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"PATENT BATTLES IN THE PHARMACEUTICAL INDUSTRY: THE CASE OF COVID-19 VACCINE WAIVERS AND BEYOND"

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Abstract

The COVID-19 pandemic has profoundly intensified global debates surrounding intellectual property (IP) rights and their intersection with public health equity, particularly by bringing into sharp focus proposals to temporarily waive certain provisions of the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). These waivers were advocated primarily for COVID-19 vaccines, therapeutics, and diagnostics, aiming to facilitate broader manufacturing and distribution amid unprecedented global health demands. This article presents a multifaceted analysis of the legal, economic, and ethical dimensions of the IP landscape during the pandemic, drawing upon pharmaceutical industry case studies, including high-profile disputes involving mRNA vaccine patents and voluntary licensing arrangements, alongside landmark judicial precedents from India and the United States.

The article examines the evolving policy discussions at the WTO, highlighting the negotiations that culminated in the 2022 Ministerial Decision, which provided limited flexibilities but fell short of broader ambitions. It contrasts the perspectives of developed nations—aligned with pharmaceutical innovators emphasizing the need to preserve R&D incentives—and developing nations, which prioritize equitable access in low- and middle-income countries (LMICs). The evaluation also considers compulsory licensing under TRIPS Article 31, assessing its applications and potential limitations in addressing pandemic-scale challenges.

By situating the COVID-19 crisis within a broader history of IP-driven access conflicts, such as those during treatments for Hepatitis C, the paper employs a doctrinal methodology to critically analyze the underlying tensions. Ultimately, it advocates for a balanced IP framework that reconciles the need for pharmaceutical innovation with the universal right to health, proposing targeted reforms such as strengthened TRIPS flexibilities for emergencies, multilateral technology transfer mechanisms, and investments in manufacturing capacities in LMICs to ensure equitable access to life-saving technologies worldwide.

Introduction

Pharmaceutical patents, governed by the WTO's TRIPS Agreement (1994), grant innovators temporary monopolies to recover research and development (R&D) costs—averaging $2.6 billion per drug—while promoting innovation through public disclosure.[290] However, these monopolies often limit access to life-saving medicines in low- and middle-income countries (LMICs), where manufacturing capacity and affordability are constrained.[291]

[290] DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics, 47, 20–33.

[291] World Health Organization. (2020). Access to Medicines: Barriers and Opportunities. Geneva: WHO.

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The COVID-19 pandemic underscored this tension: patents accelerated vaccine development through $100 billion in private investment, yet high-income countries secured 70% of global supplies by mid-2021, exacerbating inequities.

In October 2020, India and South Africa proposed a temporary TRIPS waiver for COVID19-related technologies to enhance production and access.[292] This proposal sparked contentious WTO negotiations, dividing LMICs and health advocates, who prioritized equity, from developed nations and pharmaceutical firms, who emphasized non-IP barriers like supply chains and regulatory hurdles. The 2022 WTO Ministerial Decision offered limited flexibilities for vaccine patents but omitted therapeutics, diagnostics, and technology transfer, leaving significant gaps. As of August 2025, efforts to extend these flexibilities remain stalled, underscoring the need for systemic reform.

This article examines the legal frameworks, judicial precedents, and case studies shaping pharmaceutical patent battles, focusing on the COVID-19 waiver debates. It explores historical parallels, ethical considerations, and proposes reforms to align IP with global health equity, offering insights into future pandemics.

Pharmaceutical Patents: Legal Framework

Global Standards: The TRIPS Agreement

The TRIPS Agreement mandates patents for all technological inventions (Article 27) with a 20-year term (Article 33), ensuring R&D recovery but creating access barriers in LMICs. Public health safeguards include compulsory licensing (Article 31), allowing third-party use without patent holder consent, subject to conditions like prior negotiation (waivable in emergencies) and remuneration.[293] The 2001 Doha Declaration affirmed members' rights to prioritize health, enabling flexible compulsory licensing and parallel importation (Article 6). The 2003 Article 31bis amendment facilitated imports for LMICs without manufacturing capacity, though its procedural complexity—requiring dual licensing and export notifications—has limited its use, with only Rwanda utilizing it by 2025.[294]

National Implementations

India's Patents Act, 1970 (amended 2005), is a global model for balancing IP and health. Section 3(d) restricts patents on new forms of known substances without enhanced efficacy, curbing "evergreening" practices that extend monopolies. Sections 84 and 92 allow compulsory licensing for public interest, unaffordability, or emergencies, such as pandemics. In the U.S., 28 U.S.C. S 1498 permits government use with compensation, though rarely applied to pharmaceuticals due to industry pressure.[14] In Europe, Germany's Patent Act (S 24) and the UK's Patents Act 1977 (S 55) allow compulsory licenses for public welfare, with strict procedural requirements. Brazil's Law No. 9,279/1996 similarly enables compulsory licensing for public health, used notably for efavirenz in 2007.[295]

Judicial Precedents

Judicial decisions shape IP frameworks. In Novartis AG v. Union of India (2013), India's Supreme Court upheld Section 3(d), denying a patent for Glivec (imatinib mesylate) due to insufficient efficacy, prioritizing affordable generics. Bayer v. Natco (2012) granted India's first post-TRIPS compulsory license for Nexavar (sorafenib), reducing prices from $5,500 to $175 monthly. In Europe, Italy's 2005 compulsory licensing against Merck for antibiotics addressed market dominance, setting a public health precedent. In the U.S., eBay Inc. v. MercExchange (2006) limited automatic injunctions, facilitating access by prioritizing monetary remedies. Roche v. Cipla (India, 2017)

[292] World Trade Organization. (2020). Proposal for a TRIPS Waiver (IP/C/W/669).

[293] Ibid., Article 31.

[294] World Trade Organization. (2003). Implementation of Paragraph 6 of the Doha Declaration (WT/L/540); South Centre. (2023). Analysis of Article 31bis Usage.

[295] Brazilian Industrial Property Law, No. 9,279/1996.

settled erlotinib disputes, balancing IP enforcement with generic competition.

The COVID-19 Vaccine Waiver Debate

Proposal and Rationale

In October 2020, India and South Africa proposed waiving TRIPS provisions on patents, copyrights, and trade secrets for COVID-19 technologies, as LMICs received only 14% of vaccine doses by mid-2021. Supported by over 100 countries, NGOs, and the WHO, the proposal aimed to enhance technology transfer and reduce costs. Opponents, including the U.S., EU, and pharmaceutical firms, argued that supply chain bottlenecks, raw material shortages, and regulatory complexities—not patents—were primary barriers, warning waivers could deter $100 billion in R&D investment.

WTO Negotiations and Outcome

After two years, the 2022 Ministerial Decision relaxed Article 31(f) export restrictions for vaccines in eligible countries, allowing imports without domestic manufacturing requirements. However, it excluded therapeutics and diagnostics, required remuneration, and omitted technology transfer, drawing criticism for its limited scope. By August 2025, proposals to extend the decision to therapeutics remain stalled at the WTO's 13th Ministerial Conference, reflecting geopolitical divides. Critics argue the decision's procedural complexity mirrors Article 31bis limitations, failing to address systemic inequities.

Ethical and Economic Dimensions

The waiver debate reflects ethical tensions between health as a human right (Universal Declaration of Human Rights, Article 25; ICESCR, Article 12) and innovation incentives. Economically, waivers could lower vaccine prices (ranging from $2 to $40 per dose in 2020–2022), but opponents highlight risks to the $1.4 trillion pharmaceutical market's R&D investment. Alternative models, such as advance market commitments or prize funds, could decouple innovation from monopolistic pricing, as seen in GAVI's pneumococcal vaccine program.

Case Studies in COVID-19 Vaccine Patents

Moderna's Patent Strategy

Moderna's 2020 pledge not to enforce COVID-19 patents was reversed by 2022 assertions over its mRNA platform.[296] In 2025, the UK Court of Appeal upheld Moderna's EP'949 patent, finding Pfizer/BioNTech's Comirnaty infringing, while U.S. PTAB proceedings invalidated related claims, limiting technology transfer in LMICs.[297] These disputes highlight mRNA patent thickets, complicating generic production.[298]

Pfizer–BioNTech vs. CureVac/GSK

Litigation over mRNA sequences and lipid nanoparticle (LNP) delivery systems culminated in a 2025 settlement, enabling cross-licensing but underscoring patent thickets.

Overlapping patents on vaccine components delay generic entry, particularly in LMICs.

AstraZeneca–Serum Institute Partnership

AstraZeneca's voluntary licensing to India's Serum Institute delivered over 1 billion Covishield doses to LMICs by 2023, a scalable access model. Its exclusivity, however, limited broader technology diffusion.

Arbutus vs. Moderna

Arbutus's 2025 lawsuits against Moderna over LNP technology, pending in the U.S., UK, and Germany, could delay mRNA vaccine access in LMICs lacking LNP expertise.

Johnson & Johnson's Licensing Efforts

Johnson & Johnson's single-dose vaccine licensing to manufacturers like Aspen Pharmacare in South Africa increased LMIC supply, though limited by production capacity constraints. This highlights the need for broader technology transfer.

[296] Moderna, Inc. (2020). Statement on Intellectual Property During COVID-19.
[297] Moderna v. Pfizer/BioNTech, [2025] EWCA Civ 184 (UK); USPTO PTAB, IPR2023-00123.
[298] Knowledge Ecology International. (2023). Moderna's Patent Strategy Analysis.

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Impact on Access to Medicines

Global vaccine inequity was stark: high-income countries secured 70% of doses via advance purchase agreements, while COVAX delivered only 1 billion doses by 2023, hampered by funding and export restrictions. The Medicines Patent Pool (MPP) facilitated therapeutics access (e.g., Paxlovid) but had limited vaccine impact due to patent holder reluctance. mRNA vaccine production requires specialized facilities and know-how, underscoring technology transfer as a critical bottleneck. South Africa's mRNA hub, established in 2021, struggled to produce viable vaccines by 2025 due to limited technical assistance. Regional disparities in manufacturing capacity—concentrated in North America, Europe, and parts of Asia—further exacerbate access gaps.

Beyond COVID-19: Historical Patent Battles

The COVID-19 debates echo prior IP conflicts. During the HIV/AIDS crisis, South Africa's 2001 case against 39 pharmaceutical firms over antiretroviral pricing led to dropped lawsuits and generic production, catalyzed by global advocacy. Egypt's 2014 compulsory license for Sovaldi (sofosbuvir) reduced Hepatitis C treatment costs by 90%, enabling millions to access care. India's Bayer v. Natco (2012) slashed Nexavar prices, setting a precedent for affordability. In the U.S., eBay Inc. v. MercExchange (2006) curbed automatic injunctions, facilitating access. Roche v. Cipla (India, 2017) settled erlotinib disputes, balancing IP with generic competition. Brazil's 2007 compulsory license for efavirenz reduced HIV treatment costs, demonstrating TRIPS flexibilities. These cases illustrate how legal and policy interventions can prioritize public health.

Balancing Innovation and Public Health

Patents drive pharmaceutical R&D, with $2.6 billion average drug costs, but critics argue public health emergencies justify alternatives. Prize funds, advance market commitments, and public-private partnerships, like GAVI's pneumococcal vaccine model, decouple innovation from monopolies. Compulsory licensing, under TRIPS Article 31, is underutilized in high-income countries due to industry lobbying, as seen in Canada's 2005 Tamiflu licensing backlash. A proposed comprehensive compulsory licensing system (CCLS) could standardize remuneration, balancing access and innovation. Public R&D funding, such as the U.S. NIH's $30 billion for COVID-19 vaccines, should mandate open licensing to ensure equitable outcomes.

Future of Global IP Policy

The COVID-19 experience spurred reform proposals. A 2025 WHO pandemic treaty aims to coordinate technology sharing and clarify IP obligations during crises.[299] Proposed TRIPS reforms include explicit compulsory licensing triggers and a streamlined waiver mechanism for emergencies.[300] Transparency in patent landscapes and aligning public R&D funding with open-access conditions are critical. Building LMIC manufacturing capacity, such as Africa's mRNA hubs, requires sustained investment and regulatory harmonization. Regional initiatives, like the African Union's Pharmaceutical Manufacturing Plan, aim to localize production, reducing reliance on global supply chains. International cooperation, including patent pooling and open science platforms, could further enhance access.[301]

Conclusion

The COVID-19 pandemic revealed patents' dual role: driving innovation while exacerbating inequities. The 2022 WTO Decision's limited scope underscores the need for robust TRIPS flexibility, initiative-taking technology transfer, and LMIC capacity-building. Judicial precedents like Novartis and Bayer v. Natco, alongside voluntary models like AstraZeneca's Serum Institute partnership, offer solutions. A multifaceted approach— integrating compulsory licensing, collaborative licensing,

[299] World Health Organization. (2025). Draft Pandemic Treaty Framework.
[300] South Centre. (2024). Proposed TRIPS Amendments for Pandemics.
[301] World Intellectual Property Organization. (2024). Patent Pooling for Global Health.

multilateral treaties, and regional manufacturing initiatives—is essential to align IP with the universal right to health, ensuring preparedness for future pandemics.

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