

**UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.**

In the Matter of

**CERTAIN LIQUID TRANSFER
DEVICES WITH AN INTEGRAL VIAL
ADAPTER**

Investigation No. 337-TA-1362

**NOTICE OF A COMMISSION DETERMINATION TO SUPPLEMENT A FINAL
INITIAL DETERMINATION, REVERSE-IN-PART THE PRECLUSION OF CERTAIN
ARGUMENTS AND EVIDENCE, AND REMAND FOR FURTHER PROCEEDINGS;
EXTENDING TARGET DATE**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to supplement the final initial determination (“ID”) issued by the Chief Administrative Law Judge (“CALJ”) and to reverse-in-part an order (Order No. 19) precluding certain arguments and evidence. The Commission remands the investigation to the CALJ for further proceedings consistent with the concurrently issued opinion and remand order.

FOR FURTHER INFORMATION CONTACT: Edward S. Jou, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3316. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its Internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on May 11, 2023, based on a complaint, as supplemented, (the “Complaint”) filed by West Pharmaceutical Services, Inc. and West Pharma. Services IL, Ltd. (collectively, “West” or “Complainants”). 88 FR 30342 (May 11, 2023). The Complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based on the importation into the United States, the sale for importation, and the sale within the United States after importation of certain liquid transfer devices with an integral vial adapter by reason of the infringement of claim 1 of U.S. Patent No. 10,688,295 (the “’295 patent”); the claim of U.S. Design Patent No. D767,124 (“the D’124 patent”); the claim of U.S. Design Patent No. D765,837 (“the D’837 patent”); the claim of U.S. Design Patent No. D630,732 (“the D’732 patent”); and U.S. Trademark Registration No. 5,810,583 (“the ’583 mark”). *Id.* at 30342.

The Commission’s notice of investigation named four respondents: Advcare Medical, Inc. (“Advcare”) of New Taipei City, Taiwan, Dragon Heart Medical Devices Co., Ltd. (“Dragon Heart Devices”) of Guangdong Province, China, Dragon Heart Medical, Inc. (“Dragon Heart”) of Addison, Illinois, and Summit International Medical Technologies, Inc. (“Summit”) of Franklin, Massachusetts. *Id.* The Office of Unfair Import Investigations (“OUII”) is also a party to this investigation. *Id.*

The investigation was terminated as to Dragon Heart Devices based on withdrawal of the Complaint. Order No. 9 (Aug. 24, 2023), *unreviewed by* Comm’n Notice (Sept. 20, 2023).

The ’583 mark was terminated from the investigation by withdrawal of the Complaint. Order No. 12 (Sept. 19, 2023), *unreviewed by* Comm’n Notice (Oct. 19, 2023). The three asserted design patents, the D’124 patent, the D’837 patent, and the D’732 patent, were also terminated from the investigation by withdrawal of the Complaint. Order No. 14 (Oct. 4, 2023), *unreviewed by* Comm’n Notice (Nov. 2, 2023). Accordingly, claim 1 of the ’295 patent is the sole remaining asserted claim.

On October 16, 2023, West filed an unopposed motion for summary determination that it satisfied the economic prong of the domestic industry requirement, which was granted. Order No. 17 (Nov. 28, 2023), *unreviewed by* Comm’n Notice (Dec. 28, 2023).

A claim construction hearing was held on October 26, 2023, and the CALJ issued a claim construction order on November 13, 2023. Order No. 15 (Nov. 13, 2023). The parties filed motions *in limine*, and the CALJ precluded certain evidence and arguments in Order No. 19 (Dec. 1, 2023).

An evidentiary hearing was held on December 4-5, 2023, and the CALJ issued the ID on March 15, 2024, finding a violation of section 337 based on infringement of claim 1 of the ’295 patent. The ID included a recommended determination (“RD”) on remedy and bonding, recommending the issuance of a limited exclusion order and a cease and desist order. *See* ID/RD at 73-87.

Respondents Summit, Advcare, and Dragon Heart (collectively, “Respondents”) filed a petition for review of the ID on April 6, 2024. OUII also filed a petition for review on April 6, 2024, and OUII filed a response to Respondents’ petition on April 15, 2024. Complainants filed responses in opposition to both petitions on April 15, 2024. Respondents filed a response to OUII’s petition on April 16, 2024.

On May 16, 2024, the Commission determined to review the ID in part. 89 FR 45012-15 (May 22, 2024). Specifically, the Commission determined to review the ID’s findings with respect to standing and jurisdiction, and the Commission determined to review the CALJ’s preclusion of Respondents’ and OUII’s invalidity arguments and evidence in Order No. 19. *Id.* at 45013. The Commission also corrected certain clerical errors in the ID and claim construction order. *Id.* The Commission determined not to review the remaining findings in the ID, including the findings on claim construction, infringement, and the technical prong of the domestic industry requirement. *Id.* In connection with its review, the Commission requested briefing from the parties on several issues. *Id.* at 45013-14. The parties filed opening submissions on

June 6, 2024, and reply submissions on June 17, 2024.

Having examined the record in this investigation, including the ID, the petitions for review and responses thereto, and the parties' submissions on review, the Commission has determined to affirm-in-part and reverse-in-part Order No. 19 and to supplement the ID. Specifically, as explained in the opinion issued concurrently herewith, the Commission has determined to supplement the ID's analysis of standing and jurisdiction, to affirm the preclusion of Respondents' invalidity defenses, and to reverse the preclusion of OUII's written description argument.

In accordance with the remand order issued concurrently herewith, the Commission has determined to remand the investigation to the CALJ to conduct further proceedings as appropriate to address OUII's written description argument. The Commission has also determined to extend the target date for this investigation to September 23, 2024.

The Commission vote for this determination took place on July 23, 2024.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR Part 210).

By order of the Commission.

A handwritten signature in black ink, appearing to read 'Lisa R. Barton', written in a cursive style.

Lisa R. Barton
Secretary to the Commission

Issued: July 23, 2024