

KEI comments on the implications of Access and Benefit Sharing (ABS) Commitments/Regimes and Other Proposed Commitments in the WHO Pandemic Agreement

To: Susan Kim, Principal Deputy Assistant Secretary, Office for Global Affairs. Office of the Secretary, HHS, Room (639H) Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201, Via: OGA.RSVP@hhs.gov

Re: Written Comment Re: Implications of Access and Benefit Sharing (ABS) Commitments/Regimes and Other Proposed Commitments in the WHO Pandemic Agreement, Federal Register: 88 FR 88637

Date: January 29, 2024

Dear Susan Kim,

Below are comments from Knowledge Ecology International (KEI) in response to the HHS Office for Global Affairs request for comments on the proposed WHO Pandemic Agreement, in response to the notice published in the Federal Register on December 22, 2023.

We have underlined text from the Federal Register notice, followed by KEI's comments on the specific questions raised in the notice. Also attached are three annexes on the incentives to share inventions, data, manufacturing know-how or biologic resources. Follow up questions or clarifications can be sent to James.Love@KEIOnline.Org.

Article 9, Research and Development	2
Article 10, Sustainable Production	6
Royalties	7
Suggested language of intellectual property exceptions	7
Article 11, Transfer of Technology and Know-How	9
“mutually agreed terms”	9
Incentives	10
Article 12, Access and Benefit Sharing	13
Article 13, Global Supply Chain and Logistics (SCL) Network	17
Sanctions exceptions and exemptions	18
Play-or-Pay technology transfer	18
Head-to-head trials	18
ANNEX 1: Table 2 from WHO paper on incentives for C-TAP	19
ANNEX 2: Open source dividend	20
ANNEX 3: Opportunities for H-TAP	22

Article 9, Research and Development

1. What approaches or incentives might be provided to governments, research institutions, or the private sector to encourage participation of relevant stakeholders to, as proposed in the Negotiating Text, “accelerate innovative research and development, including community-led and cross-sector collaboration, for addressing emerging and re-emerging pathogens with pandemic potential”?

Comment

While there is an ongoing need to make investments in countermeasures for possible pandemics, the current systems of incentives for drug development will be inadequate, given the uncertainty of the demand for countermeasure products. Public sector funding of R&D is needed, as well as incentives delinked from high prices or monopolies. The two primary challenges as regards this agreement are (1) to create a global framework where the costs of funding R&D are shared by multiple countries, and (2) to use financing approaches that are consistent with the objectives of timely, affordable and equitable access.

Unless policymakers develop and implement incentives that are not linked to monopolies and high prices, access to countermeasure products will be unequal, and there will be barriers to the scaling of production when that is an issue (as it was in the COVID-19 pandemic).

Given the extraordinary role that public financing plays in the development and purchase of pandemic countermeasures, the delinking of incentives from monopolies and high prices should be attractive to policymakers. Of course, it's worth noting that the COVID-19 pandemic created a lot of private sector wealth.

Stéphane Bancel, the CEO of Moderna, now has a net worth of \$3.7 billion. In 2020, Wendy Holman and her husband, former hedge fund manager Wayne Holman, were able to acquire rights to molnupiravir, a DoD- and NIH-funded drug from Emory University, and relicense those rights to Merck a few weeks later. The terms of the license with Merck gives the Holmans half the profits from the sales of the drug. Through the 3rd quarter of 2023, Merck's sales of Lagevrio, its branded version of molnupiravir, were \$7.9 billion.

Pfizer, a firm with global revenues of \$40.7 billion in 2020 from all products, reported revenues of \$80 billion in 2021 and \$99 billion in 2022, on the strength of two COVID-19 products. In 2022, sales of the mRNA vaccine Comirnaty were \$37.8 billion, and the COVID-19 therapeutic Paxlovid global sales were \$18.9 billion.

The potential for enormous private benefits from pandemic responses makes it politically challenging to implement reforms of incentive mechanisms, even though it is in the interests of taxpayers worldwide to do so.

2. What voluntary steps could Research & Development (R&D) stakeholders take that would build capacities and promote more inclusive research collaborations and participation from basic science through advanced development and clinical research, addressing the global calls for equity and inclusion?

Comment

The possible voluntary steps that could be taken depend on who is considered a stakeholder.

Governments, multilateral, regional and plurilateral institutions, private funders such as charitable foundations, and collaborations between private and public funders such as CEPI, GAVI, the Global Fund, or UNITAID, should include conditions in funding agreements requiring recipients of R&D grants to share knowledge, results, cell lines, and manufacturing know-how, and should agree to measures to ensure products are available and affordable when needed.

The European Union has used criteria to allocate R&D funding within Europe that provided incentives for researchers in more developed regions to include in grant proposals researchers from less developed regions.

Programs like the NIH awards for Regional Technology Transfer Accelerator Hubs for Institutional Development Award (IDeA) or the DOE Energy Improvements in Rural or Remote Areas (ERA) program are a few examples of US government programs to address geographic inclusion and equity.

Not everything has to be completely voluntary. Various obligations could be imposed on some firms involved in some activities to ensure technology transfer, including pay-or-play options, to require firms to either engage in technology transfer directly or to contribute money to technology transfer buy-out funds.

It's worth noting that the experience with the Pandemic Influenza Preparedness (PIP) Framework has shown that vaccine manufacturers have preferred contributing products or money over making commitments to share manufacturing know-how.

3. What national policies might be developed that (as proposed in the Negotiating Text), “support the transparent, public sharing of clinical trial protocols and results conducted either within their territories or through partnerships with other Parties, such as through open access publications”?

Comment

The registration of products for sale should be conditioned on agreements to make disclosures and publications of clinical trial protocols and the results of all trials related to the product.

The approval to conduct human use trials by regulatory agencies should also require the publication of trial protocols and results.

It would have been useful during the pandemic to have third-party run trials providing head-to-head comparisons of the efficacy and safety of multiple vaccine candidates. If there were a provision in the agreement that ensured that developers of vaccines and other countermeasures would cooperate and supply products to be used in such trials, it would be useful, not only in helping health professionals evaluate products but in improving public confidence in the use of appropriate countermeasures.

Independent and well-designed head-to-head trials are expensive and are a type of public good when results are transparent, and the pandemic agreement should address the need to fund these trials.

4. What are respective pros and cons of, the following proposed language in the Negotiating Text: “in accordance with national laws and considering the extent of public funding provided, publish[ing] the terms of government-funded research and development agreements for pandemic-related products, including information on: (a) research inputs, processes and outputs, including scientific publications and data repositories, with data shared and stored securely in alignment with findability, accessibility, interoperability and reusability principles; (b) the pricing of end-products, or pricing policies for end-products; (c) licensing to enable the development, manufacturing and distribution of pandemic-related products, especially in developing countries; and (d) terms regarding affordable, equitable and timely access to pandemic-related products during a pandemic”? In your view, are there alternative recommended actions or commitments that could be considered?

Comment

The United States was a leader in the negotiations over WHA72.8, the WHO transparency resolution, and it has been a disappointment that there has been so little effort into implementing its transparency norms.

When public funds are used, transparency should be the norm, as regards the funding agreements (which are public under FOIA in the United States, but often only released with massive redactions and rarely published proactively). All of the items in these agreements are important, and should be transparent, and others should be added, such as details concerning patent landscapes and the costs of R&D inputs, particularly clinical trial costs and subsidies. Many of these items should be transparent regardless of the source of funding.

The US Securities and Exchange Commission requires publicly traded corporations to disclose extensive data related to their finances considered relevant to investors, including such items as

executive compensation, and depending upon the size of the company or the transaction, details on R&D outlays, contracts, royalties, public subsidies, taxes, litigation and other matters. Airline prices are public. Bank fees are public. Oil and gas leasing [royalties and production quantities](#) are public. The amount of money homeowners pay in property taxes is public.

Often secret are the terms of exclusive patent licenses from governments to drug companies including the royalty rates, work requirements, access provisions, Orphan Drug Tax Credit subsidies, or the actual units sold or net prices. The WHO resolution WHA72.8 was intended as a first step in improving transparency, noting that: “policies that influence the pricing of health products and that reduce barriers to access can be better formulated and evaluated when there are reliable, comparable, transparent and sufficiently detailed data [see footnote 1 of page 2]¹ across the value chain.”

Among its several recommendations to Member States were:

(3) to work collaboratively to improve the reporting of information by suppliers on registered health products, such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives;

(4) to facilitate improved public reporting of patent status information and the marketing approval status of health products.

5. *What is the appropriate role for WHO in facilitating the R&D process in areas focusing on infectious diseases?*

Comment

The WHO should have a registry of relevant research grants and clinical trials and work with members to establish global targets and national norms for funding R&D. One example of how such norms are established is the NATO Defense pledges to spend a minimum fraction of GDP annually on defense.

The WHO should have a database of the costs of and subsidies for clinical trials, and work with WHO members to develop standards for reporting costs and subsidies.

The WHO should have a public repository of license agreements or other contracts involving patents on inventions, material transfers, know-how or data.

¹ Footnote 1 in page 2 of WHA72.8: “Including but not limited to data on: availability, especially in small markets; units sold and patients reached in different markets; and the medical benefits and added therapeutic value of these products.”

We note that the March 23, 2020 letter from the President and Minister of Health of Costa Rica to the WHO regarding the creation of C-TAP (Covid-19 Technology Access Pool) made this request, which unfortunately was ignored:

We also ask that the Global Observatory on Health R&D create a database of R&D activity related to COVID-19, including estimates of the costs of clinical trials, and the subsidies provided by governments and charities.

6. 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?

Comment

The agreement could provide that any patented invention funded by a government that is licensed on a non-exclusive basis be licensed on FRAND terms, at least in a pandemic-related field of use.

Any patented invention funded by a government or any technology or product that receives significant public sector support for its development, and that is licensed on an exclusive basis, should include contractual obligations in the funding agreement to ensure that products are available and affordable in developing countries. Or alternatively, that they are licensed on FRAND terms in developing countries through a qualifying global licensing program such as the Medicines Patent Pool or the new WHO Health Technology Access Pool (HTAP).

Government R&D funding agreements should include requirements to permit governments to march-in and mandate access to intellectual property, data and manufacturing know-how, when necessary to enable research activities, scaling of manufacturing, sharing of manufacturing technology, and distribution of countermeasures in a manner consistent with the objectives of the agreement.

Article 10, Sustainable Production

1. 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”?

Comment

It is a mistake to insist on “royalty-free” licenses and it is a mistake to put “mutually agreed terms” in the pandemic treaty. Certainly “royalty-free” and “mutually agreed terms” don’t reinforce each other.

Royalties

While there is a role for royalty-free licenses, royalties in general, based upon commercial sales of products, are not only appropriate, but they can provide an important incentive to provide non-exclusive licensing, on FRAND terms.

Some licensing is going to be “on mutually agreed terms,” but not all. The U.S. Bayh-Dole Act mandates that a license on a federally funded invention includes a number of mandatory terms, including a global royalty-free right by and for the US government, a march-in right, an obligation to manufacture in the United States, and there is consideration in the U.S. government on extending these norms to additional conditions. In a sense, these are “mutually agreed” if contracts are signed, but that is misleading if there is a take-it-or-leave-it norm.

On top of everything else, there is clearly a role for compulsory measures. In recent years the U.S. government has issued hundreds of FAR 52.227-1 authorization and consent clauses in their contracts, giving contract holders the right to use any US patented invention without permission from right holders, and without even an obligation to notify rights holders. The US government used FAR 52.227-1 dozens of times from 2020 to 2021 to address the COVID-19 pandemic, as well as the Defense Production Act to modify contracts and command technology transfer. In an emergency, you should not tie your hands to voluntary measures only.

Also, the pending EU pharmaceutical reform is full of compulsory measures during times of emergency, relating not only to patented inventions but to regulatory data and know-how.

Suggested language of intellectual property exceptions

KEI suggests the following language on exceptions in national laws on intellectual property:

- A. Parties will review and modify domestic laws to ensure that there are sufficient exceptions to exclusive rights in intellectual property in order to respond to a pandemic.

B. In the event of a pandemic, the Parties will apply the use of exceptions in domestic laws relating to intellectual property when necessary to enable the research activities, scaling of manufacturing, sharing of manufacturing technology, and distribution of countermeasures in a manner consistent with the objectives of this agreement, including those relating to the transfer of technology in a pandemic and equitable access to affordable products.

2. 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:

Comment

The proposal to waive royalties is well intended, and useful in the context of a research exception, but not necessarily for products that are sold in commercial markets.

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

Comment

The secrecy around licensing agreements is often overly broad and inappropriate. During the COVID-19 pandemic, the lack of transparency and candor have had a negative impact on the trust in public and private institutions and companies.

(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.”

Comment

This was badly managed during the COVID-19 pandemic, with a few exceptions. Pfizer and Merck did provide voluntary patent, regulatory data and know-how licenses through the Medicines Patent Pool during COVID-19 for two therapeutics, and those were useful. The WHO failed to reach agreements with some vaccine developers who were willing to license technologies, such as the Texas Children’s Hospital and Baylor College of Medicine COVID-19

Vaccine Technology. The WHO seems to be intent on improving its voluntary licensing efforts with the new Health Technology Access Pool (H-TAP).

One challenge for both the WHO H-TAP, the MPP or other pooling projects is to induce institutions like the NIH, BARDA or DOD to share more rights in inventions, data or manufacturing know-how as well as access to cell lines. KEI has proposed the development of opt-in pooling mechanisms, where rights are only shared with parties that join the pool, as well as multilateral/plurilateral funds to buy rights in patents and manufacturing know-how (see annexes).

3. *How can we work to promote a globally sustainable medical countermeasures (MCM) manufacturing system, including leveraging regional approaches to production and maintaining readiness of facilities between pandemic emergencies?*

Comment

One significant challenge is to maintain readiness capacity and readiness in times of low or no demand for products. Governments could collectively agree to use such facilities for a minimum level of non-pandemic procurements to make such standby facilities more economically feasible.

A Pandemic Agreement could be structured in such a way as to enable some obligations to be progressively, flexibly and dynamically shaped over time. The mechanisms for the implementation of the agreement are quite important.

Article 11, Transfer of Technology and Know-How

1. *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”?*

Comment

“mutually agreed terms”

The “mutually agreed terms” language is unnecessary and counterproductive if it prohibits the use of non-voluntary exceptions to rights and other mandatory measures that are appropriate.

During the COVID-19 crisis, the US used FAR 52.227-1 authorization and consent clauses in dozens of contracts and also used the Defense Production Act, to speed the development and production of countermeasures.

Incentives

KEI has proposed a voluntary pooling mechanism, a technology buyout fund and the open source dividend, all designed to enhance the incentives to share knowledge, inventions, data, know-how and access to biologic resources.

On the incentives side, there are also several useful recommendations in the WHO publication:

Strategies to facilitate sharing of technology and knowledge through WHO COVID-19 Technology Access Pool, ISBN 978-92-4-007395-1 (electronic version), World Health Organization 2023.

<https://iris.who.int/bitstream/handle/10665/373133/9789240073951-eng.pdf>

The term “buy-out” or “buy out” appears 23 times in the WHO report, which includes links to several articles on buy outs, including (but not limited) to this one:

Love J. Buying know-how to scale vaccine manufacturing. Medium. 20 March 2021 (<https://jamielove.medium.com/buying-know-how-to-scale-vaccine-manufacturing-586bd304a36>).

Among the challenges of a buy-out fund, or any effort to provide more global access to technology, know-how, etc, is the free rider issue. If everyone benefits but not everyone contributes, some will decide to not share.

In some cases, it may be necessary to limit the benefits of shared technology to governments that also commit to financing buy outs or other incentives or the sharing rights in public sector funding R&D.

- 2. 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”?*

Comment

See comment above.

3. *In your view, is there a lack of transparency concerning information regarding pandemic-related products, their technological specifications, and manufacturing details? If so, could the establishment of a new mechanism at the WHO effectively address this lack of transparency?*

Comment

Yes. For starters, the agreement should have measures to progressively implement the norms in WHA72.8, and the WHO should certainly play a role in hosting databases and repositories of data and documents, and working with national governments to create standards for reporting prices, quantities, R&D costs, and subsidies.

During the COVID-19 pandemic, many of the published US government R&D contracts were highly redacted (see: <https://www.keionline.org/covid-contracts>). The redactions covered many different topics and were unevenly applied. In some cases, redactions included funding amounts, time tables for deliverables, prices, quantities, rights in patents, rights in data, know-how or cell lines, product designs, patent numbers, and many other topics. KEI is currently litigating many of the redactions from HHS and DoD, and such litigation is expensive and time-consuming.

Secrecy over manufacturing know-how should not extend to the specifications of the products governments buy, patent landscapes or the measures required for enablement of patented inventions.

During the COVID-19 pandemic, governments were concerned about shortages of countermeasures and their inputs, and many treated basic information about supplies or products as matters of national security. Provisions in a Pandemic Agreement may not eliminate this problem, but they can help, particularly by providing a level playing field on transparency.

4. *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:

Comment

The phrase “time-bound waivers of intellectual property rights,” would be more useful if it referred to “time-bound exceptions to exclusive rights,” but not all intellectual property rights. Exclusivity is more of a problem than a property right in an invention, at least when products are

commercialized. That said, some type of mandatory research exception, royalty-free, should be part of the agreement.

(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; and

Comment

KEI is opposed to the provision that waives royalties on products, if the royalties are reasonable and consistent with more equal access. A waiver of royalties on research uses, on the other hand, is appropriate.

(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”?

Comment

This provision, dealing with Article 39.2 of the TRIPS Agreement, does not extend to data provided to regulators, which is addressed in Article 39.3 of the TRIPS Agreement.

Article 39.3 of the TRIPS Agreement allows governments to make undisclosed test or other regulatory data public, in four separate cases:

1. When the origination of the data did not involve “considerable effort.”
2. Where the disclosure is “necessary to protect the public.”
3. When the use of the data is for a non-commercial use.
4. When measures are taken, such as compensation for use, to protect against “unfair” commercial use.

An example of permitting commercial use of regulatory data without the permission of originators is the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which provides for reasonable cost sharing of regulatory data.

Article 39.2 of the TRIPS Agreement deals with data that is undisclosed and not provided to regulators, and the TRIPS obligation is to ensure “effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967).” The TRIPS requirement is to

provide the “possibility of preventing information lawfully within their control from being disclosed,” but that is short of mandatory injunction.

The U.S. Defense Product Act and recent measures undertaken or under consideration by the European Union illustrate the importance of having the tools at the national level to mandate access to know-how, data and materials including biological resources, when necessary.

Another example is the European Commission’s EU-wide compulsory licensing proposal, which includes important updates such as suspending regulatory data and market exclusivity. Both of the EU examples below showcase how the EU is updating their legislation to better prepare for future emergencies.

- Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level. For example, the regulation mandates the licensing of intellectual property and know-how where the Commission provides financing (Art. 8). <https://eur-lex.europa.eu/eli/reg/2022/2372/oj>
- Gurgula, Olga, On the European Commission’s Proposal to Create a New EU-wide Compulsory Licensing Regime (August 26, 2023). Forthcoming in the European Intellectual Property Review (EIPR), Available at SSRN: <https://ssrn.com/abstract=4552851> or <http://dx.doi.org/10.2139/ssrn.4552851>

References to the TRIPS Agreement are generally inappropriate for this agreement. Some parties are not members of the WTO, and the WTO agreements are hardly the only trade agreements dealing with the same issues.

KEI suggests the following language:

(c) encourage **[add: or when necessary and appropriate mandate]** 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.”

Article 12, Access and Benefit Sharing

A key negotiating objective of the United States has been to ensure that all countries share pathogen samples and associated data, including genetic sequence data, from emerging outbreaks quickly and transparently to facilitate response efforts, including the rapid creation of safe and effective vaccines, diagnostic tests, and treatments.

1. What sample and data access impediments have you encountered in the past or what impediments would you envision based on the proposed Pathogen Access and Benefit Sharing (PABS) System in the Negotiating Text that might thwart or delay research efforts?

Comment

It may be challenging to administer access rights for upstream researchers, since some of them are working as individuals, in universities and small firms.

2. Does implementation of Nagoya Protocol requirements impede the rapid development or deployment of vaccines, diagnostic test, and treatments? Explain.

Comment

Parties would be better off if there were agreement that pathogens are not genetic resources under the Convention on Biological Diversity and the Nagoya Protocol. That said, the reason this issue is so contentious is the belief, with considerable justification, that other measures to address equity have met resistance from the United States, the European Union and other high-income countries.

If high-income countries would support significant provisions on equity outside of and not linked to the PABS system, the negatives of linking equity to the PABS system access can be overcome. But from the looks of things, negotiators in the US and the EU are not willing to do that, and that's on them.

3. How important is a commitment by negotiating parties to provide parties with the access to pathogen samples and data that are needed to contribute to rapid creation of safe and effective vaccines, diagnostic tests, and treatments?

Comment

It is very important.

4. Are alternative strategies for "access" to samples and data available and how do they compare in terms of effectiveness and efficiency?

Comment

The Open Source Dividend proposal can be seen as a complement or a substitute obligation. There are many advantages of the Open Source Dividend approach. It would provide monetary incentives to share not only pathogen samples, but inventions, manufacturing know-how, cell lines and other inputs to countermeasures, and it would not depend upon contracts with

manufacturers, noting also that manufacturers have multiple ways of obtaining sufficient information or samples outside of the proposed PABS system.

5. How might such commitments impact researchers and institutions?

Comment

Anything that creates the need for contracts or liability will have some negative impact on access by researchers, but properly implemented, the negative impact can be minimal, depending, of course, on the obligations tied to access.

The Article 12 negotiating text proposes that sanctioned use of the WHO PABS System would be recognized as a specialized international access and benefit-sharing instrument within the meaning of paragraph 4 of Article 4 of the Nagoya Protocol; such recognition would provide for the exemption of the pathogens covered under the PABS System from additional access and benefit sharing requirements.

1. How valuable would such an “exemption” be to U.S. stakeholders? What pathogens would benefit from exemption status?

Comment

The exemption would be useful.

2. What additional incentives might be needed to encourage participation in an ABS system exempt from Nagoya Protocol requirements?

Comment

This makes many of the equity provisions in the pandemic agreement dependent upon a company seeing the PABS system as essential, when it is not difficult to appreciate the cases where samples or sequences can be obtained outside of the PABS.

The Article 12 negotiating text envisions parties agreeing to set aside certain percentages of pandemic-related products (proposed in the current negotiating text as a minimum of 20%) and facilitating their exportability.

1. What, from your perspective, are the pros and cons of such a requirement?

Comment

The pros include the benefits of more equal access to countermeasures.

2. Would such a requirement advance or hinder rapid research and development efforts?

Comment

It is doubtful that a 20 percent requirement for pandemic-related products, either 20 percent free or 10 percent free and 10 at a concessionary price, would provide a significant problem for manufacturers. For most countermeasure products, there is a high fixed cost but a relatively low incremental low cost of goods. Also, the products available for free or at concessionary prices are unlikely to undermine the primary commercial markets for products, and indeed, if capped at 20 percent, there is always the other 80 percent of the market which is not affected.

3. The Article 12 negotiating text further envisions required monetary contributions from recipients of shared samples or data, including researchers and manufacturers, for privileges of access. What in your view is the monetary value of access that would be provided in terms of an annual or percentage-based contribution from your organization? How would requiring monetary contributions from academic, government, or other non-profit research institutions impact, positive or negative, research?

Comment

The payments to compensation for inputs should be related to the revenue from commercial sales. Upstream research efforts should not be taxed or subject to royalties.

The Article 12 negotiating text specifies other benefits that should be considered for developing countries, including “(i) encouraging manufacturers from developed countries to collaborate with manufacturers from developing countries . . . to transfer technology and know-how and strengthen capacities for the timely scale-up of production of pandemic-related products; (ii) tiered-pricing or other cost-related arrangements, such as no loss/no profit loss arrangements, for purchase of pandemic-related products . . .; and (iii) encouraging of laboratories . . . to actively seek the participation of scientists from developing countries in scientific projects associated with research on WHO PABS Materials.”

4. How helpful would these additional measures be in advancing the rapid creation and/or production scale-up of safe and effective vaccines, diagnostic tests, and treatments? What are the risks or potential negative impacts could come from including such provisions?

Comment

The TRIPS Agreement has similar aspirational language on technology transfer. For example, Article 66.2 of TRIPS reads as follows:

“Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to

least-developed country Members in order to enable them to create a sound and viable technological base.”

Despite the “shall” in TRIPS 66.1, the lack of actionable specifics has rendered the provision meaningless, other than being the subject of TRIPS Council discussions..

So while most of the things encouraged in that statement sound good, there is a concern about the lack of actionable specifics.

5. What incentives might be provided to stakeholders to encourage/assure participation in such voluntary measures?

Comment

The European Union has over time embraced a variety of mechanisms to benefit lesser-developed regions. One approach is the EU R&D Framework program, which was designed to provide incentives for researchers in more developed regions to collaborate with researchers in lesser developed regions.

6. What provisions might companies, academic research institutions, and other industry stakeholders look for when assessing voluntary participation in such a proposed Access and Benefit Sharing system? What samples/data are needed the most and how could such a system improve access to needed resources? What provisions are missing that would incentivize broad participation in the system that Member States should consider?

Comment

The open source dividend proposal would provide incentives for all parties, including companies, academic research institutions, and individuals, to supply useful inputs to the development of new countermeasures. This could include analysis of samples and sequences.

Article 13, Global Supply Chain and Logistics (SCL) Network

The WHO SCL Network proposed in Article 13 envisions performing a range of functions ordinarily left to individual governments, institutions, or organizations.

1. What functions of Access to COVID–19 Tools-Accelerator (ACT–A) should or should not be institutionalized?

2. *Should the U.S. consider incentives to encourage U.S. stakeholders' participation in such an effort and what would compelling incentives be?*

The proposed text for Article 13, Global Supply Chain and Logistics (SCL) Network, as reflected in the document [A/INB/7/3](#), of 30 October 2023, is a pretty good collection of activities. The USG might consider a few additions to the many items in this Article.

Sanctions exceptions and exemptions

One area of particular concern involves sanctions, and in particular, the exemptions and exceptions for medical products and supplies.

For example:

- Members agree that any sanctions imposed on other member states shall have sufficient exemptions, exceptions, and authorizations pertaining to humanitarian assistance and trade to permit the supply of medical products or other pandemic countermeasures, and such exemptions and exceptions shall not be unduly burdensome or complex.
- Members agree that the WHO Global Supply Chain and Logistics Network (the WHO SCL Network) will have the authority, in consultation with member states, to create an “allowlist” for both suppliers and products that are exempt from sanctions.

Play-or-Pay technology transfer

The WHO SCL Network could also manage a play-or-pay agreement that requires companies selling certain countermeasures to either provide technology transfer, including know-how and rights in inventions or pay a percentage of sales revenue into a buy-out fund for rights in technology, data, biologic resources and/or manufacturing know-how.

Head-to-head trials

Another topic for cooperation concerns the design, funding and undertaking of head-to-head clinical trials and the timely sharing of health systems data on real-world outcomes.

ANNEX 1: Table 2 from WHO paper on incentives for C-TAP

The WHO publication, *Strategies to facilitate sharing of technology and knowledge through WHO COVID-19 Technology Access Pool*, World Health Organization, 2023. ISBN [978-92-4-007395-1](https://doi.org/10.1181/pre2023010001) (electronic version), surveyed WHO members on possible incentives to licensing technologies. Table 2 in that report provided a summary of responses.

Table 2. Summary of responses

Incentive	Would Consider	Unable to implement	Implemented
Financial and innovative incentives	21	8	4
Engagement with technology owners	20	3	10
Exclusive supply for the public market	16	4	13
Taxes on: income, sales, wages and property	15	1	17
Free pricing on launch of a product	15	6	13
Waiving administrative or other fees	14	1	22
Funding R&D	11	3	23
Waiving requirement for local clinical studies	10	6	18
Implementing good regulatory practices	8	1	27
Competitive regulatory timelines	8		28
Waiving importation duties and tariffs	7	1	29
Simplifying customs procedures	4	1	32
Simplifying regulatory procedures	4		34
Simplifying administrative procedures	2		36

The report includes other suggestions, including for example the proposals to create a buy-out fund for patents, know-how and other countermeasure inputs.

ANNEX 2: Open source dividend

The open source dividend proposal could be introduced as a separate article, or included under other articles. An example of how it might be addressed follows.

Parties agree

- (a) To create an Open Source Dividend fund within the WHO, to reward and provide incentives to individuals, communities or entities that openly and freely share access to ideas, inventions, data, rights in regulatory data, manufacturing know-how, pathogens or their sequences and other biologic resources including cell lines, that are used and useful for the development of countermeasures;
- (b) To contribute to the Open Source Dividend fund an amount initially set at 2 (or some other number) percent of the gross sales revenue for any pandemic-relevant vaccine, therapeutic or diagnostic countermeasure, for which global sales exceed \$100 million in any consecutive four quarters. The Governing Body of the CA+ may adjust the contribution percentage from time to time, in order to achieve revised incentive and benefit sharing objectives.
- (c) The Governing Body of the CA+ shall develop procedures for the management of the Open Source Dividend Fund, which are transparent and mindful of the need to avoid conflicts of interest, and are designed to provide effective and fair benefit sharing from commercial products to individuals, communities and entities that openly shared inputs that are used and useful in the development of countermeasures.

Relationship between PABS and Open Source Dividend

The Open Source Dividend can exist as a complement or a substitute to other benefit sharing approaches. One difference between the approaches concerns the beneficiaries.

The WHO is the direct beneficiary of the PABS system, and the WHO would use some of the donations and reserved products to benefit persons living in low-income countries.

The PABS system requires parties to share pathogens with the WHO-coordinated laboratory network. The agreements from companies are voluntarily negotiated contracts, and companies may be able to obtain pathogens or sequences outside of the PABS system, setting some constraints on the ambitions of the benefit sharing obligations contained in the SMTA contracts. Company engagement is likely to be higher when obligations are lower, and lower when obligations are higher.

The Open Source Dividend beneficiaries are more diverse, including researchers, research institutions, companies and others who voluntarily share, openly and at cost or for free, inputs

that will be considered used and useful in countermeasures. The inputs include pathogens and sequences, but also many other knowledge goods and services and biologic materials.

See a discussion of this approach in the February 17, 2023 comment by Knowledge Ecology International on Article 10. WHO Pathogen Access and Benefit Sharing System and Proposal for Open Source Dividend.

<https://www.keionline.org/wp-content/uploads/Article-10-of-zero-draft-Benefit-Sharing-Opens-Source-Dividend-17Feb2023-.pdf>

ANNEX 3: Opportunities for H-TAP

James Love, Knowledge Ecology International
November 30, 2023

Introduction	1
Geographic scope of licenses and exclusivity	2
Stage of development	3
Standardized licenses for copyright	3
Standardized licenses for copyright are important, but standardization is more challenging for patents	3
Patent office licenses of right (LOR)	3
The UK LOR	4
The German Lizenzbereitschaftserklärung vorhanden	4
Non-government licenses of right	5
Agreements with governments and donors	5
The Bayh-Dole Act provision on agreements with international entities	6
The NIH Re:Search agreement	6
Strategy for H-TAP	7
Limits on the field of use	7
Research licenses	7
Royalties	7
Knowledge asset types	8
Types of licenses	9
Licenses of right	9
Licenses under certain circumstances	9
Share-and-share-alike pooling	9
Incentives	10
Patent fees	10
The COVID-19 experience	10
Agreements to link R&D subsidies and procurement to technology sharing	10
ANNEX: The original proposal for C-TAP	11

Introduction

The decision to transform the WHO COVID-19 Technology Access Pool (C-TAP) to the Health Technology Access Pool (H-TAP) and to consider changes in its approaches to licensing is welcome.

C-TAP's limited success may be attributed to multiple issues, some of which were specific to the challenges of dealing with the COVID-19 crisis, but others that were not.

H-TAP can be successful, building upon the strong WHO brand, creating multiple licensing vehicles, and by using appropriate new incentives to license.

Geographic scope of licenses and exclusivity

One condition that defined C-TAP was the decision to only work with licenses that were global in terms of the licensed territory. This distinguished C-TAP from the Medicines Patent Pool (MPP), which routinely entered into licensing agreements that limited the geographic scope to 85 to 120 countries with low per capita incomes.

The primary challenge for global licenses concerns cases wherein a product requires considerable private sector investments, and rights holders determine that investors expect some scope of exclusivity, or an alternative reward if one exists.

That said, rights holders often license inventions on a non-exclusive basis, without geographic restriction, for technologies used in several different products (such as the NIH license of 11 technologies to C-TAP), and H-TAP can also provide licenses that can work even when private investment incentives are important.

These are some examples of how H-TAP licenses can work even when the invention is closely related to a specific product and additional investments are important for its development.

1. H-TAP has the option to grant additional licenses in situations where the patent holder can not meet demand for products on a timely basis, and/or at an affordable price.
2. A license that has a time limited exclusivity, where the exclusivity expires before the term of the patent (like the NIH dDI license).
3. A license that eliminates exclusivity after global sales exceed milestones.
4. A license that limits exclusivity to certain indications but not others.
5. A license for an indication where an alternative incentive is considered significant, such as the US priority review voucher, proposals for market entry reward prizes, advance purchase commitments, or other incentives delinked from exclusivity.
6. A license for access to manufacturing know-how and cell lines, but not the national patents.
7. A license where the patents are licensed, but the test data rights or orphan drug regulatory exclusivity rights are not licensed.
8. A license where charities or public sector entities are willing to deeply subsidize the clinical trials.

Stage of development

Both the MPP and C-TAP favored licenses on products that had achieved market approval from a respected regulatory body. This has worked for the MPP because its focus is on licenses for low income countries, a segment that is often not viable or important for rights holders. For C-TAP, the licenses were expected to be worldwide. The combination of worldwide rights and a focus on products that had already received stringent regulatory marketing approval narrowed the candidates. H-TAP should be more open to licenses in all stages of development, including pre-clinical.

Standardized licenses for copyright

Standardized licenses for copyright are important, but standardization is more challenging for patents

The most successful voluntary licenses for copyright use standardized licenses. These include the various Creative Commons copyright licenses, and the GNU GPL and Berkeley software licenses.

The Creative Commons and the Free Software Foundation have been successful in creating and branding standardized copyright licenses that are designed to promote access and benefit users. There has been a large uptake of their licenses, more than 2.5 billion CC licenses are in use today, and much of the Internet infrastructure and billions of appliances and devices rely upon the GNU GPL software licenses.

The standardization of the Creative Commons and GNU GPL licenses were key to the successful uptake, and there is also a rich history of standardized terms for non-voluntary copyright licenses, or agreements involving collection societies.

The success of the standardization for copyright licenses is due in part to the fact that unlike patents, copyrights are available without registration or maintenance fees, the Creative Commons and GNU GPL licenses are royalty-free, and the fields of use restrictions, if any, are less complex. Attempts by the Creative Commons to create a licensing strategy for patents, know-how or materials have not been successful.

Patent office licenses of right (LOR)

A “license of right” involves a commitment from a rights holder to give the public a legal right to a license, typically on terms that are considered fair and reasonable. Negotiations between the right holder and the party seeking a license typically follow, but if the negotiations fail, the patent holder permits a third party, such as a patent office, to set the terms.

The license of right option for patents is used in dozens of national jurisdictions and the European Unitary Patent system will also implement a version.

The license of right systems used by patent offices do not use a standardized license, but instead an endorsement to a patent that gives the public a right to a license. Standard forms are used for these declarations.

The UK LOR

The licenses “available as a right” section of the UK patent law is found in Article 46.

Patentee’s application for entry in register that licences are available as of right

46.-(1) At any time after the grant of a patent its proprietor may apply to the comptroller for an entry to be made in the register to the effect that licences under the patent are to be available as of Right.

. . .

(3) Where such an entry is made in respect of a patent -

(a) any person shall, at any time after the entry is made, be entitled as of right to a licence under the patent on such terms as may be settled by agreement or, in default of agreement, by the comptroller on the application of the proprietor of the patent or the person requiring the licence;

The UK patent office uses [Form 28](#) titled, “Application by the proprietor of a patent for an entry to be made in the register that licences under the patent are available as of right.” The UK Intellectual Property Office registry of “Patents Endorsed Licence of Right (LOR)” returns 9,707 patents with the LOR endorsement, from April 16, 2007 to the present, including 159 in the month of October this year.

The license of right form for the Intellectual Property Office of Singapore is also [Form 28](#). The license of right form in Kenya is [Form 22](#).

The German Lizenzbereitschaftserklärung vorhanden

Countries typically offer a 50 percent discount in patent fees when the LOR endorsement is provided. For example, the license of right in the German Patent Act § 23 states:

(1) If the patent applicant or the person registered as the patent holder in the register (Section 30 Para. 1) declares in writing to the German Patent and Trademark Office that he is willing to allow anyone to use the invention in return for appropriate remuneration, the costs for the patent are reduced Half of the annual fees due upon receipt of the declaration. The declaration must be entered in the register and published in the patent gazette.ion must be entered in the register and published in the patent gazette.

A recent search indicated that there were 41,491 patents with Lizenzbereitschaftserklärung (declaration of willingness) currently in force.

A 2012 study of the German LOR system found that a LOR endorsement was more likely as patents aged, and the usage rates varied by field of use, for example, usage rates were higher for electrical engineering and lower for chemistry and biotechnology. Interestingly, patents filed by large corporations were 6 times more likely to have a LOR endorsement than patents filed by small firms. One possible explanation for this is that small firms are not as good at evaluating the value of the patents and are more likely to see patents without a LOR endorsement as providing positive signals to uninformed investors than is the case for larger firms.

One take-a-way message from the LOR systems is that an incentive such as lower patent fees can influence licensing decisions, and that the form of the endorsements can be simple and concise, as illustrated by the forms used by patent offices.

Non-government licenses of right

Private bodies, particularly private patent pools and standards setting bodies, can and do employ commitments to license on fair and reasonable terms, including in the standards context, Fair, Reasonable and Nondiscriminatory (FRAND) obligations.

Agreements with governments and donors

The initial proposal to the WHO for C-TAP asked the WHO to create a Memorandum of Understanding (MoU) that governments and non-state actors including charitable foundations could sign regarding the intent to share technology.

“Given the urgency of this matter, Costa Rica proposes that the WHO develop an initial concise memorandum of understanding on the intent to share rights in technologies funded by the public sector and other relevant actors, and reach out to WHO Member States, non-profit institutions, industry and others, to sign such an MoU. The specific technologies and the terms of the assignments can be determined later, in the implementation stage of the pool, in consultation with R&D funders and rights holders.”

There were several reasons for wanting a simple standard MoU.

1. For campaigners, influentials or even trading partners, it is far more useful to ask governments or other funders to do something specific, than to make vague asks. It also focuses the public debate on the specifics in the MoU, and avoids misunderstandings or bad-faith spins by critics.
2. A standard MoU, as a first step in an engagement, is more manageable than trying to negotiate 190 *sui generis* agreements.

3. There are also important reasons to have such an MoU. Some governments, like the US and Canada, provide for expanded public rights in government funded R&D, when an agreement is in place.

The Bayh-Dole Act provision on agreements with international entities

The U.S. Bayh-Dole Act has this provision for rights attached to research grants and contracts.

35 U.S.C. Title 35 - PATENTS

PART II - PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS

CHAPTER 18 - PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE

Sec. 202 - Disposition of rights

(4) With respect to any invention in which the contractor elects rights, 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: Provided, That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency 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.

In the absence of an agreement of any kind, a US federal agency cannot provide the same type of rights as it can if an agreement exists. Note that the US law is very flexible in what constitutes an actionable agreement, including an “arrangement of cooperation, memorandum of understanding, or similar arrangement.”

KEI has asked the MPP and C-TAP to approach the US government with an MoU that would enable federal agencies to provide expanded rights to the MPP or the WHO in funding agreements, but this does not seem to have been pursued with any success. However, the NIH did appear to have an agreement with WIPO.

The NIH Re:Search agreement

An example of how an agreement might be used is found in the NIH’s “MODEL LICENSE AGREEMENT FOR USE BY NON-PROFITS: Providing Rights to NIH Technologies for Distribution and Sale of Products for Neglected Tropical Diseases, HIV, TB and Malaria,”¹ which contains this clause:

¹ <https://www.techtransfer.nih.gov/sites/default/files/documents/docs/nonprofit-termsheet.docx>

RELATIONSHIP TO WIPO Re:Search: For technologies NIH has made available through WIPO Re:Search, any commitments to licensing terms under that program will supersede the terms above to the extent there is overlap. See <http://www.wipo.int/research/en/>.

KEI has asked the NIH and WIPO for a copy of agreements between the NIH and WIPO for the Re:Search program, which WIPO terminated on 31 December 2022.

Strategy for H-TAP

H-TAP should create and brand multiple license vehicles, in order to accommodate the different opportunities that exist. Some should be fully open, others available when conditions and circumstances warrant. H-TAP can also create various pools that public institutions and others could opt-in to where the geographic scope of the pool would be defined by decisions by governments to join and support, or cross licensing pools for private rights holders.

Limits on the field of use

H-TAP, like the MPP and C-TAP, should allow rights holders to restrict the fields of use in a license.

Research licenses

The NIH has used different licenses for research purposes than for the commercial development of products, H-TAP may want to consider doing the same, for countries like the US which do not have a statutory or common law exception for research.

Royalties

Licenses through H-TAP, like those of the MPP, should in general be royalty bearing for commercial uses, unless the rights holders prefer royalty-free options for some or all uses. Standard licenses or license endorsements can include a simple obligation that royalties be reasonable, reference royalty guidelines or include the negotiated royalty obligations. It would be good if the H-TAP could avoid royalty obligations for sales where no patents have been granted, at least as regards the royalties for the inventions, but ~~you~~ one might have to be flexible on this, when manufacturing takes place in a market where patents have been granted.

The 2005 WHO/UNDP remuneration guidelines for non-voluntary use of patents included the option of a tiered royalty system, which uses as its royalty base the therapeutic value of the product and scaled royalties in absolute terms according to relative per capita incomes. The tiered royalty method, not based upon the costs of the generic version of a drug, can provide larger royalties in

higher income countries, and allow for more significant royalties on products that are very cheap to manufacture.

Knowledge asset types

Licenses can be used for different types of knowledge assets. These include, without limitation:

- Patents on inventions,
- Rights in regulatory data,
- Rights in orphan product regulatory exclusivity,
- Know-how to manufacture products,
- Material transfer agreements (MTAs), for providing access to cell lines or other biological materials,
- Software,
- Designs, and
- Databases.

In some cases, a license can combine rights in different types of knowledge assets, such a license that includes rights in patented inventions and regulatory test data, as well as access to know-how or biologic resources. But in other cases, the licenses might involve just one or a few types of knowledge goods.

These are cases where a global license to H-TAP for one or more types of knowledge assets would not be inconsistent with market segmentation. For example:

- Licenses to patents on inventions without rights to regulatory data or orphan product exclusivities could be global, in as far as the rights in the patented inventions, but not interfere with a right owner's opportunities to be a monopoly provider in national markets where rights exist in test data or orphan drug regulatory exclusivity.
- Licenses for access to manufacturing know-how and cell lines or other biologic resources could be global, but a rights holder could separately use patents on inventions and regulatory test data to segment markets.

Licenses to some but not all knowledge assets should be accepted, as each license enables competition and technology transfer, to some extent, and can also be complementary to other access-expanding actions by governments. For example, agreements to provide manufacturing know-how and access to cell lines, but not patents on inventions, can facilitate entry by firms that could seek and use compulsory licenses on patents in markets where that was needed and deemed appropriate.

Types of licenses

H-TAP should offer a variety of licensing options, each with the possibility of limits on the field of use and remuneration. For global licenses, these would include:

Licenses of right

A license or a LOR endorsement that provides any qualified party to obtain a license.

Licenses under certain circumstances

A non-exclusive sharing obligation when the WHO could be limited to cases where inventions or other rights are needed to address inadequate supply or excessive prices, or to respond to a public health emergency of international concern (PHEIC).

Each of these conditions could be the subject to a separate endorsement. For example, a government sharing rights in patents may be willing to give H-TAP the right to exercise the global license if there is a problem with meeting supply objectives, but not willing to provide an endorsement to remedy excessive pricing, and may want to condition either of these to a PHEIC.

Licenses under certain circumstances need not necessarily be open FRAND licenses. The MPP provides a significant filter on companies that qualify for licenses, and sometimes limit the number of companies to receive licenses, and H-TAP may do the same.

Share-and-share-alike pooling

Attached is a proposal KEI has made in the context of the INB negotiations on a pandemic treaty for a share-and-share-alike pooling of rights in government funded technology.

While C-TAP was proposed as a global pool, it may be useful to create opt-in pools where governments agree to share rights in technology they fund, but only to governments making a similar commitment.

H-TAP could also consider creating sui generis share-and-share-alike pooling for specific projects, such as the development of new treatments for tropical diseases, new antibiotic drugs, or for a diagnostics platform.

To extend the share-and-share-alike concept to private rights holders H-TAP can create cross licensing agreements, where the sharing is not between funders of technology, but between patent holders themselves. In some cases, pools could be open to non-patent holders, but perhaps with reach-through and grant back clauses, although these can raise competition concerns that would need to be vetted and considered.

Incentives

H-TAP should explore incentives, including some that could be added over time, to make licensing through H-TAP more compelling.

Patent fees

As noted above, several patent offices offer reduced patent fees for inventions that have a license of right endorsement. One typical incentive to offer a license or right endorsement is a reduction by 50 percent in patent renewal fees.

In the short run, the WHO could not influence country patent fees, but the WHO could structure the pool in such a way that for some licenses, the exclusivity would only extend to countries that provided deep discounts, even to zero, on patent fees when there is a qualifying license to H-TAP, creating an incentive to provide an incentive to license to H-TAP.

The COVID-19 experience

The COVID-19 crisis presented developers with a potentially huge market for products, and the possibility of huge public sector subsidies for R&D costs, expedited regulatory approvals and risk reducing advance purchase agreements. Even with these advantages, C-TAP struggled to obtain licenses on important technologies.

In the COVID-19 crisis, private rights holders were able to obtain access to government funding, advanced purchase funds, massive procurement contracts and expedited regulatory pathways without offering any concessions on licensing rights in or access to inventions, data, know-how or biologic resources, and there were no other incentives available. In retrospect, governments could have entered into agreements that tied R&D subsidies or procurement contracts to obligations to license intellectual property rights or provide technology transfer.

Agreements to link R&D subsidies and procurement to technology sharing

It's unrealistic to ask governments now to link all R&D subsidies and procurement agreements to technology sharing obligations, but in some specific areas, it should be possible, particularly where the money from governments is significant, on either or both of R&D and procurement spending.

If governments would find a way to cooperate, the collective purchasing power alone provides enormous leverage to induce deep technology transfer, something that could be conditioned on a

product reaching robust global sales milestones, and less challenging opportunities for collaboration certainly exist.

ANNEX: The original proposal for C-TAP

In March 2020, I approached Roman Macaya, the Executive President of Caja Costarricense de Seguro Social (CCSS), the organization that provides universal health care services to Costa Rica's population, with a proposal to have the WHO create a global pool for technology related to the COVID 19 crisis. Macaya liked the proposal and brought it to the attention of Daniel Salas Peraza, the Ministro de Salud of Costa Rica. Peraza then brought the proposal to the attention of Carlos Alavardo Quesada, the Presidente de la República. Quesada and Peraza then wrote to Dr. Tedros and several senior members of the WHO staff on March 23, 2020:

Costa Rica in the spirit of contributing to global actions to fight the pandemic, respectfully requests to the World Health Organization (WHO) to undertake an effort to pool rights to technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic.

This pool, which will involve voluntary assignments, should include existing and future rights in patented inventions and designs, as well rights in regulatory test data, know-how, cell lines, copyrights and blueprints for manufacturing diagnostic tests, devices, drugs, or vaccines. It should provide for free access or licensing on reasonable and affordable terms, in every member country.

Given the urgency of this matter, Costa Rica proposes that the WHO develop an initial concise memorandum of understanding on the intent to share rights in technologies funded by the public sector and other relevant actors, and reach out to WHO Member States, non-profit institutions, industry and others, to sign such an MoU. The specific technologies

and the terms of the assignments can be determined later, in the implementation stage of the pool, in consultation with R&D funders and rights holders.

We also ask that the Global Observatory on Health R&D create a database of R&D activity related to COVID-19, including estimates of the costs of clinical trials, and the subsidies provided by governments and charities.

This request received endorsements on March 27, 2020 from 37 NGOs and 51 individuals from industry and academia and current and former members of governments and non profit organizations.

The original proposal was for a voluntary pool for rights to “technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic,” and “include existing and future rights in patented inventions and designs, as well rights in regulatory test data, know- how, cell lines, copyrights and blueprints for manufacturing diagnostic tests, devices, drugs, or vaccines.”

To implement the pool, the President and Minister of Health in Costa Rica asked the WHO to create a “memorandum of understanding on the intent to share rights in technologies funded by the public sector and other relevant actors, and reach out to WHO Member States, non-profit institutions, industry and others, to sign such an MoU.” The WHO was also asked to ask the Global Observer on R&D to “create a database of R&D activity related to COVID-19, including estimates of the costs of clinical trials, and the subsidies provided by governments and charities.”

Dr. Tedros subsequently approved the creation of C-TAP, but without implementing the suggestions regarding the MoU and the data on R&D activities, trial costs and subsidies.

For a variety of reasons, the managers of C-TAP were initially told to avoid seeking licenses on vaccine technologies although over time the mandate was expanded to include vaccines.

CTAP was subsequently able to obtain licenses on patents and know-how from a variety of companies, non-profit organizations and government, but overall, the response was not impressive.