UNITED STATES INTERNATIONAL TRADE COMMISSION Washington, D.C.

In the Matter of

CERTAIN SLEEP-DISORDERED BREATHING TREATMENT MASK SYSTEMS AND COMPONENTS THEREOF

Inv. No. 337-TA-1134

NOTICE OF INSTITUTION OF INVESTIGATION

Institution of Investigation Pursuant to 19 U.S.C. 1337

AGENCY: U.S. International Trade Commission

ACTION: Notice

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on August 31, 2018, under section 337 of the Tariff Act of 1930, as amended, on behalf of ResMed Corp. of San Diego, California; ResMed Inc. of San Diego, California; and ResMed Ltd. of Australia. A supplement was filed on September 4, 2018. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain sleep-disordered breathing treatment mask systems and components thereof by reason of infringement of certain claims of U.S. Patent No. 9,119,931 ("the '931 patent"); U.S. Patent No. 9,027,556 ("the '556 patent"); U.S. Patent No. 9,962,511 ("the '511 patent"); U.S. Patent No. 9,962,510 ("the '510 patent"); U.S. Patent No. 9,937,315 ("the '315 patent"). The complaint further alleges that an industry in the United States exists, or is in the process of being established, as required by the applicable Federal Statute.

The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is 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 SW, Room 112, Washington, DC 20436, telephone (202) 205-2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-2000. General information concerning the Commission may also be obtained by accessing its internet server at https://www.usitc.gov. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at https://edis.usitc.gov.

FOR FURTHER INFORMATION CONTACT: Katherine Hiner, The Office of the Secretary, Docket Services, U.S. International Trade Commission, telephone (202) 205-1802.

SUPPLEMENTARY INFORMATION:

AUTHORITY: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.10 (2018).

SCOPE OF INVESTIGATION: Having considered the complaint, the U.S. International Trade Commission, on September 28, 2018, **ORDERED THAT** –

- (1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1, 5, 8, 26, and 31 of the '931 patent; claims 1, 10, 19, 36, 46, and 52 of the '556 patent; claims 1, 2, 14, 22, and 24 of the '511 patent; claims 5, 10, 28, and 30 of the '510 patent; and claims 1, 2, 30, and 33 of the '315 patent; and whether an industry in the United States exists, or is in the process of being established, as required by subsection (a)(2) of section 337;
- (2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is "full-face and nasal mask systems for treatment of obstructive sleep apnea that are currently manufactured in Mexico and/or New Zealand and currently sold under the trade names 'Simplus,' 'Eson,' and 'Eson 2' that include the unitary combination of a cushion module, a shroud module, and an elbow among other things";
- (3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:
 - (a) The complainants are:

ResMed Corp. 9001 Spectrum Center Drive San Diego, CA 92123

ResMed Inc. 9001 Spectrum Center Drive San Diego, CA 92123 ResMed Ltd. 1 Elixabeth Macarthur Drive Bella Vista NSW 2153 Australia

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Fisher & Paykel Healthcare Limited 15 Maurice Paykel Place East Tamaki, Auckland 2013 PO Box 14348 Panmure, Auckland 1741 New Zealand

Fisher & Paykel Healthcare, Inc. 173 Technology Drive, Suite 100 Irvine, CA 92618

Fisher & Paykel Healthcare Distribution Inc. 173 Technology Drive, Suite Irvine, CA 92618

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not be named as a party to this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.13. Pursuant to 19 C.F.R. 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Lisa R. Barton

Secretary to the Commission

Issued: October 1, 2018