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Vaccine 'Apartheid' Is Galvanizing Calls to Overhaul the TRIPS Regime

Andrew Green | Tuesday, Nov. 30, 2021

By the late 1990s, an HIV diagnosis was no longer considered a death sentence in the wealthy countries of the Global North. Advances in medical technology had brought new drugs onto the market that could reverse the disease's progression. However, those life-saving drugs were priced out of the reach of most patients across the Global South, where millions of people continued to die unnecessarily.

There are echoes now of that earlier era, as those same regions are largely going without COVID-19 vaccines—even as wealthier countries move on to administer booster shots for their populations.

In response to the disparity in access to HIV medication, leaders and activists at the time focused some of their outrage on the Agreement on Trade-Related Aspects of Intellectual Property (https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm), or TRIPS. A foundational document of the World Trade Organization, the agreement—which was reached in 1994 and took effect the following year—was meant to set minimum standards for protecting intellectual property. But as critics pointed out, those rules, especially the new patent protections, were invoked to block production of more affordable generic versions of HIV drugs.

The campaign to strike a more equitable balance between intellectual property protection and access to pharmaceuticals coalesced in a WTO ministerial declaration issued 20 years ago (https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) this month. Known as the Doha Declaration, it spelled out specific flexibilities in the TRIPS Agreement that could ease access to HIV medicines, while also affirming that TRIPS “can and should be interpreted and implemented in a manner supportive of WTO members' right to protect health and, in particular, to promote access to medicines for all.”

Now, the stark disparities in access to COVID-19 vaccines have spotlighted the limitations of those hard-won concessions, including the strict barriers still in place to accessing the full range of knowledge and technology needed to produce and distribute the shots. As a result, more than 100 nations have united behind a proposal to temporarily waive protections (https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:IP/C/W669.pdf&Open=True) on COVID-related products in a bid to increase vaccine production. While



An elderly patient receives a dose of a COVID-19 vaccine at a clinic at Orange Farm, near Johannesburg, South Africa, June 3, 2021 (AP photo by Denis Farrell).

opposition from Europe has stalled the waiver proposal (https://www.huffpost.com/entry/european-union-covid-vaccine-intellectual-property-proposal_n_61664498e4b0f26084edbbff), it has also galvanized calls for a broader reconsideration of an intellectual property regime that critics say never fulfilled the promises made in Doha.

In 1997, there were an estimated 64,000 AIDS-related deaths in South Africa (<https://www.unaids.org/en/regionscountries/countries/southafrica>). That year, then-President Nelson Mandela's administration approved a law (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1119675/>) that sought pathways for affordable access to drugs, including through compulsory licenses that could bypass patents and allow for the manufacturing of generic products. At root, the law was a test of what measures, under TRIPS, a country might still be permitted to take to save its citizens' lives.

Dozens of pharmaceutical companies weighed in, lodging a formal complaint against the law in a South African court. Then-U.S. President Bill Clinton's administration simultaneously threatened harsh trade penalties (<https://www.wired.com/2000/04/u-s-to-south-africa-just-say-no/>) against Mandela's government. Both the pharmaceutical industry and the White House only backed off under unprecedented international pressure.

The U.S. government would take a different position when letters laced with anthrax began arriving on Capitol Hill and at the offices of major media outlets in the week after 9/11. Facing possible shortages of Cipro, the drug recommended for treating anthrax exposure, U.S. officials threatened to issue their own compulsory license (<https://core.ac.uk/download/pdf/51096569.pdf>) in order to boost production.

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Coming just ahead of the start of the 2001 WTO ministerial conference in Doha, Washington's hypocrisy bolstered negotiators from the Global South as they sought a guarantee (https://www.southcentre.int/wp-content/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf) that "nothing in the TRIPS Agreement shall prevent members from taking measures to protect public health."

While the resulting Doha Declaration was not quite so sweeping, it did encourage an interpretation of TRIPS that prioritized public health (<https://apps.who.int/iris/handle/10665/67345>). It also shored up specific flexibilities, including compulsory licenses, so long as the goods being produced were predominantly for the domestic market. The negotiators punted on the question of what to do when the bulk of the goods were destined for poorer countries that lacked manufacturing capacity.

An eventual compromise was officially incorporated into TRIPS in 2017 (https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf), in the form of an amendment allowing poor countries to import generic drugs under a compulsory license. However, they could only do so after going

through a bureaucratic process so onerous it can take years to complete—time that patients in a medical emergency can scarcely afford.

Doha produced other limitations, which the COVID-19 crisis has brought to the fore. Its supporters pressed for an interpretation of the declaration that provided an implicit guarantee to a range of information, like the clinical data needed to secure quick regulatory approval of new medicines and vaccines produced under a compulsory license. In theory, this would allow a generic manufacturer to forgo the lengthy process of recreating these trials to verify the safety of an identical product. But the declaration did not spell out a process for actually compelling data holders to share this and other technical information and trade secrets.

Twenty years after the Doha Declaration, its greatest shortcoming may be that it did not spur a shift in perspective on the global intellectual property regime in favor of greater access to life-saving innovations.

Instead, in the subsequent decades, wealthy states have tried to intimidate countries (https://dawnnet.org/wp-content/uploads/2021/06/FPV_Issue-Paper-3_An-Evaluation-of-TRIPS-Flexibilities%E2%94%ACa.pdf) from taking advantage of the flexibilities that the declaration provided. At the same time, the industry has promulgated a narrative that intellectual property protections are necessary to recoup the investments that facilitate innovation, disregarding the heavy investment of public funds (<https://www.healthaffairs.org/doi/10.1377/hblog20210512.191448/full/>) that often go into paying for advances like the COVID-19 vaccines.

The imbalance in favor of intellectual property protection is now so entrenched that even a global pandemic has not shifted the dynamic. Instead, companies that won the race to produce viable vaccines were allowed to negotiate closed-door deals for access to the limited doses they initially produced, which inevitably went primarily to wealthier nations, even as those firms held on to the know-how for producing the vaccines, sharing it only through agreements that they set.

The result has been staggering inequality: Of the 7.81 billion doses that have been administered, only 0.7 percent have gone into the arms of those in low-income countries

(<https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html>).

Against this backdrop, the gaps in the Doha Declaration loom large. While it offers clear, if arduous, pathways to breaking patents, the COVID-19 vaccines developed by Moderna and Pfizer-BioNTech utilize cutting-edge messenger RNA technology to which most production facilities do not have access. But Doha did not spell out a mechanism for compelling companies to transfer that technological knowhow or for requiring regulators to share the clinical trial data needed to jumpstart production and facilitate distribution.

To cut through these issues, the South African and Indian delegations to the WTO proposed a TRIPS waiver more than a year ago. Their proposal would waive IP rights

(<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:IP/C/W669R1.pdf&Open=True>), including protections on trade secrets, for all COVID-19 diagnostics, therapeutics and vaccines for at least three years.

In the consensus-driven WTO, European nations have held fast as the main opponents of the proposal, even after the U.S. trade representative voiced support in May for a limited waiver (<https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>). As talks drag on, leaked

documents indicate the European negotiators (<https://www.keionline.org/wp-content/uploads/EU-Oct2021-Leak-Points-Convergence.pdf>) are maintaining that the current flexibilities, including the roundly criticized 2017 amendment, are enough to redress access disparities.

Europe's intransigence has been cause for some strategic reevaluation among waiver supporters. Even as they remain committed to the proposal, they are also looking at how to secure explicit guarantees for the kinds of exceptions under the waiver they are now demanding, in order to obviate the debate that has mired the current proposal before the next emergency arrives.

They are now pointing to the Doha Declaration as a potential model for a similar agreement to explicitly address the barriers to accessing COVID-19 vaccines and treatments, while clarifying what flexibilities exist to overcome them, like involuntary technology transfers (https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3926234). At the same time, advocates say there is an opportunity to learn the lesson of Doha and win concessions now that address potential future barriers.

A more comprehensive Doha-like declaration may appear to be a tall order when even a three-year waiver cannot garner a consensus. But the ongoing disparities in access to COVID-19 vaccines are fueling outrage at a global intellectual property regime that guards innovation so strictly it will not guarantee access even amid a global pandemic. Negotiators in Doha were able to channel such indignation into a declaration that sought to correct a similar imbalance.

As they learned, though, the real test may come not in winning specific flexibilities, but in preserving any broader reorientation long enough to ensure a more equitable response to the next pandemic.

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