January 22, 2024

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Office for Global Affairs, Office of the Secretary
HHS, Room 639H
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

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

The Boston University Global Development Policy Center is pleased to offer comments on the WHO Pandemic Agreement. Researchers at our center have a long history of advancing an evidence-based understanding of the global access to medicines regime and its implications for addressing pandemics and other health challenges. Our center also coordinates the Boston University Working Group on Trade Treaties and Access to Medicines, which brings together 16 experts from a variety of leading academic institutions, including Professors Brook Baker, Warren Kaplan, Veronika Wirtz and Rachel Thrasher.

The WHO Pandemic Accord is an important step forward in efforts to prevent and respond to future pandemics. In order to achieve the key outcomes the United States seeks from the negotiations, we offer three primary recommendations: 1) The WHO Pandemic Agreement should emphasize the mandatory measures often needed to ensure access to pandemic-related products and guarantee an adequate return on public investment. 2) Technology transfer is paramount and must be backed by funding and other incentives. 3) Temporary waivers of intellectual property rights are an appropriate and effective mechanism to respond to pandemics without disrupting innovation.

1. **The WHO Pandemic Agreement should emphasize the mandatory measures often needed to ensure access to pandemic-related products and guarantee an adequate return on public investment.**

The COVID-19 pandemic underlined the insufficiency of relying on voluntary licensing mechanisms. Although voluntary mechanisms existed, major holders of intellectual property either did not participate in a timely manner or did not participate at all, including private actors holding intellectual property rights to technology that was developed with significant amounts of public funding. The WHO-led COVID Technology Access Pool did not receive any in-licensed technology until November 2021, nearly two years into the pandemic, and even then its agreement was with the public Spanish National Research Council.[i] While Merck and Pfizer

negotiated agreements on voluntary licenses with the Medicines Patent Pool, this agreement was limited to diagnostics, did not come until two years into the pandemic, and preserved significant restrictions that limited access and affordability.[ii] Limited access to vaccines and other health technologies hampered efforts to combat the pandemic, harming both the US and the developing countries that faced significant delays in accessing necessary health products.

The lessons of the COVID-19 pandemic underline the importance of governments imposing licensing requirements for sharing intellectual property, knowledge, know-how, and data in the context of such a crisis. These requirements are particularly important for medicines and health technologies that benefited from public research, development, and production incentives. Without these requirements, there is an excessive risk that public funds will underwrite private benefits at the expense of the public sector because the private sector is either unable or unwilling to guarantee health security and protection from public health threats.[iii]

In this respect, Article 9(4) of the proposed WHO Pandemic Agreement is a promising step forward towards guaranteeing returns on public investment. The provision should be preserved in the agreement and, if possible, strengthened to require disclosure of the costs of developing any publicly funded medicines or health technologies and disclosure of the net prices paid for these products with public funding. These transparency measures would be consistent with the transparency resolution the WHO passed in 2019, WHA 72.8, which urged member states to increase transparency on various aspects of the markets for medicines, vaccines, and other health products.[iv]

However, the shortcomings in Article 10 threaten to allow a repeat of the weaknesses experienced by voluntary measures during the COVID-19 pandemic. Even for entities that receive "significant public funding," Paragraphs 1(d) and 3(a) only "encourage" measures to share knowledge. Paragraphs 3(b) and 3(c) "promote" transparency and voluntary licensing by private rights holders. Neither provision is likely to result in effective government pressure on private firms, especially those that declined to participate in these measures during the COVID-19 pandemic.

Particularly when offering public funds, governments do not need to rely on special incentives or encouragement to advance the sharing of technology: the public funding is already such an incentive and encouragement, and it is reasonable for governments to place requirements on that public funding. In the context of a pandemic, public health depends on sufficient supply of health technologies, rapidly and widely distributed, and governments should attach mandatory requirements on public funding to advance these goals. Indeed, the US government already recognizes the insufficiency of relying on voluntary measures: the Department of Commerce recently proposed a framework to use march-in rights under the Bayh-Dole Act when medicines that benefited from public funds are sold at excessive prices.[v]

2. **Technology transfer is paramount and must be backed by funding and other incentives.**

Mandatory licensing and transparency measures can ensure that health technology is not made inaccessible by intellectual property restrictions or excessive secrecy, but they will not

necessarily be sufficient to guarantee access, and additional efforts to proactively promote technology transfer are vital. In Article 11, Paragraphs 1 and 2's encouragement of technology transfer efforts is welcome. However, too often such efforts are not realized due to a lack of funding. In developing countries where small government budgets often do not allow for adequate funding for pandemic prevention and other public health measures, external financing is particularly important to ensure these countries receive necessary technology and are able to fully utilize it. The provision of funding from developed countries to developing countries is also a key component of health equity.

The Multilateral Fund for the Implementation of the Montreal Protocol provides an important example of how funding technology transfer can advance a multilateral agreement's contribution to a global public good.[vi] Managed by an Executive Committee with an equal number of representatives from industrialized and non-industrialized countries, the Fund provides financing to support developing countries in carrying out their responsibilities under the Protocol. The Montreal Protocol is widely recognized as one of the most effective international agreements in recent decades, having phased out 98% of ozone depleting substances since 1990, preventing millions of cancer cases and reducing the extent of global warming.[vii] Especially as Article 11 of the draft text of the WHO Pandemic Agreement proposes the development of "innovative, multilateral mechanisms," the US should support the creation of a reliable and mandatory funding mechanism like the Montreal Protocol's Multilateral Fund to support technology transfer under the Pandemic Agreement.

3. **Temporary waivers of intellectual property rights are an appropriate and effective mechanism to respond to pandemics without disrupting innovation.**

We welcome the inclusion of Paragraph 11(a), 11(b), and 11(c) in the draft text of the WHO Pandemic Agreement. If possible, Paragraph 11(a) should be strengthened to include an agreement for a time-bound waiver of intellectual property rights during a pandemic, rather than the current text's less precise commitment to agree. The current text risks a situation in which, after the onset of a pandemic, lengthy negotiations delay the waiver of intellectual property rights and the pandemic spreads dangerously before developing countries get access to key pandemic-related products, as occurred during the COVID-19 pandemic.

Without a waiver of intellectual property rights, existing flexibilities in the TRIPS Agreement are insufficient to ensure access to pandemic-related products.[viii] Article 31 and 31bis of the TRIPS Agreement require that a compulsory license be issued for each patent involved in the production of a product. In complex pharmaceutical products, it is not uncommon for a single product to implicate many patents. Further, if a country is not able to manufacture the product itself, another country must issue a compulsory license for export for each component of the product. This process is sufficiently cumbersome that it has only been used once in two decades.[ix]

By their nature, intellectual property rights are meant to increase prices: by restricting production of the product, they allow the owner of the intellectual property to charge higher prices than they could if competitors could freely enter the market. The motivation for this system is the idea that these higher prices will incentivize innovation. However, raising prices and restricting production is a dangerous policy outcome during a global pandemic. Under-supply of medical

countermeasures in those cases can cause immense negative externalities, not only for developing but also developed countries by increased risks of infection and re-infections globally. Temporary waivers can address the unsuitability of standard intellectual property protections to the context of a global pandemic.

Temporary waivers of intellectual property rights would not lead to a significant decline in innovation. First, the waivers are limited and temporary, and public funding already provides an incentive for innovation in pandemic-related products. Second, a large body of evidence shows that there is not a direct relationship between the strength of intellectual property protections and the quality and quantity of innovation.[x] The ideal degree of intellectual property protection also depends on a country's level of development. Indeed, a recent report released by the United States International Trade Commission (USITC) noted that "patent protection is generally found to be more beneficial to innovation in the health sector for more developed countries and less for developing countries."[xi]

Conclusion

We appreciate the opportunity to provide this input. We hope you will take this feedback into account and constructively negotiate to ensure that this important agreement leads to rapid, equitable, and global diffusion of medicines and health technologies that provides health security globally. The COVID-19 pandemic demonstrated enormous weaknesses in the global pandemic prevention and response system, and we hope this agreement will be a meaningful step forward to addressing those weaknesses.

Sincerely,

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[ii] Brook K. Baker and Rachel D. Thrasher. "From Business as Usual to Health for the Future: Challenging the Intellectual Property Regime to Address COVID-19 and Future Pandemics," *Boston University International Law Journal* (41:1), 21

[iii] Katrina Perehudoff et. al. 2022. "A global social contract to ensure access to essential medicines and health technologies," *BMJ Global Health* (Vol. 7: 11). https://doi.org/10.1136/bmjgh-2022-010057

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[v] United States Department of Commerce. 2023. "Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights," https://public-inspection.federalregister.gov/2023-26930.pdf

[vi] *About the Multilateral Fund*, Multilateral Fund for the Implementation of the Montreal Protocol (last visited Jan. 17, 2024), http://www.multilateralfund.org/aboutMLF/default.aspx

[vii] *About Montreal Protocol*, United Nations Environment Program (last visited Jan. 17, 2024), https://www.unep.org/ozonaction/who-we-are/about-montreal-

protocol#:~:text=Success%20achieved%20to%20date%20and%20the%20job%20ahead&text=To%20date%2C%20the%20Parties%20to,of%20the%20global%20climate%20system.; *Montreal Protocol emerges as a powerful climate treaty*, National Oceanic and Atmospheric Administration (Jan 11, 2023), https://www.noaa.gov/news-release/montreal-protocol-emerges-as-powerful-climate-treaty

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