UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN SLEEP-DISORDERED BREATHING TREATMENT SYSTEMS AND COMPONENTS THEREOF**	**Investigation No. 337-TA-890 (Remand)**

NOTICE OF COMMISSION DETERMINATION TO REVIEW IN-PART A FINAL INITIAL DETERMINATION ON REMAND, AND ON REVIEW, TO AFFIRM WITH MODIFICATION; VACATUR OF SUSPENDED REMEDIAL ORDERS; AND 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 review in-part the presiding Administrative Law Judge's ("ALJ") final initial determination on remand ("RID") for the limited purpose of modifying pages 20-21 and 24 of the RID. The Commission has also determined to vacate the issued remedial orders, which are currently suspended.

FOR FURTHER INFORMATION CONTACT: Panyin A. Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3042. 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 (*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*. 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 August 23, 2013, based on a complaint filed by ResMed Corporation of San Diego, California; ResMed Incorporated of San Diego, California; and ResMed Limited of New South Wales, Australia (collectively, "ResMed"). 78 *Fed. Reg.* 52564 (Aug. 23, 2013). The complaint alleged violations of section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) in 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 systems and components thereof that infringe one or

more of claims 32-37, 53, 79, 80, and 88 of U.S. Patent No. 7,997,267 ("the '267 patent"); claims 1-7 of U.S. Patent No. 7,614,398 ("the '398 patent"); claim 1 of U.S. Patent No. 7,938,116 ("the '116 patent"); claims 30, 37, and 38 of U.S. Patent No. 7,341,060 (the '060 patent); claims 1, 3, 5, 11, 28, 30, 31, and 56 of U.S. Patent No. 8,312,883 ("the '883 patent"); claims 1, 3, 6, 7, 9, 29, 32, 35, 40, 42, 45, 50, 51, 56, 59, 89, 92, 94, and 96 of U.S. Patent No. 7,178,527 (the '527 patent); claims 19-24, 26, 29-36, and 39-41 of U.S. Patent No. 7,950,392 (the '392 patent); and claims 13, 15, 16, 26-28, 51, 52, and 55 of U.S. Patent No 7,926,487 ("the '487 patent"). The following patents are collectively referred to as the mask patents: the '527 patent; the '392 patent; the '267 patent; the '060 patent; and the'883 patent. The notice of investigation named the following respondents: BMC Medical Co., Ltd. of Beijing, China; 3B Medical, Inc. of Lake Wales, Florida; and 3B Products, L.L.C., of Lake Wales, Florida (collectively "BMC"). The Office of Unfair Import Investigations ("OUII") participated in the investigation.

On January 9, 2014, the ALJ issued an initial determination ("ID") granting a motion by ResMed to amend the complaint and notice of investigation to substitute U.S. Patent No. RE 44,453 ("the '453 patent") for the '398 patent and to terminate the investigation as to the '398 patent. *See* Order No. 7 (Jan. 9, 2014). The Commission determined not to review the ID. *See* Commission Notice of Non-Review (Feb. 10, 2014); 79 *Fed. Reg.* 9000-01 (Feb. 14, 2014).

On February 24, 2014, the ALJ issued an ID granting a motion by ResMed to withdraw its allegations with respect to the '116 patent. *See* Order No. 11 (Feb. 24, 2014). The Commission determined not to review the ID. *See* Commission Notice of Non-Review (March 11, 2014). On March 18, 2014, the ALJ granted a motion by ResMed to terminate the investigation as to claims 26-28 of the '487 Patent. *See* Order No. 20 (Mar 18, 2012). The Commission determined not to review the ID. *See* Commission Notice of Non-Review (Apr. 29, 2014).

On August 21, 2014, the ALJ issued a final ID, finding a violation of section 337 by BMC with respect to certain asserted claims of the '392, '267, '060, '883, '527, and '453 patents. The ALJ found no violation of section 337 with respect to the asserted claims of the '487 patent.

On September 3, 2014, the parties filed petitions for review of the ID. On September 11, 2014, the parties filed responses to the petitions for review.

On October 16, 2014, the Commission determined to review the final ID in part. 79 *Fed. Reg.* 63163-65 (Oct. 22, 2014). On review, the Commission determined to affirm the ALJ's finding of violation of section 337. The Commission, however, found the '453 patent invalid for anticipation. Having found a violation of section 337, the Commission determined that the appropriate form of relief was (1) a limited exclusion order prohibiting the unlicensed entry of sleep-disordered breathing treatment systems and components thereof that infringe one or more of claims 1, 9, 32, 89, and 92 of the '527 patent; claims 19, 21, 29, 32, and 36 of the '392 patent; claims 32, 33, 34, and 53 of the '267 patent; claims 30, 37, and 38 of the '060 patent; and claims 1, 3, 5, 11, 28, 30, 31, and 56 of the '883 patent that are manufactured by, or on behalf of, or are imported by or on behalf of BMC Medical Co., Ltd., 3B Medical, Inc., or 3B Products L.L.C. or

any of their affiliated companies, parents, subsidiaries, agents, or other related business entities, or their successors or assigns, except for service and replacement parts for customers that purchased their covered products prior to the date the exclusion order becomes final; and (2) cease and desist orders prohibiting domestic respondents BMC Medical Co., Ltd., 3B Medical, Inc. from conducting any of the following activities in the United States: importing, selling, marketing, advertising, distributing, transferring (except for exportation), and soliciting U.S. agents or distributors for, sleep-disordered breathing treatment systems and components thereof covered by claims 1, 9, 32, 89, and 92 of the '527 patent; claims 19, 21, 29, 32, and 36 of the '392 patent; claims 32, 33, 34, and 53 of the '267 patent; claims 30, 37, and 38 of the '060 patent; and claims 1, 3, 5, 11, 28, 30, 31, and 56 of the '883 patent.

On February 18, 2015, ResMed filed a notice of appeal in the U.S. Court of Appeals for the Federal Circuit, seeking review of the Commission's determination as to the '453 patent (Appeal No. 2015-1360). On April 14, 2015, BMC filed a notice of appeal in the Federal Circuit, seeking review of the Commission's domestic industry determination as well as the Commission's finding that prior art does not render the asserted claims of the '267 patent invalid for obviousness (Appeal No. 2015-1576). The Court consolidated the two appeals on April 23, 2015.

On March 16, 2016, the parties jointly moved to dismiss ResMed's appeal as to the '453 patent. On March 17, 2016, the Commission moved to remand BMC's appeal in light of intervening domestic industry precedent in *Lelo Inc. v. International Trade Commisson*, 789 F.3d 879 (Fed. Cir. 2015). On March 29, 2016, the Court granted the motion to dismiss ResMed's appeal. On April 22, 2016, the Court granted the Commission's remand motion.

On May 12, 2016, the Commission issued a notice suspending the remedial orders in place during the pendency of the remand proceedings. 81 *Fed. Reg.* 31254-55 (May 18, 2016). The Commission also issued an order asking the parties to comment on further proceedings. On June 8, 2016, the parties submitted initial comments. The parties filed responses on July 15, 2016. On August 16, 2016, the Commission issued an order remanding the investigation to the ALJ to: (1) apply the Federal Circuit's intervening domestic industry precedent in *Lelo* to the existing record (as to the mask patents, the only patents remaining); and (2) issue an RID on remand as to violation.

On November 10, 2016, the ALJ issued the RID finding that ResMed failed to establish the existence of a domestic industry that practices the mask patents. RID at 1. No petitions for review were received.

Having examined the record of this investigation, the Commission has determined to review in-part the RID for the limited purpose of modifying pages 20-21 and 24 of the RID. The Commission does not adopt the RID's statements that "the amount a complainant spends to purchase components manufactured in the United States is immaterial to the economic prong analysis" (RID at 20-21) or that evidence of payments to domestic suppliers is "*per se* insufficient to include in the quantitative analysis." RID at 24. The Commission has determined

to otherwise not review the RID. The Commission has determined to vacate the suspended remedial orders. The investigation is terminated.

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 C.F.R. part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: January 12, 2017