ACCESS TO MEDICINES AND CORPORATE PATENT STRATEGIES: TRIPS FLEXIBILITIES AND THE RIGHT TO HEALTH IN THE POST-COVID ERA

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ABSTRACT

The COVID-19 pandemic has exemplified how tensions exist between pharmaceutical patent monopoly, business interests, and the right of humans to health. This paper discusses the interaction of corporate patent practices, such as ever greening, patent thickets, the delay of technology transfer and restrictive licensing with the TRIPS flexibilities and the obligations of States under the International Covenant on Economic, Social and Cultural Rights (ICESCR). Based on the 2001 Doha Declaration, the 2022 WTO Ministerial Decision, the compulsory-licensing practice of 2001-2024, and post-pandemic projects like the WHO Health Technology Access Programme and the mRNA Technology Transfer Programme, the paper states that legal flexibilities are needed yet inadequate by themselves. COVID-19 proved that familiarity, regulatory ability, production infrastructure, and political-economic limits can be more critical than patent position. To enhance readiness to future health emergencies, the paper advocates increased domestic utilization of TRIPS flexibilities, human-rights-compatible corporate due diligence, and structural technology-sharing systems.

Keywords: TRIPS flexibilities; compulsory licensing; right to health; access to medicines; patent evergreening; COVID-19; Doha Declaration; corporate human rights due diligence

1. Introduction

The right to access vital medicines is not only a public-health target but also a recognized part of the right to health. ICESCR article 12 obliges States to make efforts to prevent, treat and suppress disease and to guarantee medical care in cases of disease (United Nations, 1966). The Committee on Economic, Social and Cultural rights (CESCR) understands this obligation to be the need to have medicines as a necessary measure that the medicines must be available, accessible, acceptable and of the right quality, with WHO-identified essential medicines being a fundamental requirement (CESCR, 2000, paras 12, 43). Human rights in regard to intellectual creations are also emphasized by General Comment No. 17 as opposed to statutory intellectual property and encourages States to eliminate undue prices of medicines at the expense of Covenant rights (CESCR, 2001; CESCR, 2006, para.). 35).

Patents are the most important protection method by which the pharmaceutical companies based on research recover expenditures on research and development and enjoy exclusive rights in the market. Ever since TRIPS came into force in the year 1995, WTO Members have been under obligation to grant patents to pharmaceutical products, the legal standing in most of the developing nations is altered (WTO, 1994). The conflict between patent rights and public-health interests came into the limelight specifically during the crisis in HIV/AIDS and this was dealt with in the Doha Declaration on TRIPS and Public Health (WTO, 2001).

The COVID-19 challenged this balance all over the world. Despite a rapid development of vaccines and therapeutics, there was an unequal distribution of them as high-income countries received priority in purchasing them and many LMICs delayed receiving them. A temporary TRIPS waiver was proposed by India and South Africa to include patents, trade secrets, copyright and industrial designs. WTO Members resolved to a more limited 2022 Ministerial Decision on COVID-19 vaccine patents with no effort to expand to diagnostics and therapeutics after multiple attempts (WTO, 2022).

Respectively, this paper will explore corporate patent practices such as evergreening, patent thickets and restrictive licensing, as well as, the TRIPS flexibilities and the right to health. It takes into account their interaction pre- and during COVID-19 and considers new human-rights and technology-sharing systems. The discussion is doctrinal and policy-based, relying on treaties, WTO judgments, UN documents, national legislation, reported instances, official reports and scholarly research, such as Dunn et al. (2026) on 199 instances of TRIPS

flexibilities between 2001 and 2024. The paper does not dismiss the innovativeness role of patents; instead, it questions the suitability of existing patent systems and incomplete flexibilities to human-rights duties in the post-COVID era.

2. Conceptual and Legal Framework

2.1 The right to health and access to medicines

General Comment No. 14 considers essential medicines as defined in the Action Programme on Essential Drugs of the WHO a fundamental requirement of the right to health (CESCR, 2000, para. 12(a) and para. 43(d)). General comment No. 17 upholds that intellectual property should not hinder the efforts to fulfill the core covenant requirements such as rights to health and to the fruits of scientific progress pursued under Articles 15 (1) (b) (CESCR, 2006). The General Comment No. 24 commits those responsibilities to the regulation of business practices (CESCR, 2017). The Human Rights Council has also made a claim that global IP, trade and investment models must be linked against the need to provide effective access to medicines, vaccines and other health products, and that companies are not to request the reduction of TRIPS flexibilities (UNHRC, 2025, para 6162). The same principle has been given the reality treatment in the domestic constitutional jurisprudence: in Minister of Health v Treatment Action Campaign the Constitutional Court of South Africa has imposed consistent reading on section 27 of the Constitution when it read, with the right to health, that the State should extend the nevirapine programmes in alleviating mother-to-child transmission of HIV (Minister of Health v TAC (2002) 5 SA 721 (CC)).

At two points, corporate law comes into play. First, the directors of listed pharmaceutical companies are often obliged to advance the best of the company towards the best interest of shareholders, whereby statutory or common-law obligation may impose on such directors the obligation to put into consideration long-term effects and interest of the stakeholders. Second, the UN Guiding Principles on the Business and Human Rights (UNGPs) make it a duty of any business enterprise to ensure that they consider the human rights, including through due diligence on possible and factual negative effects that their operations and business association may cause (United Nations, 2011). Patent prosecution, refusals at licensing, evergreening and against generic manufacturers are thus not simply commercial decisions, but aspects of their actions that can be process by human-rights account whereby they knowingly effectively block access to life-saving products.

2.2 TRIPS, Doha and the architecture of flexibilities

TRIPS sets minimum standards in the protection of pharmaceutical patents. Article 27 entails the granting of patents on products and processes in any technology, but Articles 28 and 33 grant exclusive rights at least 20 years after date of application. Nonetheless, flexibilities can also be found in TRIPS. Article 8 authorises action needed to safeguard the health of the population, Article 30 authorises certain exceptions, Article 31 permits compulsory licensing and state utilization with conditions, such as fair compensation. WTO article 31bis, which becomes effective in 2017, also allows export under compulsory licences to a country that does not produce enough of the good. Article 6 and Article 73 delegate exhaustion and parallel importation to the national law and offer security exceptions, respectively. In least-developed countries, the transit period of pharmaceuticals will take up to 1 January 2033 (WTO, 2015).

Doha declaration further ascertained that TRIPS must underpin the right of the members to safeguard their health and to enhance the provision of medicines (WTO, 2001). It validated the rights of members to give compulsory licences establish their reason and set exhaustion regimes. All these principles were a response to the issues that began to arise during the controversy of HIV/AIDS, such as the lawsuit involving the Medicines Act in South Africa, which was resolved in 2001. Later the WHO suggested increased utilization of TRIPS flexibilities to assist in the support of the population health and medicine access (WHO, 2006).

2.3 Corporate patent strategy as a legal and commercial phenomenon

A patent is a right of exclusion and not a duty to supply or licence on reasonable terms. Internet corporate patent strategy takes advantage of that. Companies patent primary compounds and then create a nimbus of secondary patents around them such as on formulations, salts, polymorphs, use routes, dosage studies, combinations and delivery systems. They include patents in regulatory registries (like the US Orange Book), automatically stay against generic applicants, litigate on conditions that delay entry, and, following an entry, obtain a product-hopping patients onto follow-on versions just before exclusivity disappears (I-MAK, n.d.; Commonwealth Fund, 2025). The undisclosed manufacturing know-how of biologics and mRNA platforms enhances the effect of exclusion in addition to trade secrets and regulatory data packages that cannot be transferred by the mandatory license of the patent alone. The issue of law to be dealt with is not whether such practices are formally sanctioned by the patent laws - much of this is - but whether such practices in addition to pricing practices that put the

products out of reach of the health systems are congruent with the right to health and with the public-health object and purpose of TRIPS.

3. Corporate Patent Strategies and Barriers to Access

3.1 Evergreening, thickets and product hopping

High-revenue drugs have been empirically studied, and it demonstrates extensive secondary patenting. A study of top small-molecule and biologic products in the United States also finds that many products have many patents, many of which are added after faced with regulatory writers and cover minor changes of limited clinical importance (Commonwealth Fund, 2025; Frakes and Wasserman, 2025). Humira (adalimumab) exemplifies this trend whereby a large patent base hinders the introduction of biosimilar competition in the United States even though it was introduced first in Europe. The same approach has been observed with both semaglutide, oncology drugs and combination inhalers in which device and combination patents provide the ability to prolong the exclusivity of the market (I-MAK, n.d.).

A significant protection against such evergreening is offered in India under section 3(d) of the 1970 Patents Act, which has been amended in 2005. It does not permit the patentability of new forms of already known substances that fail to show an improved activity. In Novartis AG v Union of India (2013) 6 SCC 1, medicinal efficacy was construed as therapeutic efficacy and such claims on the effect of imatinib mesylate (Novartis) were denied on the basis of excellent physical attributes (para 180–190). Secondary patents like bedaquinil have also been challenged with the aid of section 25(1) pre-grant opposition (MSF, 2023). Despite these measures not being TRIPS-inconsistent, the TRIPS-plus trade arrangements and the historical objections to the Patent Rules 2024 make the dismantling of protections on evergreening worrisome (Shukla and Jakhar, 2026).

3.2 Licensing design, know-how and the COVID experience

The bottleneck that mattered decisively during COVID-19 was often not the presence of a patent in an LMIC but the lack of licensed know-how, lipid nanoparticle technology, fill-and-finish capacity and qualified regulatory pathways. Originator companies ended many voluntary licences and contract-manufacturing deals especially around viral-vector vaccines as well as small-molecule antivirals. In the case of nirmatrelvir/ritonavir (Paxlovid), Pfizer negotiated a

licence with Medicines Patient Pool (MPP) (95-country coverage) and molnupiravir with MSD (106-country coverage) negotiated a licence. Synthetic political-economy research demonstrates that the licences excluded a significant number of upper-middle-income countries, which made up a significant proportion of diagnosed infections (Gleeson and others, 2023). Econometric studies of previous MPP licences reveal the presence of a patent in the pool increases the likelihood of licensing in covered LMICs which proves that it is institutional design and not just corporate goodwill that can drive access (Galasso and Schankerman, 2024). No such technology as mRNA platform was put in any such non exclusive pool.

The WHO COVID-19 Technology Access Pool (C-TAP) was created specifically to accept voluntary, non-exclusive licences of intellectual property, data and know-how. The adoption rates of mRNA vaccinations by their creators were very low. Such rejection is legally allowed by normal patent and trade-secret law. It is harder to live with what the UNGPs posit once it is conceded that companies that have enjoyed government handouts, strings of purchase commitments and special emergency regulatory approaches had a duty to evade causing predictable access failures in those nations that could not afford monopoly prices. The second inclusion of C-TAP in the Health Technology Access Programme (HTAP) and the diversification of the WHO/MPP mRNA Technology Transfer Programme that, by 2025, features a South African hub and 14 more manufacturing partners in six WHO regions is an organizational acknowledgment that patent waivers in the absence of know-how are not realizations of supply (WHO, 2025; WHO, 2026).

3.3 Pricing, market segmentation and corporate law incentives

Access can be increased through the use of differential prices and voluntary licensing without killing the patent. They are however discretionary. In the context of an upper-middle-income market where the reputational or political cost of not licensing is less than the expected returns, the behaviour of companies who withhold licences rationally. Those directors who approved such refusals may defend that they fulfilled shareholder-value obligations. A reading of corporate obligation that is consistent with human rights would consider endemically inaccessible unavailability of a special life-saving product in a high-burden context as a negative human-rights effect that must be mitigated - such as by offering non-exclusive licenses in conditions of public health or joining technology pools, or accepting compulsory licences without retaliatory litigation or trade pressure. There are very few municipal systems of

company-law which hard-wire that standard. Soft-law tools and codes of investor stewardship are starting to do so, although there remains a long distance between the rhetoric of human-rights and the practice of patent-portfolio.

4. TRIPS Flexibilities in Practice: Before and After COVID-19

4.1 The empirical record, 2001–2024

In 2026, BMJ Global Health published a peer-reviewed synthesis of reported TRIPS flexibilities since 2001 for 199 uses, comprising 149 compulsory licences or government-use authorisations, and 46 uses of the LDC pharmaceutical transition (Dunn et al., 2026). Use is not restricted by communicable diseases and high-income countries are increasingly looking at licensing of expensive oncology and rare-disease drugs.

There are a number of examples that testify to their usefulness. The Brazilian government-use licence of efavirenz in 2007 with good news was reported to have lowered the cost by approximately 75 percent and bolstered subsequent anti-retroviral negotiations. Natco Pharma Ltd v Bayer Corporation (2012) in which the grant of a compulsory licence occurred with respect to sorafenib (Nexavar) under section 84 of the Patents Act 1970 was the first instance of compulsory licence granted in India. The Controller did not create a system that addressed the needs of the populace, medicine was unaffordable, and the patent had not been sufficiently exploited in India. Bayer treatment monthly cost was around INR 280,000 when compared to INR 8,800 of Natco. Government-use licensing of a number of medicines was also implemented in Thailand, and in 2024 Colombia became the first country to issue a compulsory licence of dolutegravir.

These examples demonstrate that viable mandatory-licensing authority can enhance price bargains. Their success, however, is very much dependent on manufacturing capacity. Article 31bis, which was introduced to streamline exports when local output is unavailable, has not been utilised frequently due to the complicated notification, anti-diversion and labelling conditions.

4.2 COVID-19: flexibilities invoked, flexibilities unused

The remdesivir and other COVID-19 candidates were also amended by several States as emergency legislation or given government-use permissions (including Israel, Hungary, the

Russian Federation and Bolivia) (Pritchett, Kersten and Sharma, 2026; Dunn et al., 2026). During the 2021 COVID-19 wave, both Natco Pharma and Bajaj Healthcare applied compulsory licences under section 92 of the Patients Act 1970 to baricitinib in India. None was given a licence, the government retaining to voluntary licence, price and supply controls, and local production. None of the large mRNA vaccines obtained an LMIC market by mandatory licensing. This led to a further shift in focus to the TRIPS waiver suggested by India and South Africa in October 2020 (WTO, 2020).

The WTO Ministerial Decision of 17 June 2022 allowed eligible Members to suspend Article 28 rights regarding COVID-19 vaccination manufacturing without consent and waived the Article 31(f) domestic-supply exception to exports to eligible Members (WTO, 2022). It, however, omitted trade secrets, regulatory data, copyright, therapeutics and diagnostics and retained remuneration/notification requirements. Its adoption has already led to more supply of vaccines and reduced demand. In a 2026 CSIS survey, there was no evident impact of mandatory licensing or the Decision on vaccine availability (Pritchett, Kersten and Sharma, 2026). This implies that early technology sharing or more powerful incentives over manufacturing capacity cannot be substituted with narrow, late-stage legal actions.

4.3 Why the classic toolkit under-performed

The gap between legal possibility and practical result is attributed to three structural reasons. First, both mRNA and monoclonal-antibody production are process-based. Validated assays and supplier qualifications or batch-release know-how will not be provided by a licence to practise a patent. Second, the broad waiver was perceived as an existential challenge to the innovation paradigm by originators and certain high-income governments and made a major investment in resisting it, a duration of two years that lasted longer than the acute shortage itself. Third, a large number of LMICs did not have fill-and-finish lines, cold-chain logistics and National Regulatory Authority capacity even in places where legal freedom to operate may have been obtained. The first legal barrier is tackled by TRIPS flexibilities. Sans capitalism industriale et regulatory, they make a factory.

The proper conclusion is thus two-fold. Still it should maintain flexibilities, abridge them and exercise them earlier; and they need to be accompanied with standing mechanisms that will transfer tacit knowledge previous to the second wave of the pathogen. Presenting the small 2022 Decision as evidence that IP was never the problem reiterates the mistake of presenting

it as evidence that IP was the sole problem.

5. Human Rights, Corporate Obligations and Post-COVID Governance

5.1 Aligning interpretation

Doha paragraph 4 and by Article 8 already permit a human-rights-consistent interpretation of TRIPS. It imposes on domestic patent offices and courts the use of patentability standards and exceptions and grounds of compulsory-licensing considering accessibility of medicines, not merely considering commercial working. It also asks high-income States to stay off trade negotiations, investment treaties or diplomatic pressure in chilling legitimate use of flexibilities by others, a pattern recorded in subsequent TRIPS-plus chapters of regional trade pacts. According to the report on access to medicines, vaccines and other health products published by the Human Rights Council in 2025, the international IP, trade and investment systems are to be viewed in the light of the duty of the States to guarantee their effective availability, and that business organizations should not strive to neutralize flexibilities (UNHRC, 2025, paras 60–62, 72).

5.2 From C-TAP to HTAP and the mRNA hubs

The post-COVID-19 institutional learning was not revolutionary, but incremental. In 2024, replacing C-TAP, HTAP plans to organize end-to-end support of diversified manufacturing of priority technologies in LMICs and fully incorporates the mRNA Technology Transfer Programme (WHO, 2024; WHO, 2026). As of May 2025 the programme identified a South African hub and 14 other manufacturing partners in 6 WHO regions; first transfers to Biovac and other manufacturers had been made; and consortia had been formed to focus R&D on beyond SARS-CoV-2 on region-specific issues like dengue, influenza and other epidemic-prone diseases. These are major capacity-building measures. They continue to rely on ongoing donor funding, on the goodwill on the part of originators to license complimentary proprietary inputs, on national procurement that can keep plants in operation between emergencies. Technology-transfer hubs are likely to turn into orphans without a demand signal.

5.3 The Pandemic Agreement and unfinished business

Article 11 of the WHO Pandemic Agreement, adopted by the Seventy-eighth World Health Assembly on 20 May 2025 addresses technology transfer in article 11 and publicly funded

R&D in article 9. Article 11 obliges Parties to facilitate technology and know-how transfer regarding pandemic-related health products in a mutually agreed manner, leaving current rights and obligations under international agreements, such as flexibilities of the TRIPS (WHO, 2025a; Medicines Law and Policy, 2025). Pathogen access and benefit-sharing (PABS) had been left to a legally binding annex, and after the deadline of May 2026 was missed, negotiations were ongoing (Moon, 2026). The post-COVID framework is still relying on voluntary licensing and TRIPS flexibilities, until these provisions are finalised and the Agreement enters into force after 60 ratifications. Timely non-exclusive licensing of publicly funded pandemic technologies would be a prerequisite of public funding and emergency-use authorisation and not just a voluntary exercise of corporate cooperation.

6. Recommendations and Conclusion

The changing relationship between IPR framework and corporate responsibility is simple to say. Patents are a valid means of supporting privately funded innovation. They are not a licence to package global supply in such a way that poorest health systems end up with the least at best. The flexibilities of TRIPS, which were restated at Doha and slightly modified in 2022, give States the legal room to remedy that fate. The human-rights law provides a rationale why they ought to employ that space, and the UNGPs provide the criteria by which corporate patent strategy ought to be measured.

This analysis gives the following recommendations.

1. There should be complete domestic law integration of Doha-consistent flexibilities: vigorous patentability protected against evergreening (including efficacy-type filtering), simplified compulsory licensing and government use in response to public-health emergencies, international exhaustion, and Bolar-type regulatory review exemptions. The pre-grant opposition and working requirements need to be safeguarded against procedural dilution.

2. TRIPS-plus patent-term extensions, patent linkage and data-exclusivity requirements, which hobble the policy space of LMICs, should not be extended by High-income States, and should not threaten trade sanctions where partners make lawful compulsory licences.

3. Public funders and regulators must impose enforceable terms of access to grants, advance purchase agreements and emergency permits, such as requiring the offer on transparent terms during declared public-health emergencies of international interest of non-exclusive licences of patents and know-how to WHO-coordinated pools or manufacturers in the region.

4. Boards of pharmaceutical corporations must categorize access failures to unique essential products as human-rights risks in UNGP due diligence, report on licensing coverage by income band, and refrain from secondary-patent strategies whose main aim is to delay such entry by generic or biosimilar products instead of making clinically meaningful innovation.

5. A renewed TRIPS implementation review needs to simplify Article 31bis, make it clear that pandemics should be defined as an emergency without further political bargaining and that standing and time-limited waiver language should be used in the future to address PHEICs, and not on a blank slate as in 2020.

The patent system was not overturned or even justified by COVID-19. It demonstrated that exclusive rights and a voluntary good will be too slow when a pathogen travels at a pace exceeding a Ministerial Conference. The abolition of pharmaceutical patents is not a condition to the right to health. It entails that corporate patent policy and the global regulations that protect it are subordinate to that goal that Doha named already: access to medicines to all.

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