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## Déjà WTO: The WHO's pandemic agreement shouldn't water down intellectual property obligations

By Cynthia M. Ho April 28, 2024



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As countries [resume final negotiations](#) on Monday for a [landmark pandemic agreement](#) intended to help prevent and rapidly respond to the next [inevitable](#) pandemic, I'm getting a sense of déjà vu. Why? The [draft text](#) has watered down intellectual property (IP) obligations in an attempt to achieve compromise on this issue. Diluting international obligations to achieve consensus is reminiscent of the [limited waiver](#) of one international patent obligation for Covid vaccines after two years of negotiations at the World Trade Organization (WTO).

Contrary to the [originally proposed broad waiver](#) of all patent and other IP requirements, the adopted limited waiver has [never been used](#) since it is so narrow as to be useless.

Countries are in danger of repeating this pattern. So, what should be done?

## What is the (IP) problem?

Intellectual property rights are generally assumed to provide an incentive to develop products, including medical therapies. But IP rights can also limit access to such products. This is especially true with patent rights that bar anyone other than the patent owner from making the patented invention. During the Covid-19 crisis, some countries [argued](#) that international obligations requiring WTO countries to maintain patent and other IP rights should be suspended. Such suspension would have enabled countries to create domestic exceptions to patent laws to make the vaccines and other treatments they needed without international liability.

All countries recognize that there was [inequitable distribution](#) of Covid-19 vaccines and other health products during the pandemic. But there is [fundamental disagreement](#) on whether intellectual property was a barrier. Some say it [was](#); others that [it wasn't](#).

Countries have been debating for [two years](#) about [whether to even include IP](#) in the pandemic agreement. Whereas the [Global South](#) (along with [U.N. experts](#) and [health advocates](#)) want robust provisions to [address IP barriers](#) for the pandemics to come, the [Global North](#) (and those in the pharmaceutical [industry](#)) either want IP obligations [excluded](#) entirely from the pandemic agreement or limited to suggestions for voluntary action.

Representatives of industry repeatedly suggest that IP is the *solution* to broader access to vaccines and other therapies, not the problem. For example, [a statement](#) by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) titled, in part, “We need to preserve what went well [during Covid],” argued against language in [the October WHO pandemic agreement draft](#) that proposed waiving IP rights during pandemics. IFPMA and others have argued not only that Covid-19 treatments were developed due to standard IP rights, but that IP promoted collaboration to increase manufacturing during the pandemic. But the claim that IP worked well during the Covid-19 pandemic ignores [more than 25 million deaths](#).

Some countries, such as the U.S., endorse equitable access to treatments but only support voluntary sharing of IP to preserve it as an incentive. However, a focus on voluntary actions ignores the inadequacy of this approach. Early in the Covid-19 pandemic, the WHO had requested that countries and companies voluntarily share IP needed to make medical products as part of [global solidarity](#). Several large vaccine makers [did not contribute](#) intellectual property for Covid-19 vaccines to WHO's [technology access pool](#), which was set up to enable more companies to scale up manufacturing. Moderna and Pfizer also [ignored license requests](#)

from capable manufacturers, even when those two companies were unable to adequately meet the demand for vaccines.

Addressing intellectual property barriers to creating needed treatments is tricky, since there is often more than one type of IP involved. For example, although Moderna [proclaimed](#) it would permit those in the Global South to use its patented vaccine, it did [not share the trade secret method](#) of making the vaccine. Although South Africa eventually [developed](#) an alternative method, that effort took nearly two years, during which many preventable deaths occurred. Moreover, beyond patents and trade secrets, in some countries there is a [type of IP protection](#) — referred to as [data exclusivity](#) — that bars potential competitors from relying on earlier clinical data to expedite approval. Problematically, such laws generally [lack an emergency exception](#).

Some countries, including Brazil and Egypt, [proposed](#) that the WHO pandemic agreement section concerning technology sharing (Article 11) should require countries to make such data available for at least government-funded products. This modest suggestion, however, is omitted from the [current draft](#).

Recent U.S. statements and actions reflect an incomplete understanding of the need to address IP barriers. For example, the White House recently issued a [Global Health Security Strategy](#) that allegedly aims to enhance prevention and response to infectious disease threats worldwide. IP does not appear anywhere in the 50-plus page document. In addition, a recent [fact sheet](#) from the Department of State and the Department of Health and Human Services purports to support equitable and timely access to vaccines and treatments for all. It mentions intellectual property as a “critical cornerstone of invention,” but fails to acknowledge that it is also a barrier to accessing innovation.

I see three lessons about intellectual property that should have been learned from the Covid-19 pandemic that the pending WHO agreement should recognize and address:

- IP is a problem for effectively addressing pandemics.
- Trying to address IP during a pandemic does not work.
- Reliance on voluntary sharing of IP during a pandemic does not work.

All three point to the [need to address IP](#) in a binding pandemic agreement as [I have previously suggested](#).

## **Examining the problems in the current draft pandemic agreement**

The preamble of the agreement already indicates a fundamental problem. Article 14 of the preamble states:

*Recognizing that intellectual property protection is important for the development of new medicines, recognizing the concerns about its dire effects on prices and recalling that the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) does not, and should not, prevent Member States from taking measures to protect public health...*

This language is problematic because it gives the impression that the only problem with IP is higher costs. That is at odds with what happened during the Covid-19 pandemic: when IP owners could not meet the demand for vaccines, many people in the Global South had no access to *any* Covid-19 vaccines. Although intellectual property rights exist to provide an incentive to develop new medicines and other therapies, this incentive alone may be ineffective unless governments provide additional funding. Indeed, the U.S. alone spent [billions](#) over decades to research mRNA vaccines, produce them, and purchase mRNA-based Covid-19 vaccines.

The language about how the TRIPS agreement does not prevent member states from taking measures to protect public health is misleading. This language is from the WTO's [Doha Public Health Declaration](#). However, the language in the draft text ignores the very next sentence in that declaration about how member states reiterate “commitment to TRIPS.” The TRIPS agreement requires member states to maintain IP rights, which create tensions with public health. What is most protective of public health is to bar patents on any drugs to ensure they are affordable. Countries such as [India](#) previously barred patents on drugs and active ingredients, instead patenting only methods of making them, to enable broad access. This approach, however, is no longer permissible for WTO member states except for the least developed countries.

Many member states of the Global South advocated during the Covid-19 pandemic to [suspend multiple TRIPS provisions](#) to fight the pandemic. This should underscore that the usual TRIPS requirements prevent countries from adequately protecting public health.

Since the preamble to the draft pandemic agreement does not recognize that IP can create barriers to creating treatments, it is not surprising that the draft's operative provisions are weak. For example, it proposes that even for patents that result from public funding, government need only “encourage” patent owners to license patents at reasonable rates. [Some view this modest language](#) as encouraging IP violations.

## A missed opportunity

It would be most efficient for countries to preemptively agree to waive international IP obligations *now*, rather than in the midst of a pandemic, which obviously was ineffective during Covid-19. Such a proposal existed in an [October draft](#) of the pandemic agreement (see Article 12(3)(a)). A recent proposal by more than a dozen countries, including Brazil, Columbia and India, went farther and recommended a so-called [peace clause](#) that would bar not only formal challenges but even “indirect pressure” against using existing flexibilities under international law. This proposal was opposed by the U.S., Japan, Canada, and the EU, among others.

The [current text](#) of the pandemic agreement excludes the peace clause, as well as any mention of a waiver of IP obligations. This is a missed opportunity.

## International options

There are two different international opportunities for addressing IP barriers to fighting pandemics. First, countries could [avoid rushing](#) to prematurely conclude negotiations on the pandemic agreement by the [self-imposed World Health Assembly meeting](#) in May, and work toward stronger provisions. Second, countries have an opportunity to revisit international IP obligations more broadly since [Colombia recently requested](#) that WTO countries do so. This request could permit amendment of TRIPS, the fundamental international IP agreement, to include a waiver during pandemics. If so, it could be powerfully enforced under the WTO dispute settlement system, which [stands out](#) in the international arena.

In contrast, even if obligations to require countries to affirmatively reduce IP barriers were included in the pandemic agreement, the proposed agreement currently lacks any real [compliance mechanism](#).

## **Beyond international agreements**

Even with inadequate agreement at the international level, nothing bars individual countries from taking steps to remove IP barriers to access on the domestic level. It's possible that the action of one or more countries could gradually build international consensus to better balance incentivizing innovation against access to needed treatments.

Countries can and should review their own domestic laws to promote greater flexibility to act to promote public health needs. One issue that countries have thus far overlooked is the need for domestic laws to mandate that companies share trade secrets, and even clinical data when necessary, to make urgently needed treatments. Academics and health policy advocates [have argued](#) that the pandemic agreement should include language to [require sharing trade secrets](#). The [October draft](#) did that. But the [most recent draft](#) suggests only that countries "encourage" sharing relevant information "as appropriate" (see Article 11(1)(f)).

A [proposed](#) EU-wide [compulsory license for emergencies](#) suggests that trade secrets should be shared for licensed patents during such emergencies. So, changing norms is possible. And, other countries should similarly consider such action. In addition, although countries are debating whether government-funded pandemic products should be priced reasonably, there is nothing that prevents governments from requiring this for all products, as [I have previously suggested](#).

In addition, countries can and should resist pressuring other countries from using flexibilities under international agreements, even if there is no mandate to do so in the pandemic agreement. Notably, the U.S.'s just-released [annual Special 301 report](#) about inadequate IP policies of other countries [embraces](#) this approach. This is a notable change from prior years that has been [welcomed by health advocates](#).

## **Looking forward**

A pandemic agreement can be [good for all](#), but only if known barriers to equitable distribution of pandemic products exists. That means temporarily removing intellectual property barriers

to permit efficient manufacture. Without that, people around the world will remain unnecessarily vulnerable to forthcoming pandemics — and leaders will be doomed to repeat past mistakes.

*Cynthia M. Ho is the Clifford E. Vickrey research professor and director of the Intellectual Property Program at the Loyola University of Chicago School of Law.*

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## About the Author

**Cynthia M. Ho**

[cho@luc.edu](mailto:cho@luc.edu)

[linkedin.com/in/cynthia-ho-15382a5/](https://www.linkedin.com/in/cynthia-ho-15382a5/)

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