Chapter 14, Problem III

The global COVID epidemic that spread throughout the world during 2020 and 2021 has disrupted virtually all aspects of human existence and will impact global politics for the foreseeable future. As of August 2021, official figures show more than 205 million coronavirus cases and in excess of 4.33 million deaths worldwide, although the true figures are believed to be substantially higher. For international lawyers, the epidemic has raised important questions regarding state responsibility, the extent to which public health emergencies can justify restrictions upon human rights (discussed in the update to Chapter 7), and the effectiveness of international organizations such as the World Health Organization. It also raises several justice and distributional issues that echo those that arose in the context of the AIDs crisis.

Amidst the death and devastation of the Covid epidemic, vaccine development proved to be a bright spot. Public-private partnerships between pharmaceutical and biotech firms, on the one hand, and governments, on the other, spurred the development of powerful new vaccines in record time. By late 2020 and early 2021, vaccines developed by Moderna, Pfizer, Oxford-AstraZeneca, and Johnson & Johnson were receiving regulatory approvals in North American and Europe.

If the creation and testing of new vaccines represented a triumph of international cooperation, their distribution has been the opposite. The massive logistical challenge of vaccinating billions of people across the globe, standing alone, would pose enormous challenges. These challenges were compounded by an outbreak of "vaccine nationalism": the United States and other developed states essentially cornered the vaccine market, purchasing more vaccines than they could use. By May 2020, the WHO was reporting that ten states had purchased some 75% of available vaccines, leaving many states with little or no access to vaccines. A handful of other states, including China, India, and Russia, produced their own vaccines, often for export, but these often lacked high-quality data regarding their safety or effectiveness. One high-profile international effort, named Covax, sought to obtain a large number of vaccine doses at predetermined prices for distribution to states unable to pay for vaccines on their own. Yet by late 2021, it was clear that Covax would not likely come near meeting its initial goal of purchasing 2 billion doses by end of 2021.

As of August 2021, more than 4.25 billion doses of vaccine had been administered. However, distribution was wildly uneven; some wealthy states reported that more than 80 percent of adults had been vaccinated, while many poor states reported vaccination rates of less than 5 percent. Broken down by continent, by summer 2021, only 1.6% of all administered doses had been administered in Africa, and 6.09% of all doses had been administered in South America.

In this context, in October 2020, India and South Africa submitted a proposal to the WTO requesting a waiver of certain TRIPs intellectual property obligations, including those regarding patents, for vaccines and other products for the "prevention, containment, and treatment of COVID-19." A revised proposal clarifies the products to be covered, and seeks a three-year waiver, to be reviewed by the WTO on an ongoing basis. Roughly 100 developing states have voiced support for the waiver or similar alternatives. Other states are opposed; Germany has spoken out against any waiver, the EU has proposed an

alternative, and the U.S. supports negotiations over a narrower waiver focused on vaccines only. During the summer of 2021, negotiations began at the TRIPs Council over a waiver.

Waiver proponents, including officials from many developing states and NGOs, make a number of arguments. First, they argue that the WTO Agreements' IP provisions confer monopoly rights, permitting large drug companies to restrict supply and raise prices.[1] Second, the proponents claim that sharing the knowledge essential to producing vaccines is critical to scaling up production and will facilitate development of new vaccines targeted at emerging variants of the virus. Third, they argue that developing states possess the manufacturing capacity and expertise to produce Covid vaccines, and could do so in a matter of months. A competing view, held by some pharmaceutical firms, argues that producing Covid vaccines, particularly the high-performing mRNA vaccines, involves highly complex technological and logistical processes, and that replicating these processes in many developing states is not a feasible short-term objective. From this perspective, the argument over a TRIPs waiver is a distraction; the better strategy, according to those who resist the waiver, is to develop, presumably through a global funding scheme, a handful of high-quality production facilities on each continent. Another school, endorsed by some European states and drug companies, argues that a TRIPs waiver would harm short-term distribution efforts by sparking an uncoordinated race for critical vaccine inputs, and threaten longer-term vaccine development efforts by undermining incentives for highly specialized biotechnology firms to invest in vaccine R&D and innovation.

While debates over a potential TRIPs waiver and related issues focus on vaccine supply, few global bodies have yet focused on the distribution and administration of vaccines so that they end up in people's arms – the so-called "last mile" problem. As experience in the United States suggests, obtaining an adequate supply of vaccine does not guarantee an effective administration of vaccines, and many fear that the technical issues accompanying a global vaccine rollout would be substantial. White House press secretary Jen Psaki alluded to this problem when discussing U.S. efforts to donate 80 million does to other states: "What we found to be the biggest challenge is not actually the supply – we have plenty of doses to share with the world – but this is a herculean logistical challenge. And we've seen that as we've begun to implement."

Notes and Questions

1. What lessons, if any, does the battle over access to HIV drugs in the 1990s hold for current debates over access to Covid vaccines? How would you expect the international response to Covid vaccines to differ from the response to HIV medications?

2. Pfizer, a vaccine manufacturer, opposes a TRIPs waiver and has stated that "weakening IP rules will not solve [access] challenges nor will it get vaccines to patients any faster." What is the strongest response to this argument? Do you think that a WTO waiver is either necessary or sufficient to successfully address global vaccine supply issues? What policies might be more effective than a TRIPs waiver?

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[1] The analysis that follows draws heavily upon Michael Trebilcock & Dan Poliwoda, *The TRIPs Vaccine Waiver Controversy,* available at https://worldtradelaw.typepad.com/ielpblog/trade_and_health/

3. As of August 2021, France, Germany, Israel, and the United States had authorized a third dose of vaccine to certain vulnerable populations. The World Health Organization has noted that "[o]ffering booster doses to a large proportion of a population when many have not yet received even a first dose undermines the principle of national and global equity. Prioritizing booster doses over speed and breadth in the initial dose coverage may also damage the prospects for global mitigation of the pandemic, with severe implications for the health, social and economic well-being of people globally."

What incentives do national political leaders in wealthy states have to prioritize vaccinations to individuals in poorer states over providing a third dose of vaccine to their own citizens? Should international law address the global allocation of vaccine supply? Would soft law or hard (treaty) law be preferable in this sort of situation?

4. For additional readings on Covid and international law, see the collection of articles in *Agora: The International Legal Order and the Global Pandemic*, 114 AM J. INT'L L. 571 (2020). For perspectives from political science, see the collection of articles at 74 INT'L ORG. E1 (2020). For contrasting perspectives on the waiver question, see Bryan Mecurio, *WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review*, 62 VA. J. INT'L L. ONLINE 9 (2021); Peter J. Hotez, et al., *Producing a Vaccine Requires More Than a Patent: Intellectual Property is Just One Piece of an Elaborate Process*, available at https://www.foreignaffairs.com/articles/united-states/2021-05-10/producing-vaccine-requires-more-patent; Joseph E. Stiglitz & Lori Wallach, *Will Corporate Greed Prolong the Pandemic*, PROJECT SYNDICATE (May 6, 2021).