

**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

**NOTICE OF THE COMMISSION'S FINAL DETERMINATION; ISSUANCE OF A LIMITED
EXCLUSION ORDER AND CEASE AND DESIST ORDERS; 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 found a violation of section 337 in this investigation and has (1) issued a limited exclusion order prohibiting importation of infringing sleep-disordered breathing treatment systems and components thereof and (2) issued cease and desist orders directed to domestic respondents.

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 (<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 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 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 "Respondents"). The Office of Unfair Import Investigations ("OUII") is participating in the investigation.

On January 9, 2014, the ALJ issued an 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* Notice of Commission Determination Not to Review an Initial Determination Granting the Complainants' Motion to Amend the Complaint and Notice of Investigation (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* Notice of Commission Determination Not to Review an Initial Determination Granting the Complainants' Motion to Partially Terminate the Investigation by Withdrawing Allegations with Respect to U.S. Patent No. 7,938,116 (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* Notice of Commission Determination Not to Review an Initial Determination Granting Complainants' Unopposed Motion for Partial Termination of the Investigation by Withdrawal of Claims 26-28 of U.S. Patent No. 7,926,487 (Apr. 29, 2014).

On August 21, 2014, the ALJ issued his final ID, finding a violation of section 337 by Respondents 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. Specifically, the ALJ found that the Commission has subject matter jurisdiction, *in rem* jurisdiction over the accused products, and *in personam* jurisdiction over the respondents. ID at 10-11. The parties stipulated to importation of the accused products and the ALJ found that the importation requirement of section 337 (19 U.S.C. § 1337(a)(1)(B)) has been satisfied. *Id.* at 3. The ALJ found that the accused products infringe asserted claims 1, 9, 32, 89, and 92 of the '527 patent; asserted claims 19, 21, 29, 32, and 36 of the '392 patent; asserted claims 32-34 and 53 of the '267 patent; asserted claims 30, 37, and 38 of the '060 patent; asserted claims 1, 3, 5, 11, 28, 30, 31, and 56 of the '883 patent; and asserted claim 2 of the '453 patent. *See* ID at 23, 46, 57-58, 71-78, 95, 99, and 102. The ALJ found that Respondents failed to establish by clear and convincing evidence that the asserted claims of the '392, '267, '060, '883, '527, or claim 2 of the '453 patents were invalid in light of the cited prior art references. *See id.* at 25-45, 48-55, 96, and 100. The ALJ concluded that the accused products satisfy each limitation of claims 4 and 7 of the '453 patent but found those claims invalid in view of the prior art. *See id.* at 103-139. The ALJ also found that the accused products satisfy each limitation of asserted claims 13, 51, 52, and 55 of the '487 patent, but found those claims invalid in view of the prior art. *See id.* at 78-92. The ALJ further found that ResMed established the existence of a domestic industry that practices the asserted patents under 19 U.S.C. § 1337(a)(2). *See* ID at 139-188.

On September 3, 2014, Respondents and the Commission investigative attorney filed petitions for review of the ID. That same day, ResMed filed a contingent petition for review of the ID. On September 11, 2014, the parties filed responses to the various petitions and contingent petition for review.

On October 16, 2014, the Commission determined to review the final ID in part. 79 *Fed. Reg.* 63163-65 (Oct. 22, 2014). Specifically, with respect to the '487 patent, the Commission determined to review the ALJ's construction of the claim term "gas washout vent" and construed the limitation to mean "a vent comprising a thin air permeable membrane extending across an opening for exhausting gas to the atmosphere." As a result of the new claim construction, the Commission determined to review the ALJ's findings on infringement, invalidity, and the technical prong of the domestic industry requirement. Regarding the '453 patent, the Commission determined to review (1) the ALJ's construction of the claim limitation "a retaining mechanism configured to secure the connecting structure to the CPAP apparatus" and struck the ID's requirement that the claimed "retaining mechanism" must include an arrangement of moving parts; (2) the ALJ's finding that the prior art REMstar device does not anticipate the asserted claims of the '453 patent; and (3) the ALJ's findings on infringement and the technical prong of the domestic industry requirement. The Commission also determined to review the ID's findings and conclusions regarding the economic prong of the domestic industry requirement under 19 U.S.C. § 1337(a)(3)(C).

On October 31, 2014, the parties filed written submissions on the issues under review, remedy, the public interest, and bonding. On November 7, 2014, the parties filed reply submissions.

Having examined the record of this investigation, including the ALJ's final ID, with respect to the '487 patent, the Commission has determined that under its construction of the claim term "gas washout vent" to mean "a vent comprising a thin air permeable membrane extending across an opening for exhausting gas to the atmosphere," a violation of section 337 has not occurred because, as all the parties agree, ResMed failed to show that its domestic industry products practice the '487 patent. To conserve resources, the Commission has determined to take no position on infringement and validity as it pertains to the '487 patent. Regarding the '453 patent, the Commission has determined that the prior art REMstar device anticipates the asserted claims of the '453 patent under the Commission's construction of the claim limitation "a retaining mechanism configured to secure the connecting structure to the CPAP apparatus" to mean "one or more parts for holding in place the CPAP apparatus that is configured to attach the connecting structure to the CPAP apparatus." Given that Commission's construction is broader than the ALJ's construction, the Commission has determined to affirm the ALJ's infringement and domestic industry, technical prong, findings. With respect to domestic industry the Commission has determined to vacate the ID's findings and conclusion that ResMed established a domestic industry under 19 U.S.C. § 1337(a)(3)(C).

Having found a violation of section 337 in this investigation, the Commission has determined that the appropriate form of relief is: (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. The proposed cease and desist orders include the following exemptions: (1) if in a written instrument, the owner of the patents authorizes or licenses such specific conduct, or such specific conduct is related to the importation or same of covered products by or for the United States; or (2) conduct limited to the provision of service and replacement parts for customers that purchased their covered products prior to the date this Order becomes final within the meaning of 19 U.S.C. § 1337(j)(4).

The Commission has also determined that the public interest factors enumerated in section 337(d) and (f) (19 U.S.C. §§ 1337(d) and (f)) do not preclude issuance of the limited exclusion order or cease and desist orders. Finally, the Commission has determined that a bond in the amount of 65 percent of entered value is required to permit temporary importation during the period of Presidential review (19 U.S.C. § 1337(j)) of sleep-disordered breathing treatment systems and components thereof that are subject to the limited exclusion order. The Commission's orders and opinion were delivered to the President and to the United States Trade Representative on the day of their issuance.

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.

A handwritten signature in cursive script, appearing to read "Jennifer Rohrbach".

Jennifer Rohrbach
Supervisory Attorney

Issued: December 23, 2014