KEI comments on six references to “mutually agreed terms” in the WHO pandemic agreement negotiating text: A/INB/9/3 Rev.1, 22 April 2024

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Introduction

There are seven references to “mutually agreed terms” in the April 22, 2024 INB9 draft text for a World Health Organization (WHO) pandemic agreement. The first six deal with technology transfer measures. This note looks at each of the first six references to evaluate the extent to which the use of the term can and predictably will be used to discourage developing countries from considering measures which have a regulatory or other mandatory character, even when strong mandates are used in higher income countries.

The phrase "mutually agreed terms" generally refers to conditions or stipulations that have been specifically negotiated and accepted by all parties involved in a contract or agreement. However, when certain terms are mandated by statute, they aren't technically "mutually agreed" in the purest sense, because the parties are required to adhere to these terms regardless of their personal agreement or preference.

An example of terms mandated by statutes are those required in Sections 202, 203, 204 and 209 of the U.S. Bayh-Dole Act, or in countless U.S. government contracting requirements and FDA statutes and regulations.

Aside from contract terms dictated by statutory mandates or take-it-or-leave-it government policies are cases where governments override contracts, such as has been done several times during COVID-19 in the United States through the use of the Defense Production Act, as well as

in India, several European countries and other countries in order to protect domestic access to counter measures.

During COVID-19, in addition to its use of the Defense Production Act to modify supply contracts and dictate manufacturing decisions, the United States included dozens of non-voluntary authorizations to use patented inventions in R&D and procurement contracts. The U.S. government's extensive non-voluntary authorizations to use patents were often invoked by references to the Federal Acquisition Regulation 52.227-1 Authorization and Consent clause. This included countless contracts for a variety of purposes, including the more than 350 agreements in this database: (https://drugdatabase.info/far-52-227-1-contracts/)

Regulatory bodies like the US FDA, the European Medicines Agency, and many others, mandate disclosures of important information, partly for safety and efficacy verification, but also on patent landscapes and other matters relevant to manufacturing know-how. This is plainly allowed by the WTO TRIPS Agreement, which provides an exception to the protection of confidential information "where necessary to protect the public" (TRIPS Article 39.3), as well as in the 2019 WHO resolution WHA72.8 on "Improving the transparency of markets for medicines, vaccines, and other health products."

The new EU emergencies legislation provides the legal means to compel the transfer of know-how needed to make a compulsory license of a patented technology effective.

> "(32.b) This Regulation should guarantee that the Commission has the authority to oblige rights-holders to provide all necessary information to facilitate the rapid and efficient production of critical crisis-related products, such as pharmaceuticals and other health-related items. This information should encompass details about know-how, particularly when it is essential for the effective implementation of compulsory licensing. While patent licensing alone might suffice to enable other manufacturers to quickly produce simple pharmaceuticals, in case of more intricate pharmaceutical products, such as vaccines during a pandemic, it is often insufficient. Where it is essential for the implementation of the compulsory licence, an alternative producer will also require access to know-how."
> Amendment 17. European Parliament legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 (COM(2023)0224 – C9-0151/2023 – 2023/0129(COD)).

In related fields mandates on transparency and knowledge sharing are also used. The European Union's new rules on AI (the 459-page Artificial Intelligence Act) give governments the ability to mandate transparency of various elements of artificial intelligence services, including those relating to drug development or the delivery of medical services.

In addition to the recent use of the U.S. Defense Production Act to expand access to inputs and products for COVID-19 countermeasures, in 2022 the U.S. government invoked the Act to promote local manufacturing and secure a reliable and sustainable supply of such strategic and critical materials for large scale batteries, both to address climate change and to enhance national security.

> "It is the policy of my Administration that ensuring a robust, resilient, sustainable, and environmentally responsible domestic industrial base to meet the requirements of the clean energy economy, such as the production of large-capacity batteries, is essential to our national security and the development and preservation of domestic critical infrastructure.
>
> The United States depends on unreliable foreign sources for many of the strategic and critical materials necessary for the clean energy transition — such as lithium, nickel, cobalt, graphite, and manganese for large-capacity batteries. . . .
> I find that action to expand the domestic production capabilities for such strategic and critical materials is necessary to avert an industrial resource or critical technology item shortfall that would severely impair the national defense capability."
> *Memorandum on Presidential Determination Pursuant to Section 303 of the Defense Production Act of 1950, as amended, Presidential Determination No. 2022-11*

The rationale for promoting domestic manufacturing of batteries in the United States is similar to the rationale many Parties have for promoting domestic or regional manufacturing of drugs or vaccines.

In general, the phrase "mutually agreed terms" describes a relationship between industry and governments as equals bargaining with each other, and does not recognize the role of the state in regulating industry. And while such voluntary arrangements are useful and important, so too is the role of the state in regulating industry in the public interest, when necessary. When voluntary agreements are not available or adequate, compulsory measures may be necessary to achieve objectives in terms of the supply of and access to products and technologies in emergencies.

Article 9. Research and development

The first reference to "mutually agreed terms" is in Article 9, paragraph 4, item (iii).

> **Article 9. Research and development**
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> 4. Each Party shall ensure that government-funded research and development agreements for the development of pandemic-related health products include, as appropriate, provisions that promote timely and equitable access to such products and shall publish the relevant terms. Such provisions may include: (i) licensing and/or sublicensing, preferably on a non-exclusive basis; (ii) affordable pricing policies; (iii) technology transfer on **mutually agreed terms**; (iv) publication of relevant information on research inputs and outputs; and/or (v) adherence to product allocation frameworks adopted by WHO.

The first sentence in Article 9 paragraph 4 is a mandate ("shall ensure") that government funded R&D agreements for pandemic-related health products include "as appropriate, provisions that promote timely and equitable access to such products and shall publish the relevant terms." In the next sentence the text states that "such provisions may include" one or more of five different provisions, including "technology transfer on **mutually agreed terms.**"

If the five provisions are taken as a closed list, then technology transfer can only be included on "mutually agreed terms." If this is an illustrative or non-exclusive list, then the reference to

“mutually agreed terms” is not restrictive, *per se*, but will likely be used to pressure countries to avoid requirements in R&D funding or procurement contracts that are fixed by statute or policy in a way that they aren't technically "mutually agreed" in the purest sense.

There is no reason to include “mutually agreed terms” in Article 9 paragraph 4, except to prejudice measures that are regulatory or mandatory in nature. Clearly no party has to take a government grant for R&D, and so almost by definition, a party receiving the grant has done so voluntarily. But the “mutually agreed terms” language is there for a reason, and that reason is to intimidate countries that attempt to mandate technology transfer in funding agreements.

Article 10. Sustainable and geographically diversified production, and technology transfer and know-how

Article 10 on Sustainable and geographically diversified production, and technology transfer and know-how includes in paragraph 1, a reference to “the transfer of relevant technology and know-how on **mutually agreed terms.”**

> 1. The Parties commit to achieving more equitable geographical distribution and scaling up of the global production of pandemic-related health products and increasing sustainable, timely, fair and equitable access to such products, as well as reducing the potential gap between supply and demand during pandemics, through the transfer of relevant technology and know-how on **mutually agreed terms**.

Here the text can be read as a commitment by parties to limit the transfer of technology AND know-how, to only “mutually agreed terms.” By adding “relevant technology,” the restriction is broader than know-how, and also includes such things as licenses to patents, rights in drug or vaccine registration data, or access to biologic resources, and other inputs or rights to technology.

The structure of the sentence is dangerous, because it can be read to bind the parties to only do the transfers of technology and know-how on mutually agreed terms, when in the context of “scaling up of the global production of pandemic-related health products and increasing sustainable, timely, fair and equitable access to such products” for an emergency.

If parties are generally free to use compulsory measures to transfer technology and know-how in general, why would they limit themselves to only voluntary measures for pandemics?

Article 11. Transfer of technology and know-how for the production of pandemic-related health products

There are three references to “mutually agreed terms” in Article 11, including paragraphs 1(a), 1(d) and 2.

> 1. Each Party shall, in order to enable the sufficient, sustainable and geographically diversified production of pandemic-related health products, and taking into account its national circumstances:
>
> (a) promote and otherwise facilitate or incentivize the transfer of technology and know-how for pandemic-related health products, in particular for the benefit of developing countries and for technologies that have received public funding for their development, through a variety of measures such as licensing, on **mutually agreed terms**;

The context for the first reference is to "promote and otherwise facilitate or incentivize," technology transfer "for technologies that have received public funding for their development," and the reference is to "a variety of measures such as licensing, on **mutually agreed terms**." The addition of "on mutually agreed terms" to license is gratuitous, unless it is intended to be a constraint on policies that would be considered regulatory or mandatory in nature for the license terms.

As noted above, the U.S. Bayh-Dole Act and its implementing regulations contain many standard take-it-or-leave-it conditions for funding and license agreements, including, in addition to the standard global government use, march-in rights and domestic manufacturing obligations, a provision in 35 U.S.C. 202(c)(4) which states that a funding agency can enter into a "treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement" that creates an obligation to include in licenses additional rights that would subsequently become essentially a mandatory term in a contact.

The second reference to mutually agreed terms, in paragraph 1(d), concerns private rights holders.

> (d) promote the transfer of relevant technology and related know-how for pandemic-related health products by private rights holders, on fair and most favourable terms, including on concessional and preferential terms and in accordance with **mutually agreed terms** and conditions, to established regional or global technology transfer hubs or other multilateral mechanisms or networks, as well as the publication of the terms of such agreements;

Again the reference to "mutually agreed terms" is either an awkward and gratuitous reference to an obligation to merely "promote" an outcome, or it is a constraint, limiting possible actions. One area where it might be seen as a constraint is if there are efforts by governments, working independently or through groups, to mandate technology transfers as a condition for obtaining or enforcing intellectual property rights, putting conditions on procurement agreements (something many commentators say should have been done in the COVID-19 pandemic), or using other obligations to share "relevant technology and related know-how." Here negotiators could eliminate the reference to "mutually agreed terms" or add a clarifying statement to make it clear that the promotion of such transfers is without prejudice to other measures a party may undertake. Certainly the U.S. government is not about to agree that it will never use the Defense Production Act, a FAR 52.227-1 authorization and consent in a contract, or other measures to force such transfers, and the European Union isn't about to agree to not use the emergency legislation that they are enacting right now. A double standard would be an appalling outcome of this negotiation.

The third reference to "**mutually agreed terms"** in Article 11 is in paragraph 2, which raises the same concerns regarding the point of including this language. Are governments being asked to limit such support to only measures that are the outcome of a negotiation with rights holders that are purely voluntary, or is this merely an awkward and gratuitous reference to give the appearance that this is the case?

> 2. Each Party shall provide, within its capabilities and subject to available resources and applicable law, support for capacity-building for the transfer of technology and know-how for pandemic-related health products on **mutually agreed terms**, especially to local, subregional and/or regional manufacturers based in developing countries.

Article 19. International cooperation and support for implementation

Article 19 includes in paragraph 1, a requirement for Parties to cooperate to "sustainably strengthen the pandemic prevention, preparedness and response capacities." Here, again is what seems to be a limiting condition: "Such cooperation shall promote the transfer of technology on mutually agreed terms." This is contrary to Amendment 17 of the new European Union compulsory licensing legislation, and several elements of the U.S. Bayh-Dole Act, the FAR 52.227-1, or the U.S. Defense Production Act, as described above.

> 1. The Parties shall cooperate, directly or through relevant international organizations, within the means and resources at their disposal, to sustainably strengthen the pandemic prevention, preparedness and response capacities of all Parties, particularly developing country Parties. Such cooperation shall promote the transfer of technology on **mutually agreed terms** and the sharing of technical, scientific and legal expertise, as well as financial assistance and support for capacity-strengthening for those Parties that lack the means and resources to implement the provisions of this Agreement, and shall be facilitated and provided by WHO, in collaboration with relevant organizations, as appropriate, upon the request of the Party, to fulfill the obligations arising from this Agreement.

Why are so many references to mutually agreed terms attached to technology transfers?

The U.S. government, the European Union and other parties to this negotiation do not and will not limit their options to only those purely voluntary measures that can be described as "mutually agreed terms," and it would be irresponsible for any government to do so, in the context of pandemic preparedness and response.

The references to "mutually agreed terms" are included in the text to promote a harmful and inequitable double standard and a predictable pretext for bilateral pressure when a developing country attaches conditions to funding or procurement agreements, regulatory approvals or other measures that powerful commercial interests oppose.

Annex on Investor-State Dispute Settlement (ISDS)

Depending upon how ultimately stated, restrictions on state actions to force the transfer of technology may lead to actions by private investors through an Investor-State Dispute Settlement (ISDS) arbitration or an investment court system (ICS).

If a country has agreed to limit measures on technology transfer to mutually agreed terms in a World Health Organization (WHO) treaty or agreement, and then implements compulsory measures that contradict these terms, the situation could potentially lead to an ISDS claim under a different agreement, such as a bilateral investment treaty (BIT) or a free trade agreement (FTA) that includes ISDS provisions.

The key issue is whether there is a contradiction between the country's obligations under the proposed WHO agreement and its obligations under another treaty which includes ISDS provisions. Investors might argue that the compulsory measures violate the agreed terms of technology transfer, and are contrary to the investor's reasonable expectations of the protection of its technology.

The investor would need to demonstrate that the host country's actions constitute a breach of the treaty's exclusive reliance on mutually agreed terms, and that as a consequence, more compulsory measures represent a direct or indirect expropriation, on the grounds that the compulsory measures directly impacted the value of its investments.

An example of such a claim occurred when Australia introduced plain packaging for tobacco products in 2011. Philip Morris filed claims under the Australia-Hong Kong Bilateral Investment Treaty (BIT) asking for 4.1 billion USD in damages, a case decided on procedural grounds.

> "The *Philip Morris v. Australia* case was not examined on the merits. The tribunal found that the claims by Philip Morris were inadmissible because the initiation of the arbitration constituted an abuse of rights, as the corporate restructuring by which Philip Morris acquired its investment in Australia occurred when there was already a reasonable prospect that the dispute would materialize. Therefore, according to the tribunal, the restructuring was carried out for the sole purpose of gaining treaty protection." Stefanie Schacherer, *International Investment Law and Sustainable Development: Key cases from the 2010s*, IISD, October 2018. https://www.iisd.org/system/files/publications/investment-law-sustainable-development-ten-cases-2010s.pdf. referencing *Philip Morris v. Australia*, PCA Case No. 2012-12, Award on Jurisdiction and Admissibility, December 17, 2015, https://www.italaw.com/sites/default/files/case-documents/italaw7303_0.pdf

Philip Morris also brought a similar case against Uruguay on the grounds that the regulation of the packaging of tobacco products breached the investment standard because of the company's legitimate expectation that the regulatory environment would not drastically change. In a split decision, Uruguay eventually prevailed in the dispute, benefiting from the obligations to regulate in the WHO Framework Convention on Tobacco Control. According to commentary by IISD, "At the same time, it is not clear whether the same approach would be taken with respect to other areas of public health or environmental protection, where the scientific evidence and consensus are not as clear and where no international legal frameworks like the World Health

Organization's (WHO) Framework Convention on Tobacco Control (FCTC) exist." Stefanie Schacherer, International Investment Law and Sustainable Development: Key cases from the 2010s, IISD, October 2018. https://www.iisd.org/system/files/publications/investment-law-sustainable-development-ten-cases-2010s.pdf. *Philip Morris Brands Sàrl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay*, ICSID Case No. ARB/10/7, http://www.italaw.com/cases/460

It is important to note that in the Philip Morris/Uruguay case, the WHO Framework Convention on Tobacco Control obligations was helpful for Uruguay to defend its regulatory policy. But if the Pandemic Accord has pro-industry restrictions on mandates to transfer technology, the opposite will be the case.

An example of where a state lost an ISDS case over the reasonable expectations involved a claim by a waste management firm against Mexico over a non-renewal of a permit to operate a landfill for hazardous industrial waste. *Tecnicas Medioambientales Tecmed S.A. v. United Mexican States*, ICSID Case No. ARB(AF)/00/2

Following the Philip Morris litigation against Australia and Uruguay, negotiators for the **Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)** included in Article 29.5 an exception to investor claims for tobacco control measures:

> **Article 29.5: Tobacco Control Measures**[/11/]
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> A Party may elect to deny the benefits of Section B of Chapter 9 (Investment) with respect to claims challenging a tobacco control measure[/12/] of the Party. Such a claim shall not be submitted to arbitration under Section B of Chapter 9 (Investment) if a Party has made such an election. If a Party has not elected to deny benefits with respect to such claims by the time of the submission of such a claim to arbitration under Section B of Chapter 9 (Investment), a Party may elect to deny benefits during the proceedings. For greater certainty, if a Party elects to deny benefits with respect to such claims, any such claim shall be dismissed.
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> /11/ For greater certainty, this Article does not prejudice: (i) the operation of Article 9.15 (Denial of Benefits); or (ii) a Party's rights under Chapter 28 (Dispute Settlement) in relation to a tobacco control measure.
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> /12/ A tobacco control measure means a measure of a Party related to the production or consumption of manufactured tobacco products (including products made or derived from tobacco), their distribution, labelling, packaging, advertising, marketing, promotion, sale, purchase, or use, as well as enforcement measures, such as inspection, recordkeeping, and reporting requirements. For greater certainty, a measure with respect to tobacco leaf that is not in the possession of a manufacturer of tobacco products or that is not part of a manufactured tobacco product is not a tobacco control measure

Negotiators should include language in the Pandemic Agreement that provides assurances that nothing in the agreement creates an obligation on parties that can be construed to create a claim in an investor-state dispute settlement (ISDS) mechanism.