

**UNITED STATES INTERNATIONAL TRADE COMMISSION**  
**Washington, D.C. 20436**

**In the Matter of**

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

**Investigation No. 337-TA-1362  
(Remand)**

**NOTICE OF A COMMISSION DETERMINATION TO REVIEW AN INITIAL  
DETERMINATION**

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to review the remand initial determination (“Remand ID”) issued by the Chief Administrative Law Judge (“CALJ”).

**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](mailto: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 Kaiping City, 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, the ’295 patent is the only remaining asserted intellectual property in this investigation, and the respondents remaining in the investigation are Summit, Advcare, and Dragon Heart (collectively, “Respondents”).

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). In particular, the CALJ granted West’s motion *in limine* no. 2, precluding Respondents and OUII from challenging the validity of the ’295 patent. *Id.* at 2-6.

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

On May 16, 2024, the Commission determined to review the Final ID in part. 89 FR 45012-15 (May 22, 2024). On July 23, 2024, the Commission determined to supplement the Final ID and to reverse-in-part Order No. 19 and remand the investigation to the CALJ for further proceedings with respect to the written description requirement. *See* Comm’n Notice (July 23, 2024); Comm’n Op. (July 23, 2024); Remand Order (July 23, 2024).

On remand, the parties agreed that a live hearing was unnecessary and the CALJ set a procedural schedule for the submission of evidence and the parties’ briefing and extended the target date to February 10, 2025. Order No. 23 (Aug. 1, 2024), *unreviewed by* Comm’n Notice (Aug. 27, 2024). The parties conducted additional expert discovery and the resulting evidence was admitted into evidence by the CALJ. Order No. 24 (Sept. 3, 2024).

On November 8, 2024, the CALJ issued the Remand ID finding that claim 1 of the ’295 is not invalid for lack of written description under 35 U.S.C. 112. OUII filed a petition for

review on November 21, 2024. Respondents filed a petition for review on November 29, 2024. West filed a response to OUII's petition for review on November 29, 2024. West filed a response to Respondents' petition for review on December 6, 2024.

Having reviewed the record on remand, including the Remand ID and the parties' petitions for review and responses thereto, the Commission has determined to review the Remand ID in its entirety. The Commission has already received briefing on remedy, public interest, and bonding. No further briefing is requested.

The Commission vote for this determination took place on December 20, 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', enclosed within a large, loopy oval flourish.

Lisa R. Barton  
Secretary to the Commission

Issued: December 20, 2024