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Vaccines and IP Preparedness in the Coronavirus Outbreak

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The COVID-19 pandemic has shed renewed light on the importance of research and development (R&D) on biopharmaceutical products needed to prevent or lessen the burden posed by outbreaks of infectious diseases. Among these, the need for new vaccines has become of paramount importance. While a race to develop different types of vaccines unfolds at unusual speed, there are still significant shortcomings in the ecosystem that leads to the production and dissemination of vaccines targeting infectious diseases like COVID-19.

In the wake of the Ebola and Zika outbreaks, I wrote about the need for Intellectual Property (IP) preparedness. The concept borrows from the World Health Organization's finding of a lack of R&D preparedness in the infectious disease domain, combining it with the framework for emergency preparedness and response in the field of public health law. Lack of R&D preparedness results in part from chronic underinvestment in products targeting diseases traditionally overlooked by the larger players in biopharma. Emerging coronavirus R&D has long been on the WHO list of underfunded R&D pipelines. This is at odds with notions of public health preparedness, which prescribe a supple set of mechanisms to prevent or respond to an outbreak, including the production and deployment of vaccines as soon as needed and/or possible.

These problems have two important IP angles to them. First, because IP is still regarded as the default legal regime to incentivize innovation (even if clearly it is not the only one, and often not even the most appropriate), certain socially

valuable goods, including many types of vaccines, fail to attract desirable levels of R&D—absent a public health crisis of atrocious proportions, as exemplified by COVID-19. Second, even when a public health crisis serves as a catalyst for R&D, rules and practices affecting the licensure and commercialization of vaccines may still prevent indicated populations (or at least the poorer segments thereof) from accessing vaccines: in February, Secretary of Health and Human Services Alex Azar suggested that there can be no price controls on coronavirus vaccines because they would have chilling effects on private sector investment down the road.

Both the incentives and the pricing issues arising in the vaccine IP space during COVID-19 magnify old problems, last observed in connection with Ebola and Zika vaccine R&D. Current IP systems—which grant exclusivity regimes as a carrot for innovation—function poorly as incentives mechanisms before an outbreak occurs. Companies moved primarily by the prospective function of patents tend to concentrate R&D resources on large, permanent markets with repeat consumers—features that most vaccine markets normally lack. And when an outbreak temporarily fixes ongoing incentives problems, IP rights can still be brandished in ways that overextend market exclusivity to the detriment of vaccine affordability.

How can IP preparedness for vaccines increase ahead of the next major public health crisis? A few interesting things are happening that could provide an answer to this question. At the incentives level, the National Institutes of Health announced the formation of a public-private partnership to bolster COVID-19 R&D, including vaccine development. The first of these large-scale public-private partnerships fully dedicated to vaccine R&D on emerging infectious disease pathogens, CEPI, was created after the 2014–2016 Ebola outbreak. With regard to the licensure of IP needed for COVID-19 R&D, an unprecedented pledge was recently launched. Participating entities committed to share their IP non-exclusively and free of charge until one year after the end

of the pandemic. And, finally, from the commercialization perspective, there has been some pressure for COVID-19 vaccines resulting from ongoing R&D to be priced affordably, although the practical effects of such pressure remain to be seen.

All of this is a start. Moving forward, however, we need to get past temporary fixes and reexamine the enduring, systemic holes in IP theory and practice that got us here in the first place.

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