7020-02

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-879]

Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof;

Commission Determination to Review an Initial Advisory Opinion in its Entirety; Issuance of Commission Advisory Opinion

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 presiding administrative law judge ("ALJ")'s initial advisory opinion, and to issue a modified advisory opinion in the above-captioned investigation.

FOR FURTHER INFORMATION: Cathy Chen, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2392. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.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 April 25, 2013, based on a complaint filed on March 28, 2013, and supplemented on April 19, 2013, on behalf of ResMed Corp. of San Diego, California; ResMed Inc. of San Diego,

California; and ResMed Ltd. of Australia (collectively, "ResMed"). 78 *FR* 25475 (May 1, 2013). The complaint alleged violations of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the sale for importation, importation, or sale within the United States after importation of certain sleep-disordered breathing treatment systems and components thereof by reason of infringement of claims 1, 2, 4, 5, 17, and 28 of U.S. Patent No. 6,216,691; claims 1 and 20 of U.S. Patent No. 6,935,337 ("the '337 patent"); claim 15 of U.S. Patent No. 7,159,587 ("the '587 patent"); claims 1, 5, 6, 11, 12, 18–20, 35, and 36 of U.S. Patent No. 7,487,772; claims 1–7 of U.S. Patent No. 7,614,398; claims 59, 60, 63, and 72–75 of U.S. Patent No. 7,743,767; and claims 17, 21–24, 29, and 32–37 of U.S. Patent No. 7,997,267. The Commission's notice of investigation named as respondents Apex Medical Corp. of New Taipei City, Taiwan and Apex Medical USA Corp. of Brea, California (collectively, "Apex"), and Medical Depot Inc., d/b/a Drive Medical Design & Manufacturing of Port Washington, New York. The Office of Unfair Import Investigations ("OUII") participated in the original investigation.

Medical Depot Inc. and Apex were terminated from the original investigation on the basis of consent orders. Order Nos. 8 (unreviewed by the Commission, July 18, 2013) and 11 (unreviewed by the Commission, Aug. 8, 2013).

On September 23, 2013, Apex filed a request for an advisory opinion under Commission Rule 210.79 (19 CFR 210.79) that would declare that its redesigned iCH and XT CPAP humidifiers and WiZARD 220 mask are outside the scope of the Commission's August 8, 2013 Consent Order. On December 11, 2013, the Commission determined to institute an advisory opinion proceeding based on Apex's request. 78 *FR* 76320-21 (Dec. 17, 2013). ResMed and OUII both participated in the advisory opinion proceeding.

On June 3, 2014, the ALJ issued an initial advisory opinion ("IAO") finding that Apex's redesigned iCH and XT CPAP humidifiers are covered, and Apex's redesigned WiZARD 220 mask is not covered, by the Consent Order. Even though Apex requested the advisory opinion, the ALJ placed the burden of proof on the patent owner, ResMed, in view of the Supreme Court's recent decision in *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843 (2014). However, the ALJ stated that the outcome of this particular advisory opinion proceeding was not dependent on which party carried the burden of proof. In addition, the ALJ found that the iCH CPAP humidifier infringes claim 20 of the '337 patent both literally and under the doctrine of equivalents, and that the XT CPAP humidifier infringes claim 20 of the '337 patent under the doctrine of equivalents. The ALJ also found that the WiZARD 220 mask does not infringe claim 15 of the '587 patent.

ResMed, Apex, and OUII each filed a petition for review of the IAO on June 16, 2014. They each filed a response to the other petitions for review on June 23, 2014.

Having reviewed the IAO, the record evidence, and the parties' submissions, the Commission has determined to continue to place the burden of proof in an advisory opinion proceeding on the party that requested the advice. Accordingly, in this proceeding, Apex must carry the burden of proving that its redesigned products are outside the scope of the Consent Order. The Commission has also determined to adopt, with modified reasoning, the ALJ's finding that Apex's redesigned iCH CPAP humidifier is covered, and the ALJ's finding that Apex's redesigned WiZARD 220 mask is not covered, by the Consent Order. The Commission has further determined Apex's redesigned XT CPAP humidifier is not covered by the Consent Order, thereby reversing the ALJ's finding on this point. A modified advisory opinion will follow shortly.

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 section 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: July 18, 2014.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2014-17394 Filed 07/23/2014 at 8:45 am; Publication Date: 07/24/2014]