UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC

Investigation No. 332-596

COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities

AGENCY: United States International Trade Commission

ACTION: Notice of Investigation and Scheduling of a Public Hearing.

SUMMARY: Following receipt on December 16, 2022, of a request from the U.S. Trade Representative (USTR), under section 332(g) of the Tariff Act of 1930, the U.S. International Trade Commission (Commission) instituted Investigation No. 332-596, *COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities.* The USTR requested that the Commission conduct an investigation and prepare a report that analyzes the universe of existing COVID-19 diagnostics and therapeutics in relation to the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) – including the range of definitions for diagnostics and therapeutics; diagnostics and therapeutics covered by patents and those in development; an overview of production, distribution, and demand; information on market segmentation of global demand and consumption; and other information relevant to the discussion of TRIPS Agreement flexibilities.

DATES:

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.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC. All written submissions should be addressed to the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at https://edis.usitc.gov.

FOR FURTHER INFORMATION CONTACT: Project Leader Philip Stone (202-205-3424 or philip.stone@usitc.gov) or Deputy Project Leader Dixie Downing (202-205-3164 or dixie.downing@usitc.gov) for information specific to this investigation. For information on the legal aspects of this investigation, contact Brian Allen (202-205-3034 or brian.allen@usitc.gov) or William Gearhart (202-205-3091 or william.gearhart@usitc.gov) of the Commission's Office of the General Counsel. The media should contact Jennifer Andberg, Office of External Relations (202-205-3404 or jennifer.andberg@usitc.gov). Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on

202-205-1810. General information concerning the Commission may be obtained by accessing its internet address (https://www.usitc.gov). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000.

SUPPLEMENTARY INFORMATION:

***Background*:** As requested in the letter received from the USTR on December 16, 2022, the Commission has instituted an investigation under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)) that analyzes the universe of existing COVID-19 diagnostics and therapeutics in relation to the TRIPS Agreement. Specifically, the USTR has requested that the Commission prepare a report that:

- Identifies the range of definitions for "diagnostics" and "therapeutics" in the medical field.
- Identifies and defines the universe of existing COVID-19 diagnostics and therapeutics covered by patents as well as COVID-19 diagnostics and therapeutics in development.
- Provides a broad overview of relevant COVID-19 diagnostics and therapeutics, including a description of the products and any intellectual property 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.
- Catalogs, to the extent practicable based on available information and a critical review of the literature:
    - 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.

The USTR explicitly asked that the Commission solicit input on the above issues from a wide variety of participants, 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. The USTR stated that input on the following would be particularly salient:

- 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.

As requested by the USTR, the Commission will deliver the report on October 17, 2023. Since the USTR has indicated that USTR intends to make this report available to the public in its entirety, the Commission will not include confidential business or national security classified information in its report. However, as detailed below, participants may submit confidential information to the Commission to inform its understanding of these issues, and such information will be protected in accordance with the Commission's *Rules of Practice and Procedure*. Participants are strongly encouraged to provide any supporting data and information along with their views.

Public Hearing: A public hearing in connection with this investigation will be held beginning at 9:30 a.m., March 29, 2023, and continuing, if necessary, on March 30, 2023, in the Main Hearing Room of the U.S. International Trade Commission, 500 E Street SW, Washington DC 20436. The hearing can also be accessed remotely using the WebEx videoconference platform. A link to the hearing will be posted on the Commission's website at https://www.usitc.gov/calendarpad/calendar.html.

Requests to appear at the hearing should be filed with the Secretary to the Commission no later than 5:15 p.m., March 15, 2023, in accordance with the requirements in the "Written Submissions" section below. Any requests to appear as a witness via videoconference must be included with your request to appear. Requests to appear as a witness via videoconference must include a statement explaining why the witness cannot appear in person; the Chairman, or other person designated to conduct the investigation, may at their discretion for good cause shown, grant such requests. Requests to appear as a witness via videoconference due to illness or a positive COVID-19 test result may be submitted by 3 p.m. the business day prior to the hearing.

All prehearing briefs and statements should be filed no later than 5:15 p.m., March 17, 2023. To facilitate the hearing, including the preparation of an accurate written public transcript of the hearing, oral testimony to be presented at the hearing must be submitted to the Commission electronically no later than noon, March 22, 2023. All posthearing briefs and statements should be filed no later than 5:15 p.m., April 12, 2023. Posthearing briefs and statements should address matters raised at the hearing. For a description of the different types of written briefs and statements, see the "Definitions" section below.

In the event that, as of the close of business on March 15, 2023, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or nonparticipant should check the Commission website as indicated above for information concerning whether the hearing will be held.

***Written submissions*:** In lieu of or in addition to participating in the hearing, interested parties are invited to file written submissions concerning this investigation. All written submissions should be addressed to the Secretary, and should be received no later than 5:15 p.m., May 5, 2023. All written submissions must conform to the provisions of section 201.8 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.8), as temporarily amended by 85 FR 15798 (March 19, 2020). Under that rule waiver, the Office of the Secretary will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding electronic filing should contact the Office of the Secretary, Docket Services Division (202-205-1802), or consult the Commission's Handbook on Filing Procedures.

Definitions of types of documents that may be filed; Requirements: In addition to requests to appear at the hearing, this notice provides for the possible filing of four types of documents: prehearing briefs, oral hearing statements, posthearing briefs, and other written submissions.

(1) ***Prehearing briefs*** refers to written materials relevant to the investigation and submitted in advance of the hearing, and includes written views on matters that are the subject of the investigation, supporting materials, and any other written materials that you consider will help the Commission in understanding your views. You should file a prehearing brief particularly if you plan to testify at the hearing on behalf of an industry group, company, or other organization, and wish to provide detailed views or information that will support or supplement your testimony.

(2) ***Oral hearing statements (testimony)*** refers to the actual oral statement that you intend to present at the hearing. Do not include any confidential business information (CBI) in that statement. If you plan to testify, you must file a copy of your oral statement by the date

specified in this notice. This statement will allow Commissioners to understand your position in advance of the hearing and will also assist the court reporter in preparing an accurate transcript of the hearing (e.g., names spelled correctly).

(3) ***Posthearing briefs*** refers to submissions filed after the hearing by persons who appeared at the hearing. Such briefs: (a) should be limited to matters that arose during the hearing; (b) should respond to any Commissioner and staff questions addressed to you at the hearing; (c) should clarify, amplify, or correct any statements you made at the hearing; and (d) may, at your option, address or rebut statements made by other participants in the hearing.

(4) ***Other written submissions*** refers to any other written submissions that interested persons wish to make, regardless of whether they appeared at the hearing, and may include new information or updates of information previously provided.

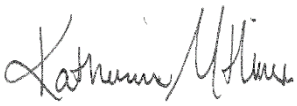
In accordance with the provisions of section 201.8 of the Commission's Rules of Practice and Procedure (19 CFR 201.8) the document must identify on its cover (1) the investigation number and title and the type of document filed (i.e., prehearing brief, oral statement of (name), posthearing brief, or written submission), (2) the name and signature of the person filing it, (3) the name of the organization that the submission is filed on behalf of, and (4) whether it contains CBI. If it contains CBI, it must comply with the marking and other requirements set out below in this notice relating to CBI. Submitters of written documents (other than oral hearing statements) are encouraged to include a short summary of their position or interest at the beginning of the document, and a table of contents when the document addresses multiple issues.

Confidential business information: Any submissions that contain CBI must also conform to the requirements of section 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the "confidential" or "nonconfidential" version, and that the CBI is clearly identified by means of brackets. All written submissions, except for CBI, will be made available for inspection by interested parties.

As requested by the USTR, the Commission will not include any CBI in its report. However, all information, including CBI, submitted in this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission, including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel for cybersecurity purposes. The Commission will not otherwise disclose any CBI in a way that would reveal the operations of the firm supplying the information.

Summaries of written submissions: Persons wishing to have a summary of their position included in the report should include a summary with their written submission on or before May 5, 2023, and should mark the summary as having been provided for that purpose. The summary should be clearly marked as "summary for inclusion in the report" at the top of the page. The summary may not exceed 500 words and should not include any CBI. The summary will be published as provided if it meets these requirements and is germane to the subject matter of the investigation. The Commission will list the name of the organization furnishing the summary and will include a link where the written submission can be found.

By order of the Commission.



Katherine M. Hiner
Acting Secretary to the Commission

Issued: February 1, 2023