Policy and Trade Alert

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USITC Sets out Process of its Investigation into TRIPS Waiver Expansion

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Key Points

- On February 1, the USITC formally announced the opening of its investigation into the merits of expanding the TRIPS Waiver to diagnostics and treatments. The investigation was initially requested by USTR, who had been leading the discussions regarding the TRIPS Waiver expansion. For more on the USTR request, see our December 2022 alert.
- The USITC announcement reiterates the specific questions asked in the initial USTR request, which are directed both at the USITC to research and respond to, and to the public to provide facts and other input concerning the market for COVID-19 diagnostics and treatments, current supply chain and trade challenges facing those products, and how a TRIPS Waiver expansion would affect that market.
- The investigation will play a key role in shaping the U.S. position on this issue at the WTO, and will likely have a decisive impact on the final outcome of the multilateral negotiations themselves. As this may be one of the only outlets by which U.S. and foreign stakeholders can formally voice their opinion with the U.S. government on the question of the Waiver's expansion, we believe that the USITC will take these public comments into serious consideration in crafting the findings of its report, due October 17, 2023.

Background: The TRIPS Waiver and its Possible Expansion

In June 2022, World Trade Organization (WTO) member countries agreed (the "Decision") to waive certain obligations found in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") for COVID-19 vaccines for an initial renewable period of five years. Specifically, this "TRIPS Waiver" allows eligible members (currently all developing countries except China) to more freely utilize certain "flexibilities"—such as compulsory licensing—in order to ignore existing patent rights of vaccines. The Decision concerns not just the vaccines themselves, but also the ingredients and processes necessary to manufacture them.

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Moreover, the Decision mandated that WTO members can enter into further discussions to decide in the near future whether to expand this TRIPS Waiver to cover the production and supply of COVID-19 diagnostics and therapeutics.

On December 6, 2022, the Office of the U.S. Trade Representative (USTR) announced its support for an extension of these discussions to expand the TRIPS Waiver, and on December 16, USTR requested the U.S. International Trade Commission (USITC) to "launch an investigation into COVID-19 diagnostics and therapeutics and provide information on market dynamics to help inform the discussion around supply and demand, price points, the relationship between testing and treating, and production and access."

The USITC Investigation

On February 1, the USITC responded to USTR and formally instituted an investigation under section 332(g) of the Tariff Act of 1930 (No. 332-596): *COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities*. USITC's announcement broadly outlined the process and the key questions.

As requested by USTR, the USITC announcement states that the investigation will focus broadly on COVID-19 therapeutics and diagnostics as they relate to a potential expansion of the TRIPS Waiver. Namely, the USITC will conduct a comprehensive mapping of the diagnostic and therapeutic market, including products in development; the linkages and functioning of existing TRIPS flexibilities; the local and global manufacturing industry of relevant products; and the existing market and its shortcomings, among other issues. Furthermore, the report will study the linkages between patent protection and innovation in the health sector, as well as the impact of patent protection on access to medicines in developing countries, and potential alternatives to compulsory licensing.

Per the USTR request, the USITC announcement also specifically seeks public input on:

- 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 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 intellectual property (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.

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

Stakeholders, "including foreign governments, non-governmental health advocates, organizations such as the MPP and Foundation for Innovative New Diagnostics (FIND), and manufacturers of diagnostics and therapeutics," will have an opportunity to participate in the public hearings, submit written and oral testimony, and provide follow-up information to what has been discussed. It is common in USITC investigations for stakeholders to engage with the process in a number of ways and in close coordination with the Commission. According to the announcement, those opportunities for engagement will follow the below deadlines:

- March 15, 2023: Deadline for filing requests to appear at the public hearing.
- March 17, 2023: Deadline for filing prehearing briefs and statements.
- March 22, 2023: Deadline for filing electronic copies of oral hearing statements.
- March 29-30, 2023: Public hearing.
- April 12, 2023: Deadline for filing posthearing briefs and statements.
- May 5, 2023: Deadline for filing all other written submissions.
- October 17, 2023: Transmittal of Commission report to the USTR.

Implications

A final decision by WTO members to expand the TRIPS Waiver to cover COVID-19 diagnostics and therapeutics would have far-reaching implications on the international approach to intellectual property, both for the pharmaceutical industry and beyond. This is especially so considering what phase of the COVID-19 pandemic the world currently finds itself in, as well as the existing availability and affordability of COVID-19 counter-measures.

Whether WTO members decide to expand the TRIPS Waiver will depend in large part on the position of the United States, which at this point has only stated a desire to gather further information on this question, and has in the past made comments suggesting that any final decisions on this matter must be backed by a sufficient evidentiary basis. The results of the USITC investigation will not only shape the position of USTR and the Biden-Harris administration on the current TRIPS Waiver expansion issue, but also similar future discussions to come on the role of IP in the next heath crisis or other global emergency.

Moreover, at present, this USITC investigation is the only formal process available for public and private stakeholders to weigh in with the U.S. government on the question of expanding the TRIPS Waiver. For those who hope to have their voice heard on this question, engaging in this investigation through submission of comments and participation in the hearing may be one of the few, if not only, opportunities to do so. The international impact of this process is clear. While discussions will continue in the WTO throughout 2023, we expect this matter to go to reach a final resolution at the 13th WTO Ministerial Conference in February 2024. As such, this USITC process will likely impact the broader international IP landscape for years to come.

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