January 22, 2024

Submitted via email to *OGA.RSVP@hhs.gov*

Office for Global Affairs
Office of the Secretary
Department of Health and Human Services (HHS)

Re: AUTM's Written Comment Re: Implications of Access and Benefit Sharing (ABS) Commitments/Regimes and Other Proposed Commitments in the WHO Pandemic Agreement

As a non-profit association, AUTM concentrates on driving the commercialization of meaningful and transformative research from universities and other public sector research institutions. As such, we are very concerned with the latest approach taken by the World Health Organization (WHO) in their draft Pandemic Agreement that would effectively undercut intellectual property (IP) protections and innovations.

In particular, Articles 10 and 11 of the agreement commit nations to agree upon a framework that includes waivers of IP rights for public and private institutions in a misguided effort to accelerate or scale up the manufacturing of products necessary to combat a pandemic. While equitable access to life-saving treatments during a pandemic is a noble and just cause, the WHO's attack on IP protections, like the World Trade Organization's (WTO) TRIPS Waiver before it, misses the mark.

Indeed, robust protections of IP rights are not limiting equitable access to medical treatments and diagnostics. Manufacturing expertise and a well-built healthcare and transportation infrastructure are the main contributors to the bottleneck preventing access to necessary care. Developing nations often lack the resources to store and administer medications, like the refrigerator units necessary to store vaccines and the labs, supplies, and technicians to carry out large-scale diagnostic testing.[1]

These shortcomings were well documented when the WTO took a similar approach and voted to waive certain patent obligations on COVID vaccines in 2022, also known as the "TRIPS Waiver." The waiver did not increase the number of vaccines as there was already a surplus available, and the waiver did not increase distribution of vaccines because underdeveloped countries lacked the resources to build out their cold chain refrigeration systems, to fight disinformation, and to hire vaccinators.[2] Considering these realities, it is unsurprising that, to date, no WTO Member has actually made use of the Waiver. The WHO should not follow the same fruitless course in attacking IP protections through their Pandemic Agreement.

[1] https://apnews.com/article/virus-outbreak-pandemics-immunizations-epidemics-united-nations-fc4c536d62c5ef25152884adb1c14168

[2] https://fortune.com/2022/05/11/covid-19-vaccines-global-surplus-new-variants/

While there are no clear benefits to the access and distribution of medical supplies from undercutting IP rights, there are serious consequences, none of which is greater than the discouragement of public and private biotech firms from developing treatments against pathogens that may be the cause of future pandemics. The market for new drug development is a long, costly, and high-risk process that takes over 10–15 years and experiences a failure rate of over 90%.[3] Recent studies have found that developing a new drug from discovery through clinical trials to the market costs an average of nearly $2.3 billion.[4] Clinical trial outcomes, regulatory decisions, and industry news can cause sudden price fluctuations and contribute significantly to the risks of investing in new drug development. Without robust IP protections in place to provide investors some peace of mind with regard to guaranteeing a return on new drugs that successfully make it to market, American companies and investors will hesitate to invest in new drug development.

That means future pandemics will not experience the same commercial investment that benefited the COVID-19 pandemic, like Pfizer's investment in Paxlovid, a COVID-19 therapeutic that would potentially be subject to this agreement. It also means that researchers, labs, and universities would shy away from developing pandemic-related treatments and innovations due to the inherent uncertainty tied to their IP protection status and the decreased likelihood that public and private investors would be willing to invest enough capital to bring such treatments and innovations to market.

The consequences of curtailing IP rights are not merely theoretical. Indeed, they were fully realized in the aftermath of the TRIPS Waiver as companies making COVID-related medications and diagnostics saw their stock prices decline by 73% more than companies focused on different therapeutic areas.[5] The pace of initial public offerings (IPOs) of biotech companies also slowed, and small and medium-sized enterprises (SMEs), which account for 75% of the global clinical COVID-related projects now in the pipeline, reduced their overall development plans.[6] The Pandemic Agreement and its similar undercutting of IP rights would only perpetuate this trend.

Instead of supporting efforts to rapidly develop cutting-edge and life-saving treatments during the most dire of circumstances, the WHO's agreement will discourage investment in the biotech industry, especially with regard to pandemic-related innovations. Investors will not risk capital on new pandemic-related drugs that are subject to IP protection waivers, especially when other new drugs do not carry the same risk.

Moreover, public and private industry are not blind to the issues that the WHO's Pandemic Agreement seeks to address. Indeed, they are often quicker and better situated to develop workable solutions to these issues. For example, American pharmaceutical companies manufacturing Covid-19 diagnostics and therapeutics entered into more than 400 voluntary licensing agreements with partners on every continent. Pfizer and Merck have also licensed their patents to the United Nations-backed Medicines Patent Pool (MPP), enabling generic producers across the globe to manufacture their antivirals. Pfizer and Moderna also voluntarily agreed not to enforce patent rights to their vaccines during the height of the pandemic, with Moderna even going so far as to promise to "never enforce its patents for COVID-19 vaccines against manufacturers in or for" low- and middle-income countries.[7]

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[3] Sun D, Gao W, Hu H, Zhou S. Why 90% of clinical drug development fails and how to improve it? Acta Pharm Sin B. 2022 Jul;12(7):3049-3062. doi: 10.1016/j.apsb.2022.02.002. Epub 2022 Feb 11. PMID: 35865092; PMCID: PMC9293739.

[4] https://www.genengnews.com/gen-edge/the-unbearable-cost-of-drug-development-deloitte-report-shows-15-jump-in-rd-to-2-3-billion/

[5] https://www.wilsoncenter.org/article/markets-response-trips-waiver#:~:text=In%20June%202022%2C%20WTO%20members,of%20Intellectual%20Property%20(TRIPs).

[6] *Id*.

[7] https://www.politico.com/news/2022/03/07/moderna-never-enforce-covid-vaccine-patents-low-income-countries-00014874#:~:text=Moderna%20pledged%20on%20Monday%20to,help%20address%20global%20vaccine%20inequity.

We are also strongly concerned that the undermining of IP protections will not stop with the biotech industry and pandemic-related research and development. Once these precedents eroding IP rights are set, we could see similar actions targeting other technologies, such as clean energy and agriculture. Weakening the protection of intellectual property is simply not the way forward, in our view, to obtain the desired outcomes of greater access and distribution of pandemic-related diagnostics and therapeutics to the developing world.

Sincerely,

Stephen J. Susalka, Ph.D.
Chief Executive Officer