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Patent Rights, Pandemic Equity and the Limits of the WTO COVID-19 Vaccine Decision

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Abstract

The World Trade Organization did not adopt the broad intellectual-property suspension proposed by India and South Africa during COVID-19. Its 17 June 2022 decision instead created a narrower, time-limited route for eligible developing members to authorise use of patented subject matter needed to manufacture and supply COVID-19 vaccines. This article asks whether that response adequately reconciled exclusive intellectual-property rights with equitable access to essential medical technology. Using doctrinal analysis of the TRIPS Agreement, the Doha Declaration, the 2022 Ministerial Decision and subsequent WTO discussions, it distinguishes patents from undisclosed manufacturing knowledge, evaluates the competing innovation and access arguments, and considers the practical conditions for technology transfer. It argues that patent flexibility can remove one legal barrier but is neither a complete waiver nor a substitute for manufacturing capacity, regulatory competence and know-how sharing. The failure to agree an extension to diagnostics and therapeutics by February 2024 illustrates the limited political consensus behind pandemic exceptions. A more credible future model combines clearly usable compulsory-licensing powers, transparent public-funding conditions, voluntary and publicly facilitated technology transfer, and enforceable safeguards for quality and equitable allocation.

Keywords: TRIPS Agreement; COVID-19 vaccines; compulsory licensing; public health; technology transfer; India; South Africa; WTO; pharmaceutical patents.

I. Introduction: what did the WTO actually change?

The most consequential result of the COVID-19 intellectual-property debate was a limited relaxation of certain patent-licensing conditions, not the abolition of vaccine patents. This matters because a government can authorise production despite a patent and still lack the technical instructions, specialised inputs and regulatory authorisations needed to manufacture a safe vaccine. The legal intervention and the industrial problem were connected, but they were not the same. [1]

The original 2020 proposal from India and South Africa responded to unequal access to pandemic medical products. It sought relief concerning several categories of intellectual-property obligations for prevention, containment and treatment. The final 2022 outcome was materially narrower. Any assessment which treats the proposal, the March 2022 negotiating reports and the adopted June decision as interchangeable will misstate the law. [2]

The central research question is: to what extent did the WTO's 2022 decision resolve legal obstacles to equitable vaccine access, and what complementary measures are needed when relevant capabilities are

protected by know-how rather than patents? The paper advances a qualified thesis: patent exceptions are legitimate and sometimes necessary public-health instruments, but their effectiveness depends upon an institutional system capable of translating legal permission into production and delivery.

II. Methodology, scope and literature

This is a doctrinal and comparative policy study. Its primary materials are the TRIPS Agreement, the 2001 Doha Declaration, the India–South Africa proposal, the WTO's 2022 Ministerial Decision and WTO reports on its possible extension. It also draws on the World Health Organization's account of subsequent pandemic-governance negotiations and selected scholarly commentary. The analysis concerns legal design and plausible mechanisms; it does not claim that the decision caused a quantifiable increase in vaccine doses. Establishing such causation would require facility-level production, licensing, procurement and distribution data not collected here.

Scholarly responses fall along three broad lines. One emphasises patent exclusivity, the public investment behind vaccines and the urgency of equitable diffusion. Another questions the waiver's practical value given limited manufacturing capacity and the role of voluntary licensing. A third focuses on legal incompleteness: patent permission alone does not disclose trade secrets, transfer tacit knowledge or neutralise separate investment-law risks. Kulkarni and Kaur, for example, identify the continuing relevance of undisclosed information and potential investor claims even after the 2022 outcome. This article builds on that distinction rather than assuming that every limitation on access can be traced to a patent. [3]

III. The pre-existing TRIPS framework

A. Patent exclusivity and its limits

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets minimum international standards for intellectual-property protection. Article 28 gives patentees important exclusive rights over patented products and processes. Those rights are not unlimited. Article 30 permits limited exceptions under specified conditions, while Article 31 provides for use without authorisation from the right holder subject to safeguards. Understanding these provisions avoids a false binary between complete private control and complete removal of IP rights. [4]

Compulsory licensing is often explained as a legal permission issued without the patent holder's voluntary consent. It does not mean that the invention becomes unprotected everywhere, nor does it ordinarily mean that the patentee receives nothing. Under the general Article 31 framework, specific conditions apply, including adequate remuneration under Article 31(h); Article 31(f) ordinarily requires use predominantly for the supply of the domestic market. During a pandemic these conditions can affect the feasibility of cross-border manufacturing arrangements, particularly where countries lack their own production facilities. [5]

B. Doha and the export problem

The Doha Declaration on TRIPS and Public Health affirmed that the Agreement should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and promote access to medicines for all. It expressly recognised members' freedom to determine grounds for compulsory licences and the existence of national emergencies. This was not a newly created power to disregard the treaty; it was

an authoritative political and interpretative statement about the flexibilities available within it. [6]

The export problem is straightforward. A country without a factory may need medicines manufactured under a licence in another country. Yet the latter country's ordinary compulsory licence is constrained by Article 31(f). Article 31bis, introduced through the TRIPS amendment process, establishes a special mechanism for specified pharmaceutical exports. Its procedural complexity was part of the debate about whether pandemic-specific simplification was desirable. [7]

IV. The proposal, the negotiations and the final decision

A. India and South Africa's October 2020 proposal

India and South Africa submitted IP/C/W/669 on 2 October 2020 and introduced it to the TRIPS Council later that month. The proposal covered obligations relating to copyright, industrial designs, patents and protection of undisclosed information in connection with COVID-19 prevention, containment and treatment. Its underlying contention was that reliance on ordinary licensing and case-by-case flexibility could be too slow, uneven or restrictive during a global emergency. The text was revised in May 2021; it remained a proposal, not a binding exception. [8]

That proposal was not devoid of costs. Suspending obligations concerning a wide set of rights raised questions about legal certainty, commercial incentives, breadth and implementation. But the question should not be reduced to whether patents are good or bad. The decisive issues are which rights impede which public-health activity, whether existing exemptions can be exercised in time, and whether any additional waiver actually changes supply.

B. What the June 2022 WTO decision provided

At the twelfth Ministerial Conference, members adopted WT/MIN(22)/30–WT/L/1141 on 17 June 2022. It enabled eligible developing-country members to authorise use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without right-holder consent, with specific adjustments to some Article 31 requirements. Authorisation could be effected through different domestic instruments, not solely a conventional compulsory-licence statute. The Decision also allowed an eligible member to export any proportion of vaccines produced under the authorisation to other eligible members, subject to safeguards. These were meaningful modifications to patent-use rules, but they were not a suspension of the full TRIPS intellectual-property regime. [9]

The Decision retained transparency, re-exportation and anti-diversion requirements. Remuneration remained relevant, with the humanitarian purpose of distribution programmes capable of informing its assessment. The instrument states that its provisions apply for five years from adoption, with a possible extension by the General Council. A careful legal analysis must therefore treat its operation as time-bound and avoid assuming any future extension not established by a subsequent decision. [10]

The measure was not restricted to mRNA vaccines as the original article suggested. Its legal wording concerns COVID-19 vaccines and patent subject matter required for their production and supply. The confusion appears to arise from discussion of mRNA technologies in the surrounding political debate. That debate is relevant, but it cannot replace the Decision's operative terms.

C. Diagnostics and therapeutics: an extension not agreed

Paragraph 8 contemplated a later decision on extending the instrument to the production and supply of COVID-19 diagnostics and therapeutics. Negotiations continued beyond the intended deadline. On 13 February 2024 the TRIPS Council reported that members had not reached consensus. The accurate result is therefore neither that a broader waiver automatically took effect nor that the 2022 vaccine decision had been expanded by implication. [11]

V. The case for temporary intellectual-property flexibility

The strongest access argument begins with distributive consequences. During a pandemic, delayed access can multiply illness and mortality across borders, and international trade rules may affect whether production can be diversified quickly. For countries dependent on imports, the ability to source from multiple manufacturers is a matter of resilience as well as price. The Doha Declaration supports interpreting TRIPS through this public-health lens. A government should not be forced to choose between treaty compliance and an otherwise feasible response to an emergency merely because it cannot secure a voluntary licence on acceptable terms. [12]

Public funding strengthens the political case for accessible outputs where governments substantially financed upstream science, clinical development, procurement or manufacturing. It does not follow automatically that every patented invention is legally public property. Funding sources differ across firms and stages, and contractual conditions vary. The better conclusion is institutional: when states pay for research and purchase guaranteed volumes, they can seek negotiated obligations on pricing, geographic licensing, supply transparency and technology sharing instead of relying exclusively on emergency waivers after shortages appear.

The waiver advocates also challenged the premise that market bargaining would necessarily allocate production in a globally efficient manner. Private licence terms may restrict territories or control the identity of permitted manufacturers. The legal significance of a waiver is greatest when a capable alternative producer faces a patent barrier and the right holder does not grant authorisation in time. The argument weakens where the alleged alternative producer lacks reliable inputs, equipment or technical knowledge.

VI. The case against a broad waiver—and what it gets right

The most serious objection is practical rather than rhetorical. Complex vaccines are not manufactured simply by reading a patent. Validated production processes, trained personnel, quality-control protocols, specialised ingredients and regulatory oversight are indispensable. In some circumstances, originator cooperation can accelerate scale-up far more effectively than legal permission alone. A waiver which induces no viable production risks creating political expectations that the instrument itself cannot meet.

A second objection concerns innovation incentives. Patents permit firms to expect a period of exclusivity in exchange for disclosure, and some commercial investment would be discouraged if emergency exceptions were unlimited or unforeseeable. This objection is important, but it is not absolute. TRIPS itself anticipates compulsory licensing, public-health emergencies and remuneration. The relevant policy design question is whether clear, proportionate, time-limited exceptions—particularly when accompanied by public research and advance-purchase funding—can preserve sufficient incentives while making access more equitable. [13]

Finally, critics point to regulatory protection. This concern should be separated from the scope of patent rights. A waiver of patent exclusivity does not waive quality, safety, efficacy or pharmacovigilance requirements, and no credible access policy should do so. The appropriate response is stronger regulatory cooperation and supervised technology transfer, not the assumption that a medicine becomes safe merely because production is lawful.

VII. Why patents and know-how must be separated

Patent documents disclose inventions to the level required by patent law, but commercially valuable manufacturing knowledge may remain undisclosed: process optimisation, troubleshooting, factory practices and quality-assurance routines. Some information is protected as trade secrets; some is simply tacit expertise held by engineers and technicians. A patent licence does not automatically convey either. This is the key weakness in claims that a waiver alone necessarily unlocks production. [14]

Imagine that a patent is permission to use a particular machine design. A vaccine factory also needs the operating manual, specialist training, calibrated instruments and a stable supply of materials. Removing a restriction on the design does not deliver those other resources. This analogy is imperfect—vaccines involve more complex process know-how—but it makes the legal distinction clear: exclusive rights and productive capability are analytically separate.

Effective technology transfer may require negotiated access to data, production protocols, physical inputs and technical support, alongside permission to operate under patents. A carefully constructed public-health strategy can offer incentives to originators, require appropriate conditions in publicly funded contracts, support qualified regional manufacturing hubs and make use of compulsory licences where negotiations fail. Each of those choices entails costs and institutional trade-offs.

VIII. India, comparative policy and lessons for the next emergency

India’s role in the waiver debate was that of a principal proposer and coalition builder. Its position reflected both public-health concerns and the strategic importance of diversified pharmaceutical manufacturing. Yet national production capacity does not itself resolve the legal situation of countries with smaller markets or weaker regulatory infrastructure. The policy question must include procurement relationships, technical training and the possibility that production under a licence serves several importing countries. [15]

The United States administration announced support in May 2021 for negotiations concerning a vaccine-specific waiver; this was a political negotiating position, not enactment of the original India–South Africa text. The European Union and other members questioned whether broader suspension would produce faster delivery than export facilitation, licensing and manufacturing cooperation. These differences explain the compromise but should not be converted into permanent descriptions of national policy without checking the relevant date and instrument.

A defensible future framework should operate on several levels. First, countries should maintain clear emergency compulsory-licensing procedures and test them before a crisis. Secondly, public research and procurement agreements should include carefully drafted access and technology-transfer provisions. Thirdly, regional manufacturing initiatives need credible regulatory supervision and funding. Fourthly, international institutions should collect information on the actual use of flexibilities and supply outcomes, so that effectiveness is evaluated through evidence rather than the symbolism of a waiver.

IX. From COVID-19 to pandemic preparedness

The debate did not end when COVID-19 vaccine supply expanded. In May 2025 the World Health Assembly adopted the WHO Pandemic Agreement, designed to strengthen cooperation in future emergencies. Its adoption should not be confused with immediate entry into force: the World Health Organization stated that further work on the Pathogen Access and Benefit Sharing annex and subsequent signature and ratification steps were necessary. The Agreement illustrates a broader institutional shift toward preparedness, production networks and benefit sharing. It does not retroactively turn the WTO's 2022 decision into a general IP waiver. [16]

The larger lesson is that a legal entitlement to make a health product is only one step in a chain. Access also depends on finance, knowledge, materials, regulatory approvals, pricing, procurement and timely distribution. International rules should make each link less fragile. Otherwise, countries may win a formal right that they cannot exercise in practice.

X. Conclusion

The 2022 WTO Ministerial Decision was a limited patent-flexibility compromise, not the comprehensive intellectual-property waiver originally sought in 2020. It simplified selected rules for authorised vaccine production and export while leaving considerable legal and practical constraints intact. The failure to agree an extension to diagnostics and therapeutics in 2024 further exposed divisions over the appropriate reach of emergency IP relief. Neither the claim that patent rights alone caused unequal vaccine access nor the claim that patents were irrelevant is justified by the instruments examined here.

A more coherent approach treats intellectual property as one part of pandemic governance. States should ensure that patent exceptions can be used promptly, while investing in manufacturing competence, voluntary and publicly supported know-how transfer, reliable regulation and equitable purchase arrangements. The durable legal lesson is not that rights must always yield or always prevail. It is that emergency rules should be calibrated to the actual barrier, with a clear account of what the intervention can—and cannot—accomplish.

Research declarationsFunding and sponsor involvementNo external funding. This research was independently undertaken without financial sponsorship, institutional grants, or external sponsor involvement.Competing interestsThe author is associated with The Legal Gazette, the intended publisher of this manuscript. No other financial, professional, institutional or personal competing interests are declared.Author contributionsYuvraj is the sole author and was responsible for conceptualization, research design, methodology, investigation, collection and analysis of legal materials, comparative analysis, drafting, revision, and final approval of the manuscript.Originality and related publicationsThis manuscript is based on and substantially revises my earlier legal blog article titled "Impact of IP Rights on COVID-19 Vaccine," published on 1 April 2022 on my Quora legal blog under Intellectual Property Law: https://intellectualpropertylaw.quora.com/Impact-of-IP-Rights-on-COVID-19-vaccine.

The present manuscript, titled "Patent Rights, Pandemic Equity and the Limits of the WTO COVID-19 Vaccine Decision: Reassessing the TRIPS Waiver Debate from 2020 to 2026," has been extensively restructured, revised, and updated. It incorporates subsequent WTO developments, the distinction between the 2020 waiver proposal and the 2022 Ministerial Decision, expanded doctrinal analysis, comparative perspectives, and developments in pandemic preparedness and technology transfer.

The earlier blog publication is disclosed transparently. This manuscript is submitted as a substantially revised scholarly work and is not concurrently under consideration elsewhere.Methods and legal currencyThis research adopts a doctrinal and comparative legal methodology. It examines primary legal sources, including the TRIPS Agreement, the Doha Declaration on TRIPS and Public Health, WTO proposals, ministerial decisions, and relevant institutional materials from the WTO and WHO. Secondary sources include selected academic literature and legal commentary.

The analysis focuses on international intellectual property and public health law, with particular reference to India and comparative developments in other jurisdictions. The legal position has been reviewed as of 1 November 2026. The manuscript does not claim empirical findings and does not rely on interviews, surveys, or original statistical research.LimitationsThe manuscript is limited to the legal and policy dimensions of intellectual property protection and equitable access to COVID-19 vaccines, particularly within the WTO/TRIPS framework. It does not undertake an exhaustive empirical assessment of vaccine production, pricing, procurement, distribution, or the measurable effects of the 2022 Ministerial Decision. Its comparative analysis is selective, and legal frameworks across jurisdictions are not treated as interchangeable. The conclusions are doctrinal and normative rather than based on original empirical data.Ethics and participant protectionsThis is desk-based doctrinal and comparative legal research using publicly accessible legal instruments, institutional documents, judicial and academic materials, and published sources. It does not involve human participants, interviews, surveys, personal records, identifiable private data, or animal research. Accordingly, institutional ethical approval and participant consent were not applicable.Data and materials availabilityThe research relies on publicly accessible legislation, international legal instruments, WTO and WHO documents, and published academic literature, all identified through citations and references. No original dataset was generated. Access to third-party materials remains subject to applicable copyright, licensing, and database terms.AI and writing assistanceGenerative AI tools were used for editorial assistance, language refinement, organisation, and writing support during the revision of the manuscript. The author independently reviewed and verified the manuscript, including its legal arguments, sources, citations, and conclusions, and accepts full responsibility for its accuracy, originality, integrity, and final content. AI tools are not authors of this work.

Notes

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