

Trade Rules for the Pandemic and Its Aftermath

Do Trade Rules on Intellectual Property Represent an Obstacle to Global Access to a Coronavirus Vaccine?

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General and Specific Questions

- **Question whether trade rules on intellectual property constitute a barrier to access to medicines, in general, has been widely debated, the subject of political movements, and the object of some reform**
 - **As evidenced by Canada's internal debate and legislation addressing compulsory licensing of patented medicines predominantly for export (CAMR)**
- **SARS-CoV-2 and the COVID-19 pandemic present a subset of the general IP question, usually framed in terms of diagnostics, vaccines and treatments (DVT), as well as personal protective equipment (PPE)**

Contingencies and Behavior

- **The question whether IP rules in general, and/or trade-related IP rules in particular, are problematic is to a certain extent “contingent”. The contingency is behavior.**
- **A student of history would say that IP rules have constituted a substantial barrier to access to medicines in general, and that behavior has been “suboptimal”**
- **There are certain factors in the present environment that have so far encouraged “better behavior”**

Reputational Repair

- **Having suffered reputational damage for decades, particularly because of pricing practices, the originator pharmaceutical industry has at least partly treated the pandemic as an opportunity for reputational repair**
- **Gilead, for example, in announcing the pricing for remdesivir, was acutely “tuned” to its mistakes with the pricing of sofosbuvir. The price was/is not “cheap”, but it did not “shock the conscience”**
 - **Bearing in mind that considerable US government subsidization went into remdesivir’s development**
- **Many of the COVID-19 vaccine projects have announced pricing “at cost”. This phrase is not easy to interpret in context, nor is there great transparency, but there is empathy expressed at least regarding the access side**

Production is the Current “Gate”

- **At the moment, the *core problem* on the vaccine front involves rapid ramping-up of production and distribution capacity**
 - **This is a problem-set with many facets, including finance**
- **As Jerry Reichman and have outlined in the paper that was posted - Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic* - the capacity problem was well known among experts in the area**
- **The major Pharma companies had largely exited the vaccine sector because of its “contingent” characteristics, among other reasons; in short, the business model did not work**

* Journal of International Economic Law (Oxford), Volume 23, Issue 3, pp. 535-561, Sept. 2020.

The Contingent Problem-Set

- **It was clear that the vaccines under development -- and now in production – would be and are protected by patents. That inherently gives the owners of the patents the right to exercise control over who produces the vaccines, where they are produced and how they are priced and distributed**
- **That poses a large-scale “potential” or contingent set of problems. The patent owners may decide to enter into exclusive arrangements with certain governments, and not make vaccines available more widely. They could decide against licensing the patents to other producers. Notwithstanding press releases to the contrary, they may charge prices that are in excess of their costs and that are un-affordable**

An International Patent Pool

- **As a precaution against these adverse contingencies, we propose an international patent pool in which all governments would participate, as a preference, and that the pool act as a licensing arm to producers. In our proposal, reasonable compensation would be paid to the patent owners (through their governments) based on revenues from the licensees, which in turn would vary depending on the level of development and other factors**
- **It is not our proposal that pharmaceutical originators do not receive a fair return on their investments in R&D. We are not averse to vaccine development as a profitable enterprise. Though, consideration should be given to the level of subsidy provided by governments where the products are developed. There may be mechanisms for shared compensation between the subsidizing governments and the patent owning enterprises. We lay out in our proposal and institutional framework for accomplishing his objectives. We envisage that an arrangement may be “less than global”**

TRIPS Issues and Voluntary Alternatives

- **We do not foresee such an arrangement raising problems under the TRIPS Agreement. Canada's Access to Medicines Regime presents certain useful elements of a model**
- **Because governments very typically have authority to issue government use licenses, we believe this authority and national legislation would largely suffice to permit implementation**
- **Voluntary licensing is an option, but we think the less satisfactory one because it is dependent on company-to-company decision making. We recognize that some companies have announced no-infringement action policies (e.g., Moderna), and that others are granting licenses (e.g., Astra-Zeneca). In principle, extensive programs of voluntary licensing would make our compulsory proposal unnecessary. We are not arguing for compulsory licensing for its own sake**

Historical Function of Compulsory Licensing

- **That is why I suggested that the intellectual property issue is “contingent” on “behavior”**
- **Historically a very important role of compulsory licensing has been to encourage “better behavior” by making clear that there are government-mandated alternatives**
- **Jerry and I also lay-out a proposal for regional procurement mechanisms making use of compulsory licensing as and if needed. That essentially expands upon earlier work of ours**

Situating the Solution

- **Based on history, I remain skeptical of the corporate-controlled approach currently being followed**
- **Would prefer if governments put together a technology pooling and licensing arrangement**
- **We are proposing a more-or-less conventional patent pooling arrangement, with government contributions of existing patents, and royalties flowing back to the innovators through their governments**