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Client Alert

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U.S. International Trade Commission to Investigate Potential Waiver of International Intellectual Property Rights for COVID-19 Diagnostics and Therapeutics

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On February 1, 2023, the U.S. International Trade Commission (the "ITC") initiated an investigation into the impact of intellectual property ("IP") rights on the production, supply, and availability of diagnostics and therapeutics used to detect and treat COVID-19. This investigation was requested by the Office of the U.S. Trade Representative ("USTR") to inform its position on negotiations over the possible expansion of a "waiver" of international IP rights for COVID-19-related diagnostics and therapeutics. Proponents of the waiver assert that a waiver of IP rights will improve supply of diagnostics and therapeutics in low-income countries.

During this investigation, the ITC will conduct public hearings with interested parties, accept written submissions, and prepare a report with its analysis of information gathered during the proceedings. Thus, the investigation gives companies and other stakeholders in the therapeutics and diagnostics industries an opportunity to shape U.S. and international policies regarding IP in the pharmaceutical and medical device space. Participating in the investigation to ensure a helpful outcome is critical for companies that rely on IP as part of their business model and operations.

I. Background

On June 22, 2022, the World Trade Organization ("WTO") adopted a five-year waiver of IP protections under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") for patents related to COVID-19 vaccines (the "Decision").[1] This waiver permits an eligible WTO Member to allow the use of the subject matter of a patent, including ingredients and processes necessary to manufacture COVID-19 vaccine, without the right holder's consent through any instrument

available in the law of the Member.[2] Under the waiver, WTO Members cannot require eligible WTO Members to honor IP rights for COVID-19 vaccine under TRIPS. The United States supported this initial waiver, and other countries that initially opposed the waiver ultimately joined the U.S.-led consensus.

The Decision also directed WTO Members to determine, by December 17, 2022, whether the TRIPS waiver should be expanded to cover, in addition to the COVID-19 vaccine, "the production and supply of COVID-19 diagnostics and therapeutics."[3] The WTO's TRIPS Council—which is made up of all WTO Members—met several times, formally and informally, to discuss the possible expansion.[4] WTO Members did not agree on whether to expand the waiver to COVID-19 diagnostics and therapeutics, which represent a much broader category of products, including products that may be used for diseases and conditions other than COVID-19. As a result, the TRIPS Council missed the deadline for deciding on the waiver expansion and has agreed to defer discussions until next year.

The United States' position on this matter will have an enormous influence on the waiver expansion discussions and whether other countries will be able to lawfully permit the use of IP by non-rights holders for a potentially very broad category of medical diagnostics and therapeutics. To help inform the United States' ultimate position on this major policy decision, USTR announced that it would ask the ITC to undertake an investigation of the market dynamics for COVID-19 diagnostics and therapeutics.[5] Following this announcement, USTR sent a formal request to the ITC to commence the investigation under Section 332 of the Tariff Act of 1930 ("Section 332"). On February 1, 2023, the ITC formally instituted Investigation No. 332-596, *COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities*.[6] The substance of the USTR request and the investigation process are discussed in more detail herein.

As part of this investigation, interested parties—including IP rights holders, researchers, producers, civil society, and other stakeholders—will have opportunities to influence the ITC's investigation through written comments, hearing testimony, and other means. We expect that opponents of IP rights will be very active in this process. The ITC's investigation and ultimate report will play a significant role in developing U.S. trade policy with respect to IP rights for many existing and future treatments and diagnostics and consequently may affect the value of rights holders' IP globally for years to come. We also anticipate that this report will be cited and used in the future to inform U.S. policy on IP issues beyond the COVID-19 context, so it is of critical importance that interested parties present meaningful responses, briefs, testimony, data, and other information to the ITC to help shape the policy environment.

II. USTR REQUEST

Under Section 332, USTR initiates an investigation by submitting a formal request letter to the Chairman of the ITC setting out the relevant details for the investigation, as it has done here.[7]

In its request to the ITC, USTR asked the Commission to investigate and prepare a report addressing the topics set out below:

- the range of definitions for "diagnostics" and "therapeutics" in the medical field;
- the universe of existing COVID-19 diagnostics and therapeutics covered by patents and those still in development; and
- a broad overview of relevant COVID-19 diagnostics and therapeutics, including a description of the products and any IP protections, and containing, to the extent practicable and where data are available:
    - an overview of production and distribution, including key components, the production processes, key producing countries, major firms, operational costs, a description of the supply chain, and the level of geographic diversification within the supply chain;

  - an overview of demand, including key demand factors, an assessment of where unmet demand exists, supply accumulation and distribution, and the impact of the relationship between testing and demand for treatment, if any exists;
  - information on market segmentation of global demand and consumption, which may be delineated by low-income countries (LICs), lower middle-income countries (LMICs), upper middle-income countries (UMICs), and high-income countries (HICs);
  - information on availability and pricing (or manufacturing costs in the cases where goods are donated) for COVID-19 diagnostics and therapeutics, if available; and
  - global trade data for COVID-19 diagnostics and therapeutics or diagnostics and therapeutics in general if specific data are not available.
- a critical review of available literature regarding:
  - the reasons for market segmentation and barriers to a more diverse geographical distribution of the global manufacturing industries for COVID-19 diagnostics and therapeutics;
  - the relationship between patent protection and innovation in the health sector and between patent protection and access to medicine in LICs, LMICs, UMICs, and HICs;
  - actions taken by WTO Members to use or attempt to use compulsory licenses for the production, importation, or exportation of pharmaceutical products and the outcomes of those actions, including the effect on product access, innovation, and global health;
  - a description of any alternatives to compulsory licensing available to WTO Members, such as voluntary licenses, including through the Medicines Patent Pool (MPP); multilateral programs, including the GlobalFund and United Nations Children's Fund (UNICEF); government-to-government programs; and private-sector donations; and
  - the effect, or lack thereof, of the MPP on access to COVID-19 diagnostics and therapeutics.[8]

Furthermore, USTR requested the ITC to solicit public comments and hold a hearing. Specifically, USTR asked the ITC to obtain public input on the following topics:

- 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 intellectual property 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.[9]

USTR asked the ITC to complete its investigation and submit a public report to the USTR discussing the Commission's objective findings and analyses on the subjects investigated no later than October 17, 2023.[10] The Commission generally will not make any recommendations on policies or other matters, but its analysis will have an important influence on the decision on the TRIPS waiver expansion and on any future discussion or negotiation regarding international trade rules on IP rights and enforcement.

III. ITC SECTION 332 INVESTIGATION NO. 332-596

On February 1, 2023, the Commission formally instituted Investigation No. 332-596 and issued a notice in the Federal Register providing further details. In addition to confirming that it would investigate the issues identified in the USTR request (as outlined in Section II), the ITC set out the following deadlines for written submissions and public hearings:

- March 15, 2023: Requests to appear at the public hearing
- March 17, 2023: Pre-hearing briefs and statements
- March 22, 2023: Filing electronic copies of oral hearing statements
- March 29–30, 2023: Public hearing
- April 12, 2023: Post-hearing briefs and statements
- May 5, 2023: All other written submissions
- October 17, 2023: Transmittal of ITC report to USTR

Interested parties may request to appear at as witnesses at the public hearing and submit relevant documents, such as prehearing briefs and statements, letters of support, and oral testimonies. Interested parties may also file post-hearing briefs addressing matters raised at the hearing. In lieu of or in addition to participating in the hearing, interested parties may file written submissions concerning this investigation. The written submissions may include, but are not limited to, relevant data and factual information responding to the topics of the report; comments analyzing the waiver issue and providing information on supply, demand, and production; and advocacy letters from political figures.

IV. BUSINESS IMPLICATIONS

The ITC Investigation No. 332-596 presents a significant opportunity for companies to comment on and shape the position of the United States on the TRIPS waiver expansion issue. The WTO is going to hold three more TRIPS Council meetings in 2023 – March 16-17, June 14-15, and October 9-10 – to continue the discussion on this issue.[11] The public comments, hearings, and results of this ITC investigation will not only provide an evidentiary basis to support the position of the United States, but they will also influence WTO's negotiations.

Currently, the upcoming ITC investigation is the formal channel for companies and other stakeholders to comment on whether the United States should support expansion the TRIPS waiver to cover the production and supply of COVID-19 diagnostics and therapeutics. Interested parties should actively engage in this comment process to ensure protection of their IP rights on a global basis and to shape the future policy environment for innovation.

ABOUT KING & SPALDING

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[1] WTO, Ministerial Decision on the TRIPS Agreement (adopted on June 17, 2022), ¶¶ 1, 6, WT/MIN(22)/30, WT/L/1141, June 22, 2022.
[2] *Id.* at ¶¶ 1-2 (indicating such instruments may include "executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not a Member has a compulsory license regime in place").
[3] *Id.* at ¶ 8 (setting a six-month deadline from the date of the Decision).
[4] *See* TRIPS Council welcomes MC12 TRIPS waiver decision, discusses possible extension, WTO (July 6, 2022), available at: https://www.wto.org/english/news_e/news22_e/trip_08jul22_e.htm; Members discuss extending MC12 TRIPS Decision to COVID-19 diagnostics and therapeutics, WTO (October 13, 2022), available at: https://www.wto.org/english/news_e/news22_e/trip_13oct22_e.htm.
[5] *See* Letter from Katherine Tai, United States Trade Representative, to David Johanson, Chairman of the ITC (Dec. 16, 2022).
[6] *See* USITC to Report on Covid-19 Diagnostics and Therapeutics and Flexibilities under the TRIPS Agreement, USITC (Feb. 1, 2023), available at: https://usitc.gov/press_room/news_release/2023/er0201_63483.htm.
[7] *See* 19 U.S.C. § 1332(g); *supra note* 4; *see also* Letter from Robert Lighthizer, United States Trade Representative, to Jason Kearns, Chairman of the USITC (November 3, 2020) (requesting an investigation of imports of fresh and chilled bell peppers).
[8] *See supra* note 4.
[9] *Id.*
[10] *See* 19 U.S.C. § 1332(g); *supra* note 4.
[11] *See* Members discuss extending MC12 TRIPS Decision to COVID-19 diagnostics and therapeutics, WTO (October 13, 2022), available at: https://www.wto.org/english/news_e/news22_e/trip_13oct22_e.htm.