

KEI initial statement regarding the US ITC Investigation 332–596, on COVID–19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities

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The WTO TRIPS Agreement has a number of important flexibilities	2
PART II - STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS	2
PART III - ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS	2
PART VII - INSTITUTIONAL ARRANGEMENTS: FINAL PROVISIONS	3
Many WTO members have been reluctant to use TRIPS flexibilities due to political pressures or a lack of generic suppliers	3
Overcoming WTO export restrictions to achieve economies of scale	4
DS114, the WTO Canada/EU pharmaceutical case	4
Article 31bis	5
The COVID-19 pandemic	6
Canada’s refusal to list COVID-19 as a public health problem on Schedule 1	6
Latin American Paxlovid compulsory licensing efforts	7
June 17, 2022 WTO decision	7
What should the WTO do as regards therapeutics and diagnostics?	8
Looking backward opposition	8
Figure 1: BIO’s COVID-19 Therapeutic Development Tracker	9
The importance of combination treatments	9
COVID 19 is mutating	10
Next Steps at the WTO	10
Next Steps at the ITC	11
Attachments:	12
ANNEX - Questions the ITC can ask certain parties	13
For Pfizer:	13
For Merck:	13
For Ridgeback:	14
For Eli Lilly:	14
For Roche:	14
For Gilead:	14
For the NIH:	15
For BARDA:	15
For the DOD:	15
For CDC:	15
For USTR:	16

My name is James Love. I am the Director of Knowledge Ecology International. These are KEI's comments regarding the US ITC Investigation 332-596, on COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities.

The WTO TRIPS Agreement has a number of important flexibilities

PART II - STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS

There is the possibility of exceptions to patent rights in Part II, Section 5 of the WTO TRIPS Agreement, such as Article 30, titled Exceptions to Rights Conferred, Article 31, titled "Other Use Without Authorization of the Right Holder," and the untitled Article 31bis.

In Part II, Section 7 of the TRIPS, titled "Protection of Undisclosed Information," there are exceptions in Article 39.3 to the protection of "test or other data" when disclosure is "necessary to protect the public," or for non-commercial uses, or when commercial use is not "unfair," such as when compensation or remuneration is provided, as is the case in the United States Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

In Part II, Section 8, titled, "Control of Anti-competitive Practices in Contractual Licences," there is Article 40, which ensures that WTO members may specify "in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition," and take "appropriate measures to prevent or control such practices."

PART III - ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

In Part III, Section 2: Civil and Administrative Procedures and Remedies, there is an important flexibility, Article 44, on injunctions. This is not only an important flexibility in the TRIPS, but it has been the most important one during the COVID-19 pandemic. Under this article, a WTO member can withhold or even eliminate the possibility of an injunction when a patented invention is infringed. In the United States, one way this flexibility is used is under 28 USC § 1498(a), concerning the use of patented inventions by or for the government.

In a recent study of 62 government contracts or amendments to contracts related to COVID-19, KEI found that 59 had received an authorization from the federal government to use any patent granted by the U.S. government. The administrative mechanism used was a FAR 52.227-1 authorization, attached to contracts for a wide range of COVID-19 countermeasures.

The beneficiaries of these government-use authorizations were well-known companies like Corning, Eli Lilly, Merck, Moderna, Novavax, Philips, Qiagen, Sanofi and Siemens, as well as many small companies and a few universities. The contracts were for diverse COVID-19 countermeasures, including vaccines, drugs, diagnostic tests and other technologies.

In each of these cases, the authorization is broad, done without naming specific patents for which the non-voluntary use is authorized, applies to patents that may be granted at a later date, and does not require prior negotiation with patent holders. The U.S. government assumes responsibility for compensating patent owners, if any, who can demonstrate their inventions were used by the contractor. (In some cases, the U.S. government requires the company to indemnify the government, with a FAR 52.227-3 clause in the contract).

When a non voluntary use of a patented invention occurs because an injunction has been denied or is not available, there is no three-step test, restrictions on exports or other restrictions in the TRIPS, although in some cases, compensation or remuneration may be required.

There is currently litigation in the U.S. concerning a FAR 52.227-1 authorization for the Moderna COVID-19 vaccine, and a problematic ruling by a district court, but we expect this to be resolved on appeal in a manner consistent with the U.S. Department of Justice position in the case.

PART VII - INSTITUTIONAL ARRANGEMENTS: FINAL PROVISIONS

There is in Part VII of the TRIPS, an Article 73 on Security Exceptions, that allows WTO members to take “any action which it considers necessary for the protection of its essential security interests. . . in an “emergency in international relations.” Some legal experts, including Professor Fred Abbott, have argued that WTO members could use this exception in the COVID=19 pandemic. (See: The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic, Research Paper 116, South Centre, Geneva, August 2020).

Many WTO members have been reluctant to use TRIPS flexibilities due to political pressures or a lack of generic suppliers

Despite the known flexibilities in the TRIPS Agreement, many countries are reluctant to use the exceptions, even when faced with significant inequality in access to drugs, vaccines and other health technologies. There are several reasons for this, including a perceived legal uncertainty over some measures, but primarily due to two factors, the challenges of a generic supplier for a product when compulsory licenses or other exceptions are used, and/or political pressure from the United States or European trading partners.

The challenges of finding a generic supplier are related to the challenges of acquiring the know-how to make a product, the regulatory barriers to entry, and the need to achieve sufficient

economies of scale in manufacturing. The parts of the TRIPS that are most important on these topics are Article 31.f, which restricts exports to 49 percent of national production under a compulsory license, and Article 39 of the TRIPS, which concerns trade secrets and the confidentiality or use of data submitted to regulatory agencies.

Overcoming WTO export restrictions to achieve economies of scale

There are several ways to overcome the export restrictions, including by declaring that a compulsory license is a remedy to an excessive price or a refusal to license, grounds that qualify for the Article 31.k exception to the Article 31.f export restriction, or to justify the exports under Article 30, something that was tested in the WTO dispute over the Canada pharmaceuticals law (DS114), using the complex, protectionist and much-criticized Article 31*bis* option, or following the US example of restricting remedies for infringement under Article 44.

Here it is worth noting the several ironies of the WTO having rules that limit exports in general, and in particular during a pandemic. The original intent of Article 31.f was explained to me by Adrian Otten, the first Director of the Office of Intellectual Property at the WTO, in a 1994 meeting on the TRIPS in Argentina. Otten explained that Article 31.f of TRIPS was designed to cripple the use of compulsory licensing of patents on a drug or other products for which economies of scale were important. He agreed then that if a WTO member would justify its compulsory license as a remedy to an anticompetitive practice, the restrictions on exports would not apply, but he said that would be challenging for developing countries that lacked the capacity to undertake a US or EU style competition proceeding, even though after being pressed, he acknowledged that Article 31.k of the TRIPS did allow for a purely administrative process.

Otten was saying that compulsory licensing of drug patents would not work because the WTO rules were explicitly designed to prevent manufacturers from taking advantage of **economies of scale** or benefiting from **comparative advantage** (often related to know-how), two of the primary rationales for trade liberalization. Otten thought that the WTO restrictions on exports in Article 31.f would have a particularly negative impact in developing countries because he reckoned they lacked the capacity to establish that a patent abuse met the legal standard of an anticompetitive practice, even when prices were excessive and access was restricted.

DS114, the WTO Canada/EU pharmaceutical case

The issue of economies of scale came up in 2000 in the context of a WTO dispute between Canada and the EU over the Canadian pharmaceuticals legislation, and specifically, Canada's use of an early working exception. Among other things, the EU objected to Canada's use of the exception to import or export patent drugs for purposes of conducting the tests required for registration. The WTO panel report on DS114 included this comment about the issue:

Report of the panel. WT/DS114/R, 17 March 2000, CANADA – PATENT PROTECTION OF PHARMACEUTICAL PRODUCTS, Complaint by the European Communities and their member States. Paragraph 4.38, Pages 79-80.

(a) The Global Nature of the Pharmaceutical Industry

- Both the brand name and generic pharmaceutical industries were global in nature. Very few countries had fully integrated brand name or generic drug industries within their borders. Even in large countries, generic producers frequently had to obtain ingredients such as fine chemicals from producers in other countries. Many countries had no generic industries at all and had to obtain generic (as well as brand name) products from other countries. Smaller countries that did have generic industries did not have domestic markets sufficiently large to enable those industries to operate on an economic scale. Those industries had to export in order to be able to manufacture in sufficient quantities to achieve economies of scale, so that domestic consumers could receive the benefits of cost-effective generic products.

- The United States agreed that a "pre-expiration testing" exception was a reasonable exception to the exclusive rights conferred under the TRIPS Agreement.²⁷⁰ However, the market in the United States was large enough for generic producers to manufacture on an economic scale. Very few countries were in that position. "Pre-expiration testing" exceptions that had the effect of confining all activities to a single country were of little use to countries that, unlike the United States, depended on international trade to obtain generic products.

In DS114, which was decided before the 2001 Doha Declaration on TRIPS and Public Health, the WTO panel found in favor of Canada's use of Article 30 of the TRIPS to permit the import and export of patented products, in the context of the early working of drug patent, establishing that the exception could be used for exports, to and from any country.

The subsequent 2001 Doha Declaration on TRIPS and Public Health provided that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all," providing even more space to use Article 30 for exports.

Article 31bis

In the debates over the 2001 Doha Declaration on TRIPS and Public Health, and the WTO's decision of August 30, 2003 (on paragraph 6 of the 2001 Declaration), public health groups such as CPTech, MSF, Oxfam pressed for a decision that recognized the flexibility in Article 30 of the TRIPS to enable exports under a compulsory license to countries where the imports were legal and the patent holders legitimate interests, if any, were protected through the payment of royalties. This approach was opposed, primarily by the European Commission, in favor of what

is now Article 31*bis*, a complex and difficult to use exception to Article 31.f that requires among other things, a series of notifications to the WHO by both the importing and exporting country, and a provision for countries to opt-out as importers.

One practical but unwelcome feature of 31*bis* is that before a government can proceed on a compulsory license, the notification to the WTO creates the need for broad interagency engagement including trade and industry ministries, and getting consensus among multiple parts of a government has proved to be a challenge.

Thirty-seven countries notified the WTO they would opt-out as importers, even in an emergency, including Australia, Canada, the European Union and its Member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States. This has the practical effect of protecting manufacturers in those countries from competition from manufacturers in developing countries, even during an emergency and even when compulsory licenses have been issued in the importing country (such as the compulsory licenses the USA issued during the COVID-19 pandemic).

The COVID-19 pandemic

In the beginning of the pandemic, Canada and Germany both passed laws relating to the emergency that created considerable freedom to enable non-voluntary use of patented inventions on a temporary basis. Few other countries followed suit, although a handful did use existing national laws to grant compulsory licenses. The FAR 52.227-1 authorizations by the U.S. government were by far the most aggressive and extensive such examples.

On April 7, 2020, more than 30 groups and three dozen experts on health, law and trade sent an open letter to the 37 WTO members that had opted out of the 31*bis* mechanism as importers, asking “countries to notify the WTO that they have changed their policy and now considers itself an eligible importing country, and in addition, to also use whatever legal means are available to revoke the opt-out as importing members, for goods manufactured under a compulsory license.” The letter was signed by a diverse set of experts including a former head of intellectual property for Novartis, a former CEO of Gilead, a number of academics around the world and several public health groups. No country made such a notification to the WTO.

Canada’s refusal to list COVID-19 as a public health problem on Schedule 1

As part of its implementation of Article 31*bis* of TRIPS, Canada has a provision in its patent law that allows the manufacture of a drug or vaccine for export to a country without domestic capacity. However, the Canadian statute requires a drug, vaccine, or disease to be listed on Schedule 1 of the Canadian *Patent Act*. On April 30, 2020, 41 Canadian experts sent a letter to the Prime Minister of Canada, the Minister of Innovation, Science & Industry, and the Minister of Health, requesting the amendment of Schedule 1 of the *Patent Act* to include ‘COVID-19

vaccine' to the list of eligible products for export pursuant to the Canadian Access to Medicines Regime. Canada refused to list COVID-19 as a public health problem on Schedule 1, while, at the same time, arguing at the WTO that Article 31*bis* of the TRIPS agreement eliminated the need for the Indian/South African proposal for a TRIPS waiver.

Latin American Paxlovid compulsory licensing efforts

There have been a handful of civil society-led efforts to obtain compulsory licenses on the patents on nirmatrelvir/ritonavir (sold by Pfizer under the brand name Paxlovid), including in Chile, Peru, Columbia and the Dominican Republic. KEI was the petitioner in the Dominican Republic case, along with Luis Abinader, a Dominican Republic national. One of the challenges in the DR case was the 5-year term for the exclusive rights to use the Pfizer-owned test data that established the safety and efficacy of Paxlovid to treat COVID-19, an obligation relating to the US/DR FTA. On December 3, 2021 KEI wrote to the USTR asking for written assurances that the USTR would waive that obligation, in order to register generic versions of the drug before 2027. USTR replied to KEI and we were told that USTR refused to provide the letter.

There were other reasons that few compulsory licenses have been granted on therapeutics, the two primary reasons being the manufacturing and regulatory pathway challenges associated with obtaining biosimilar versions of biologic drugs including several monoclonal antibodies (mAbs) that were in used to treat COVID-19 in some countries, including to treat President Trump, and the perception that small molecule drugs such as Paxlovid and molnupiravir were not sufficiently compelling medically to justify the widely anticipated although often non-transparent political pressures mobilized by the drug companies in the US and Europe.

A temporary suspension of certain TRIPS rules, as originally proposed by India and South Africa, would be useful in eliminating the WTO's absurd restriction of exports, and give greater certainty as regards government measures to provide more transparency of and reliance on company data submitted to regulatory agencies, or other know-how enhancing measures. Of equal importance, the temporary suspension would have sent an important signal that governments would not face political and trade pressures for expanding access to inventions, know-how, and data.

June 17, 2022 WTO decision

The June 17, 2022 WTO decision on TRIPS and COVID-19 (WT/MIN(22)/W/15/Rev.2) was a controversial compromise. It was for the most part modeled after the restrictive Article 31*bis* in TRIPS, dealing with the exports issue, but only for vaccines and, of course, it is temporary. There were some useful improved procedures when compared to Article 31*bis* as regards notifications, and welcomed certainty on remuneration for compulsory licenses, but also even more restrictive and frankly protectionist provisions on the countries that could import or export under a compulsory license than were found in TRIPS Articles 30, 31.k and 31*bis*, a troubling trend for the WTO, which was created with a promise to enhance and not restrict trade.

What should the WTO do as regards therapeutics and diagnostics?

The United States opposition to extending the June 17, 2022 WTO decision to therapeutics was widely reported in the news media, and has led to this ITC proceeding. It was always odd to exclude therapeutics and diagnostics, given the more challenging regulatory pathway for vaccines and the need for therapeutics in countries that received vaccines late and or had to depend upon vaccines considered less efficacious, for example, from China or Russia. It was also the case that the U.S. government itself found it useful to provide numerous FAR 52.227-1 authorizations for non voluntary uses of patents for therapeutics and diagnostics, as well as for other countermeasures, during its 2020 and 2021 response to the pandemic.

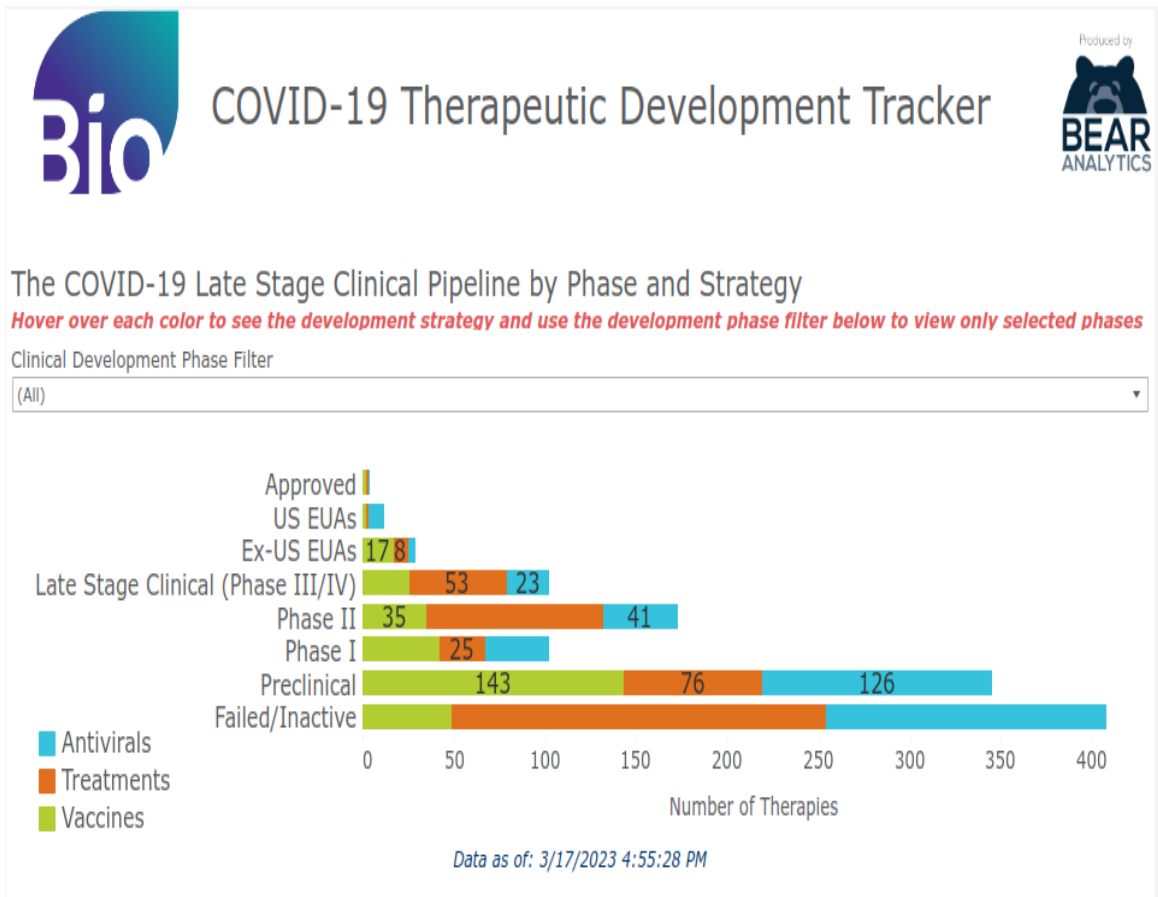
Looking backward opposition

The opposition to including therapeutics in the WTO's limited exceptions for COVID-19 rests on a backward analysis. The pharmaceutical industry has tried to influence the narrative regarding exceptions to TRIPS obligations by emphasizing that the supply of drugs like Paxlovid have exceeded demand in 2023, and the fact that the Medicines Patent Pool (MPP) has executed multiple licenses for small molecule therapeutics which include in their geographic area all the lowest and several low and middle income countries.

Paxlovid and other therapeutics for COVID-19 have only been available to patients recently, and largely through emergency use authorizations (EUAs). While the drugs have some useful efficacy in treating COVID-19, they are unlikely to be the last word in treatments. Indeed, some of the reluctance of Latin American countries to grant compulsory licenses on Paxlovid is a judgment that the drugs are not good enough to justify the political problems and the costs to health systems. Surprisingly, Pfizer itself made the argument in the Dominican Republic compulsory licensing case that the drug was not essential.

The BIO COVID-19 Therapeutic Development Tracker illustrates how shortsighted it is to look only at the small number of FDA-approved products while ignoring the much larger number of products in development.

Figure 1: BIO's COVID-19 Therapeutic Development Tracker



The history of drug development for infectious diseases is relevant when considering the importance of a pipeline.

The importance of combination treatments

The first drug to treat HIV was AZT, and its benefits were minor, as a monotherapy. A two-drug combination of AZT+3TC provided more efficacy, but it was only after the introduction of 3- and 4-drug combination treatments that HIV became a manageable chronic condition. The first 3 or 4 drug regimes have been progressively replaced by even better treatment cocktails that are easier to administer and have better compliance and fewer side effects.

The most effective treatments for hepatitis C are combination treatments, and prices only fell when Abbvie was able to introduce a combination product to compete with the Gilead combinations. Gilead itself introduced new drugs that replaced their original game changing combinations, in order to treat more versions of the virus and benefit more patients. The most

common treatment for tuberculosis is isoniazid INH in combination with three other drugs—rifampin, pyrazinamide and ethambutol.

The November 15, 2021 Pfizer voluntary licenses with the MPP include restrictions on using generic versions of Paxlovid with non Pfizer products in clinical trials. Section 1.16 of the Pfizer/MPP license states:

“For the avoidance of doubt, any sale of Licensed Products in bulk form or for a Clinical Trial may only take place if permitted and approved in advanced in writing by Pfizer.”

At least one COVID-19 drug developer, DNDi, has expressed frustration over this clause in the license.

COVID 19 is mutating

According to the US FDA, “the SARS-CoV-2 virus has mutated over time, resulting in genetic variation in the population of circulating viral strains, also called lineages.” The mutations of the virus are yet another reason to consider the importance of new treatments, including the importance of ensuring equitable access.

Next Steps at the WTO

The least complicated way to include therapeutics and diagnostics is to extend the June 17, 2022 decision, *mutatis mutandis*. If the conditions and scope are reopened, the text could get better or worse, depending on anyone’s perspective, and it could also result in negotiation-related delays. That said, if the WTO members do more than a simple extension of the current June 17, 2022 agreement, there is considerable room for improvement.

One topic that should have been addressed and which could be added would be to require members to lift any test data exclusivity obligations in trade agreements, or at least provide for the same type of exceptions they have for patented inventions. It is absurd to support the freedom to use compulsory licenses on a therapeutic to treat COVID-19, but then make it impossible to register a product for 5 years or more.

A WTO decision on therapeutics and diagnostics could also take some different approaches than the June 17, 2023 decision. For example, the WTO could affirm that non-predominate exports of a product under a compulsory license could be authorized using the Article 30 three step test, so long as the legitimate interests of the patent holder were not unduly prejudiced in the importing country, for, by example, payment of reasonable and affordable royalty.

The WTO secretariat could also be instructed to publish a model law on compulsory licensing or other exceptions for times of emergency, particularly one that uses either Article 30, or the limitations on remedies to infringement under Article 44.2 of the TRIPS that were so effectively used by the US government in the COVID-19 pandemic.

The agreement could also create a pathway for WTO members to request other members to use exceptions to ensure the supply of affordable products. Such a decision, perhaps modeled after Article 40.3 of the TRIPS, could have been used to require countries like Canada to take the steps necessary to ensure that COVID-19 is treated as a global public health problem.

Next Steps at the ITC

The ITC should reach out to US federal agencies and drug manufacturers to obtain additional information for this inquiry. The attached **ANNEX** provides suggestions on relevant questions to ask.

Attachments:

ANNEX - Questions the ITC can ask certain parties

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.](#)

ANNEX - Questions the ITC can ask certain parties

For Pfizer:

1. Provide data on the number of units of Paxlovid sold in every national market, in 2022, and the price of such sales.
2. How much money has Pfizer made from the sales of Paxlovid, by quarter?
3. What are the costs of production to manufacture a treatment course of Paxlovid?
4. Which clinical trials were used to obtain the initial FDA EUA for Paxlovid?
 - a. What was the enrollment of each trial?
 - b. What was the cost of each trial?
5. Why does the Medicines Patent Pool (MPP) license for generic versions of Paxlovid require that "any sale of Licensed Products in bulk form or for a Clinical Trial may only take place if permitted and approved in advance in writing by Pfizer"? Has Pfizer used this restriction to block the sale of such drugs in clinical trials to DNDi or any other company, and if so why?
6. How important will combination therapies be for COVID-19?
7. Is Pfizer conducting or planning to conduct clinical trials concerning expanded uses of Paxlovid?

For Merck:

1. Provide data on the number of units of the Merck version of molnupiravir sold in every national market, in 2022, and the price of such sales.
2. How much money has Merck made from the sales of molnupiravir, by quarter?
3. What are the costs of production to manufacture a treatment course of molnupiravir?
4. Which trials were used to obtain the initial FDA EUA for molnupiravir?
 - a. What was the enrollment of each trial?
 - b. What was the cost of each trial?
5. Describe the role of the U.S. government and Emory University in the research funding and development of molnupiravir.
6. When did Merck enter into an agreement with Ridgeback regarding molnupiravir? When did Ridgeback enter into an agreement with Emory regarding molnupiravir?

7. Provide a copy of the all agreements between Merck and Ridgeback, Emory or other third parties involved in the development of molnupiravir.
8. How important will combination therapies be for COVID-19?
9. Is Merck conducting or planning to conduct clinical trials concerning expanded uses of molnupiravir?

For Ridgeback:

1. When did Ridgeback acquire the rights to molnupiravir from Emory?
2. When did Ridgeback enter into an agreement with Emory for the development of molnupiravir?
3. How much money up front did Ridgeback pay Emory for the rights to molnupiravir in the Spring of 2020, and how much since?
4. How much did Ridgeback spend on the R&D for molnupiravir prior to the agreement with Merck, and how much since?
5. How much money has Ridgeback made from the sales of molnupiravir, by quarter?

For Eli Lilly:

1. Provide the license agreement between the NIH and Lilly for bamlanivimab (LY-CoV555).
2. Describe the role of the US government in research funding and the development of bamlanivimab.
3. Describe the factors that led to the FDA revoking the EUA for bamlanivimab when used as a standalone product.
4. How important will combination therapies be for COVID-19?

For Roche:

1. Describe the role of the federal government in the research funding and development of tocilizumab.
2. Has Roche undertaken any technology transfer agreements for tocilizumab?

For Gilead:

1. Describe the role of the federal government in the development of remdesivir.

2. Describe any agreements Gilead has entered into regarding technology transfer for remdesivir.

For the NIH:

1. Describe in detail the role of the NIH in funding, testing and otherwise contributing to the development of diagnostics and therapeutics and other countermeasures for COVID-19.
2. What provisions does the NIH include in its funding agreements or licenses to address the affordability of each COVID-19 product it has supported in any way?
3. What provisions does the NIH include in its funding agreements or licenses to address the need for further licensing and technology transfer for each COVID-19 product it has supported in any way?

For BARDA:

1. Describe in detail the role of BARDA in funding, testing and otherwise contributing to the development of diagnostics, therapeutics and other countermeasures for COVID-19.
2. What provisions does BARDA include in its funding agreements or licenses to address the affordability of each COVID-19 product it has supported in any way?
3. What provisions does BARDA include in its funding agreements or licenses to address the need for further licensing and technology transfer for each COVID-19 product it has supported in any way?

For the DOD:

1. Describe in detail the role of the DOD in funding, testing and otherwise contributing to the development of diagnostics and therapeutics and other countermeasures for COVID-19.
2. What provisions does the DOD include in its funding agreements or licenses to address the affordability of each COVID-19 product it has supported in any way?
3. What provisions does the DOD include in its funding agreements or licenses to address the need for further licensing and technology transfer for each COVID-19 product it has supported in any way?

For CDC:

1. Describe in detail the role of the CDC in funding, testing and otherwise contributing to the development of diagnostics and therapeutics and other countermeasures for COVID-19.

2. What provisions does the CDC include in its funding agreements or licenses to address the affordability of each COVID-19 product it has supported in any way?
3. What provisions does the CDC include in its funding agreements or licenses to address the need for further licensing and technology transfer for each COVID-19 product it has supported in any way?

For USTR:

1. During the pandemic, Knowledge Ecology International (KEI) petitioned the Dominican Republic for a compulsory license on Paxlovid. KEI asked USTR for a letter stating that USTR would not enforce provisions in the US/DR FTA requiring DR to provide 5 years of exclusive rights in drug registration data for Paxlovid, in light of the COVID-19 emergency. Did USTR provide KEI with such a letter and/or have any communication with the DR government on this topic?
2. USTR has several FTA agreements that require 5 years or more of test data protection for therapeutics. Has USTR indicated to any country that it had or will have a moratorium on enforcing this provision during the COVID-19 pandemic?