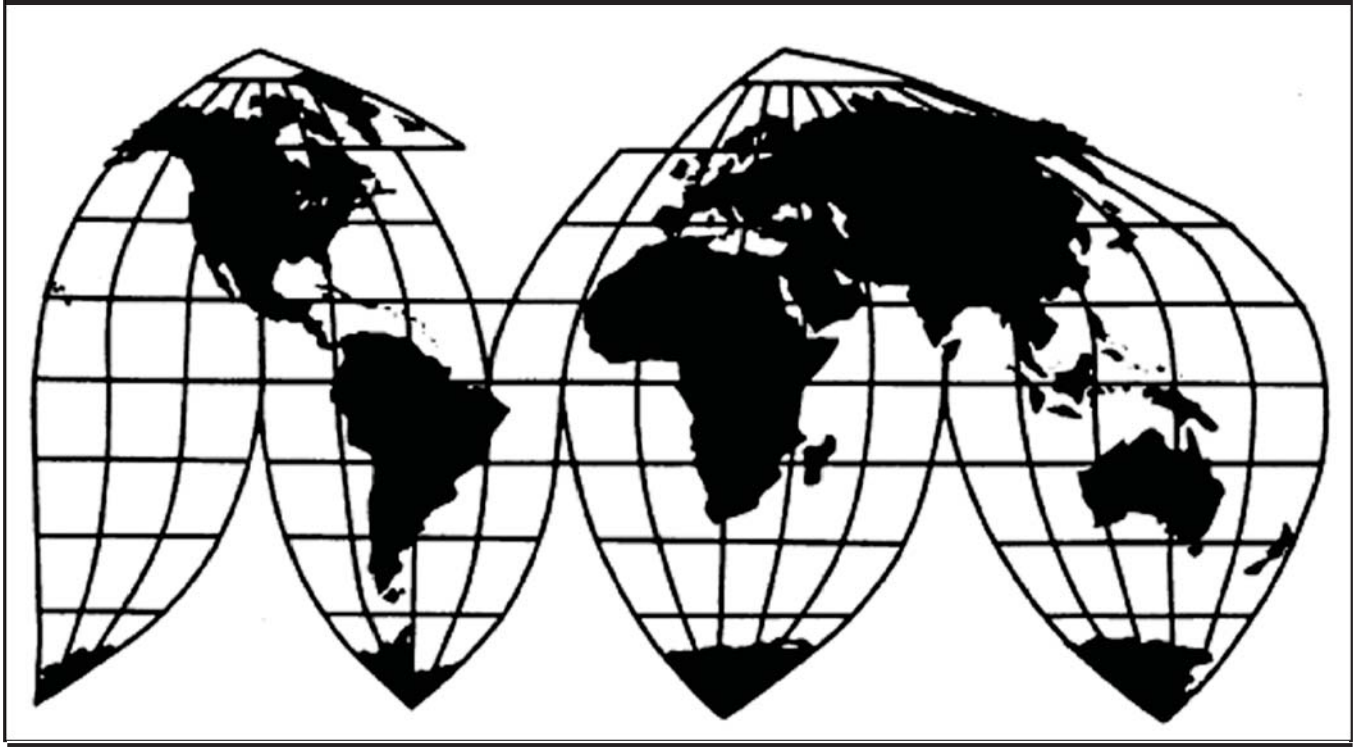
In the Matter of

CERTAIN SLEEP-DISORDERED BREATHING TREATMENT SYSTEMS AND COMPONENTS THEREOF

337-TA-890

Publication 4856 **December 2018**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

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Washington, DC 20436
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In the Matter of

CERTAIN SLEEP-DISORDERED BREATHING TREATMENT SYSTEMS AND COMPONENTS THEREOF

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Publication 4856

December 2018

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).

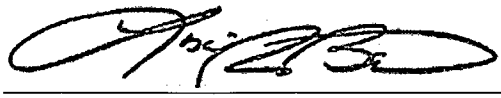
By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: January 12, 2017

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served by hand upon the Commission Investigative Attorney, Lisa M. Kattan, Esq., and the following parties as indicated, on **January 12, 2017.**



Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants ResMed Corporation, ResMed Incorporated, and ResMed Limited:

Thomas S. Fusco, Esq.
FISH & RICHARDSON P.C.
1425 K Street, NW, 11th Floor
Washington, DC 20005

☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

On Behalf of Respondents BMC Medical Co., Ltd., 3B Medical, Inc., and 3B Products, LLC:

Gary M. Hnath, Esq.
MAYER BROWN LLP
1999 K Street, NW
Washington, DC 20006

☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

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

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.

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(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).

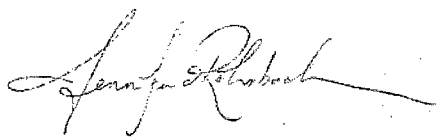
Having found a violation of section 337 in this investigation, the Commission has determined that the appropriate form of relief is: (1) a limited exclusion order prohibiting the unlicensed entry of sleep-disordered breathing treatment systems and components thereof that infringe one or more of claims 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.



Jennifer Rohrbach
Supervisory Attorney

Issued: December 23, 2014

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C. 20436

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

LIMITED EXCLUSION ORDER

The United States International Trade Commission ("Commission") has determined that there is a violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), in the unlawful importation, sale for importation, or sale within the United States after importation by Respondents BMC Medical Co., Ltd., 3B Medical, Inc. and 3B Products L.L.C. (collectively "Respondents") of certain sleep-disordered breathing treatment systems and components thereof covered by one or more of claims of 1, 9, 32, 89, and 92 of U.S. Patent No. 7,178,527 ("the '527 patent"); claims 19, 21, 29, 32, and 36 of U.S. Patent No. 7,950,392 ("the '392 patent"); claims 32, 33, 34, and 53 of U.S. Patent No. 7,997,267 ("the '267 patent"); claims 30, 37, and 38 of U.S. Patent No. 7,341,060 ("the '060 patent"); and claims 1, 3, 5, 11, 28, 30, 31, and 56 of U.S. Patent No. 8,312,883 ("the '883 patent").

Having reviewed the record in this investigation, including the written submissions of the parties, the Commission has made its determination on the issues of remedy, public interest, and bonding. The Commission has determined that the appropriate form of relief is a limited exclusion order prohibiting the unlicensed entry of covered sleep-disordered breathing treatment systems and components thereof manufactured by or on behalf of the Respondents or any of their

affiliate companies, parents, subsidiaries, licensees, or other related business entities, or their successors or assigns.

The Commission has also determined that the public interest factors enumerated in 19 U.S.C. § 1337(d) do not preclude the issuance of the limited exclusion order, and that the bond during the Presidential review period shall be in the amount of 65 percent of the entered value for the covered products.

Accordingly, the Commission hereby **ORDERS** that:

1. 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, are excluded from entry for consumption into the United States, entry for consumption from a foreign-trade zone, or withdrawal from a warehouse for consumption, for the remaining term of the patents, except under license of the patent owner or as provided by law, and except for sleep-disordered breathing treatment masks and components thereof imported for use as service or replacement parts for products imported into the United States prior to the Commission's determination becoming final within the meaning of 19 U.S.C. § 1337(j)(4).

2. Notwithstanding paragraph 1 of this Order, the aforesaid sleep-disordered breathing treatment systems and components thereof are entitled to entry into the United States for consumption, entry for consumption from a foreign trade zone, or withdrawal from a

warehouse for consumption, under bond in the amount of 65 percent of the entered value of imported sleep-disordered breathing treatment systems and components thereof pursuant to subsection (j) of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337(j)), and the Presidential Memorandum for the United States Trade Representative of July 21, 2005 (70 *Fed. Reg.* 43,251), from the day after this Order is received by the United States Trade Representative, and until such time as the United States Trade Representative notifies the Commission that this action is approved or disapproved but, in any event, not later than 60 days after the issuance of receipt of this Order.

3. At the discretion of U.S. Customs and Border Protection ("CBP") and pursuant to the procedures it establishes, persons seeking to import sleep-disordered breathing treatment systems and components thereof that are potentially subject to this Order may be required to certify that they are familiar with the terms of this Order, that they have made appropriate inquiry, and thereupon state that, to the best of their knowledge and belief, the products being imported are not excluded from entry under paragraph 1 of this Order. At its discretion, CBP may require persons who have provided the certification described in this paragraph to furnish such records or analyses as are necessary to substantiate this certification.

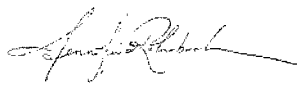
4. In accordance with 19 U.S.C. § 1337 (l), the provisions of this Order shall not apply to infringing sleep-disordered breathing treatment systems and components thereof same that are imported by or for the use of the United States, or imported for and to be used for, the United States with the authorization or consent of the Government.

5. The Commission may modify this Order in accordance with the procedures described in Rule 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

6. The Secretary shall serve copies of this Order upon each party of record in this Investigation and upon the Department of Health and Human Services, the Department of Justice, the Federal Trade Commission, and U.S. Customs and Border Protection.

7. Notice of this Order shall be published in the *Federal Register*.

By order of the Commission.



Jennifer Rohrbach
Supervisory Attorney

Issued: December 23, 2014

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C. 20436

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

CEASE AND DESIST ORDER AGAINST
RESPONDENT 3B MEDICAL, INC.

IT IS HEREBY ORDERED THAT RESPONDENT 3B Medical, Inc., 21301 U.S. Highway 27, Lake Wales, Florida 33859 ("3B Medical" or "Respondent") cease and desist 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 one or more of claims 1, 9, 32, 89, and 92 of United States Patent No. 7,178,527; claims 19, 21, 29, 32, and 36 of United States Patent No. 7,950,392; claims 32, 33, 34, and 53 of United States Patent No. 7,997,267; claims 30, 37, and 38 of United States Patent No. 7,341,060; and claims 1, 3, 5, 11, 28, 30, 31, and 56 of United States Patent No. 8,312,883. (collectively, "the Asserted Patents") in violation of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337).

I. Definitions

As used in this Order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainants" shall mean ResMed Corp. and ResMed, Inc. of San Diego, California and ResMed Ltd of Bella Vista, Australia.

(C) "Respondent" shall mean 3B Medical, Inc., of Lake Wales, Florida.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority-owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States.

(G) The term "covered products" shall mean sleep-disordered breathing treatment systems and components thereof covered by certain claims of the Asserted Patents. Covered products shall not include articles for which a provision of law or license avoids liability for infringement of certain claims of the Asserted Patents.

II. Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

III. Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order. For the remaining terms of the Asserted Patents, the Respondent shall not:

(A) import or sell for importation into the United States covered products;

(B) market, distribute, sell, or otherwise transfer (except for exportation), in the United States imported covered products;

(C) advertise imported covered products;

(D) solicit U.S. agents or distributors for imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer, or distribution of covered products.

IV. Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this order shall be permitted if:

(A) in a written instrument, the owner of the relevant Asserted Patents authorizes or licenses such specific conduct, or such specific conduct is related to the importation or sale of covered products by or for the United States; or

(B) the conduct is limited to the provision of service and replacement parts for customers that purchased their covered products prior to the date this Order becomes final.

V. Reporting

For purposes of this requirement, the reporting periods shall commence on January 1 of each year and shall end on the subsequent December 31. The first report required under this section shall cover the period from the date of issuance of this order through December 31, 2015. This reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that it has no inventory of covered products in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and

(b) the quantity in units and value in dollars of reported covered products that remain in inventory in the United States at the end of the reporting period.

When filing written submissions, Respondent must file the original document electronically on or before the deadlines stated above and submit eight (8) true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-890") in a prominent place on the cover pages and/or the first page. (See Handbook for Electronic Filing Procedures, http:/ /www.usitc.gov/secretary/fed_reg_ notices/ rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainant's counsel.[1]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI. Record-Keeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, offer for sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary

[1] Complainants must file a letter with the Secretary identifying the attorney to receive reports associated with this order. The designated attorney must be on the protective order entered in the investigation.

course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and the right to inspect and copy, in Respondent's principal offices during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

VII. Service of Cease and Desist Order

Respondent is ordered and directed to:

(A) Serve, within fifteen days after the effective date of this order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, or sale of imported covered products in the United States;

(B) Serve, within fifteen days after the succession of any persons referred to in subparagraph VII(A) of this order, a copy of the order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the last expiration date of the Asserted Patents.

VIII. Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to section V-VI of this order should be made in accordance with section 201.6 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 201.6). For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX. Enforcement

Violation of this order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure (19 C.P.R. § 210.75), including an action for civil penalties under section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), as well as any other action that the Commission deems appropriate. In determining whether Respondent is in violation of this order, the Commission may infer facts adverse to Respondent if it fails to provide adequate or timely information.

X. Modification

The Commission may amend this order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

XI. Bonding

The conduct prohibited by Section III of this order may be continued during the sixty-day period in which this order is under review by the United States Trade Representative, as delegated by the President (70 *Fed. Reg.* 43,251 (Jul. 21, 2005)) subject to the Respondent's

posting of a bond in the amount of 65 percent of the entered value of the covered products. This bond provision does not apply to conduct that is otherwise permitted by section IV of this order. Covered products imported on or after the date of issuance of this order are subject to the entry bond set forth in the exclusion order issued by the Commission, and are not subject to this bond provision.

The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of temporary exclusion orders. (See 19 C.F.R. § 210.68). The bond and any accompanying documentation are to be provided to and approved by the Commission prior to the commencement of conduct that is otherwise prohibited by section III of this order. Upon the Secretary's acceptance of the bond, (a) the Secretary will serve an acceptance letter on all parties, and (b) Respondent must serve a copy of the bond and any accompanying documentation on Complainants' counsel.[2]

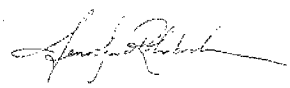
The bond is to be forfeited in the event that the United States Trade Representative approves this order (or does not disapprove it within the review period), unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to Respondent on appeal, or unless Respondent exports or destroys the products subject to this bond and provides certification to that effect that is satisfactory to the Commission.

The bond is to be released in the event the United States Trade Representative disapproves this order and no subsequent order is issued by the Commission and approved (or not disapproved) by the United States Trade Representative, upon service on Respondent of an order

[2] *See* Footnote 1.

issued by the Commission based upon application therefore made by Respondent to the Commission.

By order of the Commission.



Jennifer Rohrbach
Supervisory Attorney

Issued: December 23, 2014

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C. 20436

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

CEASE AND DESIST ORDER AGAINST
RESPONDENT 3B PRODUCTS, L.L.C.

IT IS HEREBY ORDERED THAT RESPONDENT 3B Products, L.L.C., 21301 U.S. Highway 27, Lake Wales, Florida 33859 ("3B Products " or "Respondent") cease and desist 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 one or more of claims 1, 9, 32, 89, and 92 of United States Patent No. 7,178,527; claims 19, 21, 29, 32, and 36 of United States Patent No. 7,950,392; claims 32, 33, 34, and 53 of United States Patent No. 7,997,267; claims 30, 37, and 38 of United States Patent No. 7,341,060; and claims 1, 3, 5, 11, 28, 30, 31, and 56 of United States Patent No. 8,312,883. (collectively, "the Asserted Patents") in violation of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337).

I. Definitions

As used in this Order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainants" shall mean ResMed Corp. and ResMed, Inc. of San Diego, California and ResMed Ltd of Bella Vista, Australia.

(C) "Respondent" shall mean 3B Products, L.L.C., of Lake Wales, Florida.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority-owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States.

(G) The term "covered products" shall mean sleep-disordered breathing treatment systems and components thereof covered by certain claims of the Asserted Patents. Covered products shall not include articles for which a provision of law or license avoids liability for infringement of certain claims of the Asserted Patents.

II. Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

III. Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order. For the remaining terms of the Asserted Patents, the Respondent shall not:

(A) import or sell for importation into the United States covered products;

(B) market, distribute, sell, or otherwise transfer (except for exportation), in the United States imported covered products;

(C) advertise imported covered products;

(D) solicit U.S. agents or distributors for imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer, or distribution of covered products.

IV. Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this order shall be permitted if:

(A) in a written instrument, the owner of the relevant Asserted Patents authorizes or licenses such specific conduct, or such specific conduct is related to the importation or sale of covered products by or for the United States; or

(B) the conduct is limited to the provision of service and replacement parts for customers that purchased their covered products prior to the date this Order becomes final.

V. Reporting

For purposes of this requirement, the reporting periods shall commence on January 1 of each year and shall end on the subsequent December 31. The first report required under this section shall cover the period from the date of issuance of this order through December 31, 2015. This reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that it has no inventory of covered products in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and

(b) the quantity in units and value in dollars of reported covered products that remain in inventory in the United States at the end of the reporting period.

When filing written submissions, Respondent must file the original document electronically on or before the deadlines stated above and submit eight (8) true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-890") in a prominent place on the cover pages and/or the first page. (*See* Handbook for Electronic Filing Procedures, http:/ /www.usitc.gov/secretary/fed_reg_ notices/ rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainant's counsel.[3]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI. Record-Keeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, offer for sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary

[3] Complainants must file a letter with the Secretary identifying the attorney to receive reports associated with this order. The designated attorney must be on the protective order entered in the investigation.

course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and the right to inspect and copy, in Respondent's principal offices during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

VII. Service of Cease and Desist Order

Respondent is ordered and directed to:

(A) Serve, within fifteen days after the effective date of this order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, or sale of imported covered products in the United States;

(B) Serve, within fifteen days after the succession of any persons referred to in subparagraph VII(A) of this order, a copy of the order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the last expiration date of the Asserted Patents.

VIII. Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to section V-VI of this order should be made in accordance with section 201.6 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 201.6). For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX. Enforcement

Violation of this order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure (19 C.P.R. § 210.75), including an action for civil penalties under section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), as well as any other action that the Commission deems appropriate. In determining whether Respondent is in violation of this order, the Commission may infer facts adverse to Respondent if it fails to provide adequate or timely information.

X. Modification

The Commission may amend this order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

XI. Bonding

The conduct prohibited by Section III of this order may be continued during the sixty-day period in which this order is under review by the United States Trade Representative, as delegated by the President (70 *Fed. Reg.* 43,251 (Jul. 21, 2005)) subject to the Respondent's

posting of a bond in the amount of 65 percent of the entered value of the covered products. This bond provision does not apply to conduct that is otherwise permitted by section IV of this order. Covered products imported on or after the date of issuance of this order are subject to the entry bond set forth in the exclusion order issued by the Commission, and are not subject to this bond provision.

The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of temporary exclusion orders. (*See* 19 C.F.R. § 210.68). The bond and any accompanying documentation are to be provided to and approved by the Commission prior to the commencement of conduct that is otherwise prohibited by section III of this order. Upon the Secretary's acceptance of the bond, (a) the Secretary will serve an acceptance letter on all parties, and (b) Respondent must serve a copy of the bond and any accompanying documentation on Complainants' counsel.[4]

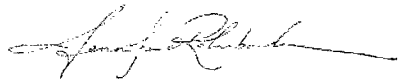
The bond is to be forfeited in the event that the United States Trade Representative approves this order (or does not disapprove it within the review period), unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to Respondent on appeal, or unless Respondent exports or destroys the products subject to this bond and provides certification to that effect that is satisfactory to the Commission.

The bond is to be released in the event the United States Trade Representative disapproves this order and no subsequent order is issued by the Commission and approved (or not disapproved) by the United States Trade Representative, upon service on Respondent of an order

[4] *See* Footnote 1.

issued by the Commission based upon application therefore made by Respondent to the Commission.

By order of the Commission.



Jennifer Rohrbach
Supervisory Attorney

Issued: December 23, 2014

CERTAIN SLEEP-DISORDERED BREATHING TREATMENT SYSTEMS AND COMPONENTS THEREOF **Inv. No. 337-TA-890**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served by hand upon the Commission Investigative Attorney, Lisa M. Kattan, Esq., and the following parties as indicated, on **December 23, 2014.**

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants ResMed Corporation, ResMed Incorporated, and ResMed Limited:

Thomas S. Fusco, Esq.
FISH & RICHARDSON P.C.
1425 K Street, NW, 11th Floor
Washington, DC 20005

☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

On Behalf of Respondents BMC Medical Co., Ltd., 3B Medical, Inc., and 3B Products, LLC:

Gary M. Hnath, Esq.
MAYER BROWN LLP
1999 K Street, NW
Washington, DC 20006

☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

PUBLIC VERSION

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

COMMISSION OPINION

This investigation is before the Commission for a final determination on the issues under review, remedy, the public interest, and bonding. The Commission has determined to affirm the presiding administrative law judge's ("ALJ") initial determination ("ID") that 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"), violated section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in connection with claims 1, 9, 32, 89, and 92 of U.S. Patent No. 7,178,527 ("the '527 patent"); claims 19, 21, 32, and 36 of U.S. Patent No. 7,950,392 ("the '392 patent"); claims 32-34 and 53 of U.S. Patent No. 7,997,267 ("the '267 patent"); claims 30, 37, and 38 of U.S. Patent No. 7,341,060 ("the '060 patent"); and claims 1, 3, 5, 11, 28, 30, 31, and 56 of U.S. Patent No. 8,312,883 ("the '883 patent"). The Commission has determined to reverse the ALJ's determination that Respondents violated section 337 in connection with claim 2 of U.S. Patent No. RE 44,453 ("the '453 patent") and finds that prior art renders the asserted claims of the '453 patent invalid. The Commission has determined to affirm the ALJ's finding that Respondents have not violated section 337 in connection with claims 13, 51, 52, and 55 of U.S. Patent No. 7,926,487 ("the '487 patent") because, as all the parties agree, Complainants, ResMed Corporation of San Diego, California; ResMed Incorporated of San

Diego, California; and ResMed Limited of New South Wales, Australia (collectively, "ResMed") failed to establish the technical prong for domestic industry under the Commission's construction of the claim term "gas washout vent."[1] The Commission has determined to vacate the ID's finding and discussion that ResMed established a domestic industry under 19 U.S.C. § 1337(a)(3)(C). The Commission adopts the ID to the extent it does not conflict with this opinion.

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

[1] ResMed states that it "would not contest a finding of no violation on the '487 patent based on the technical prong of domestic industry." ResMed Motion to Withdraw '487 Patent at 1.

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 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.

I. BACKGROUND

A. Procedural History

The Commission instituted this investigation on August 23, 2013, based on a complaint filed by 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 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 the '060 patent; claims 1, 3, 5, 11, 28, 30, 31, and 56 of 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 the '527 patent; claims 19-24, 26, 29-36, and 39-41 of the '392 patent; and claims 13, 15, 16, 26-28, 51, 52, and 55 of the '487 patent. *Id.* The notice of investigation named the Respondents identified above. *Id.* The Office of Unfair Import Investigations ("OUII") was a named party to 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 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.[2] 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.[3] 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.[4]

The ALJ held an evidentiary hearing on April 10, 2014, and April 11, 2014, and from

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[2] *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).

[3] *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).

[4] *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).

April 14, 2014, through April 17, 2014, and thereafter received post-hearing briefing from the parties.

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, 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 13, 51, 52, and 55 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 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 found that Respondents failed to establish by clear and convincing evidence that the asserted claims of the '392, '267, '060, '883, 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 further found that ResMed established the existence of a domestic industry that practices each of the asserted

patents under 19 U.S.C. § 1337(a)(2). *See* ID at 139-188.

The ID included the ALJ's recommended determination on remedy and bonding. The ALJ recommended that in the event the Commission finds a violation of section 337, the Commission should issue a limited exclusion order prohibiting the importation of infringing sleep-disordered breathing treatment systems and components thereof imported by Respondents. ID at 192. The ALJ also recommended issuance of cease and desist orders directed to Respondents, finding that Respondents maintain commercially significant inventory of at least some of the infringing products in the United States. *Id.* at 6. The ALJ noted the parties' stipulation that a bond of 65 percent of entered value should be imposed during the period of Presidential review, and recommended that the Commission set the bond in that amount. *Id.* at 194.

On September 3, 2014, Respondents filed a petition for review of the ID, challenging a number of the ALJ's findings. *See* Respondents' Petition for Review of Initial Determination ("Resp. Pet."). Specifically, Respondents sought review of the ALJ's construction of the claim term "gas washout vent" recited in the asserted claims of the '487 patent, the ALJ's finding that the accused products satisfy all the limitations of the asserted claims, and the ALJ's finding that the cited prior art does not anticipate the asserted claims. Respondents also challenged the ALJ's finding that the cited prior art does not anticipate the asserted claims of the '453 patent and does not render asserted claim 2 of the patent obvious. Respondents further challenged the ALJ's construction of the claim term "base configured to retain a body liquid therein" and the infringement finding based on that construction. Regarding the '267 patent, Respondents challenged the ALJ's construction of certain claim terms and the finding that the asserted claims

are not obvious in view of the cited prior art references. Respondents also sought review of the ALJ's finding that ResMed established the economic prong of the domestic industry requirement.

On September 3, 2014, the Commission investigative attorney ("IA") also filed a petition for review challenging the ALJ's construction of the claim term "gas washout vent" recited in the asserted claims of the '487 patent as well as the ALJ's infringement and invalidity findings based on that construction.[5] The IA also challenged the ALJ's construction of the claim term "retaining mechanism configured to secure the connecting structure to the CPAP apparatus" recited in the asserted claims of the '453 patent and the ALJ's invalidity finding based on that construction. That same day, complainant ResMed filed a contingent petition for review.[6] On September 11, 2014, the parties filed responses to the petitions for review.[7]

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 simultaneously 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

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[5] *See* Office of Unfair Import Investigations' Petition for Review of the Initial Determination ("IA Pet.").

[6] *See* The ResMed Complainants' Contingent Petition for Review ("ResMed Pet.").

[7] *See* Complainants' Response to Respondents' Petition for Review of Initial Determination (ResMed Rep.); Respondents' Opposition To ResMed's Contingent Petition For Review Of Initial Determination And Response To OUII's Petition For Review Of Initial Determination ("Resp. Rep."); Office of Unfair Import Investigations' Response to the Petitions for Review of the Initial Determination (IA Rep.).

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). In its notice of review, the Commission asked the parties to brief the following issue:

> The Commission has determined to revise the ALJ's construction of the claim limitation "a retaining mechanism" recited in the asserted claims of the '453 patent and strike the requirement that it requires an arrangement of moving parts. That is, the claim limitation "a retaining mechanism configured to secure the connecting structure to the CPAP apparatus" is construed 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." *See* ID at 124. Please discuss whether the REMstar device anticipates the asserted claims under the revised construction.

On October 31, 2014, the parties filed written submissions on the issues under review, remedy, the public interest, and bonding.[8] On November 7, 2014, the parties filed reply submissions.[9]

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[8] *See* Respondents' Brief in Response to Notice of Commission Determination to Review in Part a Final Initial Determination ("Resp. Br."); ResMed Complainants' Written Submission in Response to Commission Notice of Review ("ResMed Br.") Office of Unfair Import Investigations' Response to the Commission Question ("IA Br.").

[9] *See* Respondents' Reply Brief in Response to Notice of Commission Determination to Review in Part a Final Initial Determination; The ResMed Complainants' Response to Respondents' Brief in Response to Notice of Commission Determination to Review in Part a Final Initial Determination; Office of Unfair Import Investigations' Reply to the Private Parties' Responses to the Commission Question.

B. Patents and Technology at Issue

The technology at issue in this investigation generally relates to the field of continuous positive airway pressure ("CPAP") devices used to treat sleep-disordered breathing problems, particularly obstructive sleep apnea. *See* ID at 1.

The '527 patent describes nasal mask cushions for sealing masks to a patient's face during CPAP therapy. '527 patent (JX-1) at col. 1, ll. 23-25. These cushions are designed to reduce mask-to-face pressure and form a more effective seal for greater patient comfort and a reduction in the likelihood of skin irritation. *Id.* at col. 2, l. 34-col. 3, l. 44. ResMed owns the patent and has asserted independent claims 1, 9, and 89 and dependent claims 32 and 92 in this investigation.

Like the '527 patent, the '392 patent also describes design of a more comfortable nasal mask used to treat obstructive sleep apnea. '392 Patent (JX-5) at col. 2, l. 9-col. 3, l. 14. ResMed owns the patent and has asserted independent claim 19 and dependent claims 21, 29, 32, and 36 in this investigation.

The '267 patent describes a respiratory mask assembly for delivering breathable gas to a patient comprising a frame dimensioned to create an aperture to a nasal breathing cavity, and a swivelable, quick-release elbow assembly that interfaces with the aperture. *Id.* at Abstract. ResMed owns the patent and has asserted independent claims 32 and 53 and dependent claims 33 and 34 in this investigation.

The '487 patent describes a respiratory mask for CPAP treatment comprising a washout vent assembly consisting of at least twenty (20) holes configured to reduce noise and gas jetting. *Id.* at Abstract. ResMed owns the patent and has asserted independent claims 13 and 51 and

dependent claims 52 and 55 in this investigation.

The '060 patent describes a respiratory mask assembly for delivering breathable gas to a patient, which includes a frame that can attach to cushions to protect a patient's face, a rotatable elbow that carries gas in and out of the mask, a headgear assembly that can be used to secure the mask on the patient's head, and connectors that attach these components together. '060 patent, col. 8, l. 4-col. 9, l. 33; col. 9, ll. 34-67; col. 10, ll. 54-58; col. 17, l. 48-col. 18, l. 52; Figs 5 and 6. ResMed owns that patent and has asserted independent claim 30 and dependent claims 37 and 38 in this investigation.

The '883 patent describes a nasal pillows mask with prongs that are generally cone-shaped to provide an effective seal without irritating the nostrils, and a base for the pillows to rest on the upper lip. '883 patent at col. 2, l. 36-col. 3, l. 24; col. 10, l. 66-col. 11, l. 54. ResMed owns the patent and has asserted independent claims 1 and 31 and dependent claims 3, 5, 11, 28, 30, and 56 in this investigation.

The reissue '453 patent describes a humidifier for a CPAP apparatus that is adapted to prevent liquid from undesirably exiting an inlet of the humidifier. '453 patent (JX-8) at col. 1, ll. 53-56. ResMed owns the patent and has asserted dependent claims 2, 4, and 7 in this investigation.

C. Products at Issue

The accused products include masks and humidifiers for CPAP therapy to treat breathing problems such as sleep apnea. ID at 7 (citing Yerbury WS, CX-754C at 4-5, Q/A 18-21). For a complete list of accused products, see ID at 8-9.

II. ISSUES UNDER REVIEW

A. The '487 Patent

ResMed has asserted independent claims 13 and 51 and dependent claims 52 and 55 of the '487 patent in this investigation. Claim 13 of the '487 patent is illustrative and recites:

> 13. A respiratory mask comprising:
>
> a cushion;
>
> a breathable gas inlet to provide pressurized gas at a pressure elevated above atmospheric pressure to the patient via the cushion when the mask is in use; and
>
> at least one ***gas washout vent*** to allow gas to exit from the mask, wherein the ***washout vent*** has at least twenty through holes each having a length and a diameter that are selected to help eliminate or reduce noise while maintaining sufficient CO_2 washout during patient breathing, and
>
> wherein each of the holes has a first end positioned on an inside surface of the mask and a second end positioned on an outer surface of the mask, and wherein the first end has a diameter that is larger than a diameter of the second end.

'487 patent, col. 8, ll. 8-23 (claim 13) (emphasis added).

1. Construction of the Claim Term "Gas Washout Vent"

a. The ID

The ALJ construed the claim term "gas washout vent" to mean "vent for exhausting gas to the atmosphere," adopting the construction proposed by ResMed which purportedly applied the claim term's plain and ordinary meaning. ID at 71 (citing *Markman* Order No. 8, at 37). The ALJ rejected Respondents' and the IA's proposal to construe the claim term to mean "a vent comprising a thin air permeable membrane extending across an opening for exhausting gas to the atmosphere." *See* Markman Order at 30. The IA and Respondents argued that the patent disclosure limits the "gas washout vent" to the "thin air permeable membrane" disclosed in the patent and that the patentees disclaimed any other scope of the claim term. *Id.* at 31.

The ALJ, relying primarily on the doctrine of claim differentiation, adopted ResMed's proposed construction. *Id.* at 33. The ALJ found that references to membranes in dependent claims 34, 41, and 62 created a presumption that a membrane limitation is not present in the independent claims. *Id.* The ALJ explained that claims 34 and 41 depend from independent claims 26 and 39, respectively, and these independent claims refer to a "patient interface" with "a gas washout vent having a plurality of holes," "wherein each of the holes has a first end positioned on an inside surface of the mask and a second end positioned on an outer surface of the mask." *Id.* (citing '487 patent at col. 9, ll. 5-22; col. 10, ll. 8-24). The ALJ reasoned that claims 26 and 39 "already require that the gas washout vent be 'positioned' on the "surface of the mask" and that "[t]he only additional limitation added by claims 34 and 41 is that 'the vent is formed on a membrane.'" *Id.* (citing '487 patent at col. 9, ll. 47-49; col. 10, ll. 27-29). Likewise, the ALJ found that independent claim 56 claims "a gas washout vent having an array of through holes extending from an inside of the elbow to an outside of the elbow" and that "[t]he only additional limitation added by claim 62 is that "the plurality of holes is formed on a membrane." *Id.* (citing '487 patent at col. 11, ll. 31-50, 65-67). The ALJ concluded that because "the sole difference between these independent and dependent claims is the 'membrane' limitation that Respondents and the Staff are proposing to read into the 'gas washout vent' term, this is a situation where 'the doctrine of claim differentiation is at its strongest.'" *Id.* at 33-34 (citing *SanDisk Corp. v. Kingston Technology Co., Inc.*, 695 F.3d 1348, 1361 (Fed. Cir. 2012) (citing *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005)).

The ALJ recognized that the doctrine of claim differentiation only creates a rebuttable

presumption which "will be overcome by a contrary construction dictated by the written description or prosecution history." *Id.* at 34 (citing *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005); *Retractable Techs., Inc. v. Becton, Dickinson and Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011); *Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1368 (Fed. Cir. 2000). He found however, that the portions of the specification that the IA and Respondents pointed to as establishing a disclaimer of claim scope "are not sufficient to rebut the presumption of claim differentiation here." ID at 35. The ALJ therefore declined to restrict "gas washout vent" to a thin permeable membrane and assigned the claim term its plain and ordinary meaning.

b. Respondents' Petition

Respondents challenge the ALJ's claim construction and assert that the Commission has already construed the claim term in a related patent, U.S. Patent No. 7,159,587 ("the '587 patent"), which shares a common specification with the '487 patent. Resp. Pet. 5. Respondents point to the Commission's advisory opinion issued on August 11, 2014, in *Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof*, 337-TA-879 ("879 Advisory Opinion"). *Id.* at 6. Respondents observe that in the 879 Advisory Opinion, the Commission construed the claim term "gas washout vent portion" to mean "a vent comprising a thin air permeable membrane extending across an opening for exhausting gas to the atmosphere," adopting the construction proposed by Respondents and the IA. *Id.* Respondents note that the '487 patent is a continuation of the '587 patent at issue in the 879 Advisory Opinion and that the two patents have identical specifications in all relevant respects. *Id.* Thus, Respondents argue that the statements from the '587 patent that the Commission found limited gas washout vents to

those having a thin air permeable membrane are also present in the specification of the '487 patent. *Id.* Respondents assert that under controlling Federal Circuit precedent the same claim term must be accorded the same meaning across a family of patents. *Id.* at 10 (citing *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005); *In re Rambus Inc.*, 694 F.3d 42, 48 (Fed. Cir. 2012) ("unless otherwise compelled ... the same claim term in the same patent or related patents carries the same construed meaning")).

Respondents contend that the ALJ failed to construe the claim term "gas washout vent" based on the patent application as-filed, and instead relied on the doctrine of claim differentiation based upon dependent claims added after the '487 patent application had been filed. *Id.* at 6. According to Respondents, "the meaning of a claim term is determined as of the application's effective filing date, and subsequent actions or statements during prosecution may narrow, but may not broaden, the meaning conveyed by the application as filed." *Id.* at 6 (emphasis omitted), 11(citing *Retractable Techs.*, 653 F.3d at 1305; *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 541 (Fed. Cir. 1998) ("The doctrine of claim differentiation cannot broaden claims beyond the scope that is supported by the specification. . . . The presumption that separate claims have different scope 'is a guide, not a rigid rule.'").

c. The IA's Petition

The IA also filed a petition challenging the ALJ's construction of the claim term "gas washout vent" for the same reasons. IA Pet. at 5. The IA states that the Commission based its construction of the claim term in the 879 Advisory Opinion primarily on "ResMed's 'repeated' and 'clear and unmistakable' disavowal of gas washout vents that do not contain membranes." *Id.* at 6 (citing 879 Advisory Op. at 25).

The IA notes that the Commission preliminarily suggested in the 879 Advisory Opinion that its construction of "gas washout vent" did not appear inconsistent with the ALJ's construction in this investigation, but stated that "the *Markman* Order in the 890 investigation is an interlocutory order that has not been subject to a Commission review." *Id.* at 6-7. The IA asserts that "the Commission now has the opportunity to review the full record in this investigation, in light of its 879 advisory opinion," and argues that the Commission should assign the claim terms the same meaning because under existing law, the same claim term "in the same or related patents carries the same construed meaning" "unless otherwise compelled." *Id.* at 7 (citing *In re Rambus*, 694 F.3d at 48; *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003)).

The IA contends that the ALJ erred by not giving ResMed's disclaimers the same weight as the Commission did. *Id.* (citing ID at 33-36). In tabular form the IA compares statements in the specification of '587 patent that the Commission found resulted in a disclaimer of claim scope for the claim term "gas washout vent portion" to identical statements in the '487 patent. *See* IA Pet. at 8-12. Against this background, the IA contends that as the Commission found in the 879 Advisory opinion, ResMed disclaimed gas washout vents that do not have membranes. *Id.* at 12-13. The IA argues that the ALJ's reliance on the doctrine of claim differentiation is improper because the "the doctrine of claim differentiation cannot broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence." *Id.* at 12 (citing *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998)).

d. ResMed's Response

ResMed supports the ALJ's construction of the claim term "gas washout vent" and argues that "nothing in the specification dictates a construction for 'gas washout vent' that departs from its plain and ordinary meaning, which is 'vent for exhausting gas to the atmosphere.'" ResMed Rep. at 7 (citing *Markman* Order No. 8 at 30-37). ResMed accuses Respondents of concentrating on selected portions of the Commission's findings in the 879 Advisory Opinion, while omitting portions where the Commission "stat[ed] that 'the presiding ALJ's construction [in the 879 Advisory Opinion] is not inconsistent with another ALJ's construction of the same term in a related child patent asserted in Inv. No. 337-TA-890.'" *Id.* at 7-8 (citing Advisory Opinion at 30) (emphasis omitted). ResMed observes that the "Commission went on to state that 'the construction in the 890 investigation was based on claim differentiation principles and different record evidence, which are not applicable here.'" *Id.* at 3.

ResMed further accuses Respondents of ignoring portions of the intrinsic record that support the ALJ's construction, pointing out that "independent claims describe the 'gas washout vent' assembly as a vent that "allo[w]s gas to exit from the mask . . . ." *Id.* (citing '487 patent at col. 8, ll. 13-14 (claim 13); col. 9, ll. 12-13 (claim 26) ("allow gas to be exhausted from the breathing cavity"); col. 11, ll. 8-9 (claim 51) ("allow gas to exit from the mask"). ResMed also points to the following statements in the specification for support: that the "present invention provides a vent assembly suitable for use with a respiratory mask of the type used in CPAP treatment," ('487 patent, abstract); that the assembly "vent[s] exhaled gases to the atmosphere" ('487 patent at col. 1, ll. 62-63); and that "[t]he mask or nasal prongs or nasal pillows incorporates, or has in close proximity, the gas washout vent for venting exhaled gases to the

atmosphere" ('487 patent at col. 6, l. 66-col. 7, l. 2.). *Id.* at 8.

ResMed argues that the '487 patent does not teach that the "gas washout vent" is limited to "a thin air permeable membrane extending across an opening" but that the inventors drafted some claims with a membrane limitation, and others without. *Id.* ResMed points to independent claim 26 and argues that it makes no mention of a membrane. *Id.* ResMed explains that claim 34, which depends from claim 26, adds that requirement, requiring that the vent "is formed on a membrane that is mounted to the patient interface." *Id.* (citing '487 patent at col.9, ll.47-49 (emphasis omitted). ResMed argues that "[i]ndependent claims 39 and 51 and their respective dependent claims 41 and 62 have a similar structure" and contends that "when the inventors wished to require the gas washout vent to include a 'membrane,' they specifically said so." *Id.* ResMed concludes that "[a]s a result, the term 'gas washout vent' cannot require a membrane without rendering this other claim language redundant." *Id.* (citing *Phillips*, 415 F.3d at 1315 ("The presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.").

ResMed takes issue with Respondents' argument that "there are other limitations in dependent claims 34, 41, and 62 that differentiate them from the independent claims." ResMed explains that "independent claim 56 requires that the gas washout vent be on the elbow of the patient interface, and dependent claim 62 adds "wherein the plurality of holes is formed on a membrane attached to the elbow" and that "the only limitation added in dependent claim 62 is that the gas washout vent must be formed on a membrane." *Id.* (citing '487 patent at col. 11, ll. 39-41 (claim 56); col. 11, ll. 65-67 (claim 62); IA Pet. at 15. ResMed makes the same argument regarding independent claim 39 and dependent claim 41. ResMed Rep. at 9.

ResMed further argues that Respondents' proposed construction is inconsistent with the testimony of inventor Joanne Drew, who testified that "putting vent holes directly in the frame, as opposed to on an air permeable membrane, was part of the concept of the invention of the '487 patent. *Id.* at 11 (citing Drew Hearing Tr. at 193:4-6.) ResMed asserts that Respondents' argument that the claims of the '487 patent as filed did not contain the claims on which the ALJ's claim differentiation opinion was based should be rejected out of hand "because Respondents cite nothing in the record to support it." *Id.* at 11. According to ResMed, "the '487 application as filed did contain claims that support the ALJ's decision," noting that "while independent claims 15, 29, and 34 do not require an air permeable membrane, independent claim 24, as filed on April 28, 2006 (the filing date of the '487 patent) expressly requires the vent to have an 'air permeable portion.'" *Id.* (citing JX-0012 at 29-34).

ResMed states that "if the Commission chooses to alter the ALJ's construction of "gas washout vent," it must also reverse the ALJ's finding that the claims of the '487 patent are invalid as anticipated or obvious over the Kwok PCT because "there is no evidence in the record that the Kwok PCT discloses a gas washout vent with a "thin air permeable membrane." *Id.* at 12.

e. Analysis

The Commission determined to review the ALJ's construction of the claim term "gas washout vent" to mean "vent for exhausting gas to the atmosphere," and simultaneously construed the limitation to mean "a vent comprising a thin air permeable membrane extending across an opening for exhausting gas to the atmosphere." *See* 79 *Fed. Reg.* 63163-65 (Oct. 22, 2014). Significantly, the Commission has already construed the exact claim limitation in a

related patent, the '587 patent, which shares a common specification with the '487 patent in all relevant respects. 879 Advisory Op. at 25-28. Under Federal Circuit precedent the same claim term must have the same meaning across a family of patents. *In re Rambus*, 694 F.3d at 48 ("unless otherwise compelled ... the same claim term in the same patent or related patents carries the same construed meaning.").

In its 879 Advisory Opinion, the Commission affirmed the ALJ's construction of the claim limitation "gas washout vent portion" to mean "a vent comprising a thin air permeable membrane extending across an opening for exhausting gas to the atmosphere," finding that the patentees made "repeated" and "clear and unmistakable" disavowal of gas washout vents that do not contain membranes. 879 Advisory Op. at 25.

The ALJ purportedly assigned the claim term its plain and ordinary meaning. Order No. 8, *Markman* Order, at 37. However, giving a claim term its plain and ordinary meaning is appropriate only if the patentees have not disclaimed claim scope. *See SciMed Life Sys. Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001) ("Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question."). As detailed in the IA's petition, the same statements the Commission found resulted in a disclaimer of claim scope in the '587 patent exist in the '487 patent at issue in this investigation. The Commission made a determination that those passages evinced disclaimer of claim scope in the '587 patent and reaches the same determination here. *NTP, Inc.*, 418 F.3d at 1293.

In this investigation, the ALJ relied on the doctrine of claim differentiation to overcome the statements of disavowal in the patent. *See* ID at 33. Thus, a question remains as to whether the doctrine of claim differentiation can be used to overcome an express disavowal. Under Federal Circuit law, it cannot. "The doctrine of claim differentiation cannot broaden claims beyond the scope that is supported by the specification." *ATD Corp.*, 159 F.3d at 541 ("The presumption that separate claims have different scope 'is a guide, not a rigid rule"); *Multiform Desiccants*, 133 F.3d at 1480 ("the doctrine of claim differentiation cannot broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence). In addition, the Federal Circuit has made clear that claim differentiation only creates a rebuttable presumption, which "will be overcome by a contrary construction dictated by the written description or prosecution history." *See, e.g.*, *Seachange*, 413 F.3d at 1369 (Fed. Cir. 2005); *Retractable Techs.*, 653 F.3d at 1305; *Kraft Foods*, 203 F.3d at 1368.

The ALJ found that "the evidence in the intrinsic record is not as strong" to overcome the doctrine of claim differentiation. *Markman* Order No. 8 at 34. That is not the proper inquiry. The inquiry is not whether the intrinsic evidence is strong enough to overcome claim differentiation but whether claim differentiation can be used to negate express statements of disavowal in a patent specification. Here, the Commission has found the evidence strong enough to establish disclaimer of clam scope. *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1381 (Fed Cir. 2006) (holding that claim differentiation cannot contradict the correct meaning of the claim as defined by the "overall context of this invention and this field of art as described in the specification").

In addition, we agree with Respondents that each of dependent claims 34, 41 and 62 define more specifically how and where the vent is formed and contain additional limitations not found in the independent claims. As ResMed points out, the claims recite in their entirety:

> 34. A respiratory mask according to claim 26, wherein the vent is formed on a membrane ***that is mounted to the patient interface***.
>
> 41. A respiratory mask according to claim 39, wherein the vent is formed on a membrane ***that is mounted on the patient interface***.
>
> 62. A respiratory mask according to claim 56, wherein the plurality of holes is formed on a membrane ***attached to the elbow***.

'487 patent at col. 9, ll. 10 and 11 (emphasis added).

2. ResMed's Motion to Withdraw the '487 Patent or Alternatively to Find No Violation with Regard to the '487 Patent Based on the Technical Prong of Domestic Industry

a. ResMed's Motion

On November 7, 2014, ResMed moved to terminate the investigation as to the '487 patent.[10] ResMed states that the "ALJ's findings regarding infringement, validity and the technical prong of domestic industry are not supported under the claim construction adopted by the Commission in its Notice of Review." ResMed Mot. at 1. ResMed contends, however, that "because the requested relief sought by ResMed—exclusion of Respondents' infringing products—will not be impacted by the outcome of the Investigation regarding the '487 patent, there is good cause to terminate the investigation as to the '487 patent rather than consume additional resources of the Commission, the ALJ, the Staff, and the private parties by remanding the Investigation for further proceedings." *Id.* ResMed thus moves to withdraw the '487 patent and states that "pursuant to 210.21(a)(1), ResMed represents that there are no agreements,

[10] *See* The ResMed Complainants' Motion to Withdraw the '487 Patent or Alternatively to Find No Violation with Regard to the '487 Patent Based on the Technical Prong of Domestic Industry. ("ResMed Mot.").

written or oral, express or implied, between the parties concerning the subject matter of this Investigation." *Id.* As an alternative, ResMed asserts that "because the private parties agree that the products ResMed identified for the domestic industry requirement for the '487 patent do not meet the limitation as construed by the Commission, ResMed would not contest a finding of no violation on the '487 patent based on the technical prong of domestic industry." *Id.*

Regarding infringement and invalidity, ResMed argues that "[t]here is no expert testimony applying the Commission's construction to the Original iVolve N2 mask, or any other mask," and so a remand would be required to address those issues. *Id.* at 5. With respect to the technical prong for domestic industry, however, ResMed states that "the parties agree that the ResMed products identified for the '487 patent do not have a 'thin air permeable membrane' as required by the Commission's construction." *Id.* ResMed observes that "the ALJ's finding of no violation of Section 337 with respect to the '487 patent has been effectively vacated by the Commission's new construction, which will require a remand and a new initial determination with respect to the '487 patent." ResMed Mot. at 6-7.

ResMed requests that the Commission grant its motion to withdraw its allegations relating to the '487 patent, "rather than force the private parties, the ALJ, the Staff, and the Commission to undergo a costly remand proceeding that will have virtually no impact on the outcome of this Investigation." *Id.* ResMed states that "[d]ue to the unique facts of this Investigation, and pursuant to Commission Rule 201.4(b), ResMed additionally respectfully requests the Commission to waive the requirement of Commission Rule 210.21(a) that a motion to withdraw be filed 'at any time prior to the issuance of an initial determination on violation of section 337.'" *Id.* As noted above, ResMed states that "should the Commission decide not to

allow ResMed to withdraw its allegations regarding the '487 patent at this stage, ResMed respectfully suggests that the Commission can find no violation of the '487 patent based on a finding of lack of proof of the technical prong of the domestic industry requirement." *Id.*

b. Respondents' Response

Respondents argue that the Commission should deny ResMed's motion to withdraw its allegations pertaining to the '487 patent at this late stage. *See* Respondents' Response to ResMed's Motion to Withdraw the '487 Patent ("Resp. Mot. Rep."). According to Respondents, "[b]ased on the evidence of record, Respondents are entitled to a decision finding that the accused products do not infringe any of the asserted claims, that the asserted claims are invalid, and that there is no domestic industry for the '487 patent." *Id.* at 1. Respondents argue that "ResMed's motion to withdraw the '487 patent from this investigation is an improper attempt to avoid an adverse ruling on infringement and invalidity based on the Commission's construction of the '487 patent." *Id.*

Respondents argue that under Commission rule 19 C.F.R. § 210.21(a)(2) motions to withdraw may be filed only before the final ID issues, and not after issuance of the final ID. *Id.* at 5-6. Respondents further argue that the record evidence establishes that the accused products do not infringe under the Commission's construction and demonstrate that the asserted claims of the 487 patent are invalid. *Id.* at 8-11.

Respondents agree with ResMed that ResMed's domestic industry products do not meet the "gas washout vent" limitation as construed by the Commission and that the Commission should find that ResMed failed to meet the technical prong of the domestic industry requirement with respect to the '487 patent. *Id.* at 12.

c. IA's Response

The IA notes that ResMed admits that under the Commission's construction of the "gas washout vent" limitation, a finding of infringement would not be possible based on the current record, and that a finding that ResMed's domestic industry products practice the '487 patent would not be possible under the Commission's claim construction even if the record were re-opened on remand to take further evidence.[11] The IA agrees that "in order to grant ResMed the relief it seeks, the Commission would be obligated to waive its Rule 210.21(a)(1), which requires that a motion to withdraw be made before an initial determination issues." *Id.* (citing 19 C.F.R. § 201.4(b) and *Align Tech., Inc. v. Int'l Trade Comm'n*, --F.3d -- 2014 WL 5350419, at *8 (Fed. Cir. 2014) ("Rule 201.4(b) gives [the Commission] broad authority to waive, suspend, or even amend its rules"). The IA further agrees "with ResMed that in this circumstance, such an exception would be appropriate." *Id.* The IA submits that the most efficient way to dispose of this matter is to grant ResMed's motion to withdraw the patent and find the remainder of the motion moot. *Id.* In the alternative, the IA does not oppose ResMed's request that the Commission determine that its products do not satisfy the technical prong of the domestic industry requirement. *Id.*

d. Analysis

The Commission has determined to dispose of the '487 patent with a finding of no violation based upon ResMed's admitted failure to establish the technical prong for domestic industry under the Commission's construction of "gas washout vent." The Commission takes no

[11] *See* Office of Unfair Import Investigations' Response to ResMed's Motion to Withdraw the '487 Patent or Alternatively to Find No Violation with Regard to the '487 Patent Based on the Technical Prong of Domestic Industry.

position on infringement and validity of the patent.

ResMed, supported by the IA, moves to withdraw the '487 patent. However, as both ResMed and the IA note, the Commission would have to waive its rules to allow ResMed to withdraw the patent at this late stage. Commission rules permit withdrawal of allegations only prior to issuance of the final ID. *See* Commission Rule 210.21(a)(1). While the Commission can waive its rules to permit withdrawal of the '487 patent in this investigation after issuance of the final ID, the Commission declines to do so here.

ResMed states that "because the private parties agree that the products ResMed identified for the domestic industry requirement for the '487 patent do not meet the limitation [*i.e.*, "gas washout vent"] as construed by the Commission, ResMed would not contest a finding of no violation on the '487 patent based on the technical prong of domestic industry." ResMed Mot. at 1. Respondents agree with ResMed that ResMed's domestic industry products do not meet the "gas washout vent" limitation as construed by the Commission and that the Commission should find that ResMed failed to meet the technical prong of the domestic industry requirement with respect to the '487 patent. The IA "does not oppose ResMed's request that the Commission determine that its products do not satisfy the technical prong of the domestic industry requirement due to a failure of proof." That is, all the parties agree that there is no violation of section 337 with respect to the '487 patent because ResMed failed to show the existence of a domestic industry that practices the patent.

Respondents argue that the record evidence supports a finding that the accused products are not infringed and that the asserted claims are invalid. However, ResMed and the IA point out that, because the investigation proceeded under the ALJ's construction, there is no expert

testimony or other evidence applying the Commission's construction to the accused products and so a remand would be required to address infringement and validity. Given the posture of this investigation and the positions of the parties, a remand would not be an appropriate use of public and private resources.

B. The '453 Patent

ResMed has asserted the following claims of the '453 patent in this investigation: claims 2, 4, and 7, which depend from independent claim 1. Claim 1 recites:

> 1. A humidifier assembly for a CPAP apparatus, comprising
>
> a humidifier including
>
> a base configured to retain a body of liquid therein, at least a portion of the base being constructed of a heat conducting material,
>
> a top cover, and
>
> a seal disposed between the top cover and the base; and
>
> a connecting structure configured to connect between the CPAP apparatus and humidifier and allow communication of an outlet of the CPAP apparatus with an inlet of the humidifier, the connecting structure including
>
> a housing providing a base portion to support the humidifier thereon, and
>
> **a retaining mechanism configured to secure the connecting structure to the CPAP apparatus,**
>
> wherein the base portion includes a heating element in contact with the heat conducting material of the base of the humidifier.

'453 patent, col. 11, ll. 42-56 (claim 1) (emphasis added).

1. Construction of the Claim Term "A Retaining Mechanism Configured to Secure the Connecting Structure to the CPAP Apparatus"

a. The ID

The ALJ construed the claim term "retaining mechanism configured to secure" to require "an arrangement of moving parts for holding in place a CPAP apparatus that is configured to attach the connecting structure to the CPAP apparatus." ID at 124-25. In construing the claim

term, the ALJ began with a presumption that the claim words "secure" and "retaining" should have different meanings. *Id.* at 114 (citing *Chicago Bd. Options Exchange, Inc. v. Int'l Securities Exchange, LLC*, 677 F.3d 1361, 1369 (Fed. Cir. 2012) (observing that there is a presumption "that different claim terms have different meanings"). The ALJ found that the specification "describes two structures for connecting the humidifier to the connecting structure: a 'retaining portion **108**' and a 'securing mechanism **122**;' and one structure for connecting the CPAP apparatus to the connecting structure: a 'retaining mechanism **140**.'" *Id.* at 118. The ALJ found "it notable that these structures are not all designated as 'retaining mechanisms' but are instead uniquely identified with labels that reflect their specific functions." *Id.* The ALJ explained that "[t]he two structures on the humidifier side perform distinct and complementary functions: the "retaining portion **108**" holds the humidifier in the proper position and the "securing mechanism **122**" locks it in that position. *Id.* (citing '453 patent (JX-8) at col. 9, ll. 32-35; col. 9, l. 66-col. 10, l. 1).

The ALJ further explained that the "retaining portion alone would not provide a secure lock, and the securing mechanism alone would not provide the support necessary to hold the humidifier in position." *Id.* According to the ALJ, "[t]he 'retaining mechanism **140**' on the CPAP side of the connecting structure comprises structures that perform both of these functions, including apertures that hold the CPAP apparatus in place by receiving prongs or tabs (the 'retaining' function) and locking members to lock the CPAP apparatus in position (the "securing" function)." *Id.* (citing '453 patent (JX-8) at col. 10, ll. 9-26). Based on the disclosure of the different structures, the ALJ found that use of the term "retaining mechanism" in conjunction with the phrase "secure … to" suggests specific limitations in the context of the other "retaining"

and "securing" structures in the specification. *Id.* at 118-19. Accordingly, the ALJ concluded that the plain and ordinary meaning of "retaining mechanism configured to secure the connecting structure to the CPAP apparatus" in claim 1 of the '453 patent requires "an arrangement of moving parts for holding in place the CPAP apparatus that is configured to attach the connecting structure to the CPAP apparatus." *Id.*

b. Commission Review

The Commission determined to review the ALJ's construction of the claim limitation "a retaining mechanism configured to secure the connecting structure to the CPAP apparatus" and simultaneously construed the limitation 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" (*See* 79 *Fed. Reg.* 63163-65 (Oct. 22, 2014)), striking the ID's requirement that the claimed "retaining mechanism" must include an arrangement of moving parts. *See* ID at 124-25.

The ALJ based his construction largely on his view that the claimed "retaining mechanism" must contain moving parts in order to distinguish it from the disclosed "retaining portion" and "securing mechanism." ID at 123. The ALJ sought to give the claim terms "secure" and "retaining" different meanings in deference to the Federal Circuit's statement "that different claim terms have different meanings." *Id.* (citing *Chicago Bd. Options Exchange, Inc.*, 677 F.3d at 1369). However, in seeking to pay heed to the Federal Circuit, the ALJ improperly limited the claim term to a disclosed embodiment, even though the specification makes clear that the "securing mechanism" only *may* include moving parts. The patent, discussing Figure 17 of the '453 patent, which depicts the only example in the specification of the "retaining mechanism **140** to secure the connecting structure **100** to the CPAP apparatus," states that

> The rearward side of the connecting structure **100** provides a retaining mechanism **140** to secure the connecting structure **100** to the CPAP apparatus. It is contemplated that the retaining mechanism **140** may include a series of apertures **142** within the rearward portion of the housing **102**. The apertures **142** may receive therein, for example, prongs or tabs (not shown) provided by the CPAP apparatus."

'453 patent, col. 10, ll. 7-13 (emphasis added). That is, while the "retaining mechanism" *may* include moving parts, the "retaining mechanism" is not *required* to include moving parts. *Liebel-Flarsheim Co*, 358 F.3d at 905-06 ("[T]his court has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.").

The extrinsic evidence provides additional support. Respondents' expert testified that "retaining mechanism" has no special meaning with regard to CPAP devices that requires moving parts and ResMed's expert testified that "retaining mechanism" does not require moving parts in all cases. Bordewick Tr. 790:3-12; 1291; Sheehan Tr. 17-1292:3 ("I'm not requiring movement in every situation.").

The IA noted that the three elements, "retaining portion," "securing mechanism," and "retaining mechanism" have distinct features that distinguish them without resorting to narrowing the construction of "retaining mechanism" to require moving parts. *See* IA Rep. at 20-21. For example, the patent discussing Figure 15, states that the "retaining portion **108**" "extends generally parallel to the base portion **106** and is spaced above the base portion." '453 patent col. 9, ll. 34-38. In addition, the patent also describes a "securing mechanism **122**" in Figure 16 that "includes a resiliently biased pull member **124** that includes one or more locking lugs **126** extending generally downwardly therefrom." '453 patent col. 9, ll. 45-47. That is, the patent disclosure provides descriptions for the "retaining portion," "securing mechanism," and

"retaining mechanism" that do not require the retaining mechanism to include moving parts. The mere fact that the "retaining portion **108**" and "securing mechanism **122**" connect the humidifier to the connecting structure does not mean that the "retaining mechanism **140**," which connects the CPAP apparatus to the connecting structure must perform the functions of the "securing mechanism" and "retaining mechanism" in the same manner. *See* ID at 118.

Accordingly the Commission determined to review the ID's construction and struck its requirement that the claimed "retaining mechanism" must include an arrangement of moving parts.

2. Whether the REMstar Device Anticipates or Renders Obvious the Asserted Claims of the '453 Patent

a. The ID

The ALJ concluded that the REMstar device does not anticipate the "retaining mechanism" limitation of claim 1 of the '453 Patent. ID at 125. The ALJ based his conclusion on the finding that "[t]he pegs on the REMstar humidifier platform do not have moving parts and are not a 'mechanism' within the context of the '453 Patent." *Id.* The ALJ further found that "while the REMstar humidifier platform holds the REMstar CPAP apparatus in place, it does not attach these components together because the apparatus can be removed from the platform by simply lifting upwards." *Id.* The ALJ explained that "[t]he connecting apparatus of the REMstar humidifier platform is thus similar to the 'retaining portion' of the '453 Patent specification, which only secures the device 'in position,'" noting his finding that the '453 patent uses different terms to describe a "retaining portion," a "securing mechanism," and the claimed "retaining mechanism to secure the connecting structure to the CPAP apparatus." *Id.*

b. Commission Review

In light of the revised claim construction, the Commission determined to review the ALJ's finding that the prior art REMstar device does not anticipate the asserted claims of the '453 patent. As noted above, the Commission asked the parties to brief the following issue:

> The Commission has determined to revise the ALJ's construction of the claim limitation "a retaining mechanism" recited in the asserted claims of the '453 patent and strike the requirement that it requires an arrangement of moving parts. That is, the claim limitation "a retaining mechanism configured to secure the connecting structure to the CPAP apparatus" is construed 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." *See* ID at 124. Please discuss whether the REMstar device anticipates the asserted claims under the revised construction.

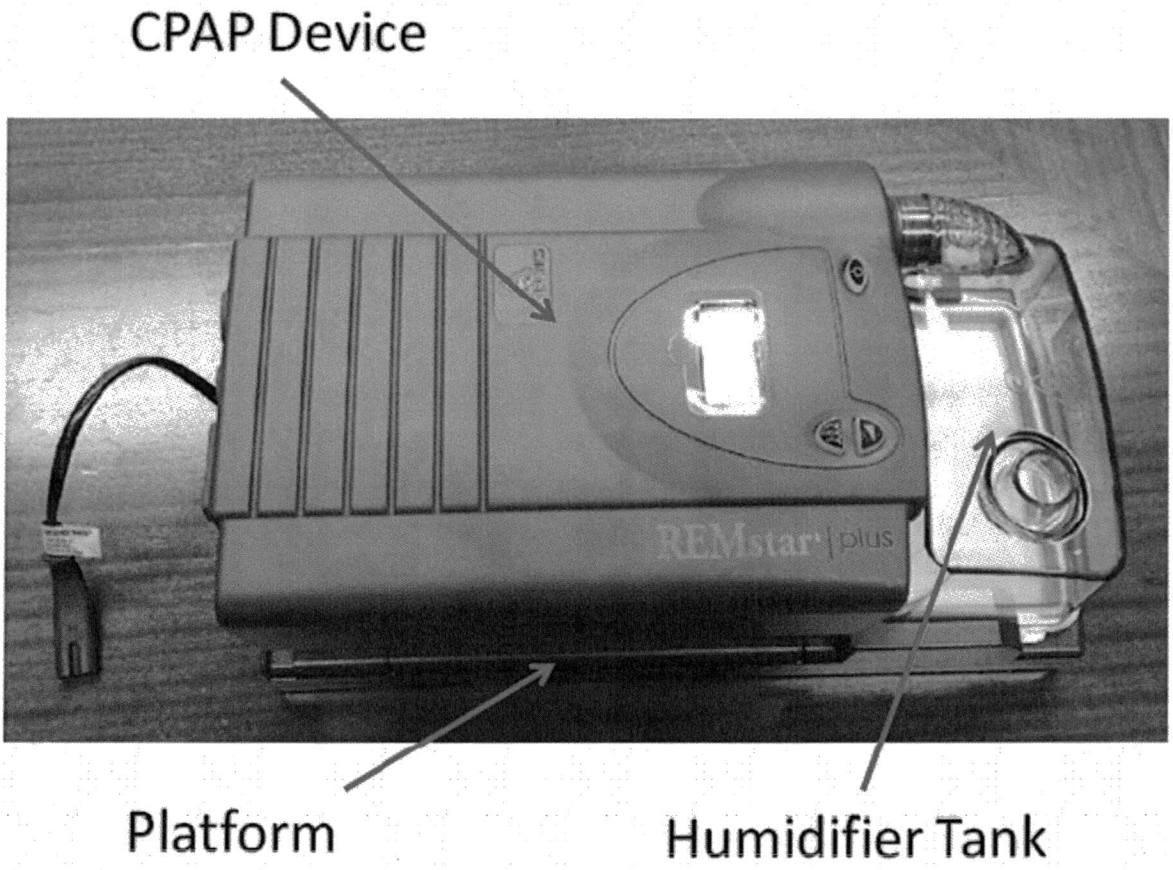
i. Respondents' Response

Respondents note that the only limitation of claims 1, 2, 4 and 7 that the ALJ found not anticipated by the REMstar device is the "retaining mechanism configured to secure" the connecting structure to the CPAP. Resp. Br. at 8 (citing ID at 127). Respondents argue that thus if the REMstar device has a "retaining mechanism" under the Commission's construction then the asserted claims are anticipated by the REMstar device.[12] *Id.*

Respondents contend that the REMstar device has a "retaining mechanism" under the Commission's construction because "[t]he platform and CPAP of the REMstar device have peg and apertures, as well as interlocking shaped parts that fit together like a puzzle" and that "[t]hese configurations not only attach the CPAP and platform of the REMstar device in normal

[12] The Commission notes that ResMed did not petition for review of the ALJ's finding that asserted claims 1, 4, and 7 of the '453 patent are anticipated by Schatzl German Patent Application DE 199 36 499 A1. *See* ID at 131-132. Thus, the only claim of the '453 patent that remains in the investigation is dependent claim 2.

use, but even keep the CPAP attached to the platform when the REMstar device is tipped at significant angles." *Id.* Respondents assert that the undisputed evidence demonstrates that the "REMstar device will keep the CPAP attached to the humidifier assembly during treatment." Resp. Pet. at 43. Respondents explain that the REMstar device has three components (shown below), a humidifier, a platform, and a CPAP flow generator, and that the platform is the connecting structure. Resp. Br. at 11 (citing Bordewick DWS, RX-2aC at Q/A 61-63). According to Respondents, "the platform and CPAP apparatus have parts 'configured to attach the connecting structure [i.e., the platform] to the CPAP apparatus.'" *Id.*



Specifically, Respondents argue that the CPAP is attached to the platform of the REMstar

device by pegs on the platform that fit within corresponding holes in the bottom of the CPAP apparatus that prevent the outlet of the CPAP and the inlet to the humidifier from becoming detached or moving out of alignment with one another." *Id.* at 12 (citing Bordewick DWS, RX-2aC at Q/A 74; Bordewick, Tr. 789:13-16; 801:10-802:4). Respondents contend that "[i]f the CPAP apparatus is bumped in use, these pegs prevent the CPAP from moving so that the connection between the CPAP and humidifier is preserved and air flow is not interrupted." *Id.* (citing Bordewick, Tr. 802:5-12; Goodman, Tr. 769:24770:6 ("the purpose of the pegs are [*sic*] to hold the CPAP exactly in place on the humidifier stand, which is vital to the assured treatment during the night."). Respondents add that "the CPAP apparatus and connecting structure of the REMstar device are shaped to fit together like puzzle pieces" and that the "shape further serves to hold the CPAP apparatus in proper position on the connecting structure so that the humidifier inlet and CPAP apparatus outlet remain connected and air flow is not interrupted during treatment." *Id.* (citing Bordewick DWS, RX-2aC at Q/A 70, 74-78).

Respondents argue that witnesses for ResMed testified that because of the "pegs/holes and complementary shapes of the CPAP and platform of the REMstar device, the assembled REMstar device is stably secured together in normal use. *Id.* at 13 (citing Sheehan RWS, CX-805aC at Q/A 39-42; Sheehan Tr. 1286:15-1287:8; Virr Tr. 164:8-19). Respondents state that "[t]he fact that the CPAP can be removed by lifting up when not in use has no bearing on whether it is secure enough to maintain the connection between the CPAP and humidifier" because "claim 1 does not require that the retaining mechanism lock the CPAP to the connecting structure." Resp. Pet. at 44; Resp. Br. at 17-18. Respondents assert that the claimed "retaining mechanism configured to secure the CPAP to the connecting structure" is met by "one which can

hold the CPAP sufficiently securely that the humidifier inlet and CPAP outlet remain aligned." *Id.* Respondents state that "[t]he pegs and shape of the REMstar device additionally keep the CPAP outlet and humidifier inlet securely aligned and connected during treatment" and as such constitute a "retaining mechanism configured to secure the connecting structure to the CPAP apparatus" as required by claim 1. *Id.* at 45.

ii. The IA's Response

The IA argues that the REMStar device anticipates claim 1 because it has "one or more parts for holding in place the CPAP apparatus that is configured to attach the connecting structure to the CPAP apparatus." IA Br. at 3. The IA contends that "the REMStar's base (the 'connecting structure') has two pegs that protrude from the end of the base opposite from the humidifier's water chamber, and that the base of the REMStar CPAP has corresponding holes which fit over the two pegs. *Id.* at 3-4 (citing RX-002aC (Bordewick WS) at Q/A 74, *citing* RDX-0022 (from RX-802 (showing RPX-079)) and RDX-0023 (from RX-790 (showing RPX-081)); ID at 104-05, *citing* RX-210 (REMStar User Manual) at 3-4; *See* RX-002aC (Bordewick WS) at Q/A 74. The IA contends that the pegs and holes are configured to hold the CPAP in place. *Id.* (citing Bordewick Tr. at 1015:24-1016:9) (testifying that the pegs help to constrain "lateral left to right movement of the CPAP relative to the connecting structure, and the rearward lateral movement of the CPAP relative to the connecting structure."). The IA further points to the testimony of John Goodman, the President and CEO of U.S. Expediters (a seller of the REMStar device), who testified that "the purpose of the pegs [on the REMStar] are to hold the CPAP exactly in place on the humidifier stand, which is vital to the assured treatment during the night. And it makes it also sure that the patient, when they're thinking about other things and

ready to go to sleep, would be able to hook up the humidifier easily." Hearing Tr. at 769:24-770-6; RX-08 (Goodman WS) at Q/A 7-15, 164-66.

The IA also argues that the "REMStar's base has cutout geometry next to where the humidifier's water chamber is placed, which "fit[s] like a puzzle piece into a correspondingly shaped portion of the CPAP unit." *Id.* at 5 (citing RX-002aC (Bordewick WS) at Q/A 75.); RDX-024 (from RX-119 (RPX-79)) and RDX-025 (from RX-0116 (RPX-0079 and RPX-0081). The IA notes the testimony of Respondents' expert that "the negative and positive geometry of connecting structure and CPAP "interlock[] from the front of the CPAP at this point and renders the CPAP and connecting structure secure with one another in this lateral position, forward, backward, side to side." *Id.* (citing Bordewick Tr. 801:10-802:4 (Bordewick). The IA adds that "[t]hus, the geometry on the base, and the corresponding negative geometry on the CPAP, are parts that are configured to hold the CPAP in place." *Id.* The IA further argues that "the REMStar's humidifier chamber also helps to hold the CPAP in place. *Id.* at 6 (citing Bordewick Tr. at 1017:2-10 ("You would be adding an additional stability element with the coupling of the inlet of the humidifier chamber to the outlet of the CPAP. And so you would get some constrained movement relative to the forward position and side to side, left to right, lateral, and vertical movement."). The IA concludes that "the clear and convincing evidence showed that the REMStar has several parts, both on the base and on the CPAP itself, that hold the CPAP apparatus in place." *Id.* at 7.

iii. ResMed's Response

ResMed argues that "[t]here is no dispute that the pegs and shaped portion of the REMstar platform do not 'attach' the CPAP device to the platform" but that "the pegs and cutout

serve only to loosely position the CPAP device on the docking station in the horizontal plane." ResMed Br. at 9 (citing Sheehan Hearing Tr. at 1286:15-1287:4; Bordewick Hearing Tr. at 917:17-918:6, 919:3-18, 948:17-25, 951:1-23; Sheehan Hearing Tr. at 1237:16-1238:2; CX-0805aC at 6-7, Q/A 39-40; Virr Hearing Tr. at 164:8-19). ResMed explains that "[w]hen the REMstar CPAP device is placed on top of the platform, the round holes and shaped portion on the bottom of the CPAP device align with the pegs and shaped portion of the platform" and that "the round holes in the bottom of the REMstar CPAP device have a larger diameter than the pegs of the REMstar platform." *Id.* (citing RPX-0079; RPX-0081). ResMed states that consequently, "when the CPAP is in place on the platform, the pegs fit loosely in the holes and the CPAP can easily be displaced by jostling." *Id.* (citing Virr Hearing Tr. at 164:8-19; Hearing Tr. (Sheehan) at 1286:15- 1287:4; Hearing Tr. (Bordewick) at 917:17-918:6, 919:3-18, 948:17-25, 951:1-23; *see also* Hearing Tr. (Sheehan) at 1237:17-1238:2; Hearing Tr. at 1092:19-1093:5.) ResMed adds that "the CPAP device can be removed entirely simply by lifting the CPAP device up from the platform" and that "the corporate representative from Respironics—the third-party manufacturer of the REMstar device—testified that 'gravity' is the only thing keeping the REMstar CPAP device on the platform." *Id.* (citing JX-0035C at 206:1-3). ResMed adds that "[t]he pegs of the REMstar platform do not interact with the holes on the bottom of the REMstar CPAP device in a way that prevents removal: there is no press fit or friction fit between the pegs and the apertures—the fit is loose" and that there is no locking mechanism to hold the CPAP securely in place. *Id.* (citing Sheehan Hearing Tr. 1286:15-1287:4; Hearing Tr. 1094:5-17; *see also* Hearing Tr. (Virr) 181:5-12.)

ResMed further argues that the claim language requires "more from the retaining

mechanism than just aligning the CPAP apparatus with the humidifier," requiring that the retaining mechanism "***secure*** the CPAP ***to*** the connecting structure." *Id.* According to ResMed, the plain and ordinary meaning of "secure to" is that two objects are attached to or fastened to each other, and that in normal use, a person would not use the term "secured to" to refer to something that can be easily displaced or removed or to something that falls off if it is jostled or tipped. ResMed states that given the plain and ordinary meaning, the ALJ correctly found that "in the context of the phrase 'secure the connecting structure to the CPAP apparatus,' I find that 'secure . . . to' connotes attachment, in accordance with its ordinary meaning." *Id.* (citing ID at 124-25.). ResMed contends that the ALJ's conclusion is supported by the record. *Id.* (citing (Hearing Tr. (Virr) at 118:9-120:16, 125:3-126:2, 132:17-133:10, 160:16-161:17; Hearing Tr. (Sheehan) at 1232:6-15.) ResMed asserts that the claim language requiring the CPAP to be "secured to" the connecting structure must mean something more than just "retained," because different terms used in the same claim limitation are to be given different meanings. *Id.* (citing *CAE Screen Plates Inc. v. Heinrich Fiedler GmbH & Co. KG*, 224 F.3d 1308, 1317 (Fed. Cir. 2000); *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) ("claims are interpreted with an eye toward giving effect to all terms in the claim").

ResMed further argues that the specification also supports the ALJ's construction that the limitation requires that the CPAP device be attached to the connecting structure. *Id.* (citing ID at 115-119.) ResMed contends that the specification of the '453 patent contains one example of the claimed "retaining mechanism configured to secure the connecting structure to the CPAP apparatus," and it is the embodiment developed by the inventors and commercialized as ResMed's S7/H2i system. (JX-0008 at 10:6-26, Figs. 17 and 18). Specifically, ResMed argues

that "the '453 specification provides that the CPAP apparatus has prongs that engage with apertures on the connecting structure (*Id.* at 10:6-13.)" and "indicates that the apertures on the connecting structure have locking mechanisms that engage with the prongs on the CPAP apparatus, thereby 'securing' the connecting structure 'to' the CPAP apparatus." *Id.* ResMed points to the disclosure that "[i]t is contemplated that the tabs or prongs on the CPAP apparatus are provided with a groove therein such that when positioned within the apertures, the locking members engage within respective grooves to thereby securely and detachably retain the connecting structure to the CPAP apparatus." *Id.* (citing '453 patent, col. 10, ll. 6-26.) According to ResMed, "this description demonstrates that the inventors used the term "secure to" in accordance with its plain and ordinary meaning, *i.e.*, one in which the CPAP apparatus is fastened or attached to the connecting structure." *Id.*

iv. Analysis

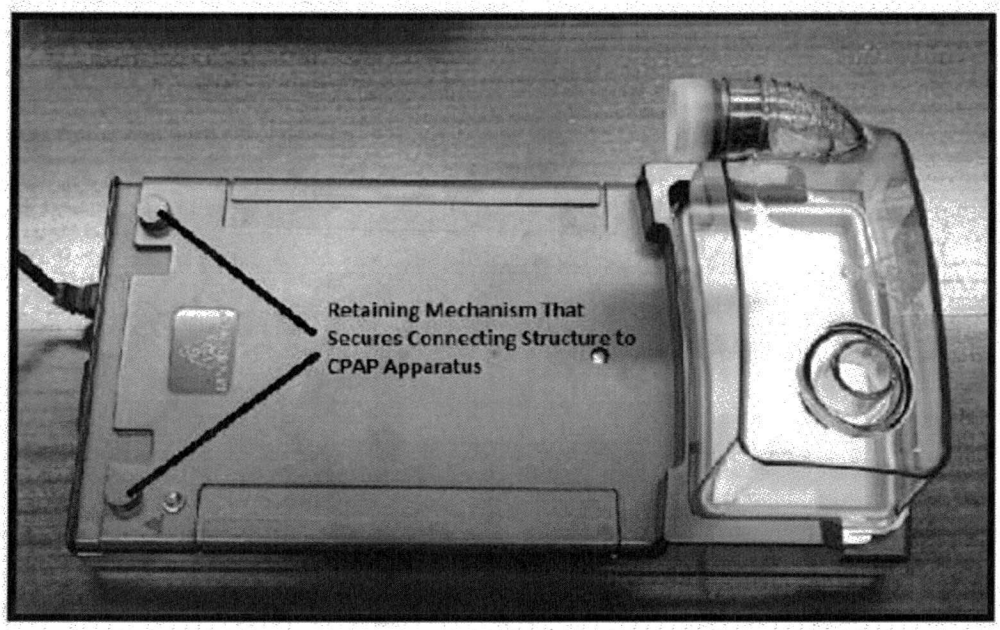
The ALJ's finding that REMstar does not meet the "secure" limitation because it does not attach or fasten the components together is in error. Accordingly, the Commission has determined to reverse the ALJ's finding that the REMstar device does not invalidate the asserted claims of the '453 patent.

Claim 1 recites in relevant part:

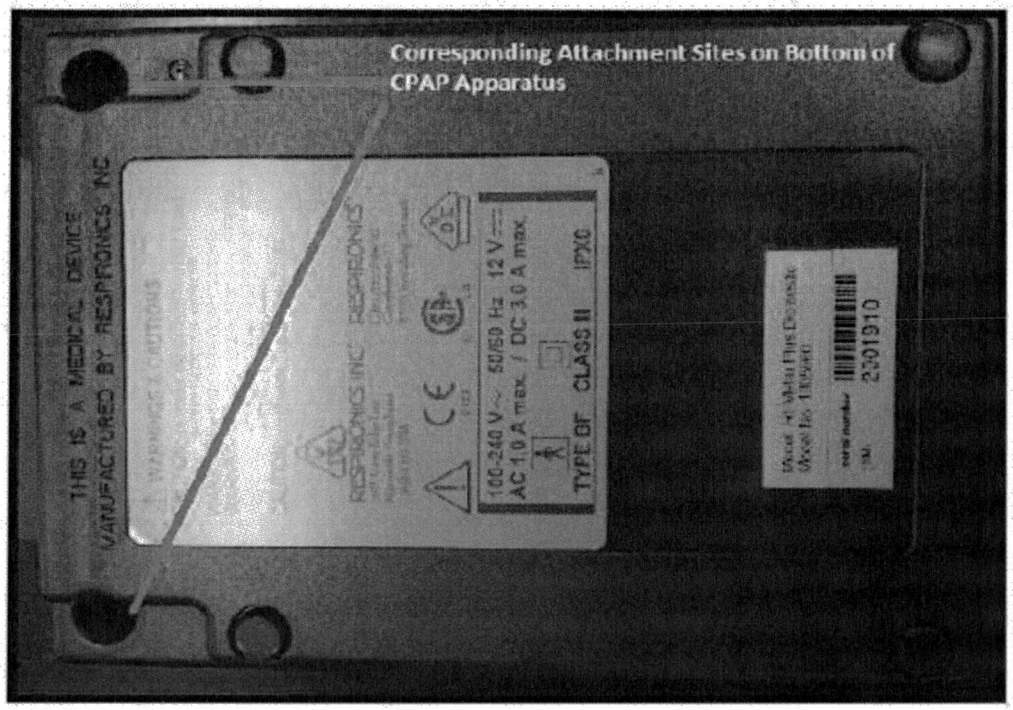
> a connecting structure configured to connect between the CPAP apparatus and humidifier and allow communication of an outlet of the CPAP apparatus with an inlet of the humidifier, the connecting structure including
>
> a housing providing a base portion to support the humidifier thereon, and
>
> **a retaining mechanism configured to secure the connecting structure to the CPAP apparatus**

'453 patent, col. 11, ll. 47-53. That is, the purpose of the connecting structure, which includes the "secure" limitation, is to connect the CPAP apparatus to the humidifier to allow

communication of an outlet of the CPAP apparatus with an inlet of the humidifier. *See* '453 patent, col. 9, ll. 25-35. The record evidence shows that the REMstar device has a connecting structure on which the humidifier and CPAP apparatus are positioned. This connecting structure has pegs that fit within corresponding holes in the bottom of the CPAP apparatus and prevent the outlet of the CPAP and the inlet to the humidifier from becoming detached or moving out of alignment with one another. Bordewick, Tr. 789:13-16; 801:10-802:4; Bordewick, Tr. 802:5-12; Goodman, Tr. 769:24770:6 ("the purpose of the pegs are [*sic*] to hold the CPAP exactly in place on the humidifier stand, which is vital to the assured treatment during the night."). The pegs provided on the base of the REMstar are shown in the picture below:

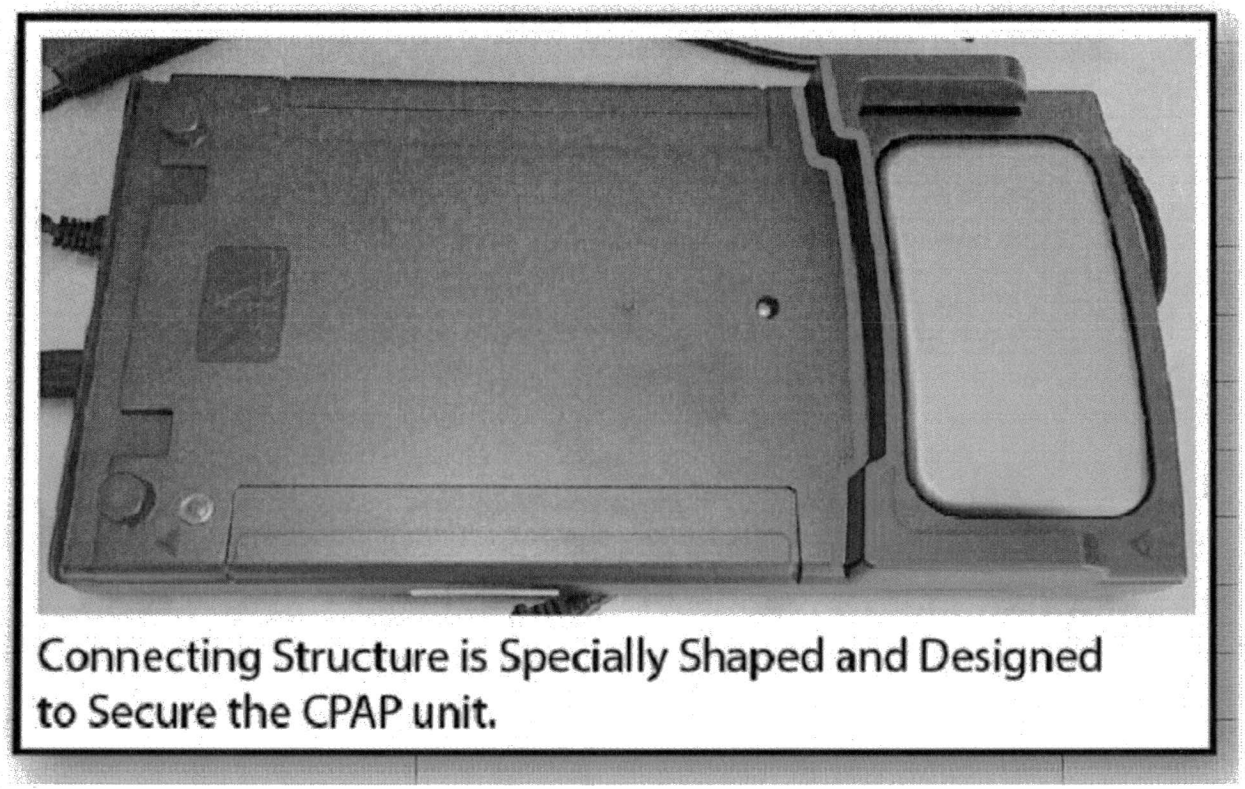


See RX-002aC (Bordewick WS) at Q/A 74. The corresponding holes on the base of the REMStar CPAP that fit over the pegs are shown below:



See RX-002aC (Bordewick WS) at Q/A 74.

The evidence further shows that the CPAP apparatus and connecting structure of the REMStar device are shaped to fit together like puzzle pieces (shown below) and that shape "serves to hold the CPAP apparatus in a proper position on the connecting structure so that the humidifier inlet and CPAP apparatus outlet are connected during use." Bordewick Tr. 789:13-16; 801:10-802:12; RX-002 (Bordewick WS) at Q/A 74-78; ID at 105, 109.



See RX-002aC (Bordewick WS) at Q/A 75.

The ALJ found that the REMstar does not meet the "secure" limitation because it does not attach or fasten the components together. ID at 125. While the ALJ's construction used the word "attach," the ALJ apparently required some kind of locked attachment and excluded attachments that are not locking from the scope of the construction. *See id.* The patent, however, does not require the components to be locked or fastened. The patentee used a broad term "secure," which in our view encompasses the pegs that fit within corresponding holes in the bottom of the CPAP apparatus that prevent the outlet of the CPAP and the inlet to the humidifier from becoming detached or moving out of alignment with one another. *See* Bordewick Tr. 789:13-16; 801:10-802:12; RX-002 (Bordewick WS) at Q/A 74-78; ID at 105, 109. Indeed, the undisputed evidence shows that the REMStar device stays attached when assembled for normal

operation, and remains in place even when tipped up to angles of about 45 degrees. *See* Bordewick Hearing Tr. 917:17-918:6; 948:17-25; 951:1-23.

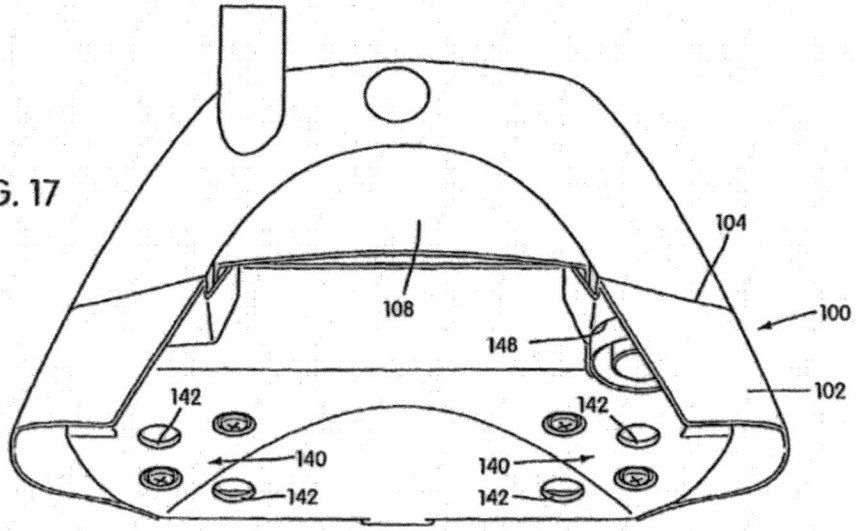
ResMed supports the ALJ's understanding and states that the REMstar's connecting structure does not interact "in a way that prevents removal: there is no press fit or friction fit between the pegs and the apertures." ResMed Br. at 9-10. Unlike other claims in the asserted patent, however, the "retaining mechanism" in claim 1 is not limited to a locking mechanism. In contrast, the patent specifically claims locking mechanisms in unasserted claims 29, 30, 58, 59, 81 and 82. *See* JX-08 ('453 patent) at 14:4-12, 15:66-16:7, and 17:41-49.

In addition, the specification teaches that use of a locking member is optional, stating:

> FIG. 17 shows a rearward side of the connecting structure **100**. The rearward side of the connecting structure **100** provides a retaining mechanism **140** to secure the connecting structure **100** to the CPAP apparatus. It is contemplated that the retaining mechanism **140** may include a series of apertures **142** within the rearward portion of the housing **102**. The apertures **142** may receive therein, for example prongs or tabs (not shown) provided by the CPAP apparatus. As shown in FIG 18, within each aperture **142**, *a locking member **144** may be provided* that is resiliently biased toward a position that partially encloses the respective aperture **142**.

'453 patent, col. 10, ll. 6-16 (emphasis added). FIGs 17 and 18 are shown below:

FIG. 17



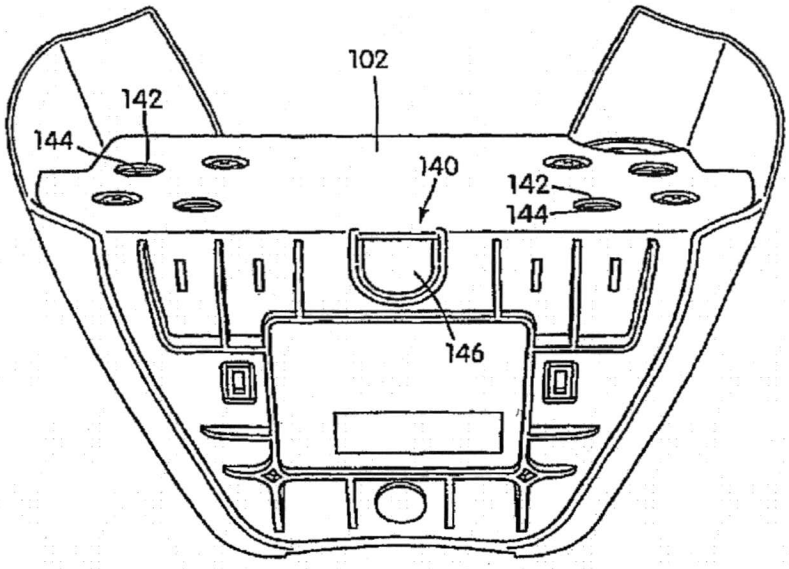


FIG. 18

As can be seen, while the embodiment described in FIG 18 shows apertures **142** including

locking members **144**, the embodiment described in FIG 17 depicts apertures **142** without locking member **144**, confirming the specification's disclosure that locking members are optional and not required components. *See* Bordewick Tr. at 896:7-897:6 (Bordewick) (claim 1 does not require a locking mechanism); Tr. 1293:15-18 (Sheehan) ("I'm not requiring the claims of the patent to have a locking member").

At bottom, the ALJ found, and ResMed contends, that the connection disclosed in the REMstar device is not secure enough to disclose the level of security required by the asserted claims. *See* ID at 125; ResMed Rep at 30-31. The asserted claims, however, do not indicate the level or degree of how secure the connection must be but simply require that the connection allow for communication of an outlet of the CPAP apparatus with an inlet of the humidifier. There is no credible dispute that the REMstar discloses this feature. Accordingly, we reverse the ID's finding that the REMstar device does not anticipate the asserted claims of the '453 patent.

3. The ALJ's Findings on Infringement and Technical Prong of Domestic Industry for the '453 Patent

The ID's findings on infringement and the technical prong of the domestic industry requirement regarding the '453 patent are also under review. *See* 79 *Fed. Reg.* 63163-65 (Oct. 22, 2014). Because the Commission's construction of the claim term of the '453 patent that was reviewed is broader than the construction in the ID, the ALJ's findings that the accused devices infringe the asserted claims of the '453 patent and that the domestic industry products practice the '453 patent are still valid under the Commission's construction. Indeed, Respondents do not contest the ALJ's findings in light of the Commission's construction of the "retaining mechanism" limitation. *See* Resp. Rep. 19.

C. Economic Prong of Domestic Industry Under 19 U.S.C. § 1337(a)(3)(C)

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). 79 *Fed. Reg.* 63163-65 (Oct. 22, 2014). On review, the Commission has determined to vacate the ALJ's finding and discussion that ResMed established a domestic industry under 19 U.S.C. § 1337(a)(3)(C).[13]

V. REMEDY

A. Limited Exclusion Order

1. Summary of the Issue and Parties' Arguments

The ID included the ALJ's recommended determination on remedy and bonding. The ALJ recommended that in the event the Commission finds a violation of section 337, the Commission should issue a limited exclusion order directed to the respondents, including their principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled and/or majority-owned business entities and their employees and agents, successors and assigns. ID at 194-95 (citing *Certain Electronic Devices, Including Mobile Phones and Tablet Computers, and Components Thereof*, Inv. No. 337-TA-847, Recommended Determination at 220 (September 23, 2013) (recommending limited exclusion order to cover all infringing articles and applying the order to "affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns.")).

The IA and ResMed support the ALJ's recommendation that the Commission should issue a limited exclusion order directed to Respondents. *See* IA Br. at 11; ResMed Br at 29-30.

[13] The Commission determined not to review the ALJ's finding that ResMed established the existence of a domestic industry under 19 U.S.C. §§ 1337(a)(3)(A) and (B).

Respondents argue that any remedial orders should be limited to products covered by the claims of any patents found to be valid and infringed. Resp Br. at 26. Respondents further argue that "any orders should permit the Respondents to repair, service or provide customer assistance as to any humidifiers on CPAP devices that have already been sold to customers" and that "[i]f Respondents are not permitted to service and repair CPAP devices that have already been sold by Respondents, U.S. consumers and the public interest will be detrimentally affected." *Id.* at 26-27. Respondents also argue that "any order should be limited to the named parties and should not extend to "agents, licensees, and distributors," because those entities are not parties to the investigation and that "Complainants have not provided any justification for including them in any orders to be issued by the Commission." *Id.*

In response, the IA does not oppose Respondents' request that they should be allowed to repair, service and provide customer assistance as to any humidifiers on CPAP devices that have already been sold to customers. The IA, however, opposes Respondents' request that any remedial order exclude Respondents' agents, licensees, and distributors. The IA observes that "such entities are part of the Commission's standard language for remedial orders, which is intended to prevent circumvention of such orders. .

2. Analysis

Section 337(d)(1) requires that "[i]f the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States …" 19 U.S.C. § 1337 (d)(1). As discussed above, we agree with the ALJ that a violation of section 337 has occurred with respect to certain asserted claims.

Thus, the Commission agrees with the ALJ's recommendation and issues a limited exclusion order directed to Respondents' products that infringe those claims. The Commission also agrees with the ALJ and IA and continues its practice of extending the exclusion order to Respondents' and their affiliates. *See* ID at 194-95. Respondents do not present a persuasive argument for deviating from normal Commission practice.

The Commission includes an exemption for service and replacement parts for customers that purchased their covered products prior to the date this Order becomes final. As Respondents' argue, such an exemption is in keeping with Commission precedent. *See* Resp Br. at 26-27.

B. Cease and Desist Orders

1. Summary of the Issue and Parties' Arguments

The ALJ also recommended issuance of cease and desist orders. The ALJ found that the evidence shows that there are commercially significant inventories of at least some of the infringing products, noting that cease and desist orders are not product-specific. ID at 195-96 (citing *Certain Kinesiotherapy Devices and Components Thereof*, Inv. No. 337-TA-823, Corrected Order to Cease and Desist (February 7, 2014))

The IA agrees with the ALJ that cease and desist orders should issue, but only as to those claims for which ResMed has established that commercially significant inventory of infringing products exists domestically. IA Br. at 11-13. In that regard, the IA argues that cease and desist orders should be directed to Respondents 3B Medical, Inc. and 3B Products, LLC, targeting products covered by claims 30 and 37-38 of the '060 patent; claims 1, 3, 5, 11, 28, 30, 31, and 56 of the '883 patent; and claims 32-34 of the '267 patent. The IA argues, however, that the cease

and desist orders should not be directed towards products that are covered by the asserted claims of the '527 and '392 patents and claim 53 of the '267 patent because the only products asserted to infringe these claims are the redesigned iVolve products, of which there is allegedly no evidence of commercially significant inventory in the United States. *Id.* (citing ID at 8, 23, 46, 57-58). The IA thus argues that the Commission should limit the cease and desist orders to only those patent claims for which ResMed has established that commercially significant inventory of infringing products exists in the United States. *See* IA Br. at 11-13.

Respondents argue that cease and desist orders should not issue because their "US inventories are not commercially significant compared to either ResMed's sales or the industry in general." Resp. Br. at 28. Respondents further argue that "any orders should permit the Respondents to repair, service or provide customer assistance as to any humidifiers on CPAP devices that have already been sold to customers." *Id.* at 26.

2. Analysis

As recommended by the ALJ, the Commission has determined to issue cease and desist orders under 19 U.S.C. §1337(f) directed to Respondents 3B Medical, Inc. and 3B Products, LLC.

The Commission generally issues cease and desist orders "when there is a commercially significant amount of infringing imported product in the United States that could be sold so as to undercut the remedy provided by an exclusion order." *Certain Protective Cases and Components Thereof*, Inv. No. 337-TA-780, Comm'n Op. (Pub. Version) at 28 (Nov. 19, 2012) (quoting *Certain Laser Bar Code Scanners and Scan Engines, Components Thereof and Products Containing Same*, Inv. No. 337-TA-551, Comm'n Op. (Pub. Version) at 22 (June 14,

2007)). Complainants bear the burden of proving that respondents have commercially significant inventories of infringing products in the United States. *Certain Integrated Repeaters, Switches, Transceivers, and Products Containing Same*, Inv. No. 337-TA-435, Comm'n Op. at 27 (Aug. 16, 2002). The record evidence shows that Respondents 3B Medical, Inc. and 3B Products, LLC have commercially significant inventories of infringing products in the United States. Vander Veen DWS, CX-765aC at Q/A 119-124; CX-154C; CX-333C; CDX-12.59aC. Thus, cease and desist orders are warranted.

The Commission declines to restrict issuance of cease and desist orders to only the patent claims for which it was established that commercially significant inventory of infringing products exists in the United States.[14] In this investigation, the undisputed evidence shows that there is commercially significant inventory of certain accused products in the United States. Accordingly, the Commission determines that issuance of cease and desist orders directed to all asserted patent claims is warranted.

VI. THE PUBLIC INTEREST

Sections 337(d) and (f) of the Tariff Act of 1930, as amended, direct the Commission to consider certain public interest factors before issuing a remedy. These public interest factors

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[14] Commissioner Johanson is of the view that the cease and desist orders against Respondents 3B Medical, Inc. and 3B Products, LLC should not be directed to the asserted claims of the '527 and '392 patents, as well as claim 53 of the '267. The Complainant has failed to demonstrate that the Respondents maintain a commercially significant inventory of the iVolve products (i.e., the only "covered" products found to infringe the asserted claims of the '527 and '392 patents, as well as claim 53 of the '267). Thus, there is insufficient evidence that domestic inventory of the iVolve if sold would undercut the remedy provided by the exclusion order issued in this investigation. *See Protective Cases and Components Thereof*, Inv. No. 337-TA-780, Comm'n Op. (Pub. Version) at 28 (Nov. 19, 2012); *see also Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, Comm'n Op., 1990 WL 10008086, at *14-*15 (Mar. 21, 1990).

include the effect of any remedial order on the "public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers." 19 U.S.C. §§ 1337(d) and (f).

The IA and ResMed argue that the public interest factors are not implicated in this investigation and that a limited exclusion order directed to Respondents' infringing products would not be contrary to the public interest. IA Br. at 10-11. The IA points to evidence showing that ResMed has a large share of the market in every product category at issue, and that there are multiple manufacturers besides ResMed and BMC in all of the accused product categories. *Id.* (citing Yerbury Tr. at 16:9-17:5 (full face mask Mirage Quattro has [ ] market share), *id.* at 25:1-4 (ResMed has [ ] of nasal pillows market), *id.* at 65:15-17 (ResMed's market share in the three categories of masks and pillows totals [ ]); *id.* at 65:22-25 (ResMed is market leader for masks); CX-266C (U.S. Sleep Market Dashboard) at 24-28, 31, 32, 34, 38, 41, 42, and 45). The IA argues that in contrast, Respondents' inventory in the United States is quite small relative to ResMed's U.S. sales and so exclusion of their accused products would not significantly affect competitive conditions in the U.S. CPAP or CPAP mask markets, the production of like or directly competitive articles in the U.S., or U.S. consumers. *Id.* (citing CX-765C (Vander Veen WS) at Q/A 120; CX-154C (Respondent 3B Medical inventory report showing between [ ] and [ ] units of accused products); at Q/A 27 ([ ] units of S9 flow generator with H5i humidifier sold by ResMed in 2013) and *id.* at Q/A 35 (showing ResMed's 2013 sales of domestic industry masks was greater than [ ] units).

Respondents argue that the industry for CPAP devices and interfaces has few suppliers. According to Respondents, they provide "high quality products at a significantly lower cost to

the government, and the exclusion of their products could undermine the Affordable Care Act's competitive bidding program's mission." Resp Br. at 30. Respondents note that they do not contend that relief should be denied in this investigation based on the public interest, if the Commission finds a violation, but that given the important public interest involved in sleep apnea treatment, any remedial orders should be carefully and narrowly crafted.

The Commission agrees with the IA and ResMed that the public interest factors do not weigh against issuance of the above-described remedial orders in this investigation. Significantly, the evidence shows that United States demand for CPAP devices and interfaces can be met by ResMed and non-infringing models offered by others. While Respondents contend that "the exclusion of their products could undermine the Affordable Care Act's competitive bidding program's mission," and that their products are of high quality, Respondents do not substantiate these assertions with any evidence or explanation of how the public interest considerations would be adversely impacted. Accordingly, the Commission finds that the public interest factors set out in section 337(d) and (f) do not preclude issuance of the orders.

Moreover, the Commission has determined to mitigate any potential impact on consumers who have already purchased Respondents' products prior to the date of this order by exempting from the scope of the orders products used for service and repair of devices that are in consumers' hands as of the date of this order.

VII. BOND

During the 60-day period of Presidential review, imported articles otherwise subject to remedial orders are entitled to conditional entry under bond. 19 U.S.C. § 1337(j)(3). The amount of the bond is specified by the Commission and must be an amount sufficient to protect the

complainant from any injury. *Id.*; 19 C.F.R. § 210.50(a)(3).

The ALJ observed that the private parties stipulated to a bond amount of 65% of the entered value of products imported during the period of Presidential review, and the IA agreed that that rate would be appropriate. ID at 196. The ALJ found no reason to alter the stipulated rate and recommended that the Commission set a bond in the amount of 65% of the entered value of products imported during the period of Presidential review.

Accordingly, the Commission has determined to set a bond of 65% of the entered value of infringing products imported during the period of Presidential review.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: January 16, 2015

CERTAIN SLEEP-DISORDERED BREATHING TREATMENT SYSTEMS AND COMPONENTS THEREOF

Inv. No. 337-TA-890

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION NOTICE** has been served by hand upon the Commission Investigative Attorney, Lisa M. Kattan, Esq., and the following parties as indicated, on **January 20, 2015.**

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants ResMed Corporation, ResMed Incorporated, and ResMed Limited:

Thomas S. Fusco, Esq.
FISH & RICHARDSON P.C.
1425 K Street, NW, 11th Floor
Washington, DC 20005

☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

On Behalf of Respondents BMC Medical Co., Ltd., 3B Medical, Inc., and 3B Products, LLC:

Gary M. Hnath, Esq.
MAYER BROWN LLP
1999 K Street, NW
Washington, DC 20006

☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

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 COMMISSION DETERMINATION TO REVIEW IN PART A FINAL INITIAL DETERMINATION FINDING A VIOLATION OF SECTION 337; SCHEDULE FOR FILING WRITTEN SUBMISSIONS ON THE 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 has determined to review in part the final initial determination ("ID") issued by the presiding administrative law judge ("ALJ") on August 21, 2014, finding a violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), in this investigation.

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.

Having examined the record of this investigation, including the ALJ's final ID, the petitions for review, and the responses thereto, the Commission has determined to review the final ID in part. Specifically, with respect to the '487 patent, the Commission has determined to review the ALJ's construction of the claim term "gas washout vent" and construe 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 has 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 has 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 strike 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 has 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).

The parties are requested to brief their positions on the issues under review with reference to the applicable law and the evidentiary record. In connection with its review, the Commission is particularly interested in responses to the following:

> The Commission has determined to revise the ALJ's construction of the claim limitation "a retaining mechanism" recited in the asserted claims of the '453 patent and strike the requirement that it requires an arrangement of moving parts. That is, the claim limitation "a retaining mechanism configured to secure the connecting structure to the CPAP apparatus" is construed 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." *See* ID at 124. Please discuss whether the REMstar device anticipates the asserted claims under the revised construction.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more 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 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or 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 or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005. 70 *Fed. Reg.* 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. Such submissions should address the recommended determination by the ALJ on remedy and bonding. Complainants and the IA are also requested to submit proposed remedial orders for the Commission's consideration and to provide identification information for all importers of the subject articles. Complainants are also requested to state the date that the patents expire and the HTSUS numbers under which the accused products are imported. The written submissions and proposed remedial orders must be filed no later than close of business on October 31, 2014. Reply submissions must be filed no later than the close of business on November 7, 2014. Such submissions should address the ALJ's recommended determinations on remedy and bonding. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

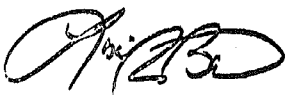
Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit eight true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of

Practice and Procedure (19 C.F.R. 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-890") in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, http://www.usitc.gov/secretary/fed_reg_notices/rules/ handbook_on_electronic_filing.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. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 C.F.R. § 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with the any confidential filing. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

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: October 16, 2014

CERTAIN SLEEP-DISORDERED BREATHING TREATMENT SYSTEMS AND COMPONENTS THEREOF **Inv. No. 337-TA-890**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION NOTICE** has been served by hand upon the Commission Investigative Attorney, Lisa M. Kattan, Esq., and the following parties as indicated, on **October 16, 2014.**

Lisa R. Barton, Secretary
U.S. International Trade Commission
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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

Before the Honorable Thomas B. Pender
Administrative Law Judge

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

FINAL INITIAL DETERMINATION ON REMAND

(November 10, 2016)

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TABLE OF ABBREVIATIONS

CDX	Complainant's Demonstrative Exhibit
CIB	Complainant's Initial Post-Hearing Brief
CPHB	Complainant's Pre-Hearing Brief
CPHS	Complainant's Pre-Hearing Statement
CRB	Complainant's Reply Post-Hearing Brief
CDIB	Complainant's Supplemental Domestic Industry Brief
CX	Complainant's Exhibit
Dep.	Deposition
JX	Joint Exhibit
RDX	Respondent's Demonstrative Exhibit
RIB	Respondent's Initial Post-Hearing Brief
RPHB	Respondent's Pre-Hearing Brief
RPHS	Respondent's Pre-Hearing Statement
RRB	Respondent's Reply Post-Hearing Brief
RDIB	Respondent's Supplemental Domestic Industry Brief
RX	Respondent's Exhibit
SIB	Staff's Initial Post-Hearing Brief
SPHB	Staff's Pre-Hearing Brief
SPHS	Staff's Pre-Hearing Statement
SRB	Staff's Reply Post-Hearing Brief
SDIB	Staff's Supplemental Domestic Industry Brief
Tr.	Transcript
DWS	Direct Witness Statement (Including Revised Direct Witness Statements)
RWS	Rebuttal Witness Statement

INITIAL DETERMINATION

Pursuant to the Commission's Order dated August 16, 2016, this is my Initial Determination on Remand in the matter of *Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof*, Inv. No. 337-TA-890.

I hereby determine that Complainants ResMed Corporation of San Diego, California, ResMed Incorporated of San Diego, California, and ResMed Limited of New South Wales, Australia (collectively, "ResMed") have not shown the existence of a domestic industry with respect to U.S. Patent Nos. 7,178,527 (the "'527 patent"), 7,950,392 (the "'392 patent"), 7,997,267 (the "'267 patent"), 7,341,060 (the "'060 patent"), and 8,312,883 (the "'883 patent") (collectively, the "Mask Patents").

I. INTRODUCTION

On July 19, 2013, ResMed filed its complaint in this Investigation, alleging infringement of certain claims of eight different patents: U.S. Patent Nos. 7,997,267 (the "'267 patent"), 7,614,398 (the "'398 patent"), 7,938,116 (the "'116 patent"), 7,341,060 (the "'060 patent"), 8,312,883 (the "'883 patent"), 7,178,527 (the "'527 patent"), 7,950,392 (the "'392 patent"), and 7,926,487 (the "'487 patent") (collectively, the "originally asserted patents"). By publication of notice in the Federal Register on August 23, 2013, this Investigation was instituted by the Commission to determine whether certain sleep-disordered breathing treatment systems and components thereof infringe one or more of those patents, and whether an industry in the United States exists as required by subsection (a)(2) of Section 337. 78 Fed. Reg. 52564 (August 23, 2013.)

On December 11-12, 2013, a tutorial and *Markman* hearing was held in this Investigation, and I issued a *Markman* Order on January 16, 2014, construing thirteen terms in the originally asserted patents. On January 9, 2014, I issued Order No. 7, an Initial Determination granting

ResMed's motion to amend the complaint to substitute U.S. Patent No. RE44,453 ("the '453 Patent") for the '398 Patent, which the Commission determined not to review on February 20, 2014. On February 24, 2014, I issued Order No. 11, an Initial Determination granting ResMed's motion to withdraw its allegations with respect to the '116 Patent, which the Commission determined not to review on March 11, 2014. On March 14, 2014, the private parties entered into a joint stipulation regarding the technical prong of domestic industry ("Technical Prong Stipulation"). An evidentiary hearing (the "Hearing") was held on April 10-11 and April 14-17, 2014.

On August 21, 2014, I issued my Initial Determination on violation.

On December 23, 2014, the Commission affirmed the finding of a violation of Section 337 for several of the asserted patents and issued (1) a limited exclusion order and (2) cease and desist orders directed to the domestic respondents. 79 Fed. Reg. 78905 (Dec. 31, 2014.)

On April 14, 2015, Respondents BMC Medical Co., Ltd., 3B Medical, Inc., and 3B Products, LLC (collectively, "BMC") filed a notice of appeal in the Federal Circuit, seeking review of the Commission's domestic industry determination. (Appeal No. 2015-1576.) On March 17, 2016, the Commission moved to remand BMC's appeal in light of intervening domestic industry precedent in *Lelo Inc. v. Int'l Trade Comm'n*, 786 F.3d 879 (Fed. Cir. 2015) ("*Lelo*"). On April 22, 2016, the Court granted the Commission's remand motion.

On August 16, 2016, the Commission issued an Order in this investigation remanding the investigation back to me to: (1) apply the Federal Circuit's intervening domestic industry precedent in *Lelo* to the existing record with respect only to the Mask Patents; and (2) issue a final initial remand determination ("RID") on violation. On August 25, 2016, I issued Order No. 23 which set the target date for the remand investigation to be February 28, 2017 and a due date for this Final Initial Determination on Remand of December 28, 2016.

ResMed and BMC each filed a single brief addressing the issues on remand on October 3, 2016. The Commission Investigative Staff filed a similar brief on October 11, 2016. Earlier, on August 25, 2016, I conducted a telephone conference with the parties during which counsel for ResMed indicated that ResMed may not brief the requested issues for the '060 and '883 patents. Consistent with that representation, ResMed did not brief domestic industry for the '060 and '883 patents, as shown by Exhibit A to BMC's Brief which is an email from ResMed's counsel stating that the issues on these two patents would not be briefed. Accordingly, I find ResMed has conceded a lack of quantitative significance for the domestic investments behind the '060 and '883 patents. Nevertheless, the patents have not been withdrawn from the Investigation and I analyze them, along with the patents which were briefed, the '267, '527, and '392 patents (the "Remaining Mask Patents"), below.

The products which were stipulated to practice the Mask Patents are masks for CPAP therapy to treat breathing problems, such as sleep apnea. (*See* CX-0754C at 4-5, Q/A 18-21.) CPAP refers to continuous positive airway pressure, and CPAP treatment generally involves the supply of air into a patient's airways at a pressure elevated above atmospheric pressure. (*See* JX-0004 at 1:22-30.) A CPAP therapy system generally consists of three main components: (1) a blower for generating the flow of air; (2) a conduit, such as a hose, for carrying the air to the patient; and (3) a patient interface, such as a mask, for delivering air to a patient's mouth or nose. (*See* JX-0002 at 1:39-41; JX-0006 at 1:33-36; JX-0008 at 1:29-31.) A humidifier may be attached between the blower and the patient interface to provide humidified air. (*See* JX-0008 at 1:31-35; JX-0004 at 2:16-18.) The patient interfaces used in CPAP therapy may take many different forms, such as a nasal mask, a nose and mouth mask, a full-face mask, nasal cushions, nasal prongs, or nasal pillows. (*See* JX-0002 at 1:65-2:1; JX-0004 at 1:52-62; JX-0006 at 1:57-60.) These masks typically consist of a rigid or semi-rigid shell, a soft face-contacting cushion, a forehead support,

headgear, and straps for securing the device to the patient's head. (*See* JX-0001 at 1:29-43; JX-0002 at 2:1-3; JX-0006 at 1:60-62.)

The parties have stipulated the following ResMed products practice certain claims of the Mask Patents:

Product	Patent	Claims Practiced
Mirage Activa (CPX-3)	'392	19-26, 30-35, 39, 41-43 and 45
	'527	1-2, 40-42, 44-45, 50-51, 55-56, 59, 89-92 and 94-96
Mirage Activa LT (CPX-2)	'267	21-22, 29, 79 and 80
	'527	1-2, 40-42, 44-45, 50-51, 55-56, 59, 89-92 and 94-96
	'392	19-26, 30-35, 39, 41-43 and 45
Mirage Liberty (CPX-5)	'267	21-25, 29-31
Mirage Vista (CPX-8)	'267	21-25, 29-31
	'392	19-26, 30-35, 39, 41-43 and 45
	'527	29-33, 35, 51, 55-56, 59, 89-92 and 94-96
	'060	15-19, 25-28 and 30-37
Mirage Micro (CPX-6)	'267	21-22, 29, 79 and 80
	'527	1-10, 29-33, 35, 40-42, 44-45, 50-51, 55-56, 59, 89-92 and 94-96
	'392	19-26, 30-35, 39, 41-43 and 45
Mirage Quattro (CPX-7)	'267	21-22, 29, 79 and 80
	'527	29-33, 35, 51, 55-56, and 59
	'392	19-22, 25-26, 30-35, 39, 41-43 and 45
Quattro FX (CPX-9)	'267	21-22, 29, 79 and 80
Mirage Swift II (CPX-14)	'060	15-19 and 25-28
	'883	1-5, 7-8, 10, 16-17, 20-22, 25, 28, 31-34, 37, 40-41, 44-46, 49, 56, 59 and 63
Swift LT (CPX-15)	'060	15-19 and 25-28
	'883	1-5, 7-8, 10, 16-17, 20-22, 25, 28, 31-35, 37, 40-41, 44-46, 49, 56, 59 and 63

(*See* Technical Prong Stipulation.)

II. RELEVANT LAW

In a patent-based complaint, a violation of Section 337 can be found "only if an industry in the United States, relating to the articles protected by the patent ... concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). Under Commission precedent, this "domestic industry requirement" of Section 337 consists of an economic prong and a technical prong. *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 12-14 (May 16, 2008). The complainant bears the burden of establishing that the domestic industry requirement is satisfied. *See Certain Set-Top Boxes and Components Thereof*, Inv. No. 337-TA-454, Initial Determination at 294 (June 21, 2002) (unreviewed by Commission in relevant part).

The economic prong of the domestic industry requirement is defined in subsection (a)(3) of Section 337 as follows:

> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark or mask work concerned --
>
> (A) Significant investment in plant and equipment;
>
> (B) Significant employment of labor or capital; or
>
> (C) Substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3). The economic prong of the domestic industry requirement is satisfied by meeting the criteria of any one of the three factors listed above.

Pursuant to Section 337(a)(3)(A) and (B), "a complainant's investment in plant and equipment or employment of labor or capital must be shown to be "significant" in relation to the articles protected by the intellectual property right concerned." *Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Comm'n Op. at 26 (February 17, 2011).

Before *Lelo*, the Commission had emphasized that "there is no threshold test for what is considered 'significant' within the meaning of the statute." *Certain Kinesiotherapy Devices and Components Thereof*, Inv. No. 337-TA-823, Comm'n Op. at 33 (July 12, 2013) ("*Kinesiotherapy Devices*"). Instead, the Commission stated the determination is made by "an examination of the facts in each investigation, the article of commerce, and the realities of the marketplace." *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op. at 39 (August 1, 2007) ("*Male Prophylactics*").

Section 337(a)(3)(C) provides for domestic industry based on "substantial investment" in the enumerated activities, including licensing of a patent. *See Certain Digital Processors and Digital Processing Systems, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-559, Initial Determination at 88 (May 11, 2007) ("*Digital Processors*"). Mere ownership of the patent is insufficient to satisfy the domestic industry requirement. *Id.* at 93 (citing the Senate and House Reports on the Omnibus Trade and Competitiveness Act of 1988, S.Rep. No. 71). However, entities that are actively engaged in licensing their patents in the United States can meet the domestic industry requirement. *Id.*

After I issued the previous Initial Determination in this investigation, the Federal Circuit issued its *Lelo* decision which restated a number of issues surrounding the economic prong of domestic industry. In particular, the Federal Circuit held that the statutory terms "'significant' and 'substantial' refer to an increase in quantity, or to a benchmark in numbers" and "[a]n 'investment in plant and equipment' therefore is characterized quantitatively, *i.e.*, by the amount of money invested in the plant and equipment." *Lelo*, 786 F.3d at 883. Continuing, the CAFC held that: "[a]ll of the foregoing requires a quantitative analysis in order to determine whether there is a 'significant' increase or attribution by virtue of the claimant's asserted commercial activity in the

United States." *Id.* In short, "Qualitative factors cannot compensate for quantitative data that indicate insignificant investment and employment." *Id.* at 885.

The Federal Circuit also addressed the nature of the evidence required for a complainant to rely on components which are purchased from U.S. entities to show domestic industry. Generally, generic purchase prices for off-the shelf items are insufficient. *Id.* at 884. There must be some evidence of investment made in capital or labor as a result of the purchased components; for example, the magnitude of labor expended to produce the components, or the amount the suppliers invested in their equipment to fulfill the complainant's orders. *Id.* "The purchase of so called 'crucial' components from third-party U.S. suppliers are insufficient to satisfy the 'significant investment' or 'significant employment of labor or capital' criteria of § 337 where there is an absence of evidence that connects the cost of the components to an increase of investment or employment in the United States." *Id.* at 885.

III. DOMESTIC INDUSTRY: ECONOMIC PRONG

A. The Parties' Contentions

1. ResMed

In its Brief On Remand Regarding The Economic Prong of Domestic Industry ("CDIB"), ResMed summarizes the previous Initial Determination as finding its domestic industry investments with respect to the Mask Patents to be qualitatively significant but making no finding regarding quantitative significance. (CDIB at 1.) ResMed also identifies the *Lelo* decision as altering the test for domestic industry in that domestic industry cannot be based solely on qualitative factors. (*Id.*) ResMed contends, however, that this does not alter the result of the investigation because its expenditures on its asserted mask patents are also quantitatively significant. (*Id.*)

ResMed argues it is not a non-practicing entity or a mere importer, but rather the "world's leading tech-driven medical device company and innovator in sleep-disordered breathing and respiratory care." (*Id.* at 2.) With respect to the Remaining Mask Patents, ResMed explains that its domestic industry activity includes clinical education, service and repair, customer service, and purchasing components from domestic suppliers. (*Id.*) ResMed explains that under 19 U.S.C. § 1337(a)(3(A), and as found by the prior Initial Determination, ResMed's expenditures in plant and equipment for each of the Remaining Mask Patents are as follows, to which I have added the same expenditures for the '060 and '883 patents:

Subsection (A) – Plant and Equipment					
	'267	**'527**	**'392**	**'060**	**'883**
Clinical Education	[ ]	[ ]	[ ]	[ ]	[ ]
Service and Repair	[ ]	[ ]	[ ]	[ ]	[ ]
Customer Service	[ ]	[ ]	[ ]	[ ]	[ ]
Domestic Suppliers	[ ]	[ ]	[ ]	[ ]	[ ]
TOTAL:	[ ]	[ ]	[ ]	[ ]	[ ]

Similarly, ResMed's expenditures in labor and capital are as follows:

Subsection (B) – Labor and Capital					
	'267	**'527**	**'392**	**'060**	**'883**
Clinical Education	[ ]	[ ]	[ ]	[ ]	[ ]
Service and Repair	[ ]	[ ]	[ ]	[ ]	[ ]
Customer Service	[ ]	[ ]	[ ]	[ ]	[ ]
Domestic Suppliers	[ ]	[ ]	[ ]	[ ]	[ ]
TOTAL:	[ ]	[ ]	[ ]	[ ]	[ ]

ResMed then argues that these domestic industry activities for the Remaining Mask Patents are quantitatively significant under the meaning of the statute and as prescribed by *Lelo*. (*Id.* at 4.) ResMed acknowledges that in *Lelo*, the Federal Circuit clarified that "[q]ualitative factors cannot compensate for quantitative data that indicate insignificant investment and employment." (*Id.*) ResMed admits that "[p]rior to *Lelo*, a complainant could establish a

domestic industry merely by relying on the qualitative significance of its domestic investments" and that "*Lelo* changed that." (*Id.* at 5.)

ResMed suggests that Respondents may argue that the domestic industry investments for the Remaining Mask Patents, which are each between [ ] dollars per year, are quantitatively insignificant "because they are too small a percentage of some other number, for example, ResMed's total sales revenue for the domestic industry products." (*Id.* at 9.) ResMed rejects the argument because "no comparative analysis of any kind is necessary to determine quantitative significance" and the existence of large, successful, sales revenue should not negate or render insignificant domestic industry investments of over [ ] per year per patent. (*Id.*)

In turning to each category of investment, or investment activity, outlined in the tables above, ResMed claims its Clinical Education investments are quantitatively significant when viewed either: in the context of ResMed's overall clinical education activities; or in the context of the sleep-disordered breathing (SDB) industry. (*Id.* at 9-10.) Regarding the first context, ResMed suggests that "[b]y comparing the amount of such investments with respect to the articles protected by the patent to the complainant's activities with respect to all of its products," the Commission has found significance. (*Id.* at 10.) ResMed analogizes to the approach taken in *Certain Handheld Electronic Computing Devices, Related Software, and Components Thereof*, Inv. No. 337-TA-769, to explain how [of its total domestic clinical education expenses are attributable to the '267 patent, [ ] to the '527 patent, and [ ] to the '392 patent. (*Id.* at 10-11.) ResMed then concludes that "[b]ased on the foregoing analysis, ResMed submits the record contains evidence demonstrating that its clinical education investments with respect to articles protected by the patent is quantitatively significant." (*Id.* at 11.)

Regarding the second context (within the SDB industry), ResMed explains that providing therapy to patients facing sleep-disordered breathing involves "several steps and people" and its

clinical education department in the U.S. trains customers to ensure equipment providers help patients use the products embodying the Mask Patents in ways that are tailored to each patient's unique needs. (*Id.* at 12.) ResMed explains how this training is critical for effective therapy. (*Id.* at 12-13.) ResMed identifies its "Mask Fitting Workshop" is its most often presented and well attended seminar, and the impact of this seminar is "far reaching" as witness testimony showed it was presented [ ] times in FY 2013 with a total attendance of [ ] persons. (*Id.* at 13.)

ResMed states, "ResMed's domestic investment in clinical education is quantitatively significant because it leads to an increase in patient compliance" (*id.* at 13) and "an increase in patient compliance leads to improved therapy for a patient suffering from sleep-disordered breathing, which is of paramount significance in the industry" (*id.* at 14). Thus, ResMed concludes "in the context of the patented sleep-apnea mask article, ResMed's investment in clinical education is quantitatively significant." (*Id.* at 14.) ResMed reiterates its position that "the Commission makes clear that no comparative analysis is required to demonstrate quantitative significance, performing such a comparison here confirms ResMed's quantitatively significant domestic industry." (*Id.*)

ResMed also claims its investment in components from domestic suppliers is quantitatively significant when viewed in the context of the patented sleep-apnea mask articles "because this investment is a quantitatively significant percentage of the overall cost of goods sold." (*Id.* at 14-15.) Here, ResMed points to evidence showing its investment in these components from domestic suppliers, as a percentage of cost of goods sold, is more than [ ] [ ] (*Id.* at 15.) ResMed explains that, as a percentage of the end product's sales price, the investment in the domestic components is around [ ], but when adapted to a percentage of the total cost of goods sold (using its 10-K reported total global sales and total cost of goods sold), the percentage rises to around [ ] (*Id.*) ResMed argues this amount is

quantitatively significant and the overall significance of its domestic industry increases when combined with clinical education. (*Id.*)

ResMed concludes its briefing to distinguish its investments from prior complainants who failed to establish a domestic industry; specifically, those from *Kinesiotherapy Devices*, *Printing and Imaging Devices*, and *Soft-Edged Trampolines*. (*Id.* at 15-19.) ResMed argues the complainant in *Kinesiotherapy Devices* attempted to rely on only the purchase of domestic components, while it, on the other hand, "additionally invests in plant and equipment and employs labor and capital for activities including service and repair, customer service, and, most significantly, clinical education." (*Id.* at 16.) Similarly, the complainant in *Printing and Imaging Devices* relied strictly on service and repair to meet the economic prong whereas ResMed's alleged domestic industry additionally includes clinical education, customer service and the purchase of domestic components. (*Id.* at 16-17.) ResMed makes the same type of additional-activity distinction between itself and the complainant in *Soft-Edged Trampolines*. (*Id.* at 17.) ResMed also notes that that complainant's proffer of significance (installation services are critical to safety) was not supported and actually contradicted by the record which is in contrast with ResMed's "ample" evidence of the connection between clinical education and patient compliance and allocated costs compared to clinical education investments as a whole. (*Id.* at 17-18.) Finally, ResMed observes the complainant in *Soft-Edged Trampolines* had an allocation problem, which I and the Commission had no problem with in this investigation. (*Id.* at 18.)[1]

[1] Although "service and repair" and "customer service" were broken out separately in the tables summarizing ResMed's investments under prongs (A) and (B), there are no corresponding discussions of quantitative significance for these categories in ResMed's domestic industry briefing, as opposed to what was done for "clinical education" and "domestic suppliers."

2. BMC

In its Brief Applying Intervening Domestic Industry Precedent in *Lelo* ("RDIB"), BMC argues that the record does not support a finding of domestic industry as to the Remaining Mask Patents. (RDIB at 1.) BMC suggests that under *Lelo*, generic purchase prices of domestic components should not be considered when those expenditures were not allocated to the statutory categories of "plant," "equipment," "labor," or "capital." (*Id.* at 4.) Further, the Federal Circuit rejected the use of qualitative factors to compensate for a lack of quantitative significance of alleged domestic investments. (*Id.*) BMC then recounts how the *Lelo* Court held that purchase prices for U.S. components which are less than five percent of the total raw cost of the domestic industry product are insignificant. (*Id.*)

Turning to the record in this investigation, BMC first argues that ResMed's domestic supplier investments should be excluded from the domestic industry inquiry altogether. (*Id.* at 6.) BMC reasons that "none of the domestic components identified by ResMed are unique or critically important to the domestic industry mask products." (*Id.* at 7.) In support, BMC cites evidence to support the notions that: other companies besides Velcro USD make the identified Velcro hook and loop fasteners (*id.*); ResMed has an alternative non-domestic supplier, [ ] [,] for its plastic tubing (*id.*); and the foam rubber is sourced from Rubberlite, Inc. as a matter of convenience and not because of "special or unique properties" (*id.*). BMC notes that the "pressure sensors" identified by ResMed as a one of the domestically supplied components actually belong to the S9 Flow Generator and not the separate mask product. (*Id.* at 7, n.3.) BMC also notes that there is no dispute that each of these domestic components are off-the-shelf and generic. (*Id.* at 8.)

BMC then alleges that there is no support in the record for any accounting of the labor expended to produce the components or the amount ResMed's identified suppliers invest in their equipment, as required by *Lelo*. (*Id.*) BMC argues there is simply no basis "to compute the

magnitude of the employment of labor or capital, or amount of investment made in plant and equipment" behind the domestically supplied components and that "the record shows that either a portion of the components are manufactured abroad or that ResMed failed to inquire into the actual location of their manufacture." (*See id.* at 8-9) Without such support, BMC argues, the investments related to these third party components should be excluded from the economic prong analysis. (*Id.* at 9.)

Moving forward, BMC argues the remaining investments identified by ResMed (clinical education, service and repair, and customer service) do not qualify as quantitatively significant. (*Id.*) BMC references my previous findings that the expenditures are a "quantitatively small fraction of ResMed's revenue in the domestic industry products" and that their significance, at that time, was qualitative-only. (*Id.* at 9-10.) BMC follows up with, "[t]he Federal Circuit in *Lelo* flatly rejected this use of a qualitative evaluation to compensate for a lack of quantitative significance." (*Id.* at 10.)

BMC then provides two tables, one for prong (A) and one for prong (B), which show the total investment credited towards each of the Remaining Mask Patents as a percentage of total revenue. (*Id.* at 12.) BMC's tables illustrate an approximate [ ] (varying between [ ] and [ ]) investment-to-revenue ratio for each patent under either a prong (A) or prong (B) perspective. (*Id.*) BMC posits that this [ ] value cannot qualify as "significant" when compared to the 5% value discussed in *Lelo*, and the 15% value I off-handedly mentioned during the case management conference of August 25th. (*Id.*) BMC argues that "[n]othing in the record explains why ResMed's domestic expenditures of around [ ] of revenue should be considered significant." (*Id.*)

BMC then provides corresponding investment-to-revenue percentages when, as it argues should be done, the investments of the domestically supplied components is removed from the analysis. (*Id.* at 13-14.) The resulting percentages are roughly halved—to [ ]%. (*Id.*)

BMC acknowledges that each of the foregoing percentages relate investment amounts to sales revenue, rather than costs of production. (*Id.* at 14.) BMC, however, characterizes ResMed as failing to provide cost information about its products necessary to do a proper value added analysis and comparison with total manufacturing costs. (*Id.*)

BMC then turns back to the investment-to-revenue percentages to compare those from ResMed with those from the complainant in *Lelo*. (*Id.* at 15.) BMC argues ResMed's domestic industry cannot possibly be quantitatively significant since its percentages are lower than what would have been the complainant's in *Lelo* (*Id.*) BMC makes a similar comparison to the complainant in *Certain Table Saws Incorporating Active Injury Mitigation Tech. & Components Thereof* for the same effect. (*Id.* at 15-16.)

BMC concludes with rebuttals of ResMed and OUII positions. Regarding ResMed's assertion that expenditures of [ ] dollars are quantitatively significant, BMC contends that significance cannot be evaluated in an absolute sense, but if it were, the facts in *Lelo* would compel a contrary result. (*Id.* at 16-17.) Additionally, if ResMed's domestic supplier expenditures are properly excluded, the investment amount actually falls under [ ] for subsection (A) and just over for subsection (B). (*Id.* at 17.) BMC also asserts that OUII's approach to the significance analysis is incorrect as it combines the expenditures for each of the Remaining Mask Patents before analyzing the grand total for significance, and then also fails to discount the investments related to domestic suppliers. (*Id.* at 18-19.)

3. Staff

In its Brief on Remand ("SDIB"), the Commission Investigative Staff ("Staff") takes the position that the record in this investigation establishes that ResMed's investments are quantitatively significant. (SDIB at 1.) Staff first presents the summary table of expenditures, allocated to each Mask Patent, as they fall under subsection (A). (*Id.* at 5.) Staff notes that "[i]n total, the ID found that over [ ] in expenses were attributable to the mask patents' domestic industry articles under prong (A)." Staff continues to note that when the '883 and '060 patents are removed from the calculus, the investments still total [ ], and then "[b]ased on this record, these expenses were quantitatively significant as an absolute dollar amount." (*Id.*)

Staff also explains how total sales figures can be broken down per-patent, as provided by ResMed's expert. (*Id.* at 5-6) Staff observes that [ ] of articles sold can be allocated to the '267 patent, [ ] to the '527 patent, and another [ ] for the '392 patent. (*Id.* at 7.) Based on this, Staff concludes "[t]hese percentages establish that the investments in clinical education are quantitatively significant." (*Id.*)

Regarding subsection (B), Staff presents the summary table of expenditures, allocated to each Mask Patent, as was done with subsection (A). (*Id.*) As with subsection (A), Staff notes that "[i]n total, the ID found that over [ ] in labor and capital expenses were attributable to the mask patents' domestic industry articles under prong (B)." (*Id.*) Staff continues to note that when the '883 and '060 patents are removed from the calculus, the investments still total [ ] and then "[b]ased on this record, these expenses were quantitatively significant as an absolute dollar amount." (*Id.* at 7-8.)

Staff concludes to address BMC's arguments; specifically contesting BMC's investment-to-revenue comparison with "BMC does so to seemingly diminish the investments relied on by ResMed, and to make the percentages they arrive at appear to be quantitatively lower, and lower

than what would appear to meet the 'significance' requirement of the domestic industry requirement." (*Id.* at 8.) Staff suggests that it is "more appropriate to examine the percentage of the actual investments in the remaining patents to the overall investments made by ResMed, instead of comparing investments made in each of the patents to revenue generated in the manner presented by BMC." (*Id.* at 8-9.)

B. Determination

After considering the parties' arguments and evidence in light of *Lelo*, I find that ResMed has not adequately shown that the investments it has made under subsections (A) and (B) of 19 U.S.C. § 1337(a)(3) are significant. Two issues related to ResMed's domestic industry in particular are implicated by *Lelo* and led to the present finding.

1. Domestically Supplied Components

The first issue is whether the expenditures toward the domestically-supplied components should be counted towards subsections (A) and (B) of the statute. The domestically-supplied components under consideration are: 1) plastic tubing, 2) foam rubber, and 3) hook-and-loop fasteners, which are allegedly used in the domestic industry mask products. (*See* RDIB at 7.)

Across all three types, BMC argues in its supplemental briefing that "any investments relating to the purchase of third party components by ResMed should be excluded from the domestic industry analysis, based on the *Lelo* decision." (RDIB at 9.) BMC argues that ResMed's evidence is "the same type of evidence that was expressly rejected by the Federal Circuit in *Lelo*." (*Id.* at 6.) BMC contends that ResMed suffers from the same defect as the complainants in *Lelo* who "did not provide any additional evidence breaking down the portion of the purchase price attributable to domestic expenditures in plant, equipment, labor or capital, the *Lelo* court determined that the evidence of component purchases from U.S. suppliers was insufficient to be considered as part of the domestic industry analysis" (*id.*), and then also cites to similar

circumstances in Investigation 337-TA-910, *Certain Television Sets, Television Receivers, Television Tuners, and Components Thereof* ("*Television Tuners*") (*id.* at 8). BMC adds that "ResMed failed to inquire into the actual location of [the components] manufacture." (*Id.*)

ResMed and the Staff, surprisingly, do not discuss the issue in their supplemental briefs. (*See generally* CDIB; SDIB.) Nevertheless, I find that the evidence in the record does signal some level of domestic investment tied to the purchase of the plastic tubing, foam rubber, and hook-and-loop fasteners by ResMed. Ultimately, though, *Lelo* and *Television Tuners* instruct that it be disregarded.

i. **Plastic Tubing**

CX-0765aC is the witness statement of ResMed's expert, Dr. Thomas Vander Veen. He testifies that "additional components of the domestic industry products are manufactured in the United States by third-party suppliers and are purchased by ResMed. These purchased components include foam rubber, rubber tubing, fabric hook-and-loop fasteners, and components of the air pressure sensor." (CX-0765aC at Q/A 76.) He testifies that this knowledge *comes* from the testimony of ResMed witness Gregory Lang and certain "component reports produced by ResMed that show the source of the components in the DI products, including the name and location of the company that components were purchased from." (*Id.* at Q/A 77.) Dr. Vander Veen adds that, to his *understanding*, "FDA regulations in the United States require medical device manufactures to track the locations where components are manufactured, not merely the location where the company they purchased components from is located." (*Id.*)

With respect to the plastic tubing, Dr. Vander Veen testifies that it is his understanding that "ResMed purchases rubber tubing manufactured in California by Smooth-Bor Plastics. The rubber tubing is used to connect the mask to the flow generator." (CX-0765aC at Q/A 86.) He refers to CX-0657C and CX-0658C as evidence of this manufacture and describes them as "supplier

approval forms." (*Id.* at Q/A 81.) The forms "appear[] to show that Smooth-Bor Plastic's[sic] factory is located in Laguna Hills, California" with an additional factory in Spartanburg, South Carolina. (*Id.*)

Mr. Gregory Lang testified with a little more detail on the location of the plastic tubing manufacture. (*See* CX-0760C at Q/A 31-39.) By way of background, Mr. Lang testified that the FDA requires that "[a]ll suppliers of components used in a regulated device must provide information about its facilities and manufacturing process for these components," and "ResMed control the quality and consistency of its suppliers." (*Id.* at Q/A 19.) Like Dr. Vander Veen, he refers to CX-0657C as a "Supplier Approval Form" for Smooth-Bor Plastics, the supplier of air-delivery tubing to ResMed. (*Id.* at Q/A 32.) From CX-0657C, he observes that Laguna Hills, CA is listed as the address of Smooth-Bor in a "General Information" field. (*Id.* at Q/A 33; CX-0657C.) CX-0658C is a similar Supplier Approval Form for Smooth-Bor (CX-0760C at Q/A35), and it lists Spartanburg, SC as a "manufacturing location" for the Slimline Tubing as a location different from that listed in the "General Information" field of the same form. (*Id.* at Q/A 37; CX-0658C.) Mr. Lang observes that this same form "notes that manufacturing will transfer to the Laguna Hills, CA location." (*Id.* at Q/A 37.)

With respect to the plastic tubing, specifically, BMC suggests that "the only evidence of the location of manufacturing for the tubing produced by ResMed was a certificate of approval that expired on June 17, 2013 for the short tube" (RDIB at 8 (describing CX-0657C)), and that "ResMed produced no certificate at all for the slimline tubing" (*id.* at 9). BMC criticizes Mr. Lang for not knowing "whether Smooth-Bor uses foreign-sourced materials or components in making its tubing" and for not making any effort to obtain this information. (*Id.*)

As an initial matter, I place little weight on the certificate expiration BMC highlights and the absence of a similar certificate for the slimline tubing. The fact that the supply chain for

ResMed's products are required by the FDA to be traceable with known locations of manufacture suggests that its Supplier Approval Forms (and the questionnaires included therein), CX-0657C and CX-0658C, are accurate as to their contents; *i.e.* the manufacturing location for the "air delivery tubing" (CX-0657C at RMDB-ITC 7648293) or "extruded tubing" (*id.* at RMDB-ITC 7648297) is Laguna Hills, CA (*id.*), and the manufacturing location for the "slimline tubing" (CX-0658C at RMDB-ITC 7648307) or "flexible plastic corrugated tubing" (*id.* at RMDB-ITC 7648310) is Spartanburg, SC (*id.*). The certificate BMC points to as having expired is cumulative of this information. The certificate simply states the Laguna Hills, CA location of Smooth-Bor complies with National Standards Authority of Ireland requirements for "the design, manufacture and sale of flexible corrugated hose and tubing for medical and commercial industries." (CX-0657C at RMDB-ITC 7648306.) The preceding pages of CX-0657C provide the same, or more, level of information.

I find these forms, along with the testimony from Mr. Lang, make it more likely than not that the plastic tubing purchased by ResMed was manufactured in the United States. Mr. Lang's apparent lack of knowledge regarding the sources of Smooth-Bor's raw materials, or ResMed's failure to investigate this as part of the Investigation, does not take away from this conclusion; and due to this domestic manufacturing, I find it reasonable to infer that there is or has been *some* level of investment in plant, equipment, and labor by Smooth-Bor of the kind that is contemplated by subsections (A) and (B) of the statute. Otherwise the domestic manufacturing could not have occurred.

These are the exact circumstances, however, which the Federal Circuit in *Lelo* and the Commission in *Television Tuners* held to be insufficient to justify including the cost of the domestically-manufactured components into an economic prong analysis.

In the underlying investigation of *Lelo*, the complainant sought to include the purchase cost of four components manufactured in the United States to satisfy economic prong subsection (A). *Kinesiotherapy Devices*, Inv. No. 337-TA-823, Initial Determination at 71 (January 8, 2013). In the Initial Determination, I found that the components were indeed manufactured in the United States. *See id.* at 71-73. The Commission adopted this finding. *See Kinesiotherapy Devices*, Inv. No. 337-TA-823, Comm'n Op. at 22-28 (July 12, 2013). The Federal Circuit adopted it as well. 786 F.3d at 881 ("Of those components, the backbone material, rubber, pigment, and the wafers used in the microcontrollers *are manufactured in the United States*, but the record is not clear whether the U.S. suppliers of the components are also the manufacturers of the components.") (emphasis added). Yet despite this fact of the location of manufacture, the Federal Circuit held:

> There is no evidence of any investment made in capital or labor as a result of the purchased components. Standard Innovation provides only generic purchase prices it paid for the off-the-shelf items. These pricing data do not reflect the magnitude of labor expended to produce the components, or the amount the suppliers invested in their equipment to fulfill Standard Innovation's orders. The record contains no data indicating the share of labor and capital costs attributable solely to purchases made by Standard Innovation.

Id. at 884. The Court provided this explanation to distinguish the nature of the complainant's evidence from that presented in *Male Prophylactics*, Inv. No. 337-TA-546. *Id. Male Prophylactics* was different, the Court held, because "the subcontractor provided a detailed accounting of the number of hours its employees spent working specifically on the complainants" which "permitted the ITC a basis to compute the magnitude of the 'employment of labor.'" *Id.* "In addition, the subcontractor provided an accounting of the amount of investment it made in equipment that its employees used to perform the contracted services." *Id.*

It is axiomatic that a rule should be inferred from the Federal Circuit's distinction; namely, the amount a complainant spends to purchase components manufactured in the United States is

immaterial to the economic prong analysis. Instead, the "magnitude of labor expended to produce those components, or the amount the suppliers invested in their equipment" (or even, arguably, the amount spent on domestic raw materials) to fulfill the complainant's order is the relevant expenditure. *See id.*

Consistent with Lelo, a requirement to prove the amount or magnitude of labor to produce components or material, or the amount the suppliers invested in their equipment, was also recognized by the subsequent Commission opinion in *Television Tuners*. There, the complainant attempted to include "expenditures incurred with domestic suppliers" in the economic prong analysis. *Television Tuners*, Inv. No. 337-TA-910, Initial Determination at 176 (Feb. 27, 2015). While the Initial Determination primarily criticized the credibility of complainant's witness on these expenditures, the Commission refuted the overall approach in light of *Lelo*. The Commission stated:

> Cresta's evidence of payments to domestic suppliers is insufficient to meet the requirements set out by the Federal Circuit in [*Lelo*]. In *Lelo*, the Federal Circuit found that it was necessary for the complainant to demonstrate the "share of labor or capital cost attributable solely to purchases made by" the complainant. *Id.* at 884-85. Moreover, the Court required that the complainant "account for the value expended on *relevant* domestic activities, as opposed to total profit or total general administrative costs." *Id.* at 884 n.4 (emphasis in original). In this investigation, Cresta offered no evidence concerning its suppliers' relevant investments in Cresta's products.

Television Tuners, Inv. No. 337-TA-910, Comm'n Op. at 64 (Oct. 30, 2015).

As BMC points out in its supplemental briefing, there is no evidence in the record of the "magnitude of labor expended" or "amount . . . invested in . . . equipment" by Smooth-Bor to provide ResMed's plastic tubing. (RDIB at 8.) All that the record shows is that ResMed paid [ ] in 2013 to Smooth-Bor for plastic tubing for the mask products (CX-0765aC at Q/A 84; CDX-0012.49aC) which was made in either California or South Carolina (CX-0657C; CX-

0658C). As such, the evidence is "insufficient to meet the requirements set out by the Federal Circuit" in *Lelo*, and I cannot include it in the calculus to determine whether ResMed's domestic investments are quantitatively significant.

ii. **Foam Rubber**

With respect to the foam rubber, Dr. Vander Veen testifies that it is his *understanding* that "ResMed purchases foam rubber manufactured in New York by Rubberlite, Inc. This foam rubber is a component of the foam cushion used in the headgear for certain products." (CX-0765aC at Q/A 85.) He refers to CX-0656C as evidence of this manufacture and describes it as a "supplier approval form." (Id. at Q/A 80.) The form "appears to show that Rubberlite's factory is located in Huntington, West Virginia." (Id.)

Mr. Gregory Lang testified with a little more detail. (*See* CX-0760C at Q/A 26-30.) Like Dr. Vander Veen, he refers to CX-0656C as a "Supplier Approval Form" for Rubberlite, the supplier of foam-backing material to ResMed. (*Id.* at Q/A 26.) In CX-0656C, he points specifically to AQA certification and ISO/IEC accreditation pages which "indicate[] that the foam-backed rubber is manufactured in Rubberlite's Huntington, West Virginia facility." (*Id.* at Q/A 29.)

As with the plastic tubing, BMC's supplemental briefing questions the reliability of the evidence showing the location of manufacture for the foam rubber. (RDIB at 9.) The nature of the evidence presented by ResMed, CX-0656C, is essentially identical to that provided for the plastic tubing and I find it more likely than not that the foam rubber purchased by ResMed was manufactured in the West Virginia. I also find it reasonable to infer that has been some level of investment in plant, equipment, and labor by Rubberlite of the kind that is contemplated by subsections (A) and (B) to enable this manufacturing.

This is simply not sufficient evidence, however, to justify including the cost of the foam rubber in the economic prong calculus for all of the reasons coming from *Lelo* and *Television Tuners* discussed above. *Lelo* and *Television Tuners* tell me that it is Rubberlite's investments in providing ResMed's foam rubber which are needed to satisfy the statute, and there is no evidence in the record of these amounts.

iii. **Hook-and-Loop Fasteners**

With respect to the hook-and-loop fasteners, Dr. Vander Veen testifies that it is his understanding that "ResMed purchases fabric hook-and-loop fasteners manufactured in New Hampshire by Velcro USD, Inc. The hook-and-loop fasteners are used on the headgear and ensure that the product remains comfortably and securely on the patient during sleep." (CX-0765aC at Q/A 87.) He refers to CX-0694C as evidence of this manufacture and describes it as "supplier approval form." (*Id.* at Q/A 79.) He understands the form to communicate that "the hook and loop fasteners used in ResMed's products are originally made in New Hampshire and then sent to Mexico for secondary processing." (*Id.*)

Mr. Gregory Lang, again, testified with a little more detail. (*See* CX-0760C at Q/A 18-25.) Like Dr. Vander Veen, he refers to CX-0694C as a "Supplier Approval Form" for Velcro, the supplier of Velcro tab-fixings and headgear. (*Id.* at Q/A 18.) He testifies that CX-0694C "shows that ResMed procures Velcro fasteners from Velcro in the United States. Specifically, the Velcro fasteners are manufactured in Velcro's Manchester, New Hampshire facility." (*Id.* at Q/A 20.) With respect to the note in CX-0694C regarding the Velcro facility in Mexico, Mr. Lang testifies that it does not impact his statement that New Hampshire is the location of manufacture, in light of the form's content that the Mexico facility "need not be audited because the Manchester, NH facility is already audited." (*Id.* at Q/A 23.)

With respect to the hook-and-loop fasteners, specifically, BMC's supplemental briefing focuses on the at least partial involvement of the Mexico facility in the production of the hook-and-loop fasteners. (RDIB at 8.) BMC uses this fact to argue that there is no "basis to compute the magnitude of the employment of labor or capital, or amount of investment made in plant and equipment" by Velcro. (*Id.*)

As with the plastic tubing and foam rubber, I find there to be sufficient evidence in the record to conclude that the hook-and-loop fastener is a component with ties to *some* level of domestic investment. CX-0694C is the same sort of Supplier Approval Form which ResMed must collect and maintain for the applicable medical device regulations as with the plastic tubing and rubber foam. The fact that some of the processing for the hook-and-loop fasteners does take place in Mexico is relevant, but is outweighed by the document's explanation that the New Hampshire facility is the one that needs auditing. (CX-0694C at RMDB-ITC 7648718; CX-0760C at Q/A 23.) This is an indication that the principal manufacturing occurs in the United States, as opposed to the "die cutting" and "ultrasonic welding" which occurs in Mexico as described by Mr. Lang. (Hr'g Tr. at 487:12-19.) As with the plastic tubing in particular, it is reasonable to infer that some amount of the purchase price paid by ResMed for the hook-and-loop fasteners is attributable to investment in the United States. Otherwise, the New Hampshire facility would not be listed in CX-0694C as a manufacturing location in need of auditing at all, and the activities in Mexico would not be characterized as "low risk." (CX-0694C at RMDB-ITC 7648718.)

None of this matters, however, because *Lelo* and *Television Tuners* have deemed this evidence *per se* insufficient to include in the quantitative analysis. Rather, the amounts which Velcro invests (in either plant, equipment, labor, or capital) in the United States to provide ResMed with hook-and-loop fasteners is what is called for. So I cannot include ResMed's hook-and-loop fastener expenditures in the analysis.

iv. **Conclusion**

For the reasons explained above, I cannot find that ResMed's investments towards the domestically-supplied plastic tubing, foam rubber, and hook-and-loop fasteners should be counted for domestic industry. Their removal results in the following tables of relevant expenditures to be considered for quantitative significance under subsections (A) and (B).

Subsection (A) – Plant and Equipment					
	'267	**'527**	**'392**	**'060**	**'883**
Clinical Education	[ ]	[ ]	[ ]	[ ]	[ ]
Service and Repair	[ ]	[ ]	[ ]	[ ]	[ ]
Customer Service	[ ]	[ ]	[ ]	[ ]	[ ]
TOTAL:	[ ]	[ ]	[ ]	[ ]	[ ]

Subsection (B) – Labor and Capital					
	'267	**'527**	**'392**	**'060**	**'883**
Clinical Education	[ ]	[ ]	[ ]	[ ]	[ ]
Service and Repair	[ ]	[ ]	[ ]	[ ]	[ ]
Customer Service	[ ]	[ ]	[ ]	[ ]	[ ]
TOTAL:	[ ]	[ ]	[ ]	[ ]	[ ]

2. Significant Investment and Employment

The second issue I must consider under *Lelo* is whether the investment and employment amounts calculated are quantitatively significant, as opposed to solely qualitatively significant, under either of subsections (A) or (B). *Lelo*, 786 F.3d at 885 ("qualitative factors alone are insufficient to show 'significant investment in plant and equipment' and 'significant employment of labor or capital' under prongs (A) and (B) of the § 337 domestic industry requirements"). Based on the evidence in the record, I do not find that ResMed's domestic investments under either of subsections (A) or (B) are significant. My finding would not be any different if ResMed's investments in the domestically-supplied plastic tubing, foam rubber, and hook-and-loop fasteners had been included in the analysis.

To begin, I note that ResMed's supplemental briefing generally fails to provide a meaningful explanation of why its combined investments in clinical education, service and repair, and customer service are quantitatively significant. Two headings in particular include the phrase "quantitatively significant," but their analyses either revert to qualitative reasoning or provide no reasoning at all.

As an example, the heading on page 9 of ResMed's supplemental briefing reads "ResMed's Clinical Education is Quantitatively Significant." (CDIB at 9.) ResMed contends this investment is significant in "the context of ResMed's overall clinical education activities." (*Id.*) However, the discussion that follows only addresses how I arrived at allocation ratios for each of the asserted patents in my prior Initial Determination (i.e. [ ] for the 267 patent, [ ] for the 527 patent, and [ ] of the 392 patent). (*See id.* at 10-11.) Then, ResMed summarily declares "[b]ased on the foregoing analysis, ResMed submits the record contains evidence demonstrating that its clinical education investments with respect to articles protected by the patent is quantitatively significant." (*Id.*) Unfortunately, this is not an explanation of why the dollar values flowing from the various percentages are quantitatively significant investments.

Similarly, ResMed contends its investment in clinical education is quantitatively significant in "the context of the sleep-disordered breathing (SDB) industry because this investment increases patient compliance and improves treatment." (*Id.* at 10.) Indeed, the subsequent discussion provides no *quantitative* characterization of this increase in compliance or the alleged improvement in treatment. (*See id.* at 12-14.) The lack of quantitative analysis is revealed through the section's conclusion statement; namely, "ResMed's domestic investment in clinical education is quantitatively significant *because* it leads to an increase in patient compliance." (*Id.* at 13 (emphasis added).) In other words, ResMed's clinical education

investments make compliance and treatment *better*—a *per se qualitative* descriptor. ResMed conflates qualitative arguments to its quantitative arguments.

I do find that ResMed provides a bare quantitative discussion when it states, "ResMed's Investment in Components from Domestic Suppliers is Quantitatively Significant." (CDIB at 14.) As the heading indicates, the section is limited to arguing why the dollars invested in the domestically-supplied components (discussed above) are significant—and not why the dollars invested in these components, plus clinical education, plus service and repair, plus customer service, are significant. (*See id.* at 14-15.) Obviously, the latter would have resulted in a larger investment dollar value to consider for significance.

Nevertheless, ResMed presents a quantitative analysis which argues significance "because this investment is a quantitatively significant percentage of the overall cost of goods sold." (*Id.* at 15.) As implied by a ResMed witness at the hearing, however, the record does not contain information on the overall production cost of each domestic article. (*See, e.g.*, Hr'g Tr. at 483:4-17.) Instead, the record contains the sale price of each domestic article and the cost of the domestic components which go into that article. ResMed recalls in its briefing that this number is no higher than about [ ]. (CDIB at 15.) This is an investment-to-revenue metric.

To convert this investment-to-revenue into investment-to-cost of goods sold, ResMed applies a global cost of goods sold to global revenue percentage of [ ]. (*Id.*) When applied, ResMed arrives at an investment-to-cost of goods sold value of [ ] Thus, ResMed argues its investment in domestic components is significant because that investment is equal to [ ] of the total cost of the good.

This [ ] value is an investment-to-cost of one of ResMed's mask *products*, *not* one of the Mask Patents, however, and it is just one product—the Mirage Activa. (*See* CX-0765aC at

Q/A 99; CDX-0012.55aC.). Therefore it is misleading to claim that ResMed's investments across all of its Remaining Mask Patents are quantitatively significant because of this [ ] value.

Regardless, as discussed in the previous section, the expenses of the plastic tubing, foam rubber, and hook-and-loop fasteners which ResMed analyzes, should not even be included in the economic prong calculus under *Lelo* and *Television Tuners*. If ResMed's [ ] multiplier (global cost to global revenue percentage) is applied to the remaining clinical education, service and repair, and customer service investments, the resulting investment-to-cost percentages outlined in the tables below are obtained. The "Sales Revenue (2013)" values below come from CDX-0012.12aC (Dr. Vander Veen). (CX-0765aC at Q/A 36; *see also* RDIB at 11.)

Subsection (A) – Plant and Equipment					
	'267	**'527**	**'392**	**'060**	**'883**
Clinical Education	[ ]	[ ]	[ ]	[ ]	[ ]
Service and Repair	[ ]	[ ]	[ ]	[ ]	[ ]
Customer Service	[ ]	[ ]	[ ]	[ ]	[ ]
Total Investment (2013)	[ ]	[ ]	[ ]	[ ]	[ ]
Sales Revenue (2013)	[ ]	[ ]	[ ]	[ ]	[ ]
Global Cost-to-Revenue %	[ ]	[ ]	[ ]	[ ]	[ ]
Calculated Cost (2013)	[ ]	[ ]	[ ]	[ ]	[ ]
INVESTMENT-TO-COST %	[ ]	[ ]	[ ]	[ ]	[ ]

Subsection (B) – Labor and Capital					
	'267	**'527**	**'392**	**'060**	**'883**
Clinical Education	[ ]	[ ]	[ ]	[ ]	[ ]
Service and Repair	[ ]	[ ]	[ ]	[ ]	[ ]
Customer Service	[ ]	[ ]	[ ]	[ ]	[ ]
Total Investment (2013)	[ ]	[ ]	[ ]	[ ]	[ ]
Sales Revenue (2013)	[ ]	[ ]	[ ]	[ ]	[ ]
Global Cost-to-Revenue %	[ ]	[ ]	[ ]	[ ]	[ ]
Calculated Cost (2013)	[ ]	[ ]	[ ]	[ ]	[ ]
INVESTMENT-TO-COST %	[ ]	[ ]	[ ]	[ ]	[ ]

The tables demonstrate that ResMed's domestic investments behind the Mask Patents, in the best case scenario of subsection (B), are equivalent to no more than [ ] of the total cost of goods. I cannot conclude that such an insignificant percentage could be a significant "increase or attribution by virtue of the claimant's asserted commercial activity in the United States." *Lelo*, 786 F.3d at 883. If anything, a picture is painted that between [ ] and [ ] of the value for these domestic articles, roughly, comes from non-U.S. investment. While there are no absolute values on what qualifies as significant, the *Lelo* Court did hold that a 5% investment-to-cost amount was modest and insignificant. *See Lelo*, 786 F.3d at 882, 885 (observing that "the total purchase prices accounted for less than five percent of the total raw cost of the devices" and holding "[t]he Commission determined that Standard Innovation's investment and employment under prongs (A) and (B) were quantitatively 'modest' . . . which we take to mean 'insignificant'"). I do not see any reason to treat ResMed's [ ] to [ ] investments any differently, and find them to be likewise quantitatively insignificant under subsections (A) and (B) of the statute. Even if the purchase prices of the domestically manufactured plastic tubing, foam rubber, and hook-and-loop fasteners are added back in, the investment-to-cost percentages only rise to [ ] to [ ], which are still not significant. The overarching fact remains that most if not all of these mask products are manufactured overseas in one or more of ResMed's Australia, Malaysia, or Singapore facilities, and then shipped to the United States packaged and ready for sale. (*See* CX-0760C at Q/A 44; Hr'g Tr. at 464:20-25, 478:14-21 (Mirage Quattro), 479:5-13 (Mirage Activa LT), 479:14-23 (Mirage Swift II), 480:16-23 (Mirage Swift LT for Her), 480:24-481:6 (Mirage Micro), 497:13-16.)

ResMed also contends that "a comparative analysis is not required to determine quantitative significance" such that "in the case of an 'extremely large business,' the percentage of

capital, labor, and other domestic investments may be relatively small when compared to its global sales." (CDIB at 7; *see* CDIB at 9.) With this in mind, ResMed argues that its large sales revenues "do[] not negate or render insignificant its domestic industry investments of over [ ] per year per patent." (*Id.* at 9.)

I agree in principle with ResMed. Investment-to-revenue percentages which become small due to overwhelming sales revenue should be given less weight in the quantitative significance determination. Investment-to-cost percentages, however, avoid distorting the economic reality in that way, and as observed above, ResMed's domestic industry investments account for less than [ ] of its cost of goods sold for each Mask Patent. While such a comparative analysis may not be *required* under *Lelo*, it is certainly *indicative* in this case of the quantitative insignificance of ResMed's domestic expenditures in clinical education, service and repair, and customer service.

The remainder of ResMed's supplemental briefing seeks to distinguish itself from other complainants who were unable to show domestic industry. (CDIB at 15-19.) I find ResMed's distinctions to be qualitative in nature or based on allocation problems, and not helpful to the quantitative significance issue at hand.

The Staff's supplemental briefing argues in support of quantitative significance but does not move me from the above conclusion. If anything, the briefing seems to suggest that [ ] and [ ] are the amounts to be evaluated for significance (*see* SDIB at 5, 7), yet these are the sum totals of all three Remaining Mask Patent investments added together, under subsections (A) and (B) respectively. To use these totals is to triple count the investments made for each of the Mirage Activa LT, Mirage Micro, Mirage Quattro, and Mirage Vista products because they each practice all three of the Remaining Mask Patents. (Technical Prong Stipulation at ¶ 28.) Likewise, the [ ] and [ ] amounts double count the investments in the Mirage Activa as it practices both the '392 and '527 patents. (*Id.*) This is not the proper analysis. "The domestic

industry relating to each patent may be the same domestic industry if both patents are practiced in a single product or in all of the products claimed to be part of the domestic industry." *Certain Single in-Line Memory Modules & Prod. Containing Same*, Inv. No. 337-TA-336, Order No. 8, 1992 WL 811523, *1 (March 19, 1992).

BMC's supplemental briefing argues that "[t]he investments identified by ResMed do not qualify as quantitatively 'significant' under the *Lelo* decision. No finding of domestic industry is possible." (RDIB at 9.) BMC argues reaches this conclusion using investment-to-revenue percentages between [ ] (*See generally* RDIB at 12-18.) While I acknowledge investment-to-revenue percentages have been used occasionally in prior 337 investigations, I see investment-to-cost to be more of an apples-to-apples comparison. Nevertheless, BMC promotes the same general conclusions I draw from the record. "ResMed has not demonstrated that the value added by the alleged activities in the U.S. is significant compared to the overall manufacturing cost" (*id.* at 14), and "the relative quantity of domestic industry is at most on part with—if not substantially less than—that at issue in *Lelo*" (*id.* at 15).

IV. CONCLUSIONS OF LAW

U.S. Patent No. 7,178,527:

- The domestic industry requirement is not satisfied with respect to the '527 patent.
- There has not been a violation of Section 337 with respect to the '527 patent.

U.S. Patent No. 7,950,392:

- The domestic industry requirement is not satisfied with respect to the '392 patent.
- There has not been a violation of Section 337 with respect to the '392 patent.

U.S. Patent No. 7,997,267:

- The domestic industry requirement is not satisfied with respect to the '267 patent.

- There has not been a violation of Section 337 with respect to the '267 patent.

U.S. Patent No. 7,341,060:

- The domestic industry requirement is not satisfied with respect to the '060 patent.
- There has not been a violation of Section 337 with respect to the '060 patent.

U.S. Patent No. 8,312,883:

- The domestic industry requirement is not satisfied with respect to the '883 patent.
- There has not been a violation of Section 337 with respect to the '883 patent.

V. INITIAL DETERMINATION AND ORDER

Based on the foregoing,[2] it is my Initial Determination that a violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, has not occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain sleep-disordered breathing treatment systems and components thereof, in connection with: claims 1, 9, 32, 89, and 92 of U.S. Patent No. 7,178,527; claims 19, 21, 32, and 36 of U.S. Patent No. 7,950,392; claims 32, 33, 34, and 53 of U.S. Patent No. 7,997,267; claims 30, 37, and 38 of U.S. Patent No. 7,341,060; and claims 1, 3, 5, 11, 28, 30, 31, and 56 of U.S. Patent No. 8,312,883.

The undersigned hereby CERTIFIES to the Commission this Final Initial Determination on Remand, together with the record of the hearing in this investigation consisting of the following: the transcripts of the evidentiary and claim construction hearings, with appropriate

[2] The failure to discuss any matter raised by the parties or any portion of the record herein does not indicate that said matter was not considered. Rather, any such matter(s) or portion(s) of the record has/have been determined to be irrelevant, immaterial or meritless. Arguments made on brief which were otherwise unsupported by record evidence or legal precedent have been accorded no weight.

corrections as may hereafter be ordered; and the exhibits accepted into evidence in this investigation as listed in the appendices hereto.[3]

The Secretary shall serve a public version of this Initial Determination upon all parties of record and the confidential version upon counsel who are signatories to the Protective Order (Order No. 1) issued in this Investigation.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review pursuant to 19 C.F.R. § 210.43(a) or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the Final Initial Determination on Remand or certain issues therein.

Confidentiality of Initial Determination and Recommended Determination:

This Final Initial Determination on Remand is being issued as confidential, and a public version will be issued pursuant to Commission Rule 210.5(f). Within 7 days of the date of this Final Initial Determination on Remand, the parties shall jointly submit: (1) a proposed public version of these opinions with any proposed redactions bracketed in red; and (2) a written justification for any proposed redactions specifically explaining why the piece of information sought to be redacted is confidential and why disclosure of the information would be likely to

[3] The pleadings of the parties filed with the Secretary need not be certified as they are already in the Commission's possession in accordance with Commission rules.

cause substantial harm or likely to have the effect of impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions.[4]

SO ORDERED.

Thomas B. Pender
Administrative Law Judge

[4] Under Commission Rules 210.5 and 201.6(a), confidential business information includes:

> information which concerns or relates to the trade secrets, processes, operations, style of works, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, or amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization, or other information of commercial value, the disclosure of which is likely to have the effect of either impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions, or causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained, unless the Commission is required by law to disclose such information.

See 19 C.F.R. § 201.6(a). Thus, to constitute confidential business information the disclosure of the information sought to be designated confidential must ***likely have the effect of*** either: (1) impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions; or (2) ***causing substantial harm*** to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained.

IN THE MATTER OF CERTAIN SLEEP-DISORDERED BREATHING TREATMENT SYSTEMS AND COMPONENTS THEREOF

337-TA-890 (Remand)

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **PUBLIC FINIAL INITIAL DETERMINATION ON REMAND** has been served upon, **The Commission Investigative Attorney, Andrew Beverina, Esq.,** and the following parties via overnight where necessary on NOV 2 9 2016.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, S.W., Room 112A
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