PANDEMIC PREPAREDNESS AND ACCESS TO PATENTED MEDICINES: A HUMAN RIGHTS AND GLOBAL JUSTICE PERSPECTIVE

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ABSTRACT

The COVID-19 pandemic exposed deep inequities in the global health architecture, particularly regarding access to life-saving medicines and vaccines. Despite rapid scientific progress and unprecedented public investments, vast populations in low- and middle-income countries were denied timely access to essential health technologies. This paper critically examines the role of intellectual property (IP) regimes—specifically the TRIPS Agreement—in obstructing equitable pandemic responses. It explores how patent protections created barriers to manufacturing and distributing vaccines and treatments, undermining the right to health and global solidarity during a crisis of unprecedented scale.

Through legal and comparative analysis, the paper investigates the shortcomings of TRIPS flexibilities and the political resistance to the proposed TRIPS waiver, which—despite support from countries like India and South Africa—was diluted due to opposition from wealthier nations. It also analyzes the structural flaws of global distribution initiatives such as COVAX, which, though well-meaning, lacked enforceable equity mechanisms and perpetuated existing global disparities.

The paper includes a comparative study of how India, the United States, the European Union, South Africa, and Brazil balanced public health obligations with IP protections during the pandemic. Grounded in a human rights and global justice framework, this research argues that the current patent-based system fails to uphold the right to health, especially in emergencies. It concludes by proposing legal and policy reforms—both international and domestic—to reorient IP regimes toward equity, solidarity, and universal access. The study calls for a shift from market-driven models to rights-based global health governance for future pandemic preparedness.

Keywords: Pandemic Preparedness, Access to Medicines, Right to Health, Global Health Justice, TRIPS Waiver.

Introduction

The COVID-19 pandemic exposed a stark paradox at the heart of global health governance: even as science delivered vaccines and therapeutics at unprecedented speed, billions of people—particularly in the Global South—faced systemic barriers in accessing them. Central to this inequity is the global intellectual property (IP) regime, particularly the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement under the World Trade Organization (WTO), which prioritizes patent protections often at the cost of timely and equitable access to life-saving medicines. While global solidarity was rhetorically invoked, the actual distribution of vaccines and treatments followed patterns of market power, geopolitical dominance, and corporate control, revealing a deeper crisis in the architecture of pandemic preparedness and public health justice.

This research paper explores the structural role of patent regimes and IP barriers in shaping pandemic responses, with a focus on how these systems conflict with the internationally recognized right to health. By analyzing the legal, ethical, and geopolitical dimensions of the TRIPS waiver debate, the practical limitations of TRIPS flexibilities, and the failures of global mechanisms such as COVAX, the paper critically examines whether the current IP framework is compatible with global justice in public health emergencies. It also evaluates India's role and compares it with other national approaches to pandemic preparedness, compulsory licensing, and global cooperation.

The aim of this research is not merely to critique but to propose a human right–centered recalibration of global IP norms to ensure equitable access to patented medicines during health crises. The analysis situates this issue within the broader discourse of global justice, arguing for a paradigm shift where access to essential medicines is recognized as a non-derogable human right, rather than a commodity subject to commercial monopoly and political discretion.

Patent Barriers and Pandemic Response

Introduction to Patent Monopolies in Global Health

Intellectual property rights, particularly patents, are designed to incentivize pharmaceutical innovation by granting inventors exclusive rights to produce and sell their inventions. However, in the context of global health emergencies like pandemics, these monopolies can significantly

delay access to essential medicines and vaccines in low- and middle-income countries (LMICs).

During COVID-19, pharmaceutical giants like Pfizer, Moderna, and AstraZeneca held exclusive rights over critical vaccine technologies, which allowed them to dictate production, pricing, and distribution—effectively sidelining public health priorities in favor of market-driven outcomes.[1]

Patents and Vaccine Nationalism

The TRIPS (Trade-Related Aspects of Intellectual Property Rights) regime of the World Trade Organization (WTO) mandates all member states to uphold strong IP protections. This structure became a legal tool for vaccine nationalism, where wealthy countries secured early vaccine access by signing advance purchase agreements with patent-holding pharmaceutical companies.[2]

As a result, nearly 75% of global vaccine doses were administered in just 10 countries by mid-2021, while many LMICs had not even vaccinated 1% of their populations. This stark imbalance arose because patented technologies were not widely shared or licensed, restricting local manufacturing capacity in the Global South.[3]

Technology Transfer and the Role of Patents

One of the critical challenges in pandemic response is the unwillingness of patent holders to engage in voluntary technology transfer. During COVID-19, mechanisms like the WHO's COVID-19 Technology Access Pool (C-TAP) and the Medicines Patent Pool (MPP) received minimal cooperation from pharmaceutical companies. Instead, private IP holders maintained tight control over mRNA technology and key manufacturing know-how.[4]

This resistance to share know-how and licenses—even under voluntary global health frameworks—demonstrates how the patent regime disincentivizes global solidarity in times of

[1] Carlos M. Correa, 'Intellectual Property and the COVID-19 Pandemic', South Centre Policy Brief No. 92, 2021.
[2] Amnesty International, "A Double Dose of Inequality", 2021 Report.
[3] WHO, "Vaccine Equity Declaration", 2021.
[4] WHO, "C-TAP Progress Report", 2022.

crisis.[5]

The Inefficiency of Relying Solely on Market-Driven Models

Market incentives alone proved insufficient in rapidly scaling up vaccine production globally. For example, Moderna, despite receiving over $10 billion in public funding, retained exclusive control over its mRNA technology and restricted its export to LMICs during critical early waves of the pandemic.[6]

Furthermore, companies like Pfizer resisted requests for technology-sharing with the WHO-supported South African mRNA hub. Such reluctance slowed the development of decentralized production capacity, particularly in Africa, where import dependence left countries highly vulnerable.[7]

Impact on Pandemic Preparedness

Patent barriers affect not only current access but also future pandemic preparedness. Without mechanisms to override or suspend exclusive rights swiftly, LMICs remain at the mercy of IP holders. This hinders their ability to stockpile essential medicines, set up regional manufacturing hubs, or respond effectively in real-time to future global health threats.[8]

Moreover, public health emergencies cannot be resolved through charity or donations alone. A robust legal framework must exist to balance the right to innovation with the right to life.[9]

In the Case of **Novartis AG v. Union of India & Others**[10] In this landmark decision, the Supreme Court of India interpreted Section 3(d) of the Indian Patents Act to prevent evergreening of pharmaceutical patents, rejecting Novartis's claim over Glivec. This case emphasized the primacy of public health over incremental innovation and established a precedent supporting affordable access to essential medicines.

[5] Ellen ‘t Hoen, “Private Patents and Public Health”, Medicines Law & Policy Brief, 2021.
[6] Knowledge Ecology International (KEI), “Public Funding and Private Monopoly: Moderna Case Study”, 2021.
[7] The Lancet, Editorial, “Africa Deserves mRNA Manufacturing Autonomy”, Vol 399, 2022.
[8] Lawrence O. Gostin, “Global Health Law”, Harvard University Press, 2014.
[9] UN Human Rights Council, Resolution 41/10 on Access to Medicines in the Context of the Right to Health, 2019.
[10](2013) 6 SCC 1

TRIPS Flexibilities and Their Practical Constraints

Introduction: Balancing IP Rights with Public Health Needs

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), adopted in 1995 under the World Trade Organization (WTO), established a binding global regime of minimum standards for intellectual property protection. However, the agreement also includes certain "flexibilities" to help member countries protect public health—most notably compulsory licensing, parallel importation, and exceptions for national emergencies.

These flexibilities are legally sanctioned tools for balancing patent rights with public interest, particularly access to medicines. However, their application has proven difficult in practice, especially for low- and middle-income countries (LMICs).[11]

Compulsory Licensing: Legal on Paper, Complex in Reality

Compulsory licensing allows governments to authorize the production or use of a patented product without the consent of the patent holder, typically for public health reasons. While TRIPS Article 31 permits this mechanism, procedural requirements—such as prior negotiations with the patent holder, notifications to the WTO, and limitations on export—often make it legally cumbersome and politically sensitive.

In the Case of **Bayer Corporation v. Union of India,**[12] the IPAB upheld India's first compulsory license granted to Natco Pharma for the cancer drug Nexavar. It reinforced the lawful use of TRIPS flexibilities to promote access to life-saving drugs and highlighted the compatibility of national patent law with global trade obligations under the Doha Declaration.

Countries like India and Thailand have issued compulsory licenses, but often face diplomatic pressure and trade retaliation from high-income nations and pharmaceutical lobby groups.[13]

Doha Declaration: Reinforcing Public Health Priority

In response to growing concerns over access to HIV/AIDS medications in Africa, the WTO

[11] Abbott, Frederick M., "The TRIPS Agreement and Its Flexibilities for Public Health", ICTSD, 2005.
[12] 2014 SCC OnLine IPAB 36
[13] Médecins Sans Frontières (MSF), "Compulsory Licensing and Access to Medicines", 2017.

issued the Doha Declaration on TRIPS and Public Health (2001). It reaffirmed the right of member states to interpret and implement TRIPS "in a manner supportive of their right to protect public health."

Doha was a political milestone but had limited enforcement mechanisms. It clarified that countries have the right to determine what constitutes a national emergency, yet it failed to compel pharmaceutical companies or member states to act accordingly.[14]

Paragraph 6 System: A Procedural Maze

One of Doha's key outcomes was the Paragraph 6 system, which allowed countries without manufacturing capacity to import generics made under compulsory licenses elsewhere. This was codified in Article 31bis, the first amendment to TRIPS.[15]

In practice, however, this system has been used only once—by Rwanda, which imported generic HIV drugs from Canada. The process was so complex that even Canada called it "unworkable," citing bureaucratic hurdles, limited commercial incentives, and legal uncertainty.[16]

Political and Economic Constraints

Even when legal mechanisms are available, geopolitical pressures and fear of trade sanctions deter many LMICs from using TRIPS flexibilities. Reports have shown that USTR (United States Trade Representative) and European Union have placed countries on watchlists for attempting to bypass patent protections—even during health emergencies.[17]

Furthermore, pharmaceutical corporations often resort to strategic litigation, lobbying, or threats of withdrawal of investment, making governments reluctant to invoke these tools.[18]

Conclusion: TRIPS Flexibilities Exist, But Are Not Truly Flexible

Although TRIPS contains important tools to ensure public health is not sacrificed to patent

[14] WTO Ministerial Declaration on the TRIPS Agreement and Public Health (Doha, 2001).
[15] WTO, TRIPS Amendment (Article 31bis), 2005.
[16] R. Elliott, "Delivering Drugs in a Time of Need: The Canadian Access to Medicines Regime", HIV/AIDS Policy & Law Review (2007).
[17] Human Rights Watch, "Global Trade and Access to Medicines: The Pressure Game", 2011.
[18] MSF, "Trading Away Health", 2015.

protections, their practical usability is severely constrained. Procedural complexities, lack of capacity in LMICs, and political-economic pressures have rendered many of these tools ineffective.[19]

In the case **of Patent Protection for Pharmaceutical Products (Canada)**[20] the panel ruled that Canada's use of the Bolar exemption was consistent with TRIPS. The case affirmed that WTO members retain policy space to facilitate early market entry of generics after patent expiry, especially in health emergencies.

To address future pandemics, reform is urgently needed. This includes simplifying compulsory licensing procedures, exempting pandemic-related technologies from export restrictions, and developing automatic waiver mechanisms during declared public health emergencies.[21]

Patent Waiver Debate during COVID-19

Background: The Proposal to Waive IP Rights

In October 2020, at the height of the COVID-19 pandemic, India and South Africa submitted a landmark proposal to the World Trade Organization (WTO), calling for a temporary waiver of certain obligations under the TRIPS Agreement. The TRIPS Waiver Proposal aimed to suspend intellectual property protections—such as patents, industrial designs, and trade secrets—related to COVID-19 technologies, including vaccines, diagnostics, and therapeutics.

The idea behind the waiver was to remove legal barriers that restricted the production of vaccines and treatments, especially in developing countries that lacked access due to high costs and limited supply[22].

Rationale: Speed, Equity, and Global Public Health

Supporters of the waiver, including over 100 WTO member states and a broad coalition of civil society organizations, argued that intellectual property rights were impeding global vaccine

[19] South Centre, "Proposal for TRIPS Waiver for COVID-19", 2020.
[20] WT/DS114/R (2000)
[21] Oxfam, "Fixing the Broken Patent System", 2021.
[22] WTO Document IP/C/W/669 (India-South Africa Waiver Proposal, 2020).

equity. They emphasized that during a pandemic, monopolies on life-saving technologies were morally indefensible and practically dangerous.[23]

The waiver was seen as a necessary measure to enable local production, reduce reliance on donations, and accelerate technology transfer—thereby strengthening global pandemic response capacity.[24]

Opposition: Arguments by the Global North and Pharma Industry

In spite of almost universal international backing, some high-income nations—chiefly the United States (initially), the European Union, Switzerland, and the United Kingdom—opposed the waiver. Their reasons were:

1. Innovation Disincentive: Granting the waiver of IP rights would debase innovation since it would deter pharma investments.

2. No Production Capacity in LMICs: Despite IP waivers, several LMICs purportedly did not have the infrastructure to manufacture sophisticated biologics such as mRNA vaccines.

3. Voluntary Licensing Works: Current frameworks such as the Medicines Patent Pool and COVAX were said to be adequate.[25]

Pharmaceutical companies also warned that IP waivers would disrupt global supply chains, erode investor confidence, and set a "dangerous precedent" for future innovation[26].

The WTO Compromise: A Hollow Outcome?

After two years of negotiations, the WTO adopted a limited compromise decision in June 2022. Instead of granting the full waiver requested, it offered a narrow interpretation—permitting only the use of compulsory licensing for vaccine production and excluding diagnostics and therapeutics.[27]

[23] Médecins Sans Frontières (MSF), "TRIPS Waiver: A Crucial Step Toward Vaccine Equity", 2021.
[24] South Centre, Policy Brief No. 92, 2021.
[25] International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), "Statement on TRIPS Waiver", 2021.
[26] European Commission, "EU Communication on IP and COVID-19", 2021.
[27] WTO Ministerial Conference Decision, June 2022.

The ultimate accord did not surrender IP rights completely; it merely defined some already present flexibilities within Article 31 of TRIPS. A criticism claimed that this "WTO Decision" was far from adequate to democratize access to vaccines and was politically watered down by lobbying pressure from IP-owning countries and business lobbyists.[28]

Ethical and Legal Implications

The TRIPS Waiver debate raised deep ethical questions about the hierarchy between IP rights and the right to life. While the WTO claims to promote equitable trade, the outcome demonstrated how structural power imbalances within the multilateral system can override public health emergencies.[29]

The failure of the waiver to take full hold shows the rigidity of the world IP regime during world crises and has spurred demands for long-term structural change, such as stripping pandemic-related technologies of IP protections by default in future health crises.[30]

Case Study: COVAX and Vaccine Inequity

Introduction: What Was COVAX Supposed to Do?

COVAX (COVID-19 Vaccines Global Access Facility) was launched in 2020, co-led by the World Health Organization (WHO), Gavi—the Vaccine Alliance, and the Coalition for Epidemic Preparedness Innovations (CEPI). It was designed to serve as a multilateral procurement platform to ensure fair and equitable distribution of COVID-19 vaccines globally—regardless of income levels.[31]

Its vision was based on global solidarity, intending to deliver 2 billion doses by the end of 2021, with priority given to frontline workers and high-risk populations in all participating countries.[32]

[28] Third World Network, "TRIPS Waiver Decision: What It Actually Means", 2022.
[29] Forman, Lisa & Ooms, Gorik, "Human Rights and Global Health Governance", 2022.
[30] Oxfam International, "The Great Vaccine Robbery", 2021.
[31] Gavi, "COVAX Explained", 2020.
[32] WHO, "COVAX: Working for Global Equitable Access", 2021.

The Reality: A Two-Tiered Vaccine System

Although it was of noble purpose, COVAX did much less than the desired. While vaccine makers made advance purchase agreements (APAs) with high-income countries, low- and middle-income countries (LMICs) were relegated to rely on COVAX and ended up getting vaccines weeks or months later. By December of 2021, just about 7% of individuals in low-income countries received at least one dose of vaccine, while more than 75% of the population in high-income countries were vaccinated.[33]

COVAX became perpetually underfunded, and rich countries shunned it, negotiating bilateral agreements and stockpiling surplus doses—effectively draining its purchasing power and equity-based approach.[34]

Dependency on Voluntary Contributions and Charity Model

COVAX was structured as a public-private partnership, and its operational model relied heavily on voluntary donations from wealthier countries and philanthropic institutions such as the Bill & Melinda Gates Foundation. Unlike compulsory global redistribution mechanisms, it lacked binding obligations for vaccine donations or sharing.[35]

This "charity-based" model gave disproportionate decision-making power to private actors and donor nations while marginalizing LMICs in governance structures. Critics argued that COVAX effectively perpetuated a neocolonial global health architecture where the Global South was dependent on the benevolence of the Global North.[36]

IP Barriers and Lack of Tech Transfer

COVAX's failure was also tied to the patent-protected monopoly structure of COVID-19 vaccines. Although it aimed to facilitate vaccine access, it did not challenge intellectual property rights or push for technology transfer to enable local production in LMICs.[37]

[33] Source: Oxfam International, "A Dose of Reality: How Rich Countries Are Undermining the COVAX Plan", 2021.
[34] The Lancet, "The Failure of COVAX", Vol. 398, 2021.
[35] BMJ Global Health, Harman et al., "Global Vaccine Equity and COVAX: The Limits of Charity", 2022.
[36] Nature, Usher A.D., "A Failing Model for Vaccine Equity", 2021.
[37] Public Citizen, "COVAX: A Cautionary Tale in Global Vaccine Access", 2022.

Unlike the TRIPS waiver movement, COVAX worked within the status quo of global pharmaceutical control, depending on manufacturers like Pfizer, Moderna, and AstraZeneca to supply doses under voluntary terms. This left COVAX vulnerable to delayed deliveries, price inflation, and limited supply during peak global demand.[38]

Ethical and Legal Reflections on Vaccine Apartheid

The COVAX experience has been widely criticized as an example of "vaccine apartheid"—where global health was effectively rationed based on economic status. While no legal obligation for equitable access existed under international law, the crisis reignited debate over the right to health under ICESCR Article 12 and state obligations under international human rights law.[39]

Legal scholars argue that voluntary frameworks like COVAX are insufficient substitutes for binding legal norms, particularly in pandemics where universal and timely access to medicine is a human rights imperative, not charity.[40]

Global Justice and Legal Reforms

Introduction: The Global Justice Dilemma in Access to Medicines

The COVID-19 pandemic has exposed deep-rooted inequities in the global health system, especially concerning access to life-saving medicines and vaccines. The global distribution of patented COVID-19 technologies reflected a larger structural injustice—where wealth and geopolitical power dictated health outcomes. The idea of global justice, particularly in the context of health, demands a framework where access to essential medicines is not a privilege of the rich but a guaranteed right for all.

Philosophers like Thomas Pogge and Amartya Sen have long argued that global institutions—trade, IP law, finance—are structured in ways that perpetuate inequality, and COVID-19 merely reaffirmed this thesis.[41]

[38] MSF Access Campaign, "COVAX and the Pitfalls of Market-Driven Models", 2021.
[39] United Nations Committee on Economic, Social and Cultural Rights, General Comment No. 14, 2000.
[40] Gostin, L.O., "A Human Rights Analysis of Vaccine Distribution", JAMA, 2021.
[41] Pogge, Thomas, "World Poverty and Human Rights", 2008; Sen, Amartya, "Development as Freedom", 1999.

In the Case of **Eldridge v. British Columbia**[42], The Canadian Supreme Court held that the failure to provide sign language interpreters for deaf patients in hospitals violated their right to equal access under the Canadian Charter. The case illustrates how legal reforms can ensure equitable healthcare access as part of human rights obligations.

Structural Critique of the Global IP Regime

The TRIPS Agreement, while promoting harmonized IP protection globally, has also cemented a global legal structure that favors pharmaceutical monopolies in the Global North. This system allows a few transnational corporations to control production, pricing, and access to critical healthcare technologies—often at the cost of public health and social justice in the Global South.[43]

Legal scholars argue that TRIPS lacks meaningful safeguards for equitable access, as the flexibilities under Articles 30, 31, and 31bis are procedurally complex and diplomatically difficult to invoke, especially for developing countries under pressure from powerful states and corporate lobbies.[44]

Pandemic Treaty and Future Legal Instruments

As of 2023, global negotiations under the WHO-led Pandemic Treaty seek to establish a binding international framework for pandemic preparedness and response. Several developing nations and civil society organizations have called for this treaty to include automatic IP waivers for pandemic-related technologies and mandatory technology transfer obligations.[45]

This move reflects a shift from voluntary mechanisms (like COVAX) to legally binding global agreements. If successful, it could mark a transformative moment in global health governance by integrating public health objectives into international law.[46]

[42] [1997] 3 SCR 624.
[43] Correa, Carlos M., "Implications of the Doha Declaration on the TRIPS Agreement and Public Health", WHO, 2002.
[44] Sell, Susan, "Private Power, Public Law", 2003.
[45] WHO Intergovernmental Negotiating Body (INB), Draft Text of the Pandemic Accord, 2023.
[46] MSF Access Campaign, "Pandemic Treaty Must Include IP Waiver Provisions", 2022.

In the case of **P.A. Jacob v. Superintendent of Police**[47]**,** the Kerala High Court held that the right to health is a component of the right to life under Article 21 of the Indian Constitution. It forms a foundational basis for demanding state accountability in pandemic contexts.

Proposals for Legal Reform of TRIPS

Legal scholars and activists have proposed structural amendments to TRIPS to ensure that IP rights do not override human rights obligations. Key proposals include:

1. Making TRIPS flexibilities obligatory during pandemics.

2. Creating a global patent pool for pandemic-related technologies.

3. Incorporating a human rights impact assessment into WTO dispute mechanisms.

4. Enabling South–South cooperation and regional manufacturing hubs, legally protected under international law.[48]

These reforms would move beyond temporary waivers to create systemic legal tools for addressing recurring injustices in global health crises.

The Role of International Human Rights Law

The International Covenant on Economic, Social and Cultural Rights (ICESCR) in Article 12 acknowledges the right to health and requires states to provide access to essential medicines. General Comment No. 14 of the UN Committee on Economic, Social and Cultural Rights (CESCR) stresses that states should ensure that IP regimes do not violate access to health technologies.[49]

Moreover, the Maastricht Principles on Extraterritorial Obligations extend these responsibilities beyond borders, requiring wealthy nations to refrain from policies that harm health access in poorer nations.[50]

[47] AIR 1993 Ker 1
[48] Third World Network, "Proposals for TRIPS Reform in the Post-COVID Era", 2022.
[49] UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), E/C.12/2000/4, 11 August 2000.
[50] Maastricht Principles on Extraterritorial Obligations of States, 2011.

In the case of **Minister of Health v. Treatment Action Campaign** [51]South Africa's Constitutional Court held that the government was constitutionally obligated to provide nevirapine to prevent mother-to-child transmission of HIV. This decision Connected pandemic preparedness to the right to health under national law.

COMPARATIVE ANALYSIS: INDIA AND OTHER COUNTRIES

Introduction: Why Comparative Analysis Matters

The COVID-19 pandemic highlighted at the global level the imperative for robust public health systems and just access to life-saving medical technologies. Nonetheless, the responses differed considerably across countries based on legal frameworks, interpretations of patent law, domestic manufacturing capability, and political intent. A comparison between India and other countries—particularly advanced economies (such as the United States and EU) and comparator countries (such as South Africa and Brazil)—offers an understanding of the strength and weakness of national strategies to pandemic preparedness and patent management.[52]

India's Proactive Stance on TRIPS Flexibilities and Patent Waivers

India has traditionally taken a global leadership role in advocating TRIPS flexibilities and access to affordable medicines. During the pandemic, India—along with South Africa—suggested a temporary waiver of selected provisions of the TRIPS Agreement in the WTO in October 2020 on the grounds that IP impediments were blocking global vaccine and drug access.[53]

India also has strong domestic legislation, especially Section 92 of the Indian Patents Act, which allows for compulsory licensing in public health emergencies. Though India did not issue compulsory licenses during COVID-19, its domestic framework gave it significant legal leverage, while its robust pharmaceutical manufacturing base (Serum Institute of India, Bharat Biotech) enabled it to supply vaccines globally.[54]

[51] 2002 (5) SA 721 (CC).
[52] WHO, "Global Vaccine Market Report", 2022; Oxfam, "A Dose of Reality", 2021.
[53] WTO IP/C/W/669, "TRIPS Waiver Proposal by India and South Africa", 2020.
[54] Indian Patents Act, 1970 (as amended), Section 92.

The United States of America: Duality of Policy and Practice

The United States funded rapid vaccine development through Operation Warp Speed, leading to breakthroughs like Moderna and Pfizer vaccines. However, it maintained a strong IP regime and allowed vaccine makers to retain exclusive patent rights and control over know-how.[55]

While the Administration of Biden expressed support for the TRIPS waiver (May 2021), it took no concrete legislative steps to force pharma companies to share IP or technologies. Moreover, the U.S. remained opposed to broader IP waiver language, weakening the WTO negotiations.[56]

European Union: Reluctance to Undermine IP Regime

The EU opposed the blanket TRIPS waiver and instead pushed for voluntary mechanisms such as COVID-19 Technology Access Pool and Partnerships like COVAX. The EU's approach emphasized preserving IP incentives while offering humanitarian aid and donations[57].

Despite domestic vaccine surpluses, EU member states were slow to commit to meaningful IP reforms or tech transfer obligations. This reluctance reflects the EU's strong alignment with the pharmaceutical industry's position that waiving patents would reduce innovation.[58]

South Africa and Brazil: Assertive Advocacy but Limited Production Capacity

South Africa co-authored the TRIPS waiver proposal and led the political and legal advocacy for equitable access. However, despite its moral leadership, it lacked sufficient domestic biomanufacturing capacity, relying heavily on external donations and slow transfers of mRNA technology.[59]

Brazil, which has legal provisions for compulsory licensing, did not use them during the pandemic, reflecting the political alignment of its then-leadership with IP-protective positions. However, its public health institution Fiocruz partnered with AstraZeneca to co-produce

[55] Public Citizen, "A Dose of Reality: U.S. Undermines Global Access", 2022.
[56] USTR Press Release, "Support for TRIPS Waiver", May 2021.
[57] European Commission, "Statement on TRIPS Waiver Discussions", 2021.
[58] BMJ, "EU Blocks Broader COVID Waiver", 2022.
[59] MSF Access Campaign, "South Africa and TRIPS Waiver Advocacy", 2021.

vaccines under technology transfer arrangements—demonstrating how legal flexibility and political will must align with operational capacity to be effective.[60]

Recommendations

Embed Automatic IP Waivers in Global Pandemic Instruments

Future international agreements like the WHO Pandemic Accord must incorporate automatic and pre-negotiated TRIPS waivers for pandemic-related health products. Negotiating waivers during an active crisis, as seen during COVID-19, leads to delays, politicization, and inequitable outcomes. Embedding these flexibilities in global law would ensure predictability, faster access, and reduced dependency on diplomatic consensus.[61]

Reform Domestic Patent Laws to Expedite Emergency Access

Countries should adopt or strengthen legal mechanisms for expedited compulsory licensing during declared public health emergencies. For instance, India's Section 92 provides a good model, but requires streamlining in implementation. Nations must remove procedural bottlenecks, such as onerous negotiations and litigation risks, which discourage states from invoking these tools.[62]

Establish Global Technology Transfer Hubs

To overcome dependency on a few pharma giants, regional manufacturing hubs should be created and supported through mandatory licensing and shared know-how protocols, especially for biologics like vaccines. The mRNA Technology Transfer Hub in South Africa is a promising step but needs wider support, political backing, and binding cooperation mandates.[63]

Introduce Human Rights Impact Assessments for IP Rules

WTO member states and international institutions must incorporate Human Rights Impact Assessments (HRIAs) in trade and IP policymaking. All FTAs, TRIPS-plus provisions, and

[60] WHO, "Brazil–Fiocruz–AstraZeneca Collaboration", 2022.
[61] MSF Access Campaign, "Fix the Pandemic Treaty", 2023.
[62] Correa, Carlos M., WHO Report on Compulsory Licensing, 2020.
[63] WHO, "mRNA Tech Transfer Initiative", 2022.

domestic patent laws should be subject to scrutiny regarding their effect on the right to health, especially in low-income countries.[64]

Ensure Public Return on Public Investment

Governments that fund R&D with public money must attach access conditions—including affordability, non-exclusivity, and openness to tech transfer. Publicly funded breakthroughs, like NIH's contribution to Moderna's vaccine, should not be privatized without obligations to serve public health imperatives.[65]

Promote Global South Coalitions and South–South Solidarity

Developing countries must form strategic coalitions to amplify demands for fairer IP norms at multilateral platforms. South–South cooperation through legal harmonization, bulk procurement arrangements, and regional innovation systems would strengthen collective bargaining and reduce dependency on the Global North.[66]

Conclusion

The COVID-19 pandemic has been a stress test for the global health architecture, revealing that the dominant paradigm of IP-driven innovation, pharmaceutical monopolies, and voluntary charity is grossly inadequate in a global emergency. Despite technological advancements and unprecedented public investments, millions were left behind due to artificial barriers created by intellectual property regimes.

At the heart of this crisis lies a fundamental question of global justice: Should access to life-saving medicines depend on geography, income, and geopolitical clout—or should it be treated as a non-negotiable human right?

This paper has demonstrated how patent protections—though important for innovation—can become ethical and operational obstacles during pandemics when deployed without constraint. The TRIPS Agreement, while allowing certain flexibilities, fails to deliver in real-time crises

[64] UN OHCHR and WHO, "Human Rights and TRIPS", 2009.
[65] Public Citizen, "NIH and the Moderna Vaccine", 2021.
[66] Third World Network, "South–South Cooperation for Health Equity", 2021.

due to its structural deference to private rights over public needs.

The TRIPS waiver debate exemplified the systemic imbalance in global governance: even during a once-in-a-century pandemic, the world could not agree on temporarily suspending IP protections to save lives. This failure was further compounded by initiatives like COVAX, which, despite noble intentions, lacked legal force and succumbed to vaccine nationalism and unequal power dynamics.

Going forward, reforming the global IP regime is not merely a legal necessity but a moral imperative. The Pandemic Treaty, WTO rules, and national patent systems must evolve to ensure that access to medicines is universal, timely, and rooted in equity. The pandemic has given us a blueprint of what not to do—it is now up to global institutions, states, and civil society to rewrite that blueprint for the next health crisis.

Without such reforms, the world risks perpetuating a cycle of preventable suffering, where science succeeds but law and policy fail.