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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