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 (Remand)

NOTICE OF A COMMISSION DETERMINATION NOT TO REVIEW AN INITIAL DETERMINATION EXTENDING THE TARGET DATE

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined not to review an initial determination ("ID") (Order No. 23) of the Chief Administrative Law Judge ("CALJ") extending the target date for completion of this investigation to February 10, 2025.

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 ("section 337"), 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. 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 has 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 Chief Administrative Law Judge ("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 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 by respondents Summit, Advcare, and Dragon Heart (collectively, "Respondents").

On May 16, 2024, the Commission determined to review the Final ID in part. 89 FR 45012-15 (May 22, 2024). Specifically, the Commission determined to review the Final 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 Final ID and claim construction order. *Id.* The Commission determined not to review the remaining findings in the Final ID, including the findings on claim construction, infringement, and the technical prong of the domestic industry requirement. *Id.*

On July 23, 2024, the Commission determined to affirm in part and reverse in part Order No. 19 and to supplement the Final ID's analysis of standing and jurisdiction. As explained in an opinion issued on that date, the Commission affirmed the preclusion of Respondents' invalidity defenses, reversed the preclusion of OUII's written description argument, and remanded the investigation for further proceedings. The Commission also issued a remand order extending the target date for completion of this investigation to September 23, 2024, and ordering the CALJ to further extend the target date to accommodate the remand proceedings.

On August 1, 2024, the CALJ issued the subject ID extending the target date to February

10, 2025. Order No. 23 at 2. The CALJ also set a procedural schedule for the remand proceedings with a deadline of November 8, 2024, for issuing a remand initial determination. *Id.*

The Commission has determined not to review the subject ID. The target date for completion of this investigation is hereby extended to February 10, 2025.

The Commission vote for this determination took place on August 27, 2024.

The authority for the Commission's determination is contained in 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.

Lisa R. Barton

Secretary to the Commission

Issued: August 28, 2024