

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

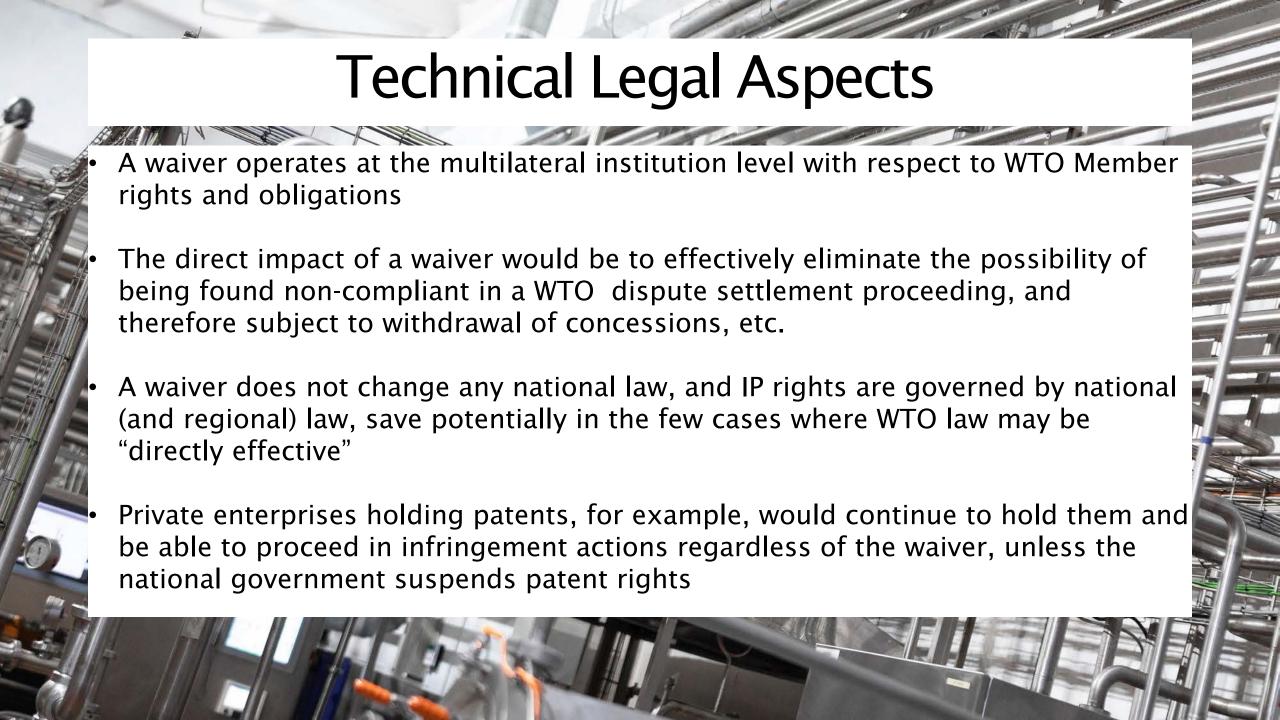
- Vaccine manufacturing in particular depending on the underlying technology and stage of production – involves substantial lead times, particularly for "greenfield" (i.e. wholly-new) facilities
 - Bulk antigen complex and process-sensitive; "fill and finish" more readily accomplished
 - mRNA may hold 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

- 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

