Knowledge Ecology International
FEBRUARY 21, 2023

Comments on WHO CA+ Zero Draft

Chapter III
Articles 6, 7, 8, 9 and X

Chapter VI
Article 19

Knowledge Ecology International
Comments on the World Health Organization CA+ ZERO DRAFT

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Article 6. Predictable global supply chain and logistics network

Paragraph 3(c)

Paragraph 3(c) requires parties to “develop a mechanism to ensure the fair and equitable allocation of pandemic-related products based on public health risks and needs;”

This can include parties using their collective procurement power to insist on terms that can advance objectives regarding equity, technology transfer and transparency. These are some terms and conditions for procurement that would be useful:

> Article 6, Paragraph 3. . . . the Parties shall:
>
> (c) develop ~~a~~ mechanism[s] to ensure the fair and equitable allocation of pandemic-related products based on public health risks and needs~~;~~ [including but not limited to the following terms and conditions in procurement contracts:
>
> > (i) An option to mandate the licensing of intellectual property and transfer of manufacturing know-how, if the WHO determines that a manufacturer is not able to meet demand on a timely basis, or that products are not reasonably priced.
> >
> > (ii) An acknowledgement and agreement that the purchasing entity will share timely information with the WHO regarding the quantities, prices and other terms of the purchase, to be made public.[1]
> >
> > (iii) A requirement that the suppliers of products share and make transparent, and periodically update in standardized formats, the patent status information and the marketing approval status of health products;[2] the costs the clinical trials used to support marketing approval,[3] product development subsidies from governments and charities[4], and other other elements along the supply chain that are beneficial in evaluating the fairness of allocations and the reasonableness of prices.

[1] WHA72.8, 1(3).
[2] WHA72.8 1(4).
[3] WHA72.8 1(2)
[4] WHA72.8 1(3).

Article 7. Access to technology: promoting sustainable and equitably distributed production, transfer of technology and know-how

Paragraph 2.

Paragraph 2 requires parties to “strengthen existing and develop innovative multilateral mechanisms that promote and incentivize relevant transfer of technology and know-how for production of pandemic-related products, on mutually agreed terms, to capable manufacturers, particularly in developing countries.”

An unwanted qualifier in this paragraph is the reference to “mutually agreed terms,” for some mechanisms are non-voluntary in nature. Either strike “on mutually agreed terms,” or replace it with a broader description of options such as:

> “though a combination of incentives, mandates and voluntary agreements”

Paragraph 3 (a) and (c).

The term “mutually agreed terms” appears in **paragraph 3(a)** and **paragraph 3(c)**. The term should be struck.

In **paragraph 3(a)** the obligation is to “coordinate, collaborate, facilitate and incentivize.” In **paragraph 3(c)**, the obligations are to “encourage.” However, the nature of the agreements can involve reserving rights in publicly-funded research on a **take it or leave it basis** (such the provisions in the U.S. Bayh-Dole Act (35 USC § 202 and 209)), in order to provide the government with worldwide rights to use or provide third parties the right to use inventions, including “under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement.”

The reference to “mutually agreed terms” can be confusing or read as restrictive, and it is not necessary given the context and otherwise clear guidance of each paragraph. The term should be struck.

Paragraph 3 (b).

During COVID-19, there was excessive secrecy regarding manufacturing capacities. One might modify this paragraph as follows:

> (b) strengthen coordination, with relevant international organizations, including United Nations agencies, on issues related to public health, intellectual property and trade, including timely matching of supply to demand and [providing the public with periodic] mapping [of] manufacturing capacities and [estimated] demand;

Paragraph 3 (d).

This paragraph is fine, although vague as regards its obligations. Periodic reporting on what is done under this paragraph might have some value, particularly if there were a way to create atype of standardized reporting.

Paragraph 4 (a).

The current text in Article 7(4)(a) requires members to support appropriate “waivers of intellectual property rights.”

> 4. In the event of a pandemic, the Parties:
>
> (a) will take appropriate measures to support time-bound waivers of intellectual property rights that can accelerate or scale-up manufacturing of pandemic-related products during a pandemic, to the extent necessary to increase the availability and adequacy of affordable pandemic-related products;

In the current WTO negotiations, the initial proposals were to waive certain WTO rules on intellectual property rights, but not the rights themselves. While the current text is fine, it may create confusion over what is being asked of countries, particularly given the provisions in paragraph 4 (b), regarding the use of flexibilities in the TRIPS Agreement.

The requirements in Article 7(4)(a) can be amended to focus on the waiver of unwanted obligations in treaties, trade and investment agreements that limit the ability of Member States to respond appropriately during an emergency. One possible formulation would be:

> (a) will take appropriate measures to support time-bound waivers of [rules regarding] intellectual property rights [or investment] that can accelerate or scale-up manufacturing of pandemic-related products during a pandemic, to the extent necessary to increase the availability and adequacy of affordable pandemic-related products;

For context: During the COVID-19 pandemic, some obligations in trade or investment agreements were seen as problematic. In a Dominican Republic compulsory licensing case involving the therapeutic Paxlovid, a provision in a trade agreement between the United States and the Dominican Republic that required five years of exclusivity regarding pharmaceutical test data would make it difficult to register a generic version of Paxlovid for five years. Some country officials have expressed concern that the use of compulsory licenses or other exceptions would trigger liability under investment agreements. The WTO TRIPS restrictions on exports under a compulsory license are particularly objectionable when there is a need to scale global production and address the health needs of countries without domestic suppliers. The waiver in Article 7(4)(a) would be narrow and limited, and only apply in “the event of a pandemic,” and not the “inter-pandemic times” covered in Article 7(3).

Paragraph 4(b).

This is an important provision, perhaps the most important intellectual property proposal in the text. The provision states that it would be mandatory to use exceptions to intellectual property

rights, “in the event of a pandemic.” That said, there are a few shortcomings in the current text, which reads as follows:

> 4. In the event of a pandemic, the Parties:
>
> (b) will apply the full use of the flexibilities provided in the TRIPS Agreement, including those recognized in the Doha Declaration on the TRIPS Agreement and Public Health of 2001 and in Articles 27, 30 (including the research exception and “Bolar” provision), 31 and 31bis of the TRIPS Agreement;

The zero draft version seems to suggest a closed list of exceptions, including those relating specifically to the 2001 Doha Declaration on the TRIPS Agreement and Public Health, and in TRIPS Articles 27, 30, 31 and 31bis. While this is not a bad list of exceptions, there are some important ones in the TRIPS Agreement that are left out.

- Article 40 of TRIPS relates to the control of anticompetitive practices.
- Article 39 of TRIPS includes in its paragraph 3 the important right to allow the commercial use of data submitted to regulators,“when necessary to protect the public.”
- Professor Fred Abbott has published Research Paper 116 for the South Centre, recommending that WTO members conclude that a pandemic such as COVID-19 constitutes an emergency in international relations within the meaning of Article 73(b)(iii) of TRIPS, which allows Governments to take actions necessary to protect their essential security interests.
- During the COVID-19 pandemic, there were concerns that copyright and design protections could be a barrier to manufacturing respirators or other products using 3D printing technologies.
- The most widely used exception in the TRIPS Agreement for COVID-19 was Article 44, which permits countries to restrict or even eliminate the possibility of an injunction when an intellectual property right is infringed. Article 44 is located in Part III of the TRIPS Agreement, concerning Civil and Administrative Procedures and Remedies, and applies to all intellectual property rights referenced in the TRIPS Agreement.

The list of types of intellectual property rights continues to grow, including a number of *sui generis* regimes not mentioned in the TRIPS Agreement, such as several different legal ways to protect data, some approaches to protecting manufacturing know-how, and emerging theories of how to protect investments in artificial intelligence.

As regards Article 44 of the TRIPS Agreement, note that during COVID-19, the U.S. government frequently granted a FAR 52.227-1 authorization to companies that allowed them to use any U.S. government patent in order to perform a research and development or procurement contract for the U.S. government. One study by KEI found that the FAR 52.227-1 authorization was included in 59 of the 62 COVID-19 contracts that were reviewed. Three KEI Briefing Notes describe the US government’s use of Article 44 of the TRIPS Agreement:

- 2022:3 KEI Briefing Note: Selected differences between Article 30, 31 and 44 of the WTO TRIPS Agreement as regards non-voluntary use of patented inventions
- 2022:2: KEI Briefing Note: U.S. federal government FAR 52.227-1 authorizations (for non voluntary use of patents) disclosed in 173 SEC exhibits
- 2022:1 KEI Briefing Note: Selected U.S. Government COVID Contracts with Authorization and Consent to Non-Voluntary Use Of Third Party Patents

The mandate is to use the "full use of the flexibilities provided in the TRIPS Agreement," a phrase used in the 2001 Doha Declaration on TRIPS and Public Health and in some other documents. While this language is welcome, it can be confusing, regarding the nature of the obligations, and in practice, no country ever makes "full use" of the permitted exceptions.

One way to deal with this complexity is to avoid using a list of flexibilities and to state the obligation along the lines of something like this:

> 4. In the event of a pandemic, the Parties:
>
> (b) will apply the use of exceptions in domestic laws relating to intellectual property that are necessary to enable the necessary 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.
>
> *new* (e) 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.

Paragraph (4)(c)

This wording is okay, but could be more clear. While some rights holders may decide to waive royalties in developing countries, it's not necessary if licenses are available to generic manufacturers of reasonable terms. Most of the MPP licenses are royalty bearing, and it's not a problem for the prices of the products, and it does provide an incentive to license. What is important is that the royalties are reasonable and access enabling.

> (c) shall encourage all holders of patents related to the production of pandemic-related products to [either] waive~~,~~ or ~~manage as~~ [set] appropriate[, reasonable and access enabling]~~, payment of~~ royalties [for] ~~by~~ developing country manufacturers on the use, during the pandemic, of their technology for 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

Article 8. Regulatory strengthening

KEI suggests the following amendments to Paragraph 2 of Article 8.

Paragraph 2.

2. Each Party shall build and strengthen its country regulatory capacities and performance for timely approval of pandemic-related products and, in the event of a pandemic, accelerate the process of approving and licensing pandemic-related products for emergency use in a timely manner, including the sharing of regulatory dossiers with other institutions. [To this end, parties shall

(a) provide appropriate exceptions to any exclusive rights in test data used to establish the safety and efficacy of products, and

(b) ensure that information regarding the design of tests for bioequivalence or biosimilarity be shared with generic producers.]

Article 9. Increasing research and development capacities

(Article 9 is one possible location for the Open Source Dividend Proposal, discussed in a separate KEI comment on Article 10.)

Paragraph 2 (b).

KEI suggests the following amendments to Paragraph 2 of Article 9.

2. With a view to promoting greater sharing of knowledge and transparency, each Party, when providing public funding for research and development for pandemic prevention, preparedness, response and recovery of health systems, shall, taking into account the extent of the public funding received:

(b) ~~endeavour to~~ include terms and conditions on prices of products, allocation, data sharing and transfer of technology, [including an option to mandate the licensing of intellectual property and transfer of manufacturing know-how, if a manufacturer is not able to meet demand on a timely basis, or that products are not reasonably priced,] ~~as appropriate,~~ and publication of contract terms;

Paragraph 3.

This is a pretty good paragraph on **transparency**. One might consider some changes, drawn from standards in WHA72.8.

3. Parties shall increase the transparency of information about funding for research and development for pandemic-related products by:

(a) disclosing information on public funding for research and development of potential pandemic-related products and provisions to enhance the availability and accessibility of the resulting work, including freely available and publicly accessible publications and public reporting of [public sector funding for] the relevant patents;

(b) making it compulsory for manufacturers that receive public funding for the production of pandemic-related products to disclose [and share with the WHO[5] the following:

[(i)] prices and contractual terms for public procurement ~~in times of pandemics~~,[6]

[(ii) clinical trial designs and outcomes, regardless of outcomes,[7]

(iii) clinical trial costs,[8]

(iv) sales revenue, prices, units sold, marketing costs, and subsidies and incentives,[9]

(v) patent status information and the marketing approval status of health products;[10]

~~taking into account the extent of the public funding received;~~]and

(c) encouraging manufacturers that receive other funds~~, external to the manufacturer,~~ for the production of pandemic-related products to disclose [the same information described in (b). ~~prices and contractual terms for public procurement in times of pandemics~~.

Paragraph 7.

KEI suggests the following amendments to Paragraph 7 of Article 9.

7. In the conclusion of contracts for the supply or purchase of pandemic-related products, each Party shall [publish contracts,] endeavour to exclude confidentiality provisions that serve to limit disclosure of terms and conditions [and work with the WHO to create and periodically review standards for best practices regarding the transparency of contracts.]

(The proposed Article X could be part of Chapter III, and would elaborate on efforts to create technology pools.)

[Article X. Pooling of rights in and access to inventions, data, biologic resources and how-how

1. Parties recognize the value of global sharing of rights in and access to inventions, data, biologic resources and know-how, and also the need to provide both mandates and incentives to share.

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[5] WHA72.8 2(3); 2(4) and 2(6).
[6] WHA72.8 1(1).
[7] Declaration of Helsinki (2013), and WHA72.8.
[8] WHA72.8 1(2)
[9] WHA72.8, 1(3).
[10] WHA72.8 1(4).

2. The WHO shall create a technology sharing pool for rights in and access to inventions, data, biologic resources and know-how, known as the Technology Sharing Pool (TSP).

Global Public Goods

a. One component of the TSP shall be for global licenses, where the rights in inventions, data, biologic resources and know-how are considered royalty free public goods.

Remunerative licenses

b. One component of the TSP shall be for global licenses, where the rights in inventions, data, biologic resources and know-how are licensed to qualified manufacturers subject to reasonable remuneration.

Share-and-share-alike licenses

c. One component of the TSP shall be for an opt-in cross-license of government rights in inventions, data, biologic resources and know-how relevant to pandemic preparedness and response. This component will be referred to as the share-and-share-alike pool. The cross licenses will allow any party that joins the pool to use or have used the rights in a field of use for pandemic preparedness and response, and in a geographic area that is limited to the parties that join the cross licensing pool. To join the share-and-share-alike pool, a government would have to commit to a standard cross licensing agreement in a field relating to pandemic preparedness and response for all federal level R&D funding.

3. Parties agree to levy a fee on all products that are not licensed to TSP, and use that revenue solely to compensate developers of products that are licensed to the TSP. The amount of the levy shall be set and periodically modified by the Governing Body.]

Chapter VI. Financing for pandemic prevention, preparedness, response and recovery of health systems

Article 19. Sustainable and predictable financing

Article 19 could include a specific reference to a fund for buyouts of patents or know-how.[11]

2. The Parties shall ensure, through innovative existing and/or new mechanisms, sustainable and predictable financing of global, regional and national systems, capacities, tools and global public goods, while avoiding duplication, promoting synergies

[11] See: Buying Know-How to Scale Vaccine Manufacturing. *Medium*, March 20, 2021.

and enhancing transparent and accountable governance of these mechanisms, to support strengthening pandemic prevention, preparedness, response and recovery of health systems, based on public health risk and need, particularly in developing countries. [This shall include but not be limited to

(a) a fund to acquire rights to manufacturing know-how, and other inputs to countermeasures, to become global public goods, with graduated and progressive obligations by stage of development and income.]

ANNEX. Selected references: equity and government-funded R&D in Zero Draft text

- **Background, Methodology And Approach**
  Paragraph 1. 1. In recognition of the catastrophic failure of the international community in showing **solidarity and equity** in response to the coronavirus disease (COVID-19) pandemic . .

- **Preamble:**
  Paragraph 3. Recognizing that all lives have equal value, and that therefore equity should be a principle, an indicator and an outcome of pandemic prevention, preparedness and response,

  Paragraph 47. Recognizing that publicly funded research and development plays an important role in the development of pandemic-related products and, as such, requires conditionalities,

  Paragraph 49. **Vision**. . . . The WHO CA+ aims to achieve greater equity and effectiveness for pandemic prevention, preparedness and response through the fullest national and international cooperation.

- **Chapter II. Objective, guiding principles and scope**
  Article 3. Objective
  The objective of the WHO CA+, **guided by equity,** the vision, principles and rights set out herein, is to prevent pandemics, save lives, reduce disease burden and protect livelihoods, through strengthening, proactively, the world's capacities for preventing, preparing for and responding to, and recovery of health systems from, pandemics. The WHO CA+ aims to **comprehensively and effectively address systemic gaps and challenges** that exist in these areas, at national, regional and international levels, through substantially reducing the risk of pandemics, increasing pandemic preparedness and response capacities, progressive realization of universal health coverage and ensuring coordinated, collaborative and evidence-based pandemic response and resilient recovery of health systems at community, national, regional and global levels.

- **Article 4. Guiding principles and rights**

To achieve the objective of the WHO CA+ and to implement its provisions, the Parties will be guided, inter alia, by the principles and rights set out below:

Paragraph 4. Equity – **The absence of unfair, avoidable or remediable differences**, **including** in their capacities, among and within countries, including between groups of people, whether those groups are defined socially, economically, demographically, geographically or by other dimensions of **inequality, is central to equity**. Effective pandemic prevention, preparedness, response and recovery cannot be achieved without **political will and commitments** in addressing the structural challenges in **inequitable access to fair, equitable and timely access to affordable, safe and efficacious pandemic-related products and services**, essential health services, information and social support, as well as **tackling the inequities** in terms of technology, health workforce, infrastructure and financing, among other aspects.

- **Chapter III. Achieving equity in, for and through pandemic prevention, preparedness, response and recovery of health systems**

- **Article 6. Predictable global supply chain and logistics network**
  Paragraph 1. The Parties, recognizing the shortcomings of the preparedness for and response to the COVID-19 pandemic, agree on the need for an adequate, equitable, transparent, robust, agile, effective and diverse global supply chain and logistics network for pandemic prevention, preparedness, response and recovery.

  Paragraph 3(b). assess anticipated demand for, and map sources of, manufacturers and suppliers, including raw materials and other necessary inputs, for sustainable production of pandemic-related products (especially active pharmaceutical ingredients), including manufacturing capacities, and identify the most efficient multilateral and regional purchasing mechanisms, **including pooled mechanisms** and in-kind contributions, as well as **promoting transparency in cost and pricing of all elements along the supply chain**;

- **Article 7. Access to technology: promoting sustainable and equitably distributed production and transfer of technology and know-how**
  Paragraph 3. During inter-pandemic times, all Parties commit to establish these mechanisms and shall:
  . . .
  (c) encourage entities, including manufacturers within their respective jurisdictions, that conduct research and development of pre-pandemic and pandemic-related products, in particular those that receive **significant public financing** for that purpose, to grant, on mutually agreed terms, licences to capable manufacturers, notably 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 response product research, development and production, in particular for pre-pandemic and pandemic-related products; and

- **Article 9. Increasing research and development capacities.**

Paragraph 2. With a view to promoting greater sharing of knowledge and transparency, each Party, when providing public funding for research and development for pandemic prevention, preparedness, response and recovery of health systems, shall, taking into account the extent of the public funding received:

- (a) promote the free, public dissemination of the results of publicly and **government-funded research** for the development of pandemic-related products

- (e) establish appropriate conditions for **publicly funded research and development,** including on distributed manufacturing, licensing, technology transfer and pricing policies.

Paragraph 3. Parties shall increase the transparency of information about funding for research and development for pandemic-related products by:

- (a) disclosing information on **public funding** for research and development of potential pandemic-related products and provisions to enhance the availability and accessibility of the resulting work, including freely available and publicly accessible publications and public reporting of the relevant patents;

- **Chapter VI. Financing for pandemic prevention, preparedness, response and recovery of health systems**
  Article 19. Sustainable and predictable financing

- Paragraph 2. The Parties shall ensure, through **innovative existing and/or new mechanisms,** sustainable and predictable financing of global, regional and national systems, capacities, tools and **global public goods**, while avoiding duplication, promoting synergies and enhancing transparent and accountable governance of these mechanisms, to support strengthening pandemic prevention, preparedness, response and recovery of health systems, based on public health risk and need, particularly in developing countries.

- Paragraph 3. The Parties shall promote, as appropriate, the use of bilateral, regional, subregional and other appropriate and relevant channels to provide funding for the development and strengthening of pandemic prevention, preparedness, response and health system recovery programmes of developing country Parties.