



THE WTO TRIPS Pandemic Waiver Proposal: Legal and Political Context

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WTO TRIPS Waivers, Local Manufacturing and
Access to COVID Vaccines

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Political and Legal Elements

- The GATT-WTO IP and pharmaceuticals debate traces back to the mid-1980s
- Ongoing TRIPS waiver negotiations at the WTO involve both a legal and a political dimension – the legal side cannot be assessed in isolation
- On the “technical” legal side, the outcome at the WTO will affect the international legal environment in a modest way
- Governments have substantial flexibility under the TRIPS Agreement to override IP rights as needed, and the context of the pandemic adds to that flexibility

Political and Legal Elements

- Politically the grant of a waiver might signal “tolerance” from the high-income country actors that may encourage governments to act
- Conversely, Pharma patent owners are concerned with signal that IP rights are an obstacle to protection of health, and potential for recurrence of scenario
- From a practical vaccine availability standpoint whether the result will be “material” is uncertain
- Although vaccines are presently the pharmaceutical product being widely deployed, treatments are likely to become a more significant option

Practical Elements

- Vaccine manufacturing in particular – depending on the underlying technology and stage of production – involves substantial lead times, particularly for “greenfield” (i.e. wholly-new) facilities
 - Bulk antigen complex and process-sensitive; “fill and finish” more readily accomplished
 - mRNA *may* hold potential for more rapid initiation, but as yet uncertain
- In-depth study of financing and other constraints on local production in Africa undertaken by multidisciplinary team
 - “Opportunities, Constraints and Critical Supports for Achieving Sustainable Local Pharmaceutical Manufacturing in Africa: With a Focus on the Role of Finance”, Final Report, 18th March 2021, available at https://nova-worldwide.com/OSF-PHP_report

Process Aspects

- A waiver of a WTO obligation may be granted pursuant to Article IX:3 & 4 of the Agreement Establishing the World Trade Organization
- A waiver of an obligation under one of the multilateral trade agreements (MTAs), including the TRIPS Agreement, is initially considered by the relevant Council, here the TRIPS Council
 - The TRIPS Council should issue a report to the General Council in any case
- The internal rules of the TRIPS Council provide that decisions are to be made by “consensus”, and failing that referred to the General Council for decision

Process Aspects

- Article IX:3 of the WTO Agreement requires that three-fourths of the Members vote in favor, but this is generally constrained by the consensus rule within the WTO
- The consensus rule is a long-standing feature of WTO institutional process that reflects the limitations of the system – unlike the United Nations, the WTO does not have a “Security Council” equivalent or the possibility of a veto other than through the consensus rule

Technical Legal Aspects

- A waiver operates at the multilateral institution level with respect to WTO Member rights and obligations
- The direct impact of a waiver would be to effectively eliminate the possibility of being found non-compliant in a WTO dispute settlement proceeding, and therefore subject to withdrawal of concessions, etc.
- A waiver does not change any national law, and IP rights are governed by national (and regional) law, save potentially in the few cases where WTO law may be “directly effective”
- Private enterprises holding patents, for example, would continue to hold them and be able to proceed in infringement actions regardless of the waiver, unless the national government suspends patent rights

Technical Legal Aspects

- Compulsory licensing statutes would continue to apply
- National trade secret law would continue to apply
 - Subject to “eminent domain”
- Regulatory constraints remain
- Governments would need to act on a country-by-country basis to give effect to a waiver



Political Dimension

- The political dimension is a question of signaling
- If a country such as the United States votes in favor of the waiver, it is presumably signaling that regardless of the steps a country takes to override IP rights it will not challenge that action at the WTO
- There is a second level dimension whether that tolerance would extend to bilateral relations, or to actions under separate trade and investment agreements



Political Dimension

- The Trump Administration took a position at the WTO firmly against the waiver
- The Biden administration is approaching the matter more “softly”, with the added element of the “progressive” side of the Democrat party favoring the waiver
- This requires the administration to engage in a political cost-benefit analysis probably with more consideration given to the domestic political side than the international dimension