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**

NOTICE OF A COMMISSION DETERMINATION TO REVIEW IN PART A FINAL INITIAL DETERMINATION FINDING A VIOLATION OF SECTION 337; REQUEST FOR WRITTEN SUBMISSIONS ON ISSUES UNDER REVIEW AND ON REMEDY, THE PUBLIC INTEREST, AND BONDING

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined to review in part a final initial determination ("Final ID") issued by the presiding chief administrative law judge ("CALJ") finding a violation of section 337. The Commission requests written submissions from the parties on the issue(s) under review and submissions from the parties, interested government agencies, and other interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below.

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"), Dragon Heart Medical Devices Co., Ltd. ("Dragon Heart Devices"), Dragon Heart Medical, Inc. ("Dragon Heart"), and Summit International Medical Technologies, Inc. ("Summit"). *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 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).

An evidentiary hearing was held on December 4-5, 2023, and the CALJ issued the 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 on remedy and bonding, recommending the issuance of a limited exclusion order and a cease and desist order. *See* Final ID at 73-87.

Respondents Summit, Advcare, and Dragon Heart (collectively, "Respondents") filed a petition for review of the Final 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.

Having reviewed the record of the investigation, including the Final ID, Order No. 19, and the parties' petitions for review and responses thereto, the Commission has determined to review the Final ID in part. Specifically, the Commission has determined to review the preclusion of Respondents' and OUII's invalidity arguments and evidence in Order No. 19 (Dec. 1, 2023). The Commission has also determined to review the Final ID's findings with respect to standing and jurisdiction (Final ID at 15-17). In addition, the Commission has determined to correct an error in the Final ID: On page 13, the reference to "one of West's customers" shall be replaced with "one of Summit's customers." The Commission has also determined to correct a typographical error in the *Markman* Order (Order No. 15): On pages 16 and 17, the references to "column 4 lines 43 to 45" and "4:43-45" shall be replaced with "column 4 lines 53 to 55" and

"4:53-55." The Commission has 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.

In connection with its review, the Commission requests responses to the following questions. The parties are requested to brief their positions with reference to the applicable law and the existing evidentiary record. In your responses to the questions below, please provide citations, if any, to where you presented these facts and arguments to the CALJ in connection with Complainants' motion *in limine* no. 2.

1. How and when did Respondents and OUII disclose their invalidity contentions? Was this sufficient notice to Complainants, and how did Complainants respond to these disclosures?

2. Please explain whether and to what extent the substance of Respondents' and OUII's written description arguments overlap with their claim construction and non-infringement arguments? Are the written description arguments contingent on the claim construction of "trifurcated connector body" adopted by the CALJ in Order No. 15 and the Final ID and by the Commission? Were the full and complete bases for Respondents' and OUII's alleged written description defense timely disclosed to Complainants prior to the close of fact and expert discovery?

3. Did the parties propound discovery requests and produce discovery regarding the alleged lack of written description under 35 U.S.C. § 112? What discovery was produced by each party? Did these discovery responses provide adequate and timely notice of this affirmative defense?

4. After Mr. Merchant testified that Summit did not assert any invalidity defense (Order No. 19 at 4-5), did OUII question Mr. Merchant regarding any alleged written description invalidity defense?

5. How should Respondents' *pro se* status affect the Commission's consideration of Respondents' briefing and representations as to Respondents' alleged written description defense? Please discuss how leniency for *pro se* litigants applies specifically to the facts concerning Respondents' alleged written description defense under Federal Circuit and Supreme Court precedent. Explain how Courts consider prejudice and harm to parties when a *pro se* litigant fails to provide adequate and timely notice of an affirmative defense before the close of discovery.

6. Should OUII be allowed to raise an invalidity defense that was not pled or disclosed by Respondents? Under the CALJ's Ground Rules and the Commission's Rules, when and in what form was OUII first required to disclose its contention that the '295 patent was invalid based on the affirmative defense of lack of written description? If the prehearing brief is the earliest time OUII is required to make such disclosure, how should prejudice to Complainants be considered? Should OUII be required to respond to any contention interrogatories, if served upon it by the private parties?

7. Is there "good cause" to waive the pleading requirements under Commission Rule

210.13(b), 19 CFR 210.13(b) ("For good cause, the presiding administrative law judge may waive any of the substantive requirements imposed under this paragraph or may impose additional requirements."), with respect to Respondents' alleged assertion of invalidity? Did Respondents or OUII in their responses to the motion *in limine* present an argument that the CALJ should find good cause to waive the substantive requirement that the bases of invalidity defenses must be pled in the answer to the complaint under Rule 210.13(b)?

8. Does Commission Rule 210.14(c), 19 CFR 210.14(c) ("When issues not raised by the pleadings or notice of investigation, but reasonably within the scope of the pleadings and notice, are considered during the taking of evidence by express or implied consent of the parties, they shall be treated in all respects as if they had been raised in the pleadings and notice. Such amendments of the pleadings and notice as may be necessary to make them conform to the evidence and to raise such issues shall be allowed at any time, and shall be effective with respect to all parties who have expressly or impliedly consented."), apply to the invalidity contentions asserted by Respondents or OUII? Is Rule 210.14(c) limited by its terms to amendment of pleadings to conform to the evidence admitted at the hearing by the consent of the parties? Did Respondents or OUII present an argument to the CALJ in their responses to the motion *in limine* that the requirements of Rule 210.14(c) were met?

9. Please discuss any harm or prejudice to the Complainants from permitting Respondents and/or OUII to present evidence at the hearing as to the affirmative defense of written description given the facts submitted in response to questions 1-8 above.

10. Please explain whether and to what extent the Federal Circuit's decision in *Lannom Mfg. Co. v. U.S. Int'l Trade Comm'n*, 799 F.2d 1572 (Fed. Cir. 1986) applies to the facts in this investigation. *See* Order No. 19 at 6 n.2.

11. If the Commission were to reverse the grant of Complainants' motion *in limine* no. 2, can the invalidity defense be decided by the Commission on review, or should the Commission remand the investigation to the CALJ for further proceedings?

12. Based on the present record, would claim 1 of the '295 patent be invalid for lack of written description pursuant to 35 U.S.C. 112 under the Commission's adopted construction for "trifurcated connector body" and applicable case law?

13. Explain the relevance, if any, of the circumstances surrounding Complainants' voluntary recall of the Vial2Bag DC product in an assessment of whether the written description shows that the inventors were in possession of an invention covering the redesigned Vial2Bag Advanced device as of the filing date of the '295 patent.

14. What additional evidence regarding the written description defense would the parties have presented at hearing if Complainants' motion *in limine* no. 2 had been denied?

The parties are invited to brief only the discrete issues requested above and the issues of remedy, the public interest, and bonding, as discussed below. The parties are not to brief other

issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia,* (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the Respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and cease and desist orders would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding.

In its initial submission, Complainants are also requested to identify the remedy sought and Complainants and OUII are requested to submit proposed remedial orders for the Commission's consideration. Complainants are further requested to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on May 30, 2024. Reply submissions must be filed no later than the close of business on June 10, 2024. Opening submissions are limited to 80 pages. Reply submissions are limited to 50 pages. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or

before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (Mar. 19, 2020). Submissions should refer to the investigation number ("Inv. No. 337-TA-1362") in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing and must be served in accordance with Commission Rule 210.4(f)(7)(ii)(A) (19 CFR 210.4(f)(7)(ii)(A)). All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of 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, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on May 16, 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.

Lisa R. Barton
Secretary to the Commission

Issued: May 16, 2024