



## INTERNATIONAL TRADE COMMISSION

### [Investigation No. 337-TA-1362 (Remand)]

#### **Certain Liquid Transfer Devices with an Integral Vial Adapter; Notice of a Commission Determination Finding a Violation of Section 337; Issuance of a Limited Exclusion Order and a Cease and Desist Order; Termination of the Investigation**

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

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to affirm the determination finding a violation of section 337 of the Tariff Act of 1930, as amended, in the remand initial determination (“Remand ID”) issued by the Chief Administrative Law Judge (“CALJ”) and to take no position with respect to a portion of the Remand ID. The Commission has also determined to issue a limited exclusion order prohibiting further importation of infringing products by the three remaining respondents and a cease and desist order against one respondent.

**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 by withdrawal of the Complaint. Order No. 9 (Aug. 24, 2023), *unreviewed by Comm’n Notice* (Sept. 20, 2023).

The ’583 mark and the three asserted design patents (the D’124 patent, the D’837 patent, and the D’732 patent) were terminated from the investigation by withdrawal of the Complaint. Order No. 12 (Sept. 19, 2023), *unreviewed by Comm’n Notice* (Oct. 19, 2023); 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). The Commission determined not to review the Final ID’s findings with respect to claim construction, infringement, and the technical prong of the domestic industry requirement. *Id.* at 45013. 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 CALJ admitted the resulting evidence into the record. 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.

On December 20, 2024, the Commission determined to review the Remand ID in its entirety. On review, the Commission has determined to take no position with respect to certain statements in the Remand ID.<sup>1</sup> Specifically, the Commission takes no position on the second sentence of the last paragraph on page 5 continuing to page 6 (“The Commission concluded that OUII, . . .”) and the subsequent citations (“*Id.* at 18 . . . ; *see also*; . . . ; *but cf.* . . . .”); and the Commission takes no position on the second sentence in the first full paragraph on page 7 (“Because OUII . . . .”). The Commission has determined to affirm the remainder of the Remand ID. Because the Commission previously determined not to review the finding on summary determination with respect to the economic prong of the domestic industry requirement and the findings in the Final ID with respect to claim construction, infringement, and the technical prong of the domestic industry requirement, the Commission has determined that there has been a violation of section 337 with respect to infringement of claim 1 of the '295 patent.<sup>2</sup>

For remedy, the Commission has determined to issue a limited exclusion order prohibiting further importation of infringing products by the three remaining respondents and a cease and desist order against Respondent Summit. The Commission has determined that the public interest factors do not counsel against issuing remedial orders. The Commission has determined that bond should be set in the amount of zero percent (0%) (*i.e.*, no bond).

The Commission vote for this determination took place on February 3, 2025.

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).

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<sup>1</sup> Commissioner Schmidlein stepped down from the Commission on January 31, 2025.

<sup>2</sup> Commissioner Kearns respectfully dissents from the Commission's decision and has filed a separate opinion explaining his views.

By order of the Commission.

**Issued:** February 3, 2025.

**Lisa Barton,**

*Secretary to the Commission.*

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