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## U.S. International Trade Commission to Investigate COVID-19 Diagnostics and Therapeutics Market and Potential TRIPS Waiver; Public Hearing in March 2023

In June 2022, World Trade Organization (WTO) members approved a waiver of certain intellectual property (IP) protections under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for vaccines used in combatting the COVID-19 pandemic, a move [supported by](#) the Biden Administration and U.S. Trade Representative Katherine Tai (USTR). In response to calls for a potential expansion of the waiver to cover IP related to additional products, the USTR [recently requested](#) that the U.S. International Trade Commission (ITC), an independent, non-partisan, quasi-judicial federal agency with broad investigative powers on matters of trade, conduct a fact-finding investigation and prepare a report on the COVID-19 diagnostics and therapeutics market and how a potential waiver of the TRIPS provisions concerning IP rights may affect medical innovation and access to medicines.

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On February 1, 2023, [the ITC instituted an investigation \(Inv. No. 332-596\)](#) pursuant to the USTR's request. As part of its investigation, the ITC is now soliciting input from a wide variety of stakeholders, "including foreign governments, non-governmental health advocates, organizations such as the Medicines Patent Pool (MPP) and Foundation for Innovative New Diagnostics (FIND), and manufacturers of diagnostics and therapeutics." All such stakeholders and interested members of the public wanting to offer information and voice their perspectives on the COVID-19 diagnostics and therapeutics market and how a potential waiver may affect the market and consumers now have the opportunity to file briefs and submit other evidence to the Commission, with written submissions due by May 5, 2023. The Commission has also set a public hearing for March 29–30, 2023, at which it will hear oral testimony and receive evidence from interested parties. Those desiring to testify at the public hearing—whether in person or via videoconference for "good cause"—must file written requests to appear by March 15 and submit any pre-hearing briefs and written copies of their testimony by March 17 and 22, respectively.

The ITC and USTR have indicated that they are particularly interested in written information and oral testimony addressing the following:

- How the TRIPS Agreement promotes innovation in and/or limits access to COVID-19 diagnostics and therapeutics;
- Successes and challenges in using existing TRIPS flexibilities;
- The extent to which products not yet on the market or new uses for existing products could be affected by an extension of the Ministerial Decision to diagnostics and therapeutics;
- Whether and how existing TRIPS rules and flexibilities can be deployed to improve access to medicines;
- To what extent further clarifications of existing TRIPS flexibilities would be useful in improving access to medicines;
- The relationship between IP protection and corporate research and development expenditures, taking into account other expenditures, such as share buybacks, dividends, and marketing;
- The relevance, if any, of the fact that diagnostic and therapeutic products used with respect to COVID-19 may also have application to other diseases; and

- The location of jobs associated with the manufacturing of diagnostics and therapeutics, including in the United States.

After collecting this information, the ITC will prepare a publicly available report titled *COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities*, which it will submit to the USTR by October 17, 2023. This report is likely to be used in the context of future legislative or policy actions, including influencing the USTR's decision on whether to support a future expansion of the TRIPS IP waiver to cover COVID-19 diagnostics, therapeutics, or both.

If you are interested in submitting information to the ITC or testifying at the hearing, or if have any questions about this Alert or Inv. No. 332-596, please contact [Matthew Rizzolo](#), [Brendan McLaughlin](#), or your regular Ropes & Gray contact.