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Global health equity: the next waiver

Putting life science in the service of the global South requires reconstitution of the biotech model, not patent waivers

The US administration and the Europe Union support a World Health Organization (WHO) plan to empower producers in low- and middle-income countries to develop and manufacture mRNA vaccines. Corporations in the global North do not, arguing that exports from rich countries to poor ones rather than patent waivers can tackle vaccine inequities and reduce the threat from new waves of COVID infection. This narrow view of innovation harks back to dogma that may be appropriate for leveraging new technologies into the elite medical systems of rich nations but it does not work as a mechanism for global health.

When the WHO outlined its plan in April 2021, mRNA technology had just defied the expectations of many observers and become a high-profile success in helping developed nations vaccinate their way out of the pandemic. They had many desirable characteristics — high efficacy, adaptability to virus evolution and scalable manufacture, as BioNTech/Pfizer and Moderna had proved. At the same time, the international COVAX agreement was clearly failing to deliver anywhere close to the number of vaccine doses need to dampen virus spread and evolution in poorer countries. The WHO wanted drug firms in the global South to gain access to a package of mRNA technologies, to enable a local supply of mRNA vaccines and echo the success of producers in the North.

To the surprise of many, the US administration came out in favor of the WHO proposal, almost immediately declaring support for COVID-19 patent waivers. The United States, working with the European Union, South Africa and India — collectively, 'the Quad' — proposed revisions to World Trade Organization agreements as a mechanism for delivering access to the proposed technologies. By May 2022, the United States had put 11 NIH-originated technologies into the WHO COVID-19 Technology Access Pool, a move that was not received well by industry. The International Federation of Pharmaceutical Manufacturers & Associations said such patent waivers were the wrong solution, mere "political posturing." The Biotechnology Innovation Organization suggested the United States should become the global COVID vaccine manufacturing hub, exporting vaccines to poorer nations. It asked the administration to protect US companies from "coerced transfer of technology by foreign governments."

The industry's protective response is understandable in its own context. In the 'biotech model', intellectual property rights open a door to a chain of finance that escalates from seed funding through venture capital and public stock markets. Without watertight patent coverage, the argument goes, investors may become anxious that technical consolidation will not generate returns. Virtuous funding cycles stop turning and investor money evaporates from the life sciences.

However, a flaw sits at the core of the industry mantra that innovation depends on patents. The opposite is true: patents depend on innovation. The kind of time-limited monopoly that patents provide is only granted to inventors once they demonstrate utility and novelty. Innovation therefore stems not from patents but from curiosity and the search for new knowledge, a search that may or may not be driven by desires to solve a particular problem and improve how the world works.

That patents are not necessary for COVID-19 vaccine development is demonstrated by the well-publicized development of a stabilized recombinant protein vaccine, Corbevax, by Baylor College of Medicine vaccinologists Peter Hotez and Maria Elena Bottazzi in an open patent environment. Corbevax has been freely licensed to Biological E, a Hyderabad, India-based company that has already delivered around 100 million doses for distribution in India, and Hotez expects similar licenses for producers elsewhere.

Both the traditional biotech model and the model proposed by the WHO ignore the contextual discrepancies between the top and bottom halves of the planet in how things work. mRNA technology is a key feature in manufacturing vaccines as global defenses against pandemic threats, but the current costs and complex logistics involved in their production, as well as the need for an extreme cold chain, count against the current generation of products. That will change, of course. The pipeline of next-wave vaccines contains a number of mRNA products that self-amplify to reduce dosing requirement and increase productivity. Other mRNA vaccines have been tested that require only standard refrigeration, and oral or nasal vaccines would ease the dependence on healthcare services for vaccine delivery. The technical solutions will emerge, but the real challenge will be mobilizing them in a manner that provides a more complete solution to the dynamics of the current and future pandemic.

The biotech model may also prove useful as a template for constructing the pathway from initial innovation to applications that cannot be driven by capital-accumulating market forces. Entrepreneurial-minded researchers with global philanthropic aspirations need non-profit channels that run in parallel to those that have accreted over the past few decades in biotech. Those channels provide not only access to finance but also a conduit for information, for feedback about the nature of unmet medical needs from those who see those needs at first hand. The same type of information flow is desperately needed to address global health inequities. Triggered by concerns about the persistence and recurrence of COVID-19, the mechanisms that WHO and the Quad are exploring in COVID-19 may prove to be part of a more general coherent, needs-driven approach.

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