org
[46] Hoen, E. (2016) *PRIVATE PATENTS AND PUBLIC HEALTH.* Health Action International. https://www.accesstomedicines.org
[47] Gore, C, *et al.* (2023) 'Negotiating public health intellectual property licensing agreements to increase access to health technologies: an insider's story,' *BMJ Global Health,* 8(9), p. e012964. https://doi.org/10.1136/bmjgh-2023-012964

pools rather than patent-driven profits, offers a pathway to democratize innovation.[48]

The Medicines Patent Pool (MPP), initially conceived to address HIV treatment access, demonstrates the potential of such models. By negotiating voluntary licenses with patent holders, the MPP enabled generic production of antiretrovirals, slashing costs by 90% and distributing over 27 billion doses across 148 countries. Yet, this success remains confined to specific diseases and geographies, as voluntary mechanisms often exclude upper-middle-income countries (UMICs) where patent holders seek to preserve profits.[49] A binding international framework, such as the proposed WHO Consultative Expert Working Group Agreement, could institutionalize delinkage by mandating transparency, resource-sharing, and equitable technology transfer. Such reforms would align IP systems with human rights obligations, ensuring that innovations like mRNA vaccines or gene therapies are treated as global public goods rather than proprietary commodities.

The MPP's evolution from an HIV-focused initiative to a broader platform for health technologies highlights both the promise and limitations of voluntary licensing models. While tiered royalties and public-private market segmentation have expanded access to UMICs, the exclusion of countries like Brazil from key COVID-19 therapeutic licenses underscores the inherent tension between corporate profit motives and public health imperatives.[50] The MPP's reliance on patent holders' willingness to collaborate—often driven by reputational incentives like ESG compliance—reveals the fragility of voluntary mechanisms in crises. During COVID-19, despite the MPP's rapid licensing of molnupiravir and nirmatrelvir, restrictive agreements and manufacturing bottlenecks delayed equitable distribution, perpetuating shortages in LMICs. This failure underscores the need for compulsory measures to complement voluntary efforts, particularly in emergencies. CLs, when wielded decisively, can dismantle monopolies and decentralize production, as seen in India's 2012 compulsory license for Bayer's Nexavar, which reduced costs by 97% and saved thousands of lives.[51] However, the political and legal hurdles to invoking CLs—exemplified by the EU's TRIPS-plus policies and U.S. opposition to the TRIPS waiver—reflect a global governance architecture still beholden to neoliberal trade orthodoxy.

Ultimately, achieving health equity demands a triad of reforms: robust use of CLs to override IP barriers

[48] Medicins Sans Frontieres Access Campaign (2003) '*3 reasons why we need a Waiver on monopolies of ALL COVID-19 medical tools*'. https://msfaccess.org/3-reasons-why-we-need-waiver-monopolies-all-covid-19-medical-tools.
[49] Hoen, E. (2016) *PRIVATE PATENTS AND PUBLIC HEALTH.* Health Action International. https://www.accesstomedicines.org
[50] Gore, C, *et al.* (2023) 'Negotiating public health intellectual property licensing agreements to increase access to health technologies: an insider's story,' *BMJ Global Health,* 8(9), p. e012964. https://doi.org/10.1136/bmjgh-2023-012964
[51] Medicins Sans Frontieres Access Campaign (2003) '*3 reasons why we need a Waiver on monopolies of ALL COVID-19 medical tools*'. https://msfaccess.org/3-reasons-why-we-need-waiver-monopolies-all-covid-19-medical-tools.

during crises, systemic delinkage of R&D from profit motives through public funding, and the expansion of collaborative models like the MPP to encompass a wider range of diseases and technologies.[52] The MPP's adaptability during COVID-19, though imperfect, offers a blueprint for scaling access to biologics and non-communicable disease treatments, provided manufacturing capabilities in LMICs are strengthened. Concurrently, binding international agreements must enforce technology transfer under TRIPS Article 66.2, enabling LMICs to produce generics without reliance on voluntary goodwill.[53]

The ethical imperative is clear: as the Indian Supreme Court affirmed in Novartis v. Union of India, public health must supersede corporate interests. Yet, the persistent refusal of HICs to reform IP regimes—evidenced by the EU's suppression of generics and the U.S.'s obstruction of the TRIPS waiver—betrays a complicity in systemic violence against LMIC populations. The "great vaccine robbery" was not an anomaly but a symptom of a system that privileges profit over lives. To prevent future atrocities, health technologies must be reclassified as global commons, with mandatory licensing recognized as a human rights obligation.[54] Only through such transformative action—rooted in political courage, multilateral solidarity, and an unwavering commitment to ICESCR principles—can the right to health transcend legal abstraction and become a universal reality.

LEGAL AND POLITICAL BARRIERS

The relationship between policy aspirations and structural barriers in global health governance is clearly shown by the obstacles confronting Resolution 47/14 and the persistent disparities in pharmaceutical access underscored by the COVID-19 pandemic.[55] Resolution 47/14 signifies a pivotal advancement in incorporating human rights into HIV/AIDS strategies, highlighting decriminalization, universal health coverage, and equitable treatment access; however, its execution is compromised by the systemic obstacles that sustain disparities in pandemic responses. The resolution's appeal to use TRIPS Agreement flexibilities to guarantee inexpensive medications reflects the pressing need for accessible COVID-19 treatments; yet, both scenarios highlight a continual disparity between global obligations and actionable enforcement. Key states' abstentions during the resolution's approval, motivated by geopolitical opposition to progressive human rights standards, mirror the political impasse over the

[52] Medicins Sans Frontieres Access Campaign (2003) '*3 reasons why we need a Waiver on monopolies of ALL COVID-19 medical tools*'. https://msfaccess.org/3-reasons-why-we-need-waiver-monopolies-all-covid-19-medical-tools.

[53] Gore, C, *et al.* (2023) 'Negotiating public health intellectual property licensing agreements to increase access to health technologies: an insider's story,' *BMJ Global Health,* 8(9), p. e012964. https://doi.org/10.1136/bmjgh-2023-012964

[54] Hoen, E. (2016) *PRIVATE PATENTS AND PUBLIC HEALTH.* Health Action International. https://www.accesstomedicines.org

[55] Human Rights Council (2021) 'Human rights in the context of HIV and AIDS,' *Resolution Adopted by the Human Rights Council* [Preprint].

extension of TRIPS exemptions for COVID-19 diagnoses and treatments.[56] These contradictions highlight a persistent issue: global health equality is dependent on surmounting ideological divisions and corporate interests that favor profit above public health.

The structural similarities between HIV/AIDS and COVID-19 problems further reveal how intellectual property frameworks and geopolitical power differences sustain health inequities. For example, the patents maintained by pharmaceutical corporations such as Pfizer and Merck on COVID-19 antivirals—secured until 2041 and 2038, respectively—reflect previous obstacles to accessible antiretroviral treatments for HIV.[57] Both crises demonstrate that voluntary licensing arrangements, such as the Medicines Patent Pool, often exclude middle-income countries, resulting in states like Brazil and Malaysia depending on disjointed, improvised solutions. Likewise, the resolution's focus on data gathering to tackle HIV-related disparities risks repeating the shortcomings seen in COVID-19 replies, where insufficient disaggregation masked the needs of vulnerable populations. The hesitance of high-income countries (HICs) to implement TRIPS flexibilities, despite their own use of compulsory licensing in crises, underscores a hypocrisy that erodes global confidence.[58] This duality—promoting fairness while opposing structural reforms—exposes a fundamental paradox in global health governance, as resolutions and accords are impeded by the same structures they want to alter.

The efficacy of frameworks such as Resolution 47/14 depends on tackling the fundamental causes of these concurrent issues: neoliberal trade policies, corporate domination of health systems, and the absence of enforceable financial instruments to assist low-income nations.[59] The COVID-19 pandemic's revelation of pharmacological disparities substantiates the resolution's assertion that health justice is unattainable without the abolition of punitive legal structures and the redistribution of authority in global health governance. In the absence of persistent pressure to change intellectual property legislation, enforce accountability for voluntary pledges among governments, and prioritize public health above profit, solutions to both HIV/AIDS and pandemics will continue to be disjointed.[60] The resolution's congruence with the SDGs provides a forward trajectory, contingent upon the substitution of geopolitical rivalry with cooperation, and the establishment of equality as an essential foundation of

[56] Banda, M. (2019) *WTO TRIPS AGREEMENT: A HINDRANCE TO THE ECONOMIC DEVELOPMENT OF LEAST DEVELOPED COUNTRIES? THE CASE OF MALAWI AND RWANDA, University of South Africa (UNISA).* Journal-article. https://www.wto.org/english/docs_e/legal_e/27-trips.pdf
[57] Human Rights Council (2021) 'Human rights in the context of HIV and AIDS,' *Resolution Adopted by the Human Rights Council* [Preprint].
[58] Banda, M. (2019) *WTO TRIPS AGREEMENT: A HINDRANCE TO THE ECONOMIC DEVELOPMENT OF LEAST DEVELOPED COUNTRIES? THE CASE OF MALAWI AND RWANDA, University of South Africa (UNISA).* Journal-article. https://www.wto.org/english/docs_e/legal_e/27-trips.pdf
[59] Human Rights Council (2021) 'Human rights in the context of HIV and AIDS,' *Resolution Adopted by the Human Rights Council* [Preprint].
[60] Banda, M. (2019) *WTO TRIPS AGREEMENT: A HINDRANCE TO THE ECONOMIC DEVELOPMENT OF LEAST DEVELOPED COUNTRIES? THE CASE OF MALAWI AND RWANDA, University of South Africa (UNISA).* Journal-article. https://www.wto.org/english/docs_e/legal_e/27-trips.pdf

global health diplomacy.

CONCLUSION

The right to health, established in international human rights law and national constitutions, serves as both a moral obligation and a practical means to confront systemic disparities in access to essential medicines; however, its actualization depends on the removal of structural obstacles imposed by intellectual property systems. Judicial precedents in Latin America, Africa, and Asia illustrate that courts may serve as essential enforcers of health rights, addressing policy deficiencies via decisions that value human dignity above bureaucratic stagnation or financial limitations.[61] Significant instances in Colombia, Costa Rica, and South Africa demonstrate how legal action, sometimes initiated by civil society, pushes governments to meet their treaty responsibilities under the ICESCR, despite political opposition. Nonetheless, these triumphs are scattered, limited by geographical variances in legal frameworks and corporate power. The COVID-19 pandemic exposed the dire ramifications of these inequities: although courts in India and South Africa previously led the way in utilizing TRIPS flexibilities to reduce drug prices and enhance access to HIV treatments, these countries found themselves impotent as vaccine apartheid, reinforced by stringent intellectual property protections, left billions vulnerable. This contradiction highlights a stark reality—judicial heroism alone cannot mitigate a global system that prioritizes business above human life.

The TRIPS waiver discourse exemplifies this systemic inadequacy. Notwithstanding the Doha Declaration's commitment to promote public health, affluent countries and pharmaceutical interests hindered equal access to vaccinations and treatments, so maintaining a cycle of "innovation for profit"[62] that directly violates ICESCR responsibilities. The EU's TRIPS-plus policies and the U.S.'s opposition to patent suspensions illustrate a neoliberal doctrine that prioritizes corporate interests above health justice, despite evidence from LMICs such as India and Brazil demonstrating that compulsory licensing and local manufacturing may save millions of lives. The Novartis case, which dismissed evergreening to protect generic competition, provides a framework for aligning intellectual property regimes with human rights; nonetheless, such precedents are still outliers rather than standard practices. The decision to withhold the waiver for diagnostics and treatments, despite several preventable fatalities, demonstrates not legal uncertainty but political timidity. This is a violation of the ICESCR's mandate, which necessitates international collaboration to provide the "highest attainable standard of health" for

[61] Hogerzeil, H.V *et al*. (2006) *Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts?, The Lancet,* p. 305.
[62] Council for Trade-Related Aspects of Intellectual Property Rights, India, and South Africa (2020) *WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION, CONTAINMENT AND TREATMENT OF COVID-19, Council for Trade-Related Aspects of Intellectual Property Rights,* pp. 1-4. https://www.wto.org/english/tratop_e/covid19_e/covid19_e.htm

everyone.

To eradicate this injustice, the right to health must be reconceptualized as an essential cornerstone of global governance. This necessitates enforceable procedures to ensure state accountability for ICESCR compliance, proactive policy measures that separate R&D from monopolistic patents, and global solidarity to counter TRIPS-plus demands. Judicial systems, however essential, cannot shoulder this responsibility independently: the examples of Colombia and Brazil demonstrate that legal action may pressure healthcare resources without resolving underlying issues. States must implement clear constitutional frameworks that prioritize vital medicines as public goods, invest in local pharmaceutical capability, and unabashedly use TRIPS flexibilities. The Medicines Patent Pool's achievement in decreasing HIV medicine prices by 90% demonstrates that cooperation, rather than competition, fosters equal access.

The struggle for health justice ultimately serves as a measure of global solidarity. The "great vaccine robbery" during COVID-19 represented not just a policy failure but also a moral degradation, revealing how intellectual property radicalism sustains colonial power structures. To prevent future disasters, vaccinations and treatments should be designated as global commons, with compulsory licensing acknowledged as a human rights requirement. The way forward is unequivocal: as reiterated by India's court in Novartis, public health considerations must take precedence over private interests. The inquiry is whether the Global North will acknowledge this lesson or continue to be involved in a system that prioritizes profit above human life. Health equality necessitates a profound transformation: one that prioritizes human rights in commerce, reformulates intellectual property rules to address public need, and converts the right to health from a legal concept into a tangible experience for everyone.