



## Office of the United States Trade Representative

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### Summary of Consultations

USTR's consultations with more than two dozen stakeholders, including public health advocates, organized labor, academics, think tanks, companies, and trade associations, identified vital commonalities. The groups shared a concern with saving lives, and with striking a balance between the need to promote innovation in these sectors and the need to promote access to the products of innovation. However, the consultations also identified key differences, including on basic factual questions about the marketplace for COVID-19 diagnostics and therapeutics. It is the facts and interpretations behind these different views of the role of intellectual property protections in global health that USTR will ask the International Trade Commission to explore.

#### *Support for Extending the Ministerial Decision to COVID-19 Diagnostics and Therapeutics*

Those that support extending the Ministerial Decision to the production and supply of COVID-19 diagnostics and therapeutics include a number of public health and other civil society organizations and academics, and some Members of Congress.

Many proponents of extending the Ministerial Decision have longstanding critiques of the TRIPS Agreement and consider access to COVID-19 diagnostics and therapeutics to be the latest in a series of global health challenges in which patents have posed barriers to access to medicines. Creating further flexibilities in the TRIPS Agreement is, from this perspective, a matter of principle.

As a matter of immediate access, many supporters acknowledge a lack of global demand for COVID-19 products, but they believe that market dynamics are suppressing effective demand. Supporters blame delayed WHO guidance and prequalification, inadequate financial support for robust test-and-treat programming, and high prices and limited opportunities to negotiate prices, as patents for the technologies and products create a legal minefield for others that seek to develop, produce, and supply COVID-19 diagnostics and therapeutics. In addition, supporters contend that testing is not sufficiently robust, which obfuscates the true demand for therapeutics.

Supporters have focused on the most widely-used patented therapeutics: Pfizer's Paxlovid, Merck's molnupiravir, and Eli Lilly's baricitinib. Supporters believe that the voluntary licenses offered by these companies are not sufficient, as the prices can be higher than the at-cost price, particularly for upper middle-income countries (UMICs), and the licenses do not provide full transparency of the prices, available volumes, and commercial terms.

Supporters also argue that compulsory licenses under the existing TRIPS flexibilities are untenable for some Members because TRIPS Article 31(f) requires in-country production facilities to supply products primarily for the domestic market unless the “complicated” Article 31*bis* procedures are used to import products from other producing Members, and that some lower middle-income countries (LMICs) have historically faced significant commercial and political pressure to not issue compulsory licenses.

Supporters have differing views on how to extend the Ministerial Decision to COVID-19 diagnostics and therapeutics, including extending it *mutatis mutandis*, limiting the use of dual-use products to only the treatment of COVID-19, or drafting a positive list of products with only the most commonly used therapeutics.

Supporters reject the argument that extending the Ministerial Decision would threaten future development since the majority of the profits from COVID-19 products are earned from high-income countries that would be excluded from the extension.

### ***Opposition to Extending the Ministerial Decision to COVID-19 Diagnostics and Therapeutics***

Those that oppose extending the Ministerial Decision to the production and supply of COVID-19 diagnostics and therapeutics include pharmaceutical manufacturers, diagnostic manufacturers, a number of industry associations, and some Members of Congress and academics.

Opponents assert that patents on COVID-19 diagnostics and therapeutics are not a barrier to accessing these products, citing excess capacity and availability through voluntary licenses, purchasing programs, and donations. Research published in *BMJ Global Health* shows that rapid diagnostic test (Ag-RDTs) production was projected to reach 1.9 billion per month in 2022. For therapeutics, the reported production capacity for Paxlovid is almost three times the global demand, and for molnupiravir is more than twice the global demand.

Opponents blame a variety of non-patent barriers for the lack of patient access, including last-mile logistics, such as cold storage and transportation, waning demand for COVID-19 diagnostics and therapeutics, trade barriers, such as export restrictions and tariffs, and inadequate domestic health workforce and infrastructure.

Opponents point out potential issues related to the safety, quality, and effectiveness of medicines made under compulsory licenses, and that the most widely-used patented therapeutics are already available through voluntary licenses and purchasing programs. For example, through the Medicines Patent Pool (MPP), Paxlovid is available to manufacturers in 95 countries, with 38 manufacturers in 13 countries already having signed sublicensing agreements; molnupiravir is available to manufacturers in 106 countries through the MPP, with 28 manufacturers already having signed sublicensing agreements; and ensitrelvir fumaric acid is available to manufacturers in 117 countries. Paxlovid is also reportedly available to 132 countries through the Global Fund and UNICEF, and molnupiravir is reportedly available to more than 100 countries through UNICEF. Remdesivir is reportedly available to more than 127 countries through voluntary, royalty-free licensing agreements with nine manufacturers based in India, Pakistan, and Egypt.

Opponents are also concerned that allowing countries with anticompetitive approaches to innovation, such as China, to make use of an extended Ministerial Decision would allow those countries to unfairly obtain and use American innovation to benefit their domestic economies, and that an extension of the Ministerial Decision would harm American industry and workers by undermining investment and research and development.