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

The Council for Innovation Promotion (C4IP) is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere. The organization was founded by two former U.S. Patent and Trademark Office Directors and is advised by former federal judges and government officials, all of whom direct C4IP's mission as it develops policy on all areas of intellectual property.

C4IP welcomes the opportunity to provide information to help the U.S. delegation to the Intergovernmental Negotiating Body (INB) in its negotiations on a WHO convention, agreement, or other international instrument on pandemic prevention, preparedness, and response. C4IP has focused its comments on the most recent version of the Negotiating Text of the WHO Pandemic Agreement, dated October 30, 2023 (herein referred to as the "Draft Treaty"). Given C4IP's mission and ongoing engagement with the innovation community, we have focused our comments on the innovation-related provisions of the Draft Treaty.[1]

In sum, and as explained further below, C4IP has grave concerns about these provisions of the Draft Treaty. After just emerging from a global pandemic where the innovation supported by a strong intellectual property system was critical for a successful medical response,

1 Further, due to the abbreviated period of time to respond to this Request in relation to its complexity, we have focused on the most problematic provisions relating to intellectual property. The lack of comment on other intellectual-property provisions should not be construed to mean that we believe them to be problem-free.

the Draft Treaty's overall hostility to intellectual property is unfounded, counterproductive, and potentially harmful to the innovation that will be needed to address future pandemics.

For example, one of the Draft Treaty's first references to intellectual property links it to cost,[2] losing sight of how innovations such as new drug treatments can dramatically lower costs by reducing the amount of time patients need to recover. Moreover, cost is inherent to virtually all aspects of improving pandemic readiness, including many other necessary changes mentioned in the Preamble—improving worldwide healthcare infrastructure and building and sustaining a highly-trained workforce, for example.[3]

But perhaps the most problematic aspect of the Draft Treaty's pervasive anti-IP tone is the impact its enactment would be on innovation, leaving the United States and the world much less prepared for the next pandemic. Actions must certainly be taken to improve upon the global response to the COVID-19 pandemic in preparation for the next one, but jettisoning a key driver of future medical inventions is not one of them.

I. Intellectual Property Was Key to the COVID-19 Pandemic Response

As terrible as the first wave of the COVID-19 pandemic was, the state of medical technology meant that critical interventions, such as N95 masks and ventilators, already existed. And sooner than anyone expected, state-of-the-art technology allowed the creation of highly effective mRNA vaccines, among others. These medical interventions already existed and came into existence quickly because of innovation supported by strong intellectual property systems in the United States and several other countries.

When contrasted with the technology on hand to fight the 1918 influenza pandemic, where there were no ventilators, advanced personal protective equipment, or effective medical treatments,[4] it is clear how much innovation was incentivized by intellectual property: ventilators, masks capable of filtering out virus particles, and the groundbreaking discoveries that led to highly effective mRNA vaccines. In sum, the innovation propelled by the intellectual property system has a record of success in promoting medical advancements, which are critical to pandemic preparedness.

2 Negotiating Text of the WHO Pandemic Agreement (October 30, 2023) [hereafter "Draft Treaty"], Preamble, para. 10.

3 *Id.*, Preamble, paras. 5, 9.

4 Barbara J. Jester et al., *100 Years of Medical Countermeasures and Pandemic Influenza Preparedness* 1469, 1470-71, AM. J. PUBLIC HEALTH (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6187768/pdf/AJPH.2018.304586.pdf.

In contrast, the problems faced during the COVID-19 pandemic can be traced to non-IP sources, such as a lack of existing capacity to distribute or manufacture medical treatments in all areas of the globe.[5]

Yet, as discussed further below, many of the proposals in the Draft Treaty would undermine strong intellectual property rights, and with that, the rapid rate of innovation that should not be taken for granted. Undermining IP will not solve the problems of global equity and access, but instead it will mean less medical advancement overall, to the detriment of everybody.

II. The Draft Treaty's Pandemic-Specific Provisions Would Discourage Future Medical Innovators from Investing in Pandemic-Related Technology

During a pandemic, the Draft Treaty proposes that pandemic-related intellectual property be "waived" or that owners forego royalty collections.[6] While these provisions are intended to facilitate a rapid world-wide response to the next crisis, they will almost certainly have the opposite effect in practice. This is because companies are highly incentivized to pursue innovation where there is reliable intellectual property support. And, with such support in place, companies are secure in finding and forming beneficial partnerships on their own, as we saw during the COVID-19 pandemic.[7]

Yet, instead of allowing new partnerships to form in organic and creative manners with the support of strong IP, the Draft Treaty directs countries to require companies that have received public funding to forgo enforcement and payment of royalties by developing country manufacturers, at least for a limited period of time during a pandemic.[8] In other words, if a company accepts public funding for pandemic-related research, it comes with strings attached in the form of mandated pricing and control.

5 Sivan Yaari, *The Battle for Refrigeration of Vaccines in Africa*, ESI-AFRICA (Jan. 28, 2022), https://www.esi-africa.com/energy-efficiency/op-ed-the-battle-for-refrigeration-of-vaccines-in-africa/; Andrea Gennari, Tania Holt, Emma Jordi, and Leah Kaplow, *Africa Needs Vaccines. What Would It Take to Make Them Here?* MCKINSEY & COMPANY (Apr. 14, 2021), https://www.mckinsey.com/industries/life-sciences/our-insights/africa-needs-vaccines-what-would-it-take-to-make-them-here; Prashant Yadav, *What Happens When the Vaccine Factory of the World Can't Deliver?* NEW YORK TIMES (May 20, 2021), https://www.nytimes.com/2021/05/20/opinion/india-covid-vaccines-covax.html?searchResultPosition=17; Safia S. Jiwani and Daniel A. Antiporta, *Inequalities in Access to Water and Soap Matter for the COVID-19 Response in Sub-Saharan Africa*, INT'L J. FOR EQUITY IN HEALTH (2020), https://link.springer.com/content/pdf/10.1186/s12939-020-01199-z.pdf.

6 Draft Treaty, Art. 11.

7 *See, e.g., Johnson & Johnson Announces Landmark Agreement to Enable its COVID-19 Vaccine to be Manufactured and Made Available by an African Company for People Living in Africa* (March 8, 2022), https://www.jnj.com/johnson-johnson-announces-landmark-agreement-to-enable-its-covid-19-vaccine-to-be-manufactured-and-made-available-by-an-african-company-for-people-living-in-africa.

8 *Id.*, Art. 11, para. 3(b).

The U.S. experience with such price-control requirements in government contracts has demonstrated exactly the negative impact that such controls have on both product innovation and the creation of beneficial partnerships. Between 1989 and 1995, the U.S. National Institutes of Health (NIH) inserted "reasonable pricing" clauses in its model Cooperation Research and Development Agreement. When ending this practice, the NIH Director stated, "An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with [Public Health Service] scientists without providing an offsetting benefit to the public."[9]

The U.S. experience is instructive as it demonstrates that in an effort to control pricing and access through conditioning public funding for research, the real-world result is the disappearance of public-private partnerships. In the case of pandemics, this means that the United States and other nations would reduce the effectiveness of a key tool at their disposal—the ability to direct funds towards addressing the pandemic.

The Draft Treaty also directs countries to encourage private companies to do the same with their intellectual property, which may create some of the same disincentives to invest as described above depending on how coercive the "encouragement" is.[10]

III. The Draft Treaty's Plan for Pandemic Research Threatens to Broadly Chill Medical Innovation

The Draft Treaty also puts forth a general plan for a worldwide hub to facilitate pandemic-related research before and during a pandemic. But by placing restrictions on the role that intellectual property can play in this system to help promote innovation, these provisions threaten to undermine the progress of medicine more generally.

For example, the Draft Treaty calls for non-exclusive licensing of government-owned technologies "for the development and manufacturing of pandemic-related products."[11] Non-exclusive licensing, however, frequently fails to result in new products and technologies because the incentive to invest in extensive research and development is not present when other licensees can easily copy a successful product.

9 National Institutes of Health, *NIH News* (1995), https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf.

10 Draft Treaty, Art. 11, para. 3(b).

11 *Id.*, Art. 11, para. 2(b).

Again, past U.S. experience is instructive. The United States used to have a policy of granting non-exclusive licenses to government-owned technology. The result was that by 1978, the U.S. government had obtained approximately 28,000 patents but had licensed fewer than four percent since few private entities would risk an investment without secure IP ownership.[12] This ultimately led the United States to reverse course and pass a law commonly known as the Bayh-Dole Act, which allowed the exclusive licensing of government-funded inventions.[13] This law has been described as "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century . . . [that] unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money."[14]

The non-exclusive licensing proposed by the Draft Treaty is likely to meet the same fate as it did in the United States, making it yet another aspect of the draft that is likely to have the opposite of its intended effect—rather than create more and new products for pandemic preparedness that are widely accessible across the globe, the Treaty will result in fewer new products, if any at all. And unfortunately, if nothing is developed with government-owned technology, that means innovations will sit on the shelf, unused and not benefiting those who provided the funds to government in the first place.

The Draft Treaty also calls for the establishment of the WHO Pathogen Access and Benefit-Sharing System (the WHO PABS System), which appears to be a worldwide network of laboratories that locate and share pathogens (referred to as WHO PABS Materials), subject to cost-and-benefit sharing provisions and limitations on protecting the results of their research.[15] In particular, participants are both prohibited from seeking intellectual property protection[16] or profiting from their research without sharing the proceeds.[17] The Draft Treaty also penalizes companies who decline to join the network and yet which produce

12 Vicki Loise and Ashley J. Stevens, *The Bayh-Dole Act Turns 30*, SCIENCE (2010), https://www.science.org/doi/pdf/10.1126/scitranslmed.3001481.

13 An Act to amend the patent and trademark laws, Pub. L. 96-517, 94 Stat. 3015 (1980).

14 *Innovation's Golden Goose*, ECONOMIST TECHNOLOGY QUARTERLY (2002), https://bayhdolecoalition.org/wp-content/uploads/2023/05/The-Economist-December-14-2002-Innovation_s-Golden-Goose-Article.doc.pdf.

15 Draft Treaty, Art. 12.

16 This provision reads "Recipients of WHO PABS Material shall not seek to obtain any intellectual rights on WHO PABS Material." Draft Treaty, Art. 12, para. 4(a)(iv). From this wording, it is unclear whether this means no intellectual property rights covering solely the PABS Material itself or also would extend to any invention made using PABS Material. But the benefit-sharing provision in the immediately following paragraph suggests that, regardless, recipients would be expected to share any profits from a patented invention.

17 Draft Treaty, Art. 12, para. 4(b)(1).

pandemic-related products by having their countries to treat them as if they had joined.[18] In effect, this provision creates a monopoly over WHO PABS Materials that controls any resulting product or profit produced as a result.

The devastating impact of this scheme on medical innovation, particularly in infectious diseases, is difficult to overstate. What company would want to engage in infectious disease research without knowing in advance if it might become enveloped within the WHO-led monopoly? After all, given that "WHO PABS Materials" is undefined, it could theoretically encompass virtually any pathogen. WHO's own list of priority diseases for the next pandemic includes a "Disease X"—an as-yet unknown pathogen that might cause human disease.[19] It would be therefore reasonable for any company considering entering the infectious disease space to assume that any pathogen might ultimately come under WHO's purview, and decide to pursue research elsewhere. The result will be a dearth of private innovation in infectious diseases, leaving the world flat-footed when faced with the next pandemic.

IV. The Draft Treaty's Data-Sharing Plans Will Distort and Impede Innovation and Clinical Research

The Draft Treaty mandates extensive data sharing, yet lacks any safeguards for intellectual property, such as trade secrets, that may be in that data or discernable from it. This mandate will have a detrimental impact on medical innovation by dissuading companies from pursuing cutting-edge areas of medical research in favor of more conventional research where the information required to be shared will be routine, or to pursue different areas of innovation altogether.

For example, Article 9 calls for national policies to facilitate the sharing of clinical trial protocols and results.[20] Notably, this is not limited to pandemic-related protocols and trials, but would apply to any protocol or trial after treaty implementation. A similar recent proposal from the European Commission has been criticized for failing to protect companies' trade secrets, and in turn, their investment in innovation.[21] The same would happen here.

18 *Id.*, Art. 12, para. 5.

19 World Health Organization, *Prioritizing Diseases for Research and Development in Emergency Contexts*, https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts (last visited January 19, 2024).

20 Draft Treaty, Art. 9, para. 3(e)-(f).

21 *See, e.g., European Health Data Space (EHDS): Key issues to address in trilogues*, DIGITAL EUROPE (2023), https://cdn.digitaleurope.org/uploads/2024/01/EHDS-trilogues-DIGITALEUROPE-position-paper-1.pdf.

By mandating broad data disclosures without such protections, companies will be incentivized to structure their clinical trials to avoid reporting as much as possible. And companies should be incentivized to conduct the best clinical trials, not to avoid the implications of bad policies.

The Draft Treaty also calls for the creation of a database of all pandemic-related products "including the technological specifications and manufacturing process documents for each product."[22] The definition of "pandemic-related products," is extremely broad, including regular medical products such as syringes and oxygen, and is not limited to the products enumerated therein.[23] This provision could accordingly require disclosure by any medical company of specifications and manufacturing details of all their products, including any trade secrets associated with their production. Again, without appropriate protections for intellectual property and trade secrets in particular, no company will want to pursue innovation if it can be copied by others before they have at least recovered their research and development costs.

V. The Ambiguous and Contradictory Language of the Draft Treaty Suggests It Is Not Ready for Presentation to the World Health Assembly This Year

According to the Request for Comments, the INB intends to submit the outcome of the upcoming negotiations to the World Health Assembly in May 2024.[24] However, the many ambiguities and inconsistencies in the current draft language have made it difficult to understand the intent of certain provisions and suggest it is in no state to advance to the next level of consideration.

Some of these ambiguities have been noted in the comments above, where assumptions about meaning needed to be made. A particularly egregious example occurs at footnote 16 and accompanying text, where it is unclear what limits on seeking intellectual property protection are intended to be placed on any participant in the WHO PABS system. This point is critical to fully assess the impact this provision will have on innovation, yet the operative

22 Draft Treaty, Art. 11, para. 2(e).

23 "Pandemic-related products" is defined as "products that are needed for pandemic prevention, preparedness and response, which may include, without limitation, diagnostics, therapeutics, medicines, vaccines, personal protective equipment, syringes and oxygen." *Id.*, Art. 1, para. f.

24 Department of Health and Human Services, *Notice and Request for Comments on the Implications of Access and Benefit Sharing (ABS) Commitments/Regimes and Other Proposed Commitments Being Considered Under a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response*, 88 FR 88637 (Dec. 22, 2023), https://www.federalregister.gov/documents/2023/12/22/2023-28341/notice-and-request-for-comments-on-the-implications-of-access-and-benefit-sharing.

language does not even use clear terminology, referring only to "intellectual rights," in addition to the ambiguity in scope discussed earlier.[25]

Another part of the draft presenting problematic ambiguity and inconsistency appears in Article 11, which is also critical to understanding the intellectual property implications of this draft since this section imposes mandatory limits on IP enforcement during a pandemic. The clearest provision, Art. 11, para. 3(b), was already discussed in Section II, above. But the paragraph immediately preceding it, Art. 11, para. 3(a) both contains ambiguous language and appears to contradict para. 3(b). While 3(b) calls on countries to require government-funded patent holders to forgo enforcement during a pandemic and encourage the same for other patent holders, 3(a) states that countries will be required to "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." [26] The juxtaposition of these two provisions gives rise to a number of interpretive questions:

- What is meant in 3(a) by "relevant institutions" who need to waive their rights, and how is it different than the patent holders who need to waive their rights referred to in 3(b), and where a differentiation is made between which rightsholders were government-funded and not?

- What is the significance of 3(a) referring to "intellectual property" whereas 3(b) refers only to "patents"? Does this mean that 3(a) is meant to include waiver of copyrights and trademarks, and if so, why?

- 3(a) refers only to a time-bound waiver, whereas 3(b) refers both to time-bound waivers and foregoing royalties. Given this discrepancy, what is the true intended scope of limitations on rightsholders in this Draft Treaty?

Because this paragraph is phrased as a mandatory requirement of any signatory country—not an aspirational one—these ambiguities are troubling. They also prevent a complete assessment of the full impact on intellectual property rights of this current draft.

25 Draft Treaty, Art. 12, para. 4(a)(iv).

26 *Id.*, Art. 11, para. 3(a).

VI. Conclusion

For the reasons stated above, C4IP believes the Draft Treaty's treatment of intellectual property rights, if enacted, will undermine the vibrant innovation ecosystem that, in the 100 years between the influenza and COVID-19 pandemics, produced a sea change in medical technology. This progress happened without any centralized planning hub or treaty, but in large part because strong incentive systems like intellectual property organically encouraged rapid medical progress. With the likelihood that the next pandemic will happen even sooner, we cannot afford to let that progress slow. C4IP is concerned that the Draft Treaty would do exactly that, and accordingly, strongly urges the Administration to insist that these provisions be withdrawn.

Sincerely,

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