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## **Public Citizen Comment re: Implications of Access and Benefit Sharing (ABS) Commitments/Regimes and Other Proposed Commitments in the WHO Pandemic Agreement**

January 31, 2024

Thank you for this opportunity to comment. Public Citizen appreciates the U.S. government's commitment to securing an agreement that will help protect Americans and people everywhere from future pandemics while advancing equitable access to medical tools. We thank you for your work.

Public Citizen is a consumer advocacy organization with more than 500,000 members and supporters and a fifty-year history protecting the public's interest before federal agencies, Congress and the courts. Our access to medicines program has provided technical assistance to health agencies and organizations in dozens of countries. We rallied support for a more robust global response to the Covid-19 emergency.

### **Introduction**

The Biden administration has recently taken steps to rein in high drug prices and challenge the abuse of patent monopolies. These steps include embracing compulsory licensing authority and incorporating fair pricing conditions in research and development funding agreements. We are concerned that U.S. negotiating positions at WHO<sup>1</sup> have yet to incorporate these U.S. policy advances. At a November session of the WHO Intergovernmental Negotiating Body (INB), U.S. Ambassador Hamamoto stated:

“eliminating intellectual property protections will not effectively improve equitable access during pandemic emergencies, and will in fact harm the systems that have served us well in the past. The United States believes strongly in IP [intellectual property] protections which serve to fuel investment and innovation.”<sup>2</sup>

But the White House recognizes that intellectual property can be a barrier to access. Increasingly, U.S. policy seeks to overcome IP-related barriers, either by regulating pricing in patent monopolies (Inflation Reduction Act; fair pricing conditions in research & development agreements), curbing their abuse (patent reform; Federal Trade Commission work on patent listings) or articulating public interest exceptions to exclusive rights (march-in rights). Recent policy announcements by the Biden administration illustrate this recognition, and suggest areas where the U.S. can be more supportive in WHO negotiations.

Neither the current text of the Pandemic Instrument nor most proposals to it suggest “eliminating” IP protections. The current text proposes “encouraging” manufacturers, including those receiving public funds, to grant non-exclusive licenses to developing country manufacturers and commitments to agree

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<sup>1</sup> World Health Organization (WHO) Convention, Agreement or other International Instrument on Pandemic Prevention, Preparedness and Response (Pandemic Instrument).

<sup>2</sup> Kerry Cullinan, *Intellectual Property Negotiations Belong at WTO, European Countries Tell Pandemic Accord Negotiations*, Health Policy Watch (Nov. 6, 2023),

<https://healthpolicy-watch.news/intellectual-property-negotiations-belong-at-wto-european-countries-tell-pandemic-accord-negotiations/>

on IP waivers, limited in both time and scope, as necessary.<sup>3</sup> Manufacturers retain exclusivity outside of narrow exceptions.

Moreover, U.S. policy supports both provisions. At the height of the Covid-19 emergency, the U.S. announced “the Biden-Harris Administration’s support for waiving intellectual property protections for COVID-19 vaccines”:

“The Administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines. We will actively participate in text-based negotiations at the World Trade Organization (WTO) needed to make that happen. ...The Administration’s aim is to get as many safe and effective vaccines to as many people as fast as possible.”<sup>4</sup>

This is a policy and vision seemingly more progressive than the U.S. presented to WHO in November. We believe the U.S. can, and must, be more supportive of strong provisions supporting equity and access in the Pandemic Instrument.

Our comment first describes U.S. policy developments we believe helpfully should inform negotiating positions in the Pandemic Instrument. Next, we illustrate that existing statutory authority provides a path for the U.S. to support stronger equity commitments in the Instrument. Then we respond to specific questions in the Request for Comment.

## **Recent U.S. Policy Announcements Should Inform the Pandemic Instrument Negotiation**

### ***March-In Rights***

In December, when the Biden administration announced a [framework](#) for “march-in rights”, it said, “Under our Administration’s new proposal, if American taxpayers paid to help invent a drug – it’s time for that drug to be accessible to patients, including at a reasonable price.”<sup>5</sup> The White House further described its proposal as follows:

“... to put drug companies on notice if products developed using federal funds are not made available to the public on reasonable terms, including based on price. The proposal would promote the federal government’s ability to license a patent — such as those used to create life-saving drugs — to a competitor with the goal of increasing competition and bringing costs down for families.”<sup>6</sup>

The Bayh-Dole Act recognizes cases where IP poses a barrier to access. The Biden administration has bolstered this recognition in announcing its framework and has explicitly acknowledged that high prices

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<sup>3</sup> Pandemic Instrument Article 10.1(d); Article 11.3(a).

<sup>4</sup> *Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver*, (May 5, 2021), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-i-covid-19-trips-waiver>

<sup>5</sup> The Biden-Harris Administration is Taking on Price Gouging, *The White House*, YouTube, (Dec. 13, 2023), <https://www.youtube.com/watch?v=NVIIRRIcWUM>

<sup>6</sup> *FACT SHEET: Biden-Harris Administration Announces Dozens of Pharma Companies Raised Prices Faster than Inflation, Triggering Medicare Rebates*, The White House Briefing Room: Statements & Releases (Dec. 14, 2023), <https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/14/fact-sheet-biden-harris-administrati-on-announces-dozens-of-pharma-companies-raised-prices-faster-than-inflation-triggering-medicare-rebates/>

maintained by monopoly control over government-funded inventions are grounds for march-in when such inventions are not accessible to the public. For medicines, this means that if a drug relies on taxpayer funded inventions (such as government-owned patents), an agency can invoke march-in rights to license one or more generic manufacturers to make the drug cheaper and more accessible. Effectively, the policy grants a compulsory license to increase access and affordability to publicly funded medicines.<sup>7</sup>

Public interest safeguards under the Bayh-Dole Act, including march-in rights, as well as the Biden administration's position that they can be a mechanism for overcoming pricing and intellectual property barriers to publicly-funded medicines, indicates that similar provisions can be supported in the Pandemic Instrument, even in a binding capacity.

### **R&D Funding Conditions**

Similarly, the Biden administration announced new pricing and access conditions for research & development funding agreements. The HHS agreement with Regeneron to develop a COVID-19 therapy included a Most Favored Nation clause to promote affordability.<sup>8</sup> This was shortly followed by another announcement that similar clauses had been used in other recent Project NextGen agreements and that the Administration for Strategic Preparedness and Response (ASPR) was making fair pricing a standard part of its contract negotiations.<sup>9</sup> ASPR is responsible for the development of health security technologies.

“Building off last week’s announcement, today HHS announced that the Administration for Strategic Preparedness and Response (ASPR) is making fair pricing a standard part of contract negotiations for medical products developed or purchased as part of its commitment to obtain best value for the US taxpayer.”<sup>10</sup>

In other words, the U.S. will now always seek to attach fair pricing conditions to its pandemic-related research & development agreements – the same issue at stake in Article 9 of the pandemic accord. The U.S. could help reinstate the Article 9 provision on equitable access conditions in publicly funded R&D agreements.<sup>11</sup> Coherent with U.S. law and practice, these conditions could include, for example,

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<sup>7</sup> *Expanding Access and Affordability to Taxpayer Funded Drugs: The Use of March-In Rights*, Public Citizen, <https://www.citizen.org/article/expanding-access-and-affordability-to-taxpayer-funded-drugs-the-use-of-march-in-rights/> (last visited Jan. 22, 2024).

<sup>8</sup> *HHS Announces Details of Partnership with Regeneron to Develop Life-Saving Monoclonal Antibodies*, HHS News (Sept. 8, 2023), <https://www.hhs.gov/about/news/2023/09/08/hhs-announces-details-partnership-regeneron-develop-life-saving-mono-clonal-antibodies.html>.

<sup>9</sup> *New HHS Actions and Research Highlight How President Biden’s Administration is Lowering Prescription Drug Costs*, HHS News (Dec. 14, 2023), <https://www.hhs.gov/about/news/2023/12/14/new-hhs-actions-and-research-highlight-how-president-bidens-administration-lowering-prescription-drug-costs.html>.

<sup>10</sup> *FACT SHEET: Biden-Harris Administration Announces Dozens of Pharma Companies Raised Prices Faster than Inflation, Triggering Medicare Rebates*, The White House Briefing Room: Statements & Releases (Dec. 14, 2023), <https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/14/fact-sheet-biden-harris-administration-announces-dozens-of-pharma-companies-raised-prices-faster-than-inflation-triggering-medicare-rebates/>.

<sup>11</sup> *Pandemic Instrument Zero Draft*, [https://apps.who.int/gb/inb/pdf\\_files/inb4/A\\_INB4\\_3-en.pdf](https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_3-en.pdf) (last visited Jan. 22, 2024) (“...when providing public funding for research and development for pandemic prevention, preparedness, response and recovery of health systems, shall, taking into account the extent of the public funding received:

affordable pricing of end-products; retention of rights by the funder; licensing to enable the development, manufacturing and distribution of pandemic-related products; timely supply and timely registration. Coherent with U.S. law and development goals, these conditions also could include timely registration abroad or emergency-use listing; and provisions for technology and know-how transfer at the time of a pandemic.

Reinstating the provision on access conditions in funding agreements would also support provisions in Articles 10 and 11, as terms can be included in public funding agreements to ensure equity goals related to sustainable production and transfer of technology and know-how.<sup>12</sup>

### **Existing Statutory Authority and Biden Administration Policy Support Stronger Equity Commitments in the Pandemic Instrument**

Existing U.S. law authorizes the government to take measures to advance health goals, for example, by ensuring publicly funded inventions are available to the public, increasing manufacturing of health tools, or otherwise supporting a time-pressured emergency response. Such authorities empower the government to act as needed. These authorities are not limited to voluntary measures encouraging private entities to act. Instead, they acknowledge that safeguards on public funding and availability of non-voluntary measures are important tools to support government action and the public interest.

The U.S. should promote similar aims in the Pandemic Instrument by supporting stronger equity provisions. The U.S. can use its existing statutory authority to implement many of these commitments, suggesting that the U.S. could reasonably support greater operationalization of equity in the Instrument.

Example authorities that safeguard public investments, offer mechanisms to incentivize private parties to act or compel action where necessary include:

#### ***The Bayh-Dole Act***

The U.S. retains rights over inventions it funds. The Bayh-Dole Act maintains key public interest safeguards for taxpayer-funded inventions.

These safeguards include:

- the right to “march-in” and license competition when the owner of a taxpayer funded invention has not achieved practical application of the invention, or where marching-in is necessary to alleviate health or safety needs not being met by the owner. Practical application means that the

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9.2b “endeavour to include terms and conditions on prices of products, allocation, data sharing and transfer of technology, as appropriate, and publication of contract terms

9.2e: “establish appropriate conditions for publicly funded research and development, including on distributed manufacturing, licensing, technology transfer and pricing policies.”).

<sup>12</sup> Articles 10 and 11 include provisions to encourage or require non-exclusive licensing and/or waive or manage royalties on pandemic-related products where public funding is involved (Articles 10.1(d) and 11.3(b)). Additionally, Articles 11.1, 11.2(a), and 11.2(b) concern strengthening existing mechanisms to promote technology transfer (such as through pooling mechanisms), facilitating and incentivizing manufacturers to transfer technology and know-how, and making available non-exclusive licensing of government-owned technology. All of which can be included in government R&D and licensing agreements with the goal of promoting equitable access to pandemic-related tools.

invention is being used and the benefits of the invention are available to the public on reasonable terms;<sup>13</sup> and

- a nontransferable, irrevocable, royalty-free license to practice or have practiced the invention for or on behalf of the United States throughout the world.<sup>14</sup>

These rights provide the government with valuable leverage that can be deployed to encourage private entities to act or to circumvent them.

Various provisions in the Pandemic Instrument make particular reference to “encouraging” actions to promote accessibility of publicly funded tools, “on mutually agreed terms,” for example, in Articles 10.1(d), 11.2(b), 11.3(b). Considering the leverage the U.S. retains over publicly funded inventions, the U.S. can support language that also requires parties to the Instrument to have available compulsory authority, and at least suggests acting on it. This additionally supports the removal of “on mutually agreed terms” from such provisions.

Removal of language stipulating “voluntary” and “on mutually agreed terms” would be more supportive of the full scope of policy options available to governments to implement commitments in Articles 10 and 11.

### ***Defense Production Act***

The U.S. used the Defense Production Act (DPA) at various points during the COVID-19 pandemic, and also recently announced it would use DPA to address shortages of critical medicines in the United States.

DPA can be used to require companies to prioritize government contracts and bolster national production. Additionally, it can be used to incentivize manufacturers to act to meet supply demands. For example, President Biden utilized DPA in brokering a partnership in which Merck would produce drug substance, formulate, and fill vials of Johnson & Johnson’s vaccine when it became clear that the latter would not meet its supply expectations.<sup>15</sup>

Biden administration officials said of the measure at the time:

“The Defense Production Act, which gives the government the power to compel companies to support war effort, provided some ‘implicit’ incentive for the companies to cooperate, administration officials said. ‘You have the potential to use the DPA if there isn’t cooperation,’ one of the officials said.”<sup>16</sup>

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<sup>13</sup> 35 U.S.C. §§ 203(a)(1)-(2).

<sup>14</sup> 35 USC § 202(c)(4).

Notably, under the Bayh-Dole Act, the royalty-free right may be used “as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreement relating to weapons development and production.”

<sup>15</sup> See, Merck, Merck to Help Produce Johnson & Johnson’s COVID-19 Vaccine; BARDA to Provide Merck With Funding to Expand Merck’s Manufacturing Capacity for COVID-19 Vaccines and Medicines (March 2, 2021), <https://www.merck.com/news/merck-to-help-produce-johnson-barda-to-provide-merck-with-funding-to-expand-mercks-manufacturing-capacity-for-covid-19-vaccines-and-medicines/>

<sup>16</sup> How The White House Got 2 Pharma Rivals To Work Together On COVID-19 Vaccine, NPR, (March 3, 2021), <https://www.npr.org/2021/03/03/973117712/how-the-white-house-got-2-pharma-foes-to-work-together-on-covid-19-vaccine>

The DPA grants the President authority to support national defense.<sup>17</sup> As highlighted by Rizvi, Ravinthiran, and Kapczynski, the definition of national defense includes “‘military or critical infrastructure assistance to any foreign nation,’ and ‘critical infrastructure assistance and protection’ (which includes systems and assets, the degradation of which would have a debilitating impact on ‘national public health’), as well as ‘emergency preparedness activities.’”<sup>18</sup> The recognition of assistance to foreign nations within this definition may indicate usefulness beyond domestic commitments in the pandemic instrument.<sup>19</sup>

This authority is supportive of obligations under Article 10 obligating parties to take measures to support and scale up production capacity to meet demand. Additionally, existing authority under DPA would support removal of language limiting action to “encouraging” “on mutually agreed terms,” for example in Article 10.1(d). At the least, these could be substituted with language such as, “Parties shall take measures to require or encourage” entities to act. This would acknowledge use of leverage and compulsory measures, such as that provided by DPA, where necessary.

### **Section 1498**

28 U.S.C. § 1498 provides a legal mechanism to authorize third-party use of patents, however unlike the Bayh-Dole Act which covers government-funded inventions, this statute can be applied to any U.S. patent. The U.S. used this statute throughout the pandemic in contracts for COVID-19 countermeasures to permit use of inventions by third parties without the authorization of patent holders.<sup>20</sup>

Section 1498 facilitates government use of patents, including to support pandemic response. Other countries may wish to adopt similar national policies that facilitate government use of patents to better respond to health emergencies. For example, a European Union proposal for regional compulsory licensing seeks to provide additional policy options to increase access to medical tools needed for a public health emergency response, including a provision to compel sharing of trade secrets necessary for countermeasure production.<sup>21</sup>

It is our understanding that the U.S. has advocated to include “voluntary” and “on mutually agreed terms” in many of the Article 10 and 11 provisions. We recommend removing these caveats. As described above, the U.S. has the existing authority to compel action where needed. Stronger language such as committing parties to “take measures to require or encourage” entities (particularly those that receive public funding) to act in the interest of pandemic response would better operationalize equity commitments and more adequately recognize State’s options to either negotiate voluntary agreements or compel action where necessary.

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<sup>17</sup> Defense Production Act of 1950, as amended (50 U.S.C. 4533)

<sup>18</sup> Rizvi, Ravinthiran, Kapczynski, Sharing The Knowledge: How President Joe Biden Can Use The Defense Production Act To End The Pandemic Worldwide, (6 Aug 2021), <https://www.healthaffairs.org/content/forefront/sharing-knowledge-president-joe-biden-can-use-defense-product-on-act-end-pandemic>

<sup>19</sup> See, <https://lpeproject.org/blog/how-to-vaccinate-the-world-part-2/>

<sup>20</sup> *Selected U.S. Government COVID Contracts with Authorization and Consent to Non-Voluntary Use Of Third Party Patents*, KEI Briefing Note 2022:1 (July 19, 2022), <https://www.keionline.org/wp-content/uploads/KEI-bn-2022-1.pdf>

<sup>21</sup> European Commission, Directorate-General for Health and Food Safety, Proposal for a Directive on the Union code relating to medicinal products for human use (Apr. 26, 2023), [https://health.ec.europa.eu/publications/proposal-directive-union-code-relating-medicinal-products-human-use\\_en](https://health.ec.europa.eu/publications/proposal-directive-union-code-relating-medicinal-products-human-use_en).

The availability of non-voluntary measures plays a role in incentivizing voluntary agreements, including public funding agreements. However, in the event that these do not provide sufficient incentive to prompt private partners to act, non-voluntary measures become important tools for implementing commitments.

U.S. policy and practice increasingly support this. A stronger position on access to publicly funded technologies for pandemic-related products aligns with the Biden administration's recognition of circumstances for marching-in on taxpayer funded medicines. Namely, the grant of licenses on publicly funded technologies on the basis of price, availability to the public on reasonable terms, and for the alleviation of health and safety needs<sup>22</sup> suggests similar tools should be available to Parties in the emergent context of a pandemic. The Administration's announcement to make reasonable pricing provisions standard in contract negotiations for health security-related medicines developed or purchased by ASPR established a standard of practice that should be advanced in the Pandemic Instrument, namely including access conditions in public funding agreements. These policy positions provide a precedent to include stronger access standards in the Instrument, including through greater recognition of both voluntary and non-voluntary measures that may be needed as part of a fast, global pandemic response.

In sum, examples of existing statutory authority laid out above show areas where the U.S. can agree to more than hortatory statements in the Pandemic Instrument. For example, retaining obligations and replacing language obligating Parties to "encourage" with language obligating parties to "take measures to require."

Additionally, all references to "voluntary" and "on mutually agreed terms" should be omitted from provisions under Articles 10 and 11. This is supported by U.S. law and increasingly by practice under the Biden administration.

Doing so would show the U.S. is committed to a Pandemic Instrument that prioritizes equity and learns from the failure to distribute medical countermeasures quickly and equitably during the COVID-19 pandemic.

As an example, baseline edits to Article 10.1(d) could be as follows (similar changes can be made to various Article 10 and 11 provisions):

Parties shall:

10.1(d) [ADD take measures to require, make available authority to require, and/or] encourage entities, including manufacturers within their respective jurisdictions, in particular those that receive significant public financing, to grant, subject to any existing licensing restrictions, ~~on mutually agreed terms,~~ non-exclusive, royalty-free licences to any manufacturers, particularly from developing countries, to use their intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of pandemic-related product development and production, in particular for pre-pandemic and pandemic diagnostics, vaccines and therapeutics for use in ~~agreed~~ developing countries...

This example is meant to illustrate the points above, however, we recommend the U.S. remain receptive to additional proposals endeavoring to provide greater operationalization of equity in the Instrument. As described above, in many cases, existing authority provides a pathway to reasonably support stronger

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<sup>22</sup> NIST Releases for Public Comment Draft Guidance on March-In Rights, NIST News (Dec. 7, 2023), <https://www.nist.gov/news-events/news/2023/12/nist-releases-public-comment-draft-guidance-march-rights>.

equity commitments in the Instrument. Doing so will show a commitment to addressing the inequity of the COVID-19 pandemic in addition to preventing future economic loss resulting from another fractured pandemic response.

## **Public Citizen’s Response to Prompts for Articles 9, 10, and 11**

The remainder of our comments will address prompts set forth in the Request for Comment under Articles 9, 10, and 11, highlighting Biden administration policies and actions, where appropriate.

### **Article 9**

**Are there provisions that could reasonably be included in government-funded research or advanced development agreements, or policies related to licensing of government-owned and/or government-funded technology that would promote global access to pandemic-related products, without disincentivizing innovation or partnering with the U.S. government around research and development?**

#### **Government Funding Agreements**

##### *Reasonable Pricing*

The Biden administration should develop standard and comprehensive reasonable pricing clauses to ensure that products developed with public funds are reasonably and affordably priced. As promising first steps, HHS included a fair pricing clause with Regeneron that is now a standard negotiating clause for agreements from ASPR prohibits charging a higher list price in the United States compared to other high income nations.<sup>23</sup>

However, MFN clauses are a minimum and these agreements include various caveats which may limit their use in certain circumstances.<sup>24</sup> Agreements can and should go further in pursuit of reasonable pricing and global access to products developed with public funds.

In order for pricing to be “reasonable,” it must correlate with actual development costs of the product. This requires transparency of costs throughout the R&D process as well as clear understanding of how to offset these costs once a product reaches market. As laid out in Robert Weissman’s written [testimony](#) to the Senate HELP Committee on PAHPA reauthorization, reasonable pricing should be defined based on core principles, including keying price to R&D costs and magnitude of risk in development. Where the government incurred most of the R&D expense and risk in development, a reasonable price for the drug would necessarily be lower. Further, where the government has assumed most of the risk of developing

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<sup>23</sup> *HHS Announces Details of Partnership with Regeneron to Develop Life-Saving Monoclonal Antibodies*, HHS News (Sept. 8, 2023),

<https://www.hhs.gov/about/news/2023/09/08/hhs-announces-details-partnership-regeneron-develop-life-saving-mono-clonal-antibodies.html>; *New HHS Actions and Research Highlight How President Biden’s Administration is Lowering Prescription Drug Costs*, HHS News (Dec. 14, 2023), <https://www.hhs.gov/about/news/2023/12/14/new-hhs-actions-and-research-highlight-how-president-bidens-administration-lowering-prescription-drug-costs.html>.

<sup>24</sup> David Lim, Lauren Gardner, & Katherine Ellen Folley, *Regeneron deal may not reach such great heights*, Politico (Sept. 19, 2023), <https://www.politico.com/newsletters/prescription-pulse/2023/09/19/regeneron-deal-may-not-reach-such-great-heights-00116641>.



a drug, there should be a certain return beyond which a private manufacturer should no longer be entitled to supracompetitive profits. At that point, an automatic license should be issued to all qualified manufacturers and these manufacturers should have access to needed materials and data to produce the medicine.

President Biden's support for reasonable pricing provisions in R&D contracts is a welcome acknowledgment of the fact that public funds must be repaid with affordability and accessibility for the public. Though they could go further to support access, the Biden administration's support for reasonable pricing provisions sets a precedent that pricing and access provisions in public funding agreements should be included in the Pandemic Instrument.

Additional global access conditions that can be included in funding agreements:

- An automatic license to the World Health Organization (WHO) and efforts such as the WHO's mRNA Technology Transfer Program.<sup>25</sup> Along with a license for relevant intellectual property and testing data, U.S. research and development contracts should require grantees to engage affirmatively in technology transfer, including the sharing of biomaterials, product recipes and manufacturing methods. The affirmative objective should be to build up manufacturing and development capacity in developing countries.
- A duty for manufacturers to make best efforts to scale up production to meet global need and to license with low and fixed royalties to qualified third parties to manufacture for developing country markets. Licensing for developing countries can be easily arranged through the Medicines Patent Pool (MPP), an international institution established for exactly this purpose.<sup>26</sup>
- A duty to timely and broadly register or seek emergency use/listing authorization of pandemic-related medical products in relevant markets. Funding agreements with global or transnational companies should ordinarily be expected to register in all countries, including lower income countries where they frequently delay or decline to seek regulatory approval. Regional manufacturers should register regionally, whereas national manufacturers should register domestically.
- An obligation for affordable pricing for developing countries. Generally, this should be marginal pricing for low- and middle-income countries and substantially discounted pricing for upper-middle-income nations. Companies should be able to satisfy the pricing obligation by providing non-exclusive licenses, if they prefer. It is important that affordability and licensing arrangements cover middle-income countries to ensure rapid, worldwide availability of critical new products. By way of example, Public Citizen has estimated that the need for the Covid treatment Paxlovid (Nirmatrelvir/ritonavir) in non-high income countries is at least 10 times what has been purchased.<sup>27</sup>

### *Licensing Provisions*

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<sup>25</sup> *mRNA Technology Transfer Programme moves to the next phase of its development*, WHO News (Apr. 20, 2023), <https://www.who.int/news/item/20-04-2023-mrna-technology-transfer-programme-moves-to-the-next-phase-of-its-development>.

<sup>26</sup> *About Us*, Medicines patent pool, <https://medicinespatentpool.org/> (last visited Jan. 22, 2024).

<sup>27</sup> Letter to Katherine Hiner, Acting Secretary to the U.S. International Trade Commission from Peter Maybarduk, Public Citizen Access to Medicines Director (Apr.12, 2023), <https://www.citizen.org/article/post-hearing-brief-for-investigation-no-332-596-covid-19-diagnostics-and-therapeutics-and-flexibilities-under-the-trips-agreement/>.

Licensing provisions in the Pandemic Instrument can encourage equitable access to pandemic-related products, including by encouraging technology transfer and contributing to sustainable production. Conditions in funding agreements (as previously included under Article 9) should include requirements to license to qualified third parties, including IP, data, and transfer of technology and know-how, for building manufacturing and development capacities in developing countries. Provisions should also include the same affirmative obligation to work on licensing and access strategies with WHO and its partners, such as the Medicines Patent Pool, which includes the sharing of IP, data, and know-how.<sup>28</sup> Provisions in licensing agreements could include:

- “‘Reach-through’ provisions, ensuring that any party using a licensed technology must apply the same access and affordability provisions as included in the original contract terms. Reach-through provisions prevent gaming of the affordability and accessibility obligations, for example, through modest alterations of the original product. They also extend the affordability and accessibility benefits to follow-on and combination products, re-paying the taxpayers for their initial investments.
- Duties to license to other qualified drug researchers and manufacturers to facilitate innovation. The licensing obligation should include intellectual property and data rights for the end product, but also materials needed for conducting research. There is evidence to suggest that companies are restricting access to Covid vaccines that would be used for research purposes, imposing potentially severe impediments to important research.<sup>29</sup>

In 2010, MPP received its first license from NIH for government-owned patents related to the HIV medicine darunavir.<sup>30</sup> More recently, NIH licensed Covid technologies to MPP for access through WHO’s COVID-19 Technology Access Pool (C-TAP).<sup>31</sup> This step by NIH should set a precedent that federal agencies can build upon by working more with WHO and MPP to share knowledge globally. When the federal government licenses its patent to these multilateral mechanisms, it encourages patent holders for other products to do the same. In the future, similar actions can aid in manufacturing scale-up and prevent rationing.<sup>32</sup>

WHO recently announced a new Health Technology Access Pool (H-TAP), building upon lessons learned from C-TAP.<sup>33</sup> We encourage further sharing of technology and knowledge through these mechanisms. Further policy options to facilitate participation in these mechanisms, as taken from WHO’s report on encouraging technology and knowledge sharing with CTAP, include:

- buyout technologies to share them through access mechanisms

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<sup>28</sup> Allison Durkin, Patricia Anne Sta Maria, Brandon Willmore, & Amy Kapczynski, *Addressing the Risks That Trade Secret Protections Pose for Health and Rights*, 23 Health & Human Rts. 129 (2021).

<sup>29</sup> PrEP4All, *Science Held Hostage: How Pharma is Using mRNA Vaccine Contracts with Government to Delay Future Innovation* (Apr. 2023), <https://prep4all.org/wp-content/uploads/2023/06/PrEP4AllPreventionEquityAlert-4-2023.pdf>.

<sup>30</sup> Medicines Patent Pool, *PATENTS RELATED TO DARUNAVIR*, Progress & Achievements: Licenses <https://medicinespatentpool.org/licence-post/patents-related-to-darunavir> (last visited Jan. 22, 2024).

<sup>31</sup> *NIH Contributions to WHO COVID-19 Technology Access Pool and Q&As*, NIH Policy (May 12, 2022), <https://www.techtransfer.nih.gov/policy/ctap>.

<sup>32</sup> Zain Rizvi, Public Citizen, *The NIH Vaccine* (June 25, 2020), <https://www.citizen.org/article/the-nih-vaccine/>.

<sup>33</sup> Elaine Ruth Fletcher, *Second World Local Production Forum Launches New Collaborations; Civil Society Protests IP Barriers*, Health Policy Watch (Nov. 10, 2023), <https://healthpolicy-watch.news/second-world-local-production-forum-launches-new-collaborations-civil-society-protests-ip-barriers/>.

- include terms to ensure access and innovation into research and development funding and government procurement agreements, including requiring participation in the relevant technology access pool
- license government-owned inventions, and request reciprocity from sublicensees, binding them to a commitment to share foreground intellectual property and knowledge; and
- engage with technology holders in a more systematic, structured approach.<sup>34</sup>

### *Appropriate Scope of Licensing Government-Owned Inventions*

Non-exclusive licensing should be the norm. Non-exclusive licensing of government technology protects against monopolization of resulting products which may be important for pandemic response. Because it is impossible to know in advance what these products will be, nonexclusive licensing will provide an avenue to promote downstream innovation in the event that the relevant technology is needed for pandemic response.<sup>35</sup>

The Bayh-Dole Act provides criteria for the grant of exclusive or partially exclusive licenses for government-owned technology. These criteria include that exclusive licenses should be granted in cases where the “the proposed terms and scope of exclusivity are not greater than reasonably necessary to provide the incentive for bringing the invention to practical application or otherwise promote the invention's utilization by the public.”<sup>36</sup> Federal agencies have a responsibility to determine that the scope of an exclusive license is not broader than necessary. If, after a rigorous determination process, the government does not opt for nonexclusive licensing, provisions should still be included to protect global access. Such provisions include:

- Limits on the geographic scope of exclusivity to ensure patents do not lead to inequitable access in developing countries;
- Limits on the period of exclusivity based on revenue benchmarks. This is reasonable based on the requirements of 35 U.S.C. § 209 that the scope of exclusivity not be “greater than reasonably necessary to provide the incentive for bringing the invention to practical application.”
- Require licensees to pursue registration and accessibility in countries with demonstrated need for the product. This can be achieved through bilateral country arrangements with affordable and publicly disclosed prices. Or through transfer of technology and rights to needed IP to third parties. In the event that it is found that markets are not being adequately served, the U.S. should retain the right to grant governments or WHO-partners patent rights to pursue access.

### *Retaining Rights to Government-Owned or Funded Technologies*

Operation Warp Speed contracts weakened or eliminated Bayh-Dole requirements and FAR safeguards.<sup>37</sup> Skirting these requirements hamstrung the leverage that the federal government could exercise in

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<sup>34</sup> WHO, Strategies to facilitate sharing of technology and knowledge through WHO COVID-19 Technology Access Pool (Oct. 3, 2023), <https://www.who.int/publications/i/item/9789240073951>.

<sup>35</sup> Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, (Oct. 2003), [www.ftc.gov/reports/promote-innovation-proper-balance-competition-patent-law-policy](http://www.ftc.gov/reports/promote-innovation-proper-balance-competition-patent-law-policy).

<sup>36</sup> 35 U.S.C. § 209 (a)(2); Joint Comments by KEI, UACT, Social Security Watch & Health Gap on the proposed NIH Exclusive License in CAR Therapy to Lyell Immunopharma (and NIH Response), Knowledge Ecology International Blog ( Sept. 19, 2019), <https://www.keionline.org/31713>.

<sup>37</sup> James Love, *KEI receives seven new contracts for COVID 19 research from BARDA and DOD, including five using “Other Transactions Authority” that weaken or eliminate Bayh-Dole and FAR Safeguards*, Knowledge Ecology International Blog (July 1, 2020), <https://www.keionline.org/covid19-ota-contracts>.

pursuit of reasonable pricing and equitable access.<sup>38</sup> The use of “Other Transaction Agreements” in U.S. COVID contracts degraded public interest provisions such as the royalty free rights and grounds for march-in under the Bayh-Dole Act.

The Bayh-Dole Act includes important safeguards that can be used in the public interest, including during pandemics. Similarly, other R&D funders include access conditions that maintain leverage over products aided through the development process. For example, the Coalition for Epidemic Preparedness Innovations (CEPI), a public-private partnership that the U.S. funds, included various access conditions as part of its COVID-19 funding agreements.<sup>39</sup> In a few cases, these included “step-in rights” and retention of a “public health license,” both of which could be leveraged to expand affordable supply or require technology sharing in particular circumstances.<sup>40</sup>

#### *These Provisions Would Not Disincentivize Innovation or Deter Collaborations with the Federal Government*

The prospect of innovating drugs with high profitability in high income markets after receiving significant federal subsidization, in the order of billions, will continue to drive the research and development of pandemic-related technologies, even with equitable licensing terms for low- and middle-income countries. Although this federal subsidization and profit incentive is so significant that other measures should not be necessary to elicit industry collaborators, other policy options exist to further incentivize the equitable sharing of information. These include grant back licenses from follow on improvements to licensed products, trade secrecy confidentiality requirements in the licensing agreements with manufacturers from lower income countries, and restricting the field of use of trade secrets on know-how to the pandemic, which can insulate commercial incentives (possibly too much) of the originator manufacturers. And even where disclosure occurs to competitors, compensation may be an appropriate solution in the context of averting the humanitarian and economic catastrophe of a pandemic.<sup>41</sup>

Fair pricing conditions in research and development agreements will not disincentivize innovation or deter collaboration. These clauses are keyed to research and development costs and the risks of a particular technology’s development. The clause would still allow companies to generate generous profits on medicinal technologies derived from significant federal subsidization, but would merely prohibit supracompetitive profits that can lead to medicine inaccessibility in the emergency context of a pandemic. The generous profits in countries with high capital would continue to drive innovation on taxpayer-funded technologies, even with equitable licensing provisions to further access in low- and middle-income countries.

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<sup>38</sup> Sharon Lerner, *The Trump Administration is Waiving the Public’s Right to Affordable Coronavirus Treatments*, Intercept (July 1, 2020), <https://theintercept.com/2020/07/01/coronavirus-treatment-drug-contracts-trump/>.

<sup>39</sup> CEPI, *Enabling Equitable Access to COVID-19 Vaccines: Summary of equitable access provisions in CEPI’s COVID-19 vaccine development agreements* (Feb. 14, 2022), <https://cepi.net/wp-content/uploads/2020/12/Enabling-equitable-access-to-COVID19-vaccines-v8-14-February-2022.pdf>.

<sup>40</sup> Zain Rizvi, Public Citizen, *COVAX’s Choices* (Nov. 16, 2020), <https://www.citizen.org/article/covaxs-choices/>.

<sup>41</sup> Allison Durkin, Patricia Anne Sta Maria, Brandon Willmore, & Amy Kapczynski, *Addressing the Risks That Trade Secret Protections Pose for Health and Rights*, 23 *Health & Human Rts.* 129 (2021).

## Article 10

**What approaches or incentives might be used to encourage manufacturers and others “to grant, subject to any existing licensing restrictions, on mutually agreed terms, non-exclusive, royalty-free licenses to any manufacturers, particularly from developing countries, to use their intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of pandemic-related product development and production, in particular for pre-pandemic and pandemic diagnostics, vaccines and therapeutics for use in agreed developing countries”?**

Nonexclusive licensing of government-owned technology should be the norm. It is impossible to know in advance what technologies will be needed as part of a pandemic response. Nonexclusive licensing acknowledges this fact and promotes downstream innovation in the event a technology is needed for pandemic response. More than once, the U.S. has led by example in this respect, including during the COVID-19 pandemic.

In 2010, the U.S. via the NIH granted MPP its first license for government-owned patents related to the HIV medicine darunavir. This forward-looking contribution helped establish MPP and encouraged subsequent licenses from the pharmaceutical industry.

In May 2022, the Biden administration, again via the NIH, announced that it had licensed 11 COVID-19 research tools and early-stage vaccine and diagnostic candidates to the MPP through C-TAP.<sup>42</sup> One such technology was the SARS-CoV-2 stabilized spike protein, which is included in multiple COVID-19 vaccines.

The HHS announcement of these licenses encapsulates the benefits of nonexclusive licensing of government technologies and of licensing through health-focused entities.

“The licenses will allow manufacturers from all around the world to work with MPP and C-TAP to use these technologies for the potential development of COVID-19 vaccines, treatments, and diagnostics to benefit people living in low- and middle-income countries ... C-TAP aims to boost global supply of vaccines, treatments, and diagnostics for COVID-19 by facilitating the sharing of intellectual property, knowledge, and data with quality-assured manufacturers that have capacity to scale up production. NIH scientists regularly make discoveries—both patented and unpatented—that can be transferred to the private sector for further research and development and eventual commercialization. ... ‘Controlling COVID-19 globally and addressing future public health threats is only possible if all communities, including the most vulnerable, have access to lifesaving treatments, vaccines and diagnostics,’ said Health and Human Services Secretary Xavier Becerra. ‘Sharing our scientific knowledge and health technologies with C-TAP to foster the development of crucial medical countermeasures is another step we are taking to assist our global partners in our shared fight against this devastating disease.’”

The U.S. can continue this leadership by licensing more broadly to WHO-partners, like MPP, C-TAP, and H-TAP. This will prevent exclusivities from throttling supply and allowing companies to profiteer off of taxpayer funded technologies.

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<sup>42</sup> *NIH Licenses COVID-19 Research Tools and Early-Stage Technologies to WHO Program*, HHS News (May 12, 2022), <https://www.hhs.gov/about/news/2022/05/12/nih-licenses-covid-19-research-tools-early-stage-technologies-who-program.html>

Beyond government agencies directly licensing to health-focused entities, the government should negotiate, on a product-by-product basis, global access plan requirements for any publicly funded drug. Reinstating the Article 9 provision on access conditions would be supportive of this. Adopting such approaches would support licensing and technology/know-how transfer for global access, such as reach-through provisions that require licensees of publicly owned technologies to equitably license their products.

Importantly, the paragraph referred to in this prompt (Article 10.1(d)), specifically mentions entities that receive public financing. This opens up additional avenues to encourage and incentivize manufacturers if nonexclusive licensing or access conditions in R&D agreements have not been established at an earlier stage.

By retaining leverage over government-owned and government-funded technologies, governments have more space to achieve appropriate promotion of sustainable production and technology transfer for pandemic-related products. In the event that leverage is not sufficient to encourage manufacturers, it can be used to compel action.

During the COVID-19 pandemic, limited supply purchased by high-income countries brought vaccine inequities which left the majority of the world without access to needed medical tools.<sup>43</sup> Reluctance from pharmaceutical companies to share IP to ramp up production or to enter into voluntary agreements, laid bare the limitations of relying solely on “voluntary” measures on “mutually agreed terms.”<sup>44</sup> Expensive, single-source drugs, sold under concealed conditions, do little for global pandemic response. Patent holders’ licensing arrangements can mitigate the problems of monopoly supply over time, but they fall far short of increasing timely, fair, and equitable access to pandemic-related products. The U.S. holds rights over inventions it funds which can be exercised in cases where the invention is not adequately benefiting the public. For example, the U.S. government has authority under the Bayh-Dole Act, or other analogous statutes, to give permission to global partners to use government-funded or government-owned medical inventions and data.<sup>45</sup> The U.S. can also leverage or invoke the Defense Production Act, as the Biden administration did during the COVID-19 pandemic, for example, to broker a partnership between Johnson & Johnson and Merck.<sup>46 47</sup>

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<sup>43</sup> Paul Schemm & Jennifer Hassan, *WHO chief warns of ‘catastrophic moral failure’ as rich countries dominate vaccine supplies*, Wash. Post (Jan. 18, 2021), [https://www.washingtonpost.com/world/who-chief-warns-of-catastrophic-moral-failure-as-rich-countries-dominate-vaccine-supplies/2021/01/18/033644a0-5978-11eb-a849-6f9423a75ffd\\_story.html](https://www.washingtonpost.com/world/who-chief-warns-of-catastrophic-moral-failure-as-rich-countries-dominate-vaccine-supplies/2021/01/18/033644a0-5978-11eb-a849-6f9423a75ffd_story.html).

<sup>44</sup> Christopher Rowland, Emily Rauhala, & Miriam Berger, *Drug companies defend vaccine monopolies in face of global outcry*, Wash. Post (Mar. 20, 2021), <https://www.washingtonpost.com/business/2021/03/20/covid-vaccine-global-shortages/>.

<sup>45</sup> For example, 35 U.S.C. §§ 202, 209; 15 U.S.C. § 3710.

E.g., 35 U.S.C. § 202(c)(4) (“The Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world”).

<sup>46</sup> *Biden Administration Announces Historic Manufacturing Collaboration Between Merck and Johnson & Johnson to Expand Production of COVID-19 Vaccines*, HHS News (May 2, 2021), <https://public3.pagefreezer.com/content/HHS.gov/30-12-2021T15:27/https://www.hhs.gov/about/news/2021/03/02/biden-administration-announces-historic-manufacturing-collaboration-between-merck-johnson-johnson-expand-production-covid-19-vaccines.html>.

<sup>47</sup> The U.S. government also provided over \$200 million in support so Merck could produce the vaccine manufactured by Johnson & Johnson. Christopher Rowland & Laurie McGinley, *Merck will help make Johnson & Johnson coronavirus vaccine as rivals team up to help Biden accelerate shots*, Wash. Post. (May 3, 2021), <https://www.washingtonpost.com/health/2021/03/02/merck-johnson-and-johnson-covid-vaccine-partnership/>.

And critically, the U.S. itself included involuntary measures in contracts for COVID-19 countermeasures that allowed the use of third-party inventions without their authorization to accelerate the innovation and supply of these vital interventions. The recognition that it is impossible during a pandemic emergency to canvas all intellectual property barriers to innovating countermeasures and entering mutually agreed licensing arrangements with every relevant party by the U.S. through the inclusion of these provisions in contracts suggests similar policy options should be afforded to Parties to the Instrument.

**How helpful or harmful would the following proposed obligations for governments be for public health, business, and innovation interests generally:**

- (a) encourage research and development institutes and manufacturers, in particular those receiving significant public financing, to waive or manage, for a limited duration, royalties on the use of their technology for the production of pandemic-related products;**

Sustainable production will rely on licensing with low and fixed royalties to qualified third parties for developing country markets. Without this, scalable capacity in pandemics will not be possible. As shown by the pandemic, the few pharmaceutical suppliers could not meet global demand and can not be reasonably expected to do so in future pandemics. This requires licensing of pandemic-related materials in pre-pandemic times as well as during pandemics.

In cases of public funding, a condition of funding should be the licensing of relevant technology and know-how, including a condition of reasonable<sup>48</sup> royalties, for example with licensees in developing countries. This supports affordability and prevents profiteering.

Many parties, including pharmaceutical companies, waived or managed royalties related to pandemic-related products. For example, sublicensing agreements through MPP for COVID treatments nirmatrelvir and molnupiravir, stipulated that Pfizer, Merck, Ridgeback Biotherapeutics, and Emory University would not receive royalties while COVID-19 remained classified as a Public Health Emergency of International Concern.<sup>49</sup> Additionally, Oxford University, in its licensing agreement AstraZeneca reportedly did not require payment of royalties during the pandemic. However, lack of transparency in the latter agreement left no understanding of whether these royalties were reasonable.<sup>50</sup>

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<sup>48</sup> See, James Love, Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies, World Health Organization, (2005),

[https://www.keionline.org/wp-content/uploads/who\\_undp\\_2005\\_royalty\\_guidelines.pdf](https://www.keionline.org/wp-content/uploads/who_undp_2005_royalty_guidelines.pdf)

<sup>49</sup> Medicines Patent Pool, *35 generic manufacturers sign agreements with MPP to produce low-cost, generic versions of Pfizer's oral COVID-19 treatment nirmatrelvir in combination with ritonavir for supply in 95 low- and middle-income countries*, Press Releases (Mar. 17, 2022),

<https://medicinespatentpool.org/news-publications-post/35-generic-manufacturers-sign-agreements-with-mpp-to-produce-low-cost-generic-versions-of-pfizers-oral-covid-19-treatment-nirmatrelvir-in-combination-with-ritonavir-f-or-supply-in-95-low-and>; Medicines Patent Pool, *27 generic manufacturers sign agreements with MPP to produce low-cost versions of COVID-19 antiviral medication molnupiravir for supply in 105 low- and middle-income countries*, News (Jan. 20, 2022), <https://medicinespatentpool.org/news-publications-post/27-generic-manufacturers-sign-agreements-with-mpp-to-produce-molnupiravir>.

<sup>50</sup> Jay Hancock, Kaiser Health News, *Oxford's COVID vaccine deal with AstraZeneca raises concerns about access and pricing*, Fortune ( Aug. 24, 2020),

<https://fortune.com/2020/08/24/oxford-astrazeneca-covid-vaccine-deal-pricing-profit-concerns/>.

For commercial entities, the waiver or management of royalties will not affect innovation incentives so long as a commercial product arrives to high-income markets. In the limited cases where this is not true, government subsidies to defray actual, tangible research and development costs may be appropriate.

**(b) promote the publication, by private rights holders, of the terms of licensing agreements or technology transfer agreements for pandemic-related products;**

Timely publication of terms is crucial during emergencies. Drug corporations' licenses undertaken outside health-oriented licensing bodies tend to be far less transparent and include more onerous terms. This hinders pandemic-response, particularly in countries left to negotiate licenses with private suppliers exercising monopoly control over pandemic-related products. Greater transparency ensures greater accountability and measurable access outcomes. Just as other rapid information sharing, such as that of pathogen data, is prioritized in the text, so too should be sharing of licensing agreement terms.

The Medicines Patent Pool approach can be a guide. Licensing agreements are made publicly available on MPP's website, including with commercial entities.<sup>51</sup> No tangible harms to manufacturers arise from transparency obligations over the terms of licensing agreements during a pandemic. A parallel can be drawn with the claim that information as basic as pricing is proprietary and commercially sensitive; price competition is a normal function of markets, and claims that concealing prices fosters innovation are dubious.<sup>52</sup> Similarly, when originator manufacturers have monopoly control over a technology and are the stakeholder with the most information in entering licensing agreements with other countries, it makes little sense to deprive countries seeking licenses of the little leverage they may have: the ability to reject as unreasonable licensing offers that are out of step with those offered in the competitive market. The claim that publishing the licensing agreement is harmful to innovation is dubious in light of the field of use of restrictions to the pandemic context and confidentiality protections that can be instituted for trade secrets covering know-how.

**(c) promote the voluntary licensing and transfer of technology and related know-how for pandemic-related products by private rights holders with established regional or global technology transfer hubs or other multilateral mechanisms or networks."**

Voluntary licensing and transfer of technology and know-how help mitigate issues of monopoly supply over time. However, drug corporations' bilateral licensing practices during COVID lacked transparency and included onerous terms. During the COVID-19 pandemic, in absence of a robust generics market, supply that did become available to upper-middle-income countries excluded from voluntary schemes often remained unaffordable.<sup>53</sup> Further, secrecy in drugmakers' supply agreements suppressed demand and kept prices high.

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<sup>51</sup> Licenses, Medicines Patent Pool, <https://medicinespatentpool.org/progress-achievements/licences> (last visited Jan. 22, 2024); MPP, Statutes, by-laws, and policies, Medicines Patent Pool, <https://medicinespatentpool.org/who-we-are/statutes-by-laws-policies> (last visited Jan. 22, 2024).

<sup>52</sup> Robin C. Feldman & Charles Tait Graves, *Naked Price and Pharmaceutical Trade Overreach*, 22 Yale J.L. & Tech. 61, 97 (2020), [https://repository.uclawsf.edu/cgi/viewcontent.cgi?article=2771&context=faculty\\_scholarship](https://repository.uclawsf.edu/cgi/viewcontent.cgi?article=2771&context=faculty_scholarship).

<sup>53</sup> For example, Pfizer's paxlovid was priced at over \$500/course in some developed countries and \$250 in some developing countries. These prices are substantially greater than the price negotiated by the Clinton Foundation for generic paxlovid (\$25/course). See Brook K. Baker, Health GAP, Submission to U.S. International Trade Commission Investigation No. 332-596 "COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities" (Mar. 15, 2023), [https://healthgap.org/wp-content/uploads/2023/03/Health-GAP-US-ITC-Submission\\_baker.pdf](https://healthgap.org/wp-content/uploads/2023/03/Health-GAP-US-ITC-Submission_baker.pdf).



Voluntary licensing is most effective as a tool for accelerating affordable and reliable supply of generic products when conducted through health-focused organizations like MPP. These entities have experience promoting access and practicing transparency.

In some cases, voluntary licensing is insufficient to address the need for timely, fair, and equitable access to pandemic-related products.

During the COVID-19 emergency, patent holders showed reluctance to license to health agencies. Licenses through MPP for COVID treatments came much later on, meaning actual production and distribution of these countermeasures were not available until 2022, well past the point when they were most needed for pandemic response.<sup>54</sup>

Additionally, drug corporations exclude many countries from their licenses, and importantly, fail to license many medicines at all. For example, Pfizer excluded more than 50 developing countries from its Medicines Patent Pool license for nirmatrelvir-ritonavir (Paxlovid), accounting for over half of the world's population. Similarly, some MPP licensees for COVID antivirals include technology transfer conditions that exclude supply to certain territories, leaving many without an avenue for affordable access.<sup>55</sup>

Where voluntary measures are insufficient, health agencies must be empowered to prioritize health needs, including through use of compulsory licensing to support access.

As stated previously, the United States recognized circumstances for the non-voluntary use of other parties' inventions in accelerating the development and supply of COVID-19 countermeasures, as it can be extremely impractical to canvas all relevant IP rights and enter mutually agreed terms with all relevant parties for production of these interventions in a public health emergency. Similar leeway should be granted to Parties to the Pandemic Instrument in responding to the catastrophe of a pandemic.

Licensing and technology transfer can result in innovation gains when licensees improve upon licensed technologies. With grant-back license provisions, originator manufacturers can also benefit from these innovation gains. Moreover, licensing and technology transfer can be protective of company know-how, though circumstances during a pandemic may favor urgent involuntary measures to ensure sharing of this vital information as part of an emergency response. In those circumstances, compensation structures may be appropriate. A similar situation would arise domestically if the Biden administration exercises march-in rights on a taxpayer funded medicine: potentially, the government would compensate the manufacturer where the government chooses not to exercise its royalty-free right. Thus,

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<sup>54</sup> Medicines Patent Pool, *35 generic manufacturers sign agreements with MPP to produce low-cost, generic versions of Pfizer's oral COVID-19 treatment nirmatrelvir in combination with ritonavir for supply in 95 low- and middle-income countries*, Press Releases (Mar. 17, 2022), <https://medicinespatentpool.org/news-publications-post/35-generic-manufacturers-sign-agreements-with-mpp-to-produce-low-cost-generic-versions-of-pfizers-oral-covid-19-treatment-nirmatrelvir-in-combination-with-ritonavir-for-supply-in-95-low-and-middle-income-countries>; Medicines Patent Pool, *27 generic manufacturers sign agreements with MPP to produce low-cost versions of COVID-19 antiviral medication molnupiravir for supply in 105 low- and middle-income countries*, News (Jan. 20, 2022), <https://medicinespatentpool.org/news-publications-post/27-generic-manufacturers-sign-agreements-with-mpp-to-produce-molnupiravir>.

<sup>55</sup> Brook K. Baker, *MPP COVID-19 Antiviral Medicines Licenses – Licensed Territories, Supply Options for Excluded Territories, and Supply Barriers Arising from Trade-Secret Transfer*, Joint PIJIP/TLS Research Paper Series (Oct. 11, 2023), <https://digitalcommons.wcl.american.edu/research/106>.

compensating manufacturers for the voluntary, and involuntary, sharing of vital technical information, particularly where it derives from public funding, can be among the options available to Parties to the Instrument.

## **Article 11**

**What measures could be taken, or incentives provided, to “strengthen existing, and develop innovative, multilateral mechanisms [under WHO], 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”?**

As addressed in previous responses, licensing to health-focused entities, such as WHO-partners like MPP, C-TAP, and the newly announced H-TAP, promotes equitable access and transparency far more than private company licensing. The U.S. can lead by example to strengthen such entities by more broadly licensing government technologies. Beyond this, licensing to such entities can be stipulated in government R&D agreements to promote access to resulting inventions in LMICs. Additional incentives for licensing to health focused entities have been detailed in response to Article 9 and 10 prompts.

We would encourage including language in this article, either in this paragraph or elsewhere, that promotes licensing to health-focused pooling entities, such as MPP, C-TAP, H-TAP, and GARDP. This would appropriately acknowledge the role of health-focused entities in promoting equitable pooling of resources, which can be utilized alongside or in coordination with any new mechanisms and prevent reliance on private licensing agreements.

**What measures could be taken, or incentives provided, to “make available non-exclusive licensing of government-owned technologies, on mutually agreed terms as appropriate, for the development and manufacturing of pandemic-related products, and publish the terms of these licenses”?**

As addressed in previous responses, the U.S. government has shown leadership in this area on more than one occasion. Licensing government-owned technology on a non-exclusive basis, including to health-focused pooling entities, prevents repetition of supply bottlenecks and excessive pricing brought by monopoly control over COVID-19-related countermeasures. It is sensible to license government technology on a non-exclusive basis, particularly if it may be used in a pandemic response.

Additionally, considering the rights the U.S. government retains over inventions it funds, these might also be considered “government-owned” technologies, such as where an invention relies on government-owned patents. As discussed previously, the U.S. can use these rights as leverage in the context of a pandemic to encourage or require licensing that is supportive of public access.

**What net impacts, positive or negative, would you envision arising from commitments presently outlined in Article 11.3, including:**

- (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;**

Waivers are one tool that can be used to support affordability and equitable access to countermeasures during a pandemic. Including an IP waiver provision in the Pandemic Instrument would acknowledge that these may be needed to facilitate access, along with other provisions of the Instrument.

The Biden administration acknowledged countries' health interest in compulsory licensing to support production and access, supporting waiving IP protections for COVID-19 vaccines.<sup>56</sup> Compulsory licensing can help ensure affordability and timely supply of pandemic-related products. As found in the U.S. International Trade Commission (USITC) report commissioned by USTR on COVID-19 diagnostics and therapeutics and certain flexibilities under the TRIPS Agreement, compulsory licenses are “associated with increased generics and lower prices, and increased access to pharmaceuticals,” while patent protection “has little to no positive effect for innovation in developing countries and negative effects for access and affordability.”<sup>57</sup> The U.S. recognition of the public health benefits of compulsory licensing measures as well as the IP waiver in these circumstances indicates that U.S. negotiators should be supportive of similar measures in the Pandemic Instrument.

It is also necessary to acknowledge that the TRIPS waiver decision adopted during the COVID-19 pandemic was far narrower than that originally proposed by South Africa and India.<sup>58</sup> Additionally, the waiver decision has not been extended to cover COVID-19 diagnostics and therapeutics, which may have provided an additional avenue to facilitating access during the pandemic. Instead, the lack of a timely and comprehensive waiver left fewer options to counteract the vast unmet need in developing countries.<sup>59</sup> The waiver decision agreed upon during the COVID-19 pandemic should not be the basis for future waiver decisions.

**(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;**

As addressed previously, licensing with reasonable or waived royalties, particularly as a condition of public funding can encourage scale up of global manufacturing and can incentivize licensing to developing country manufacturers. The net impact of including conditions in public funding agreements that waive or manage royalties to developing country manufacturers would be very beneficial. Typically, these markets have limited profitability for manufacturers that tend to focus on revenues from high income countries—thus, there would be minimal consequences to innovation incentives as

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<sup>56</sup> Office of the United States Trade Representative, Executive Office of the President, *U.S. to Support Extension of Deadline on WTO TRIPS Ministerial Decision; Requests USITC Investigation to Provide More Data on COVID-19 Diagnostics and Therapeutics*, Press Releases (Dec. 6, 2022), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2022/december/us-support-extension-deadline-wto-trips-ministerial-decision-requests-usitc-investigation-provide-0>.

<sup>57</sup> USITC, *COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities* 16, 64-65 (Oct. 2023), <https://www.usitc.gov/publications/332/pub5469.pdf>.

<sup>58</sup> See Medecins Sans Frontieres, *India and South Africa proposal for WTO waiver from intellectual property protections for COVID-19-related medical technologies*, Briefing Document (Nov. 18, 2020), [https://msfaccess.org/sites/default/files/2020-11/COVID\\_Brief\\_WTO\\_WaiverProposal\\_ENG\\_v2\\_18Nov2020.pdf](https://msfaccess.org/sites/default/files/2020-11/COVID_Brief_WTO_WaiverProposal_ENG_v2_18Nov2020.pdf).

<sup>59</sup> Public Citizen, *Comments to USITC: TRIPS Flexibilities for COVID-19 Diagnostics & Therapeutics* (May 5, 2023) <https://www.citizen.org/article/comments-to-usitc-trips-flexibilities-for-covid-19-diagnostics-therapeutics/>

manufacturers continue to pursue high profits in wealthier nations while averting the extreme inequity and loss of life that occurs in lower income nations due to this resource prioritization.<sup>60</sup>

- (c) encourage manufacturers within its jurisdiction to share undisclosed information, in accordance with paragraph 2 of Article 39 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, with qualified third-party manufacturers when the withholding of such information prevents or hinders urgent manufacture by qualified third parties of a pharmaceutical product that is necessary to respond to the pandemic”?**

Without the sharing of know-how and technology transfer to enable the expeditious production of medicines by manufacturers in developing country markets, licensing to developing country manufacturers in a pandemic may have limited practical effect. That is, the benefits of the freedom to operate for these manufacturers in developing markets goes hand in hand with providing the knowledge necessary to operate. As discussed in the Article 9 prompt, such sharing can be a provision of R&D or licensing agreements to ensure that developing country markets are served or compulsory measures can be leveraged. The EU regional compulsory licensing proposal includes a provision to require sharing of know-how. This recognizes that this information is crucial to scaling up production in an emergency and can be deployed if manufacturers are unwilling to come to reasonable agreements to share technology and know-how.

Thank you again for the opportunity to comment.

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<sup>60</sup> Amy Kapczynski & Jishian Ravinthiran, *How to Vaccinate the World, Part 2*, LPE Blog (May 4, 2021), <https://lpeproject.org/blog/how-to-vaccinate-the-world-part-2/>.