



American Intellectual Property Law Association

January 31, 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 Comments Re: Implications of Access and Benefit Sharing (ABS) Commitments/Regimes and Other Proposed Commitments in the WHO Pandemic Agreement (88 Fed. Reg. 88637 Dec. 22, 2023)*

Dear Ms. Kim:

The American Intellectual Property Law Association (“AIPLA”) appreciates the opportunity to offer the following comments in response to the December 22, 2023 request for Written Comments Re: Implications of Access and Benefit Sharing (ABS) Commitments/Regimes and Other Proposed Commitments in the WHO Pandemic Agreement (hereinafter, “WHO PA”; 88 Fed. Reg. 88637, Dec. 22, 2023, Notice).

Founded in 1897, the American Intellectual Property Law Association is a national bar association of approximately 7,000 members including professionals engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Our mission includes helping establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public’s interest in healthy competition, reasonable costs, and basic fairness.

In December 2021, the World Health Organization’s (WHO) Member States established an intergovernmental negotiating body (INB) to draft and negotiate an international instrument to address pandemic prevention, preparedness, and response.¹ The Notice references a document with discussion text that is available at the WHO’s website.²

At the 2021 WHO meeting, the United States (US) “expressed support for development of such an agreement and expects that the INB will formally submit its Draft instrument at the 77th World Health Assembly taking place in May 2024.”³

The US has indicated that it is seeking three key outcomes in any approved instrument:

¹ 88 Fed. Reg. 88637 (Dec. 22, 2023), see Supplemental Information at column 2.

² <https://inb.who.int/home/inb-process>.

³ See fn 1.

Enhance the capacity of countries around the world to prevent, prepare for, and respond to pandemic emergencies and provide clear, credible, consistent information to their citizens.

Ensure that all countries share data and laboratory samples from emerging outbreaks quickly, safely, and transparently to facilitate response efforts and inform public health decision making regarding effective disease control measures, including the rapid creation of safe and effective vaccines, diagnostic tests, and treatments.

Support more equitable and timely access to, and delivery of, vaccines, diagnostic tests, treatments, and other mitigation measures to quickly contain outbreaks, reduce illness and death, and minimize impacts on the economic and national security of people around the world.⁴

In the Notice, “stakeholders are invited to provide comments on any and all issues raised by the negotiating text. . . .”⁵

In general, AIPLA is supportive of the desired key outcomes to the extent that they do not adversely affect the myriad of intellectual (IP) rights that, for example, so successfully enabled the development of an entire new class of vaccines in just a few months to address the COVID-19 pandemic. AIPLA fundamentally disagrees with any assumptions that suggest IP rights are a barrier to achieving such successful, life sustaining outcomes. The opposite is, in fact, true.

AIPLA does have concerns with the current WHO PA⁶ Draft text in so far that it is replete with ambiguous language, cedes national authority under ill-defined conditions, and arguably weakens the incentives and abilities of private sector actors to promptly develop and enhance technological solutions to current and future medical challenges.

The WHO PA is, appropriately, general in nature (i.e., not COVID-specific). The attempt at generality, however, renders the proposed provisions so ambiguous as to yield to WHO the authority for addressing virtually any health issue that WHO assesses as “pandemic-related.” Under the definition in the WHO PA language, a “pandemic-related product”⁷ could include not only a vaccine, a therapeutic, or a diagnostic, but could also include fundamental medical resources such as oxygen, and distribution resources such as those involved in the vaccine cold-chain.⁸

For example, consider that the WHO PA defines a “pandemic” as:

⁴ 88 Fed. Reg. 88637 (Dec. 22, 2023), see Supplemental Information at columns 2-3.

⁵ See fn 1.

⁶ Document A/INB/7/D, available at https://apps.who.int/gb/inb/pdf_files/inb7/A_INB7_3-en.pdf?ref=aretenews.com.

⁷ WHO PA at Article 1(f).

⁸ Wikipedia contributors. "Cold chain." *Wikipedia, The Free Encyclopedia*. Wikipedia, The Free Encyclopedia, 12 Jan. 2024. Web. 24 Jan. 2024. “**Cold chain** is defined as the series of actions and equipment applied to maintain a product within a specified low-temperature range from harvest/production to consumption. An unbroken cold chain is an uninterrupted sequence of refrigerated production, storage and distribution activities, along with associated equipment and logistics, which maintain a desired low-temperature interval to keep the safety and quality of perishable or sensitive products, such as foods and medicines.” (Internal citations omitted, emphasis in original.)

the global spread of a pathogen or variant that infects human populations with limited or no immunity through sustained and high transmissibility from person to person, overwhelming health systems with severe morbidity and high mortality and causing social and economic disruptions, all of which requires effective national and global collaboration and coordination for its control⁹

Here, the WHO PA includes subjective terms such as “sustained,” “high transmissibility,” “overwhelming,” and “severe.” The WHO PA, however, gives no metrics for making the quoted subjective determinations, which may render many of the terms of the agreement indefinite. In uncertain and rapidly developing times, such as during a pandemic, triggers that inject additional uncertainty cause confusion. This subjective and vague language illustrates the concerning scope of products and technologies that could fall within the “pandemic-related product” definition.

The WHO PA also seeks to control the free flow of information as it coins the term “infodemic,” to justify, at least during pandemics, the control of scientific information.¹⁰ For example, Article 9 includes a provision regarding “infodemic management.” This could include trade secrets and fundamental know how, the release of which would infringe fundamental rights. To decide what information should and should not be released raises the serious specter that vital information may be kept from broad distribution. Balancing these interests should not be given to a single extra-national authority.

Also, using terms that are nonspecific, unclear, and unduly broad, as well as terms such as “equitable” that are being highly debated at this time, is at odds with objective public health measures, such as classic disease isolation, identification, and treatment, which are scientifically and socially agnostic.

These are just examples of the comprehensive and subjective nature of the proposed WHO PA that would require member states to cede their national authority when WHO considers a global condition to be a pandemic.

Similarly, the WHO PA language is replete with the establishment of mandatory activity. Virtually all of the proposals in the WHO PA are prefaced by activities that member states “shall” do.¹¹

Also, among other provisions, Article 12 of the WHO PA would establish a “WHO Pathogen Access and Benefit-Sharing System (WHO PABS System), to ensure rapid and timely risk assessment and facilitate rapid and timely development of, and equitable access to, pandemic-related products for pandemic prevention, preparedness and response.”¹² This provision would, *inter alia*, require the WHO control at least 20% of pandemic-related resources regardless of their origin as long as the manufacturer of such resources used or accessed WHO PABS System material (including pathogen sequence information) directly or indirectly.¹³ In order to quickly

⁹ WHO PA at Article 1(e).

¹⁰ See, e.g., WHO PA, at Article 1(c)

¹¹ See WHO PA throughout.

¹² See WHO PA at Article 12, first paragraph.

¹³ See, e.g., WHO PA, Article 12, paragraph 4(b)(ii)(a) and paragraph 5.

respond in a pandemic, prompt access to pathogens and their genetic information is essential. The WHO PABS System would create hurdles to this access and, by doing so, would impede pandemic response and hinder the development of necessary products.

In specific, the Access and Benefit Sharing (ABS) provisions in Article 12¹⁴ are problematic and may dramatically disincentivize research efforts and response. For example, the provisions in Article 12(4)(b)(ii) would result in impediments and costs too onerous, or outright impossible, for stakeholders and manufacturers. Article 12(4)(b)(ii) also states: “(b) on an annual basis, contributions from Recipients, based on their nature and capacity, to the capacity development fund of the sustainable funding mechanism established in Article 20 herein.” During a pandemic private sector companies should be encouraged to quickly seek out and find solutions. Article 12 would do just the opposite by creating logistical challenges and financial hurdles.

AIPLA does not support an ABS system as currently drafted in Article 12.

Not only would such language risk disrupting the financial pipeline that underlies private sector research and development, it would also reach through to inter-entity collaborations that have been so effective in the rapid mobilization of technology in emergency situations. Embedding international health obligations into, for example, technology licensing agreements, would create untenable unpredictability and inhibit the collaboration needed for rapid technology actualization.

Further, the specter of third-party oversight and resource management would likely cause innovators to rely more heavily on trade secret protection than patents – patents that provide enabling disclosures to the public. Such a shift would be anathema to the goals of the WHO PA.

AIPLA also fears that the private sector investment in technology development would be negatively affected by the obligations and vagaries thereof as set forth in the WHO PA. Thus, rather than creating more effective means of addressing future health crises, the current WHO PA would alter the long-established IP rights that have, over time, developed into a carefully balanced system that incentivizes innovation and provides the technological and scientific foundation critical to swift pandemic response.

It is largely because of strong IP systems that during the COVID-19 pandemic, stakeholders – in many instances through collaborations¹⁵ – quickly developed innovations, such as personal protective equipment, vaccines, diagnostics, antibody therapies, and other products, some of which became the subject matter of patent applications. Patent protection incentivized the development of these innovations. If stakeholders no longer patented their inventions, such innovations would not be published in patent applications and society would lose this important benefit.¹⁶

¹⁴ The terms for ABS should be mutually agreed terms in good faith, not arbitrary, artificial terms imposed by WHO or others who are not a party to the ABS material transfer agreement.

¹⁵ Patents also provide incentive for collaboration, where inventors from different institutions work together on innovations and inventions and can file patent applications jointly, as co-inventors. The system also enables institutions to become co-applicants. Various patent systems, such as those in the EU provide similar incentives. Contract law works together with patent law to provide incentives for collaboration.

¹⁶ See Article 9 Questions 1, 2, 4-6, Article 10 Questions 1-3, Article 11 Questions 1-4, Article 12 Questions 1-7, and Article 13 Question 1. The patent system provides incentives to accelerate innovation and collaboration. In

Similarly, it is the private sector that was able to implement an entirely new class of RNA-based vaccines when they were most needed. Leveraging these private sector innovations with public sector incentives and regulatory flexibilities brought the three COVID-19 vaccines to market in less than a year.

The IP-based protections had permitted the establishment of a highly capable and reactive private sector infrastructure ready to be unleashed when needed. Unfortunately, while AIPLA agrees with the US goals in enhancing this capability, the draconian requirements and centralization of innovation would likely limit technology development and delay presentation of solutions that have come about due to, in part, the IP systems that encourage widespread, multi-actor innovation. Thus, weakening or hampering IP rights would disrupt licensing and collaboration that has been so effective in the past.¹⁷ Therefore, AIPLA disagrees with various provisions in the WHO PA¹⁸ that call for things like “royalty-free licenses” and disclosure of “know-how” and “trade secrets,”¹⁹ which are so critical to private sector innovation.

Another problematic assumption made in the WHO PA is that there is a lack of transparency; however, mechanisms are currently in place to ensure transparency. For example, the US Food and Drug Administration (FDA) *requires* that clinical trials be publicly disclosed.²⁰ Results of the clinical trials must be posted on the website (relatively soon, within 12 months from the primary completion date). Private open access options for publishing are also available.²¹

AIPLA recommends including provisions within the WHO PA that would enhance IP rights holders’ ability to control their IP (including trade secrets and “know-how”), implement

exchange for a patent disclosing an invention, a patent applicant receives a limited, lawful monopoly in the form of an issued patent. Without patents, inventions might be kept as trade secrets instead. Publication or otherwise divulging such innovations would destroy them as trade secrets. This creates more, new unforeseen risks, which would be detrimental to owners of the technology.

¹⁷ The US Bayh-Dole Act also incentivizes innovation, providing freedom in licensing patent rights in government-funded research. The Bayh-Dole Act was established in 1980 and permits ownership by contractors, such as Universities, non-profits and businesses, of inventions arising from government-funded research. According to an online article published in 2022 by the Center for Strategic and International Studies “[s]ince it was enacted in 1980, the Act has led to over \$1.3 trillion in U.S. economic growth, created more than 4.2 million jobs across the country, and contributed to the success of over 11,000 new startup companies from universities throughout America” (available at: https://www.csis.org/blogs/perspectives-innovation/legacy-bayh-doles-success-us-global-competitiveness-today#:~:text=The%20Implications%20of%20the%20Bayh%2DDole%20Act&text=In%20essence%2C%20it%20allows%20institutions,who%20can%20then%20commercialize%20them.)).

¹⁸ Manufacturers must be free to negotiate licensing terms, considering various factors, and should not be forced to enter into artificial schemes, such as royalty-free licensing schemes, which would destroy incentives for manufacturers to protect their inventions. For example, if manufacturers were unable to sustainably protect their rights by patenting their inventions, there would be far less information provided to the public as patent applications and patents are published. AIPLA’s position is that each US stakeholder should be free to decide if it wants to participate in the WHO SCL Network, and that any incentives should not impede the IP rights (including but not limited to patent or trade secret rights) of any US stakeholder. Participation in the WHO SCL Network should be voluntary and not compulsory.

¹⁹ In some instances, technologies for “pandemic-related products” must be protected using trade secrets. Sharing of the underlying know-how would result in irrevocable loss of the trade secrets. Stakeholders should be allowed to lawfully maintain trade secrets without outside intervention, as such trade secrets are protected by state and federal laws, such as the Defend Trade Secrets Act.

²⁰ Registered on a website established by the National Library of Medicine at clinicaltrials.gov.

²¹ See Article 9 Question 3, Article 11 Question 3, Article 12 Question 1.

safeguards against loss of IP rights, and generally strengthen enforcement of IP rights, to encourage and facilitate sharing of information.

Thank you for the opportunity to provide our comments and thank you in advance for consideration of these comments. Because of the short time period allowed for comments, AIPLA has not had sufficient time to provide specific answers to the questions asked. Nonetheless, AIPLA will continue to study and consider the draft text and will follow the discussion as it progresses, offering suggestions on language that may be more likely to achieve the three key outcomes without adversely affecting the IP rights that so successfully permitted the development of technology that helped address the COVID-19 pandemic. Please do not hesitate to contact us.

Sincerely,

A handwritten signature in blue ink that reads "Ann M. Muetting". The signature is written in a cursive style with a large, looping "M" and "g".

Ann M. Muetting

President

American Intellectual Property Law Association