January 29, 2024

Ms. Susan Kim
Office for Global Affairs, Office of the Secretary
Department of Health and Human Services
Room (639H) Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

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

Submitted via email (OGA.RSVP@hhs.gov)

Dear Ms. Kim:

Intellectual Property Owners Association (IPO) appreciates the opportunity to respond to the Notice and Request for Comments on the Implications of Access and Benefit Sharing (ABS) Commitments/Regimes and Other Proposed Commitments in the WHO Pandemic Agreement (88 FR 88637).

Background

IPO is an international trade association representing a "big tent" of diverse companies, law firms, service providers and individuals in all industries and fields of technology that own, or are interested in, intellectual property rights. IPO membership includes over 125 companies and spans over 30 countries. IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; supporting and advocating for diversity, equity, and inclusion in IP and innovation; and disseminating information to the public on the importance of IP rights.

IPO's vision is the global acceleration of innovation, creativity, and investment necessary to improve lives. The Board of Directors has adopted a strategic objective to foster diverse engagement in the innovation ecosystem and to integrate diversity, equity, and inclusion in all its work to complement IPO's mission of promoting high quality and enforceable IP rights and predictable legal systems for all industries and technologies.

IPO supports and appreciates the objective of furthering future international coordination for pandemic prevention, preparedness, and response. In order to advance this goal, IPO believes that the Pandemic Agreement (the "Agreement") should prioritize addressing structural challenges, such as supply chain issues and health care delivery system

deficiencies, which were demonstrated challenges during the COVID-19 pandemic and are likely to be barriers to accomplishing the stated objectives.

IP, however, is not such a barrier. IPO has extensive concerns about how IP provisions currently proposed in the Agreement would impact the innovation ecosystem that will be needed to address the very challenges arising from any future pandemic. A number of these specific concerns are found below.

Waiver of IP Rights Will Hinder, Not Help, the Ability to Respond to a Future Pandemic

IPO opposes the proposal for a waiver of intellectual property rights. Article 11.3(a) states:

> During pandemics, each Party shall, in addition to the undertakings in paragraph 2 of this Article:
> (a) commit to agree upon, within the framework of relevant institutions, time-bound waivers of intellectual property rights to accelerate or scale up the manufacturing of pandemic-related products to the extent necessary to increase the availability and adequacy of affordable pandemic related products;

IPO believes that this waiver of IP rights, even if time bound, will hinder, not help, the ability to respond to a future pandemic. The current IP framework, embodied in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), provides for the protection of innovation and assists in the sharing of intellectual property which enables more rapid and effective innovation, collaboration, and partnership. The unpredictability resulting from modifying this framework via the proposed waiver can be expected to adversely impact the innovation system globally, rather than to encourage innovation to address our global challenges.

The unprecedented development of innovative technology platforms and solutions that allowed us to quickly pivot to tackle the COVID-19 pandemic provides an emphatic demonstration of an effective IP framework. The incentives provided by the IP system enabled innovators to build the infrastructure that allowed them to devote the resources, technical knowledge, and know-how necessary to develop the solutions that were ultimately required to counter COVID-19. IP enabled an unprecedented amount of innovation and facilitated collaboration between innovators and their partners. Companies worked together to produce vaccines and needed respirators, for example. They cooperated to provide technology to facilitate contact tracing, produce high quality personal protective equipment, improve testing, and create treatments for COVID-19. It is maintaining the IP system that will fuel the next generation of solutions for future pandemics.

The huge breadth of the existing technology foundation that allowed for the full attention to, and speed in, developing these solutions can be traced directly to the guarantees offered by IP protection, as reflected in the TRIPS Agreement. Effective vaccines, for example, were successfully developed in response to the pandemic in such a short period

of time precisely because the key players understood that for many years, and across the globe, the immense resource commitments, the enormous financial risks, and the partnerships that they entered into, would be protected by an effective IP system.

This IP system is an important ingredient in a global economic system that supports the efforts of innovators to identify, and engage with, partners in order to further strengthen manufacturing capacity and commit to safe products all around the world. IPO believes that this sourcing system, facilitated by the IP system, results in better, faster, and safer solutions for end users. This system provides for additional transparency that allows consumers to make more informed decisions about the products that they may choose to purchase, use, and/or ingest and for investors to make more informed decisions about the products that they may choose to support with their resources.

In sum, IP helps facilitate, not impede, technology transfer. It provides a framework in which people can exchange and share information and grow the global network of technology in a practical sense. It allows innovators to partner to create new technologies and to share technical information with trusted suppliers and manufacturers with the knowledge it will be protected and used effectively. That is a success story of the COVID-19 pandemic: Innovators, suppliers, investors, and manufacturers, among others, partnered effectively with each other because their inventions were protected by IP.

The benefits of protecting IP rights have led to countless innovations that have improved human existence. Consequently, policy measures designed to modify the current framework must be evaluated with exceptional care. This is particularly the case where the TRIPS Agreement provides for limited exceptions to the rights conferred.

Accordingly, IPO is concerned that this proposal for time bound waivers of IP rights will undercut global efforts to counter future pandemics. Such stepping back from support for innovators and collaborators will have negative effects on investment across all industries. Creating circumstances where innovators cannot attract investments for research and development, where they avoid effective partnership arrangements, where they eliminate voluntary licensing initiatives, or where they withdraw from other basic knowledge-sharing arrangements would be costly for the citizens of the world.

Relationship to Public Funding

Article 11(3)(b) of the Agreement currently states:

> "During pandemics, each Party shall, in addition to the undertakings in paragraph 2 of this Article:…(b) encourage all holders of patents related to the production of pandemic-related products to waive or manage, as appropriate, for a limited duration, the payment of royalties by developing country manufacturers on the use, during the pandemic, of their technology for the production of pandemic-related products, ***and shall require, as appropriate, those that have received public financing for the development of pandemic-related products to do so***." (Emphasis added.)

This section of the Agreement is very concerning to IPO. The relationship between public funding of research and intellectual property is a matter of U.S. law covered by the Bayh-Dole Act. The Act allows government contractors (i.e., universities, non-profit organizations, or any business receiving Federal grants) to obtain patents on inventions they made using federal funding. While outlining the rights of the contractors to the inventions, the Act also provides for rights retained by the government. The retained rights include the so-called "march-in rights" under which a funding agency may require the contractor (or, for certain grounds, an assignee/exclusive licensee of the invention) to grant a license to a responsible applicant on ***reasonable terms*** under limited circumstances; and if such request is refused, the agency may itself grant a license. These circumstances include those when action is deemed necessary to alleviate health or safety needs. However, because the Act requires granting license on ***reasonable terms***, obligating contractors/assignees/exclusive licensees to ***waive or manage payment of royalties*** by developing country manufacturers per Article 11(3)(b) would conflict with the Bayh-Dole Act. The U.S. needs to be able to set its own policy in this area and should not cede this area of domestic policy, which greatly impacts the innovation ecosystem, to an international agreement.

Further, the waiver requirement of Article 11(3)(b) would discourage private sector innovators from accepting public financing for research that could result in a pandemic-related product. It would therefore be likely to thwart large-scale participation of private companies in public-private partnerships to develop vaccines, diagnostics, and therapeutics to counter future pandemics.

The waiver requirement would also disrupt the innovation ecosystem in the U.S. by discouraging partnerships between universities or start-up companies, which may have accepted federal funding, and other companies. These partnerships are necessary for the conversion of early-stage research, carried out in the universities and start-up companies, into commercialized products. As a 2012 Congressional Research Service Report has noted, "Patent ownership is regarded as a means to "encourage the ***additional, and often substantial investment necessary*** for generating new goods and services in the private sector."[1] (Emphasis added). Private companies would be significantly disincentivized to partner with the universities and start-up companies when exposed to the risk of having to license without receiving reasonable royalties.

The waiver requirement would also largely be to the detriment of smaller players, who are dependent on government funding, rather than larger players who can self-fund R&D. The majority of academic IP licenses are made to small companies and startups,[2] who depend on attracting high risk investment in order to survive to continue R&D. A responsible venture capitalist would be less likely to provide this investment in the face of the risks that would be created by Article 11(3)(b).

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[1] Congressional Research Service Report, Dec. 2, 2012, The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology, EveryCRSReport.com.

[2] *See, e.g.*, AUTM U.S. Licensing Activity Survey (FY 2016) ("In 2016, licenses issued to small and startup companies (5,013) represented the majority (70.0 percent) of executed licenses.)".

Compelled Disclosure of Trade Secrets

As noted in the U.S. Trade Representative's 2023 Special 301 Report, "[r]ight holders operating in other countries report an increasing variety of government measures, policies, and practices that require or pressure technology transfer from U.S. companies" and such measures "discourage foreign investment in national economies, hurt local manufacturers, distributors, and retailers, and slow the pace of innovation and economic progress."[3]

IPO is concerned that provisions in the Agreement would negatively impact the ability of innovators to protect trade secrets. For example, Article 9.4 would require the publication of the terms of government-funded research and development agreements for pandemic-related products, including information on:

> (a) research inputs, processes and outputs, including scientific publications and data repositories, with data shared and stored securely in alignment with findability, accessibility, interoperability and reusability principles; (b) the pricing of end-products, or pricing policies for end-products; (c) licensing to enable the development, manufacturing and distribution of pandemic-related products, especially in developing countries; and (d) terms regarding affordable, equitable and timely access to pandemic-related products during a pandemic.

IPO has concerns with provisions that would require the sharing the specific details of contractual agreements, which often contain sensitive and confidential information related to business operations, such as technical research inputs, processes, and financial arrangements such as pricing.

IPO is also concerned that provisions in the Agreement may result in forced or pressured technology transfer. For example, IPO is concerned that Articles 11.1 and 11.2, when taken together, may lead to coercive policies by governments to force the transfer of technology.[4] As history has shown, voluntary partnerships between trusted partners -- rather than coercive or mandatory forced transfer policies -- are the best approach to facilitate the sharing of information.

Trade secret protection, together with protection provided by patents and other IP rights, are what enabled innovators to work together to develop COVID-19 diagnostics, vaccines, and other solutions within an unprecedented short time. As described above,

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[3] *See* 2023 Special 301 Report at p. 24, https://ustr.gov/sites/default/files/2023-04/2023%20Special%20301%20Report.pdf.

[4] Article 11.1 states that, "The Parties...shall strengthen existing, and develop innovative, multilateral mechanisms, including through the pooling of knowledge, intellectual property and data, that promote the transfer of technology and know-how for the production of pandemic-related products, on mutually agreed terms as appropriate, to manufacturers, particularly in developing countries," and Article 11.2(c) indicates that the Parties shall make use of the flexibilities provided in the TRIPS Agreement.

this collaboration was facilitated by IP protection, which provided a framework for companies to share sensitive trade secrets and know-how with partners, including competitors. Protection meant the companies could share their knowledge and technologies without fear of competitors using it to their disadvantage.

Collaboration among academia, biotech/pharma and governments has been, and will continue to be, critical to the response of any threats posed by new pandemics. A policy that encompasses transfer of unregistered forms of IP would remove the safeguards that permit parties to share information. This would have the unintended consequence that companies would engage in fewer, not more, partnerships to address pandemic response.

Diagnostics, vaccine and therapeutic development and production are complex technologies that require specialized equipment, trained staff, quality assurance processes, access to specialist consumables, as well as specially designed facilities. It will take time, potentially a very long time, for new producers to develop the production and quality management processes needed to produce these life-saving products of the quality and volume needed. Trade secret transfer will not shorten this timeline or accelerate this process, and may have the opposite effect if collaborative technology transfer and knowledge sharing have been hindered by a lack of safeguards.

Forced trade secret transfer also risks diverting raw materials from established manufacturers and productive facilities to ones that are new, still establishing production, and scaling up. This would disrupt global supply chains, and lead to less, rather than more, supply of such products.

Trade secret transfer along the lines proposed in the Agreement may also have the effect of disincentivizing companies, including those based in the U.S., from investing in R&D for new diagnostics, vaccine and therapeutic development.

Access and Benefit Sharing

IPO supports prompt pathogen sample/data sharing among countries. The existing global framework appears to have worked relatively well during the COVID-19 pandemic to achieve this objective. IPO believes that Article 12 will likely hinder U.S. stakeholders' efforts to develop new technologies to timely respond to the unknown technological challenges that the next public health emergency may present.

More specifically, although the current system may need further improvement, particularly with respect to supply chains, IPO is concerned that certain provisions in Article 12, such as Article 12(4)(b), will likely prevent rapid sharing and efficient use of pathogen sample/data.

There is no evidence showing that monetary sharing or technology transfer as proposed under Article 12(4)(b) have facilitated pathogen sample/data sharing during the COVID-19 pandemic. Article 12(4)(b) or like provisions are vague, overly burdensome and impractical. They arbitrarily set up specific financial obligations without considering

many key factors such as how the shared sequence/data is used and how much additional efforts/investment would be needed beyond the use of the shared sequence/data. IPO believes that Article 12(4)(b) or like provisions will likely impede research and jeopardize efficient and rapid response to the next public health emergency challenge.

IPO supports the objectives of preserving sustainable biodiversity in an effective and meaningful way. IPO also supports prompt access to pathogen samples and data that are needed to contribute to rapid creation of safe and effective vaccines, diagnostic tests, and treatments. However, IPO is concerned about Article 12(4)(b) as explained above.

IPO recommends deletion of Article 12(4)(b) and like provisions, and/or replacing them with ones that encourage voluntary contracting between relevant parties in good faith. IPO suggests relying on voluntary material transfer agreements negotiated and mutually agreed by relevant parties based on the specific facts in each transaction. There is no need for WHO to impose additional conditions, such as Article 12(4)(b). IPO believes Article 12(4)(b) would hinder rapid research and development.

Procedures for Amending the Agreement Without Participation of Non-parties

To ensure legal certainty for innovators and the public, IPO urges that any future review or amendment of the Agreement should not be limited to contracting parties, as the potential outcome is likely to affect innovation ecosystems involving non-contracting parties. (*See* Articles 22 & 28).

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IPO thanks the Department of Health and Human Services for its attention to IPO's comments submitted herein. The issues related to the Agreement are, of course, complicated. Further dialogue and evidence-based discussions would be welcome.

Sincerely,

Krish Gupta

Krish Gupta
President