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

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

COMPLAINT OF RESMED LTD, RESMED INC., AND RESMED CORP. UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED

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* Certain cited references are on order from the USPTO and will be submitted upon receipt.

I. INTRODUCTION

1.1 ResMed Corp, ResMed Inc., and ResMed Ltd (sometimes collectively referred to as "ResMed" or "Complainants") request that the United States International Trade Commission commence an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("Section 337"), to remedy the unlawful importation into the United States, sale for importation into the United States, and/or sale within the United States after importation by the owner, importer, or consignee, of certain sleep-disordered breathing treatment mask systems and components thereof (collectively referred to as "the Accused Products"), that infringe two valid and enforceable United States patents owned by ResMed Ltd, and licensed to ResMed Inc. and ResMed Corp.

1.2 This Complaint is based on Proposed Respondents' (Fisher & Paykel Healthcare Limited, Fisher & Paykel Healthcare, Inc., and Fisher & Paykel Healthcare Distribution Inc.) unlawful and unauthorized importation into the United States, sale for importation, and/or sale within the United States after importation, of certain sleep-disordered breathing treatment mask systems and components thereof. Proposed Respondents' products infringe one or more claims of U.S. Patent No. 8,960,196, titled "Mask System with Interchangeable Headgear Connectors," ("the '196 patent") and U.S. Patent No. 9,119,931, titled "Mask System," ("the '931 patent," and collectively "the Asserted Patents.")

1.3 ResMed asserts that the Accused Products infringe at least the patents and claims listed in the chart below:

U.S. Patent No.	Asserted Claims (Independent claims in bold)
'196 patent:	**23-31**, 32-40, **41**-48, 49-56, **57**-72, **73**-86
'931 patent:	**1**, 5-8, 11-14,18-22, 25, 26, 28-31, **33**, 34-37, 40, 41, **43**, 46, 48, 49, **51**, 53-55, **57**, 58, 60-65, 69-71, 77, 78

1.4 Specifically, Proposed Respondents' Simplus™ mask system infringes claims 23-31, 32-40, 41-48, 49-56, 57-72, and 73-86 of the '196 patent. The Eson™ mask system infringes claims 23, 27-30, 32-36, 38-40, 41, 42-46, 48-52, 54-57, 59-62, 64-69, 71-73, 75-78, 80-82, and 84-86 of the '196 patent. The Eson™ 2 mask system infringes claims 23, 27-30, 33-36, 38-40, 41, 42-46, 49-52, 54-57, 59-62, 65-69, 71-73, 75-78, 80-82, and 84-86 of the '196 patent. *See*, Section VII below for explanations of the accused Simplus™ and Eson™ mask systems.

1.5 The Simplus™ mask system infringes claims 1, 5-8, 11-14, 18-22, 25, 26, 28-31, 33, 34-37, 40, 41, 43, 46, 48, 49, 51, 53-55, 57, 58, 60-65, 69-71, 77, and 78 of the '931 patent. The Eson™ mask system infringes claims 33-37, 40, 41, 57, 58, 60-64, 69, 71, 77, and 78 of the '931 patent. The Eson™ 2 mask system infringes claims 33-37, 40, 41, 57, 58, 60, 61, 69, 71, 77, and 78 of the '931 patent.

1.6 Proposed Respondents' activities with respect to the importation into the United States, the sale for importation into the United States, and/or the sale within the United States after importation of certain sleep-disordered breathing treatment mask systems and components thereof, described more fully, *infra*, are unlawful under 19 U.S.C. § 1337(a)(l)(B)(i), in that these mask systems infringe one or more claims of the Asserted Patents.

1.7 Certified copies of the Asserted Patents accompany this Complaint as Exhibits 1 and 4. ResMed Ltd owns by assignment the entire right, title, and interest in and to these patents. Certified copies of the recorded assignments of each of the Asserted Patents accompanies this

Complaint as Exhibits 2, 5 and 6. Each of the Asserted Patents is licensed to ResMed Inc. and sublicensed to ResMed Corp. *See* Exs. 38 and 39.

1.8 As required by Section 337(a)(2) and defined in Section 337(a)(3), an industry in the United States exists relating to articles protected by the Asserted Patents.

1.9 ResMed seeks relief from the Commission in the form of a permanent limited exclusion order, pursuant to Section 337(d), excluding from entry into the United States Proposed Respondents' Accused Products that infringe one or more claims of the Asserted Patents. ResMed also seeks a permanent cease and desist order, pursuant to Section 337(f), halting the importation, sale, offer for sale, marketing, advertising, or soliciting of sleep-disordered breathing treatment mask systems and components thereof by Proposed Respondents and their related companies that infringe the Asserted Patents. Additionally, ResMed requests the imposition of a bond pursuant to Section 337(j) during the period the Commission's relief is under Presidential review.

II. COMPLAINANTS

2.1 Complainant ResMed Ltd is a corporation organized under the laws of Australia, having its principal place of business in Bella Vista, New South Wales, Australia. ResMed Ltd owns the Asserted Patents at issue in this Complaint. Complainant ResMed Corp is a corporation organized under the laws of the state of Minnesota with its principal place of business in San Diego, California. Complainant ResMed Inc. is a corporation organized under the laws of the state of Delaware with its principal place of business in San Diego, California. ResMed Ltd licenses the patents at issue to ResMed Inc. which in turn sublicenses them to ResMed Corp. ResMed Corp and ResMed Ltd are, respectively, direct and indirect subsidiaries of ResMed Inc.

2.2 ResMed is a leading developer, manufacturer and distributor of medical equipment for diagnosing, treating, and managing sleep-disordered breathing and other respiratory disorders. ResMed is dedicated to developing innovative products that improve the lives of those who suffer from these conditions, and to increasing awareness among patients and healthcare professionals of the potentially-serious health consequences of untreated sleep-disordered breathing (sometimes referred to as "SDB"). Since its founding in 1989, ResMed has focused on developing and commercializing systems for the treatment of obstructive sleep apnea ("OSA"), a major subset of SDB. ResMed's development of innovative therapies for the treatment of OSA has resulted in over 3,000 patents granted or pending worldwide. ResMed's product line incorporates patented technology that is highly effective at treating OSA.

2.3 Originally founded in Australia, ResMed is now a U.S. corporation with its parent, ResMed Inc., incorporated in Delaware and headquartered in San Diego. ResMed Inc.'s principal American subsidiary, ResMed Corp is a wholly-owned subsidiary of ResMed Inc. and is ResMed Inc.'s principal America subsidiary. ResMed Corp is co-located in San Diego with the parent company. ResMed Corp also operates facilities in Atlanta, Georgia and Denver, Colorado where, along with the San Diego facility, it engages in a variety of activities all designed to support its domestic industry with respect to its mask systems including the Quattro™ FX and Quattro™ FX for Her, Quattro™ Air and Quattro™ Air for Her, and AirFit™ F10 and AirFit™ F10 for Her (collectively, "the Patented Products"). ResMed Ltd is principally responsible for ResMed's production/assembly, research and manufacturing operations, which are located in various places around the world.

2.4 ResMed Ltd has invested hundreds of millions of dollars in research and development, including substantial investments directed to increasing education and awareness

of the health consequences of untreated SDB among both the general public and physicians. It has been estimated that SDB in general, and OSA in particular, affects approximately 20% of the adult population, making it as widespread as diabetes or asthma. However, awareness of OSA is relatively low; one study in 2002 concluded that about 90% of people with OSA remain undiagnosed and untreated. ResMed works to raise awareness of the risks of untreated SBD through programs such as online training courses and continued support of ongoing research on SBD.

III. PROPOSED RESPONDENTS

3.1 Proposed Respondent Fisher & Paykel Healthcare Limited ("FPH Ltd.") is a corporation organized under the laws of the country of New Zealand with its principal place of business at 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand.

3.2 On information and belief, proposed Respondent Fisher & Paykel Healthcare, Inc. ("FPH Inc.") is a U.S. distributor of FPH Ltd. products. FPH Inc. is a corporation organized under the laws of the state of Delaware with its principal place of business at 173 Technology Drive, Suite 100, Irvine, CA 92618.

3.3 On information and belief, proposed Respondent Fisher & Paykel Healthcare Distribution Inc. ("FPHD Inc.") is a U.S. distributor of FPH Ltd. products. FPHD Inc. is a corporation organized under the laws of the state of California with its principal place of business at 173 Technology Drive, Suite 100, Irvine, CA 92618. FPH Ltd., FPH Inc. and FPHD Inc. are collectively referred to as "FPH."

3.4 As detailed below, on information and belief, FPH are manufacturers and distributors of reusable medical equipment, including mask systems and components thereof for the treatment of sleep-disordered breathing, such as obstructive sleep apnea.

3.5 FPH develops, manufactures, and markets sleep-disordered breathing treatment mask systems and components thereof that infringe one or more claims of the Asserted Patents. On information and belief, these sleep-disordered breathing treatment mask systems and components thereof are manufactured, assembled, packaged, and/or tested outside of the United States. On information and belief, FPH and/or others then import the accused sleep-disordered breathing treatment mask systems, and components thereof into the United States, sell them for importation, or sell them in the United States after importation.

IV. PRODUCTS AND TECHNOLOGY AT ISSUE

4.1 The products at issue are mask systems used in the treatment of SDB, particularly obstructive sleep apnea ("OSA"). As the name implies, a person with OSA will experience obstructed breathing while sleeping as throat muscles relax and close off the breathing passage. After a period as long as ten seconds, the person will reopen the breathing passage by expelling air, only to have the passage close again as the throat muscles relax again, a cycle which may repeat itself several hundred times in the course of a night. The disrupted sleep pattern that results from having OSA not only causes the person to feel unrested after sleeping, but also can cause a drop in blood oxygen levels, placing a strain on the person's overall respiratory and circulatory systems.

4.2 In the 1980's, Professor Colin Sullivan at Royal Prince Alfred Hospital in Sydney, Australia, and Dr. George Gregory at the University of California, San Francisco, began devising methods of treating OSA through the use of continuous positive airway pressure, or "CPAP." CPAP therapy involves the use of mild air pressure to keep the patient's airway open during sleep. A CPAP therapy system consists of three main elements working together: 1) a flow generator for creating the flow of air, 2) a conduit, usually a flexible tube, for carrying the flow of air to the patient, and 3) an interface (usually a facial mask or a pair of "nasal pillows"

that are inserted into the nasal cavities) that provides a connection to the patient's airway. The continuous flow of air prevents the airway from collapsing during sleep and thus disrupts the OSA cycle described above, leading the patient to an uninterrupted, good night's sleep.

ResMed CPAP Machine in Use

4.3 The success of CPAP therapy in the treatment of OSA has been widely recognized. Indeed, the University of Maryland Medical Center describes CPAP as the "first-line treatment for mild-to-moderate or severe obstructive sleep apnea."[1]

4.4 In CPAP therapy, air is provided to the patient by a flow generator. The flow generator generally uses an electric motor driving a fan or turbine to create the high pressure air that is supplied to the mask. Many patients prefer to use humidified air during CPAP treatments, and so CPAP flow generators are often paired with a humidifier. This is important because patient noncompliance is a major concern for the administration of CPAP therapy.

4.5 Additionally, the patient interface (mask, nasal pillows, etc.) represents a critical element of any CPAP therapy system. The mask must maintain an effective seal against the

[1] http://www.umm.edu/patiented/articles/continuous_positive_airflow_pressure_cpap_devices_used_sleep_apnea_000065_8.htm (accessed March 22, 2016), attached as Exhibit 41.

patient's face because air leakage can significantly reduce the therapeutic effects of the CPAP system. At the same time, if the mask is uncomfortable or constricting, the patient may find the system difficult to use and cease using the system altogether. Like the addition of humidified air, patient noncompliance because of mask discomfort is another major concern in the administration of CPAP therapy.

4.6 ResMed offers a range of flow generators and mask systems designed to maximize the efficacy of the CPAP therapy delivered. ResMed also offers a range of ventilator products. A complete description of ResMed's products can be found at http://www.resmed.com/products.

4.7 The accused FPH mask systems are sold under the brand names "Simplus™" and "Eson™" and "Eson™ 2."

V. THE ASSERTED PATENTS

5.1 At issue in this investigation is Proposed Respondents' infringement of two United States patents: the '196 and '931 patents. ResMed summarizes the general technology involved as well as the Asserted Patents below.

A. General Background

5.2 As noted previously, SDB, particularly OSA, can lead to serious and harmful effects on a person's overall respiratory and circulatory systems. One manner of treating these disorders is through the use of CPAP treatments. During CPAP treatment, air is continually supplied into a patient's airways at pressures above the ambient atmospheric pressure while the patient sleeps. This higher pressure air helps keep the patient's airways open, thereby ensuring a steady supply of oxygen and helping a patient achieve a more restful and healthy sleep. Various different types of CPAP treatment may involve different cycles or levels of pressure during the course of a single treatment (i.e., over the course of single sleeping period). The air is supplied

by an air flow generator, through an air conduit, and into a patient interface that generally consists of a full face mask, or nasal prongs and pillows.

5.3 The mask systems generally consist of a mask shell attached to a conduit of some kind, with, for example, an elbow joint. The mask shell includes a cushion or padding so that it rests comfortably and well-sealed to the patient's face. The mask may be secured onto a patient's head with a harness consisting of straps. It may also include other support structures, such as a forehead pad to comfortably brace the mask against the patient's forehead. The mask generally also will include a vent for exhaling exhaust gas when a patient breathes out; this vent usually will be located on or near the mask shell itself. ResMed's patented inventions involve innovative mechanisms for connecting the cushioned mask shell to the headgear that comfortably maintains the mask position on the patient's face during sleep.

5.4 Descriptions of the patents asserted in this Complaint are set forth in the remainder of this section. The contents of this Complaint, including the subsections titled "Non-Technical Description of the Patented Invention," does not and is not intended to construe either the specification or claims of the patents asserted herein.

A. U.S. Patent No. 8,960,196

1. Identification of the Patent and Ownership by ResMed

5.5 ResMed Ltd owns by assignment the entire right, title, and interest in the '196 patent titled "Mask System with Interchangeable Headgear Connectors," which issued on February 24, 2015. The '196 patent issued from U.S. Patent Application Serial No. 13/904,748, filed on May 29, 2013, and is a continuation of application No. 12/010,680, filed on January 29, 2008, now U.S. Patent No. 8,517,023. U.S. Patent Application Serial No. 12/010,680 claimed the benefit of U.S. Provisional Application No. 60/898,108, filed on January 30, 2007. ResMed

Inc. is the exclusive licensee of the '196 patent and has sublicensed the patent to ResMed Corp, its U.S. sales subsidiary.

5.6 The inventor of the '196 patent, Robert Edward Henry, assigned to ResMed Ltd all right, title, and interest in and to the invention disclosed and claimed in the '196 patent. *See* Ex. 2. The '196 patent is valid, enforceable, and is currently in full force and effect. A certified copy of the '196 patent is attached as Exhibit 1.

5.7 Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by Appendices A and B. Appendix A contains the prosecution history of the '196 patent; Appendix B contains each currently available reference mentioned in that prosecution history.

2. Non-Technical Description of the Patented Invention[2]

5.8 The '196 patent generally discloses a mask system for delivering breathable gas to a patient. The mask system includes a common frame having a central bore that lacks built-in or integral headgear attachment points and a sealing cushion. The mask system further includes a headgear connector adapted to be connected to the frame and to the headgear straps of a selected headgear. An embodiment of the invention is pictured in Figure 5A:

[2] These descriptions and other non-technical descriptions within this Complaint are for illustrative purposes only. Nothing contained within this Complaint is intended to, either implicitly or explicitly, express any position regarding the proper construction of any claim of the Asserted Patents.

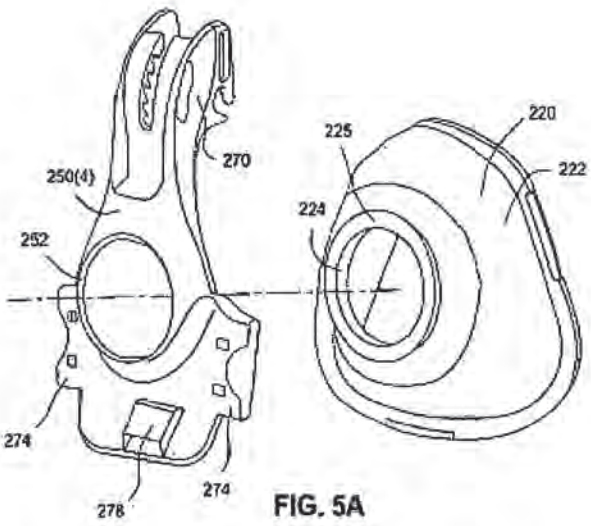

FIG. 5A

3. Foreign Counterparts to the '196 Patent

5.9 The foreign counterparts to the '196 patent are listed in Exhibit 3. No other foreign patents or patent applications corresponding the '196 patent have been filed, abandoned, withdrawn, or rejected.

B. U.S. Patent No. 9,119,931

1. Identification of the Patent and Ownership by ResMed

5.10 ResMed Ltd owns by assignment the entire right, title, and interest in the '931 patent titled "Mask System," which issued on September 1, 2015. The '931 patent issued from U.S. Patent Application Serial No. 14/447,673, filed on July 31, 2014, and is a continuation of application No. 13/964,280, filed on August 12, 2013, which is a continuation of application No. 13/745,077, filed on January 18, 2013, now U.S. Patent No. 8,528,561, which is a continuation of application No. 12/736,024, filed as application No. PCT/AU2009/000241 on February 27, 2009, now U.S. Patent No. 8,550,084. Application No. 12/736,024 claims the benefit of U.S. Provisional Application No. 61/064,406, filed March 4, 2008, Provisional Application No. 61/071,893, filed May 23, 2008, and Provisional Application No. 61/136,617,

filed September 19, 2008. ResMed Inc. is the exclusive licensee of the '931 patent and has sublicensed the patent to ResMed Corp, the U.S. sales subsidiary.

5.11 The inventors of the '931 patent—Errol Savio Alex D'Souza, Matthew Eves, David James Lockwood, Zoran Valcic, Jamie Graeme Wehbeh—assigned to ResMed Ltd all right, title, and interest in and to the invention disclosed and claimed in the '931 patent. *See* Exs. 5-6. The '931 patent is valid, enforceable, and is currently in full force and effect. A certified copy of the '931 patent is attached as Exhibit 4.

5.12 Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by Appendices C and D. Appendix C contains the prosecution history of the '931 patent; Appendix D contains each currently available reference mentioned in that prosecution history.

2. Non-Technical Description of the Patented Invention[3]

5.13 The '931 patent generally discloses a mask system for treatment of SDB via the delivery of a supply of air at positive pressure into the patient's airway. *See* Ex. 4, the '931 Patent, at 1:21-24. The mask system has a coupleable shroud module with headgear connectors, a cushion module, including a vented, rigid or semi-rigid frame defining a breathing chamber, and a cushion constructed of soft, elastomeric material to form a seal with regions of the patient's face. *See id.* at Abstract. The mask system of the '931 patent improves therapy efficacy and patient compliance by providing mask systems that are more comfortable and better fitting. *See, e.g.*, Ex. 4, '931 Patent, at 1:36-42. The comfort and fit of the mask system is improved by various features, such as folds in the cushion to allow for greater adaptability and

[3] These descriptions and other non-technical descriptions within this Complaint are for illustrative purposes only. Nothing contained within this Complaint is intended to, either implicitly or explicitly, express any position regarding the proper construction of any claim of the Asserted Patents.

flexibility in the fit and an arrangement of headgear connectors that avoids covering the patient's field of vision. An embodiment of the invention is pictured in Figure 1B:

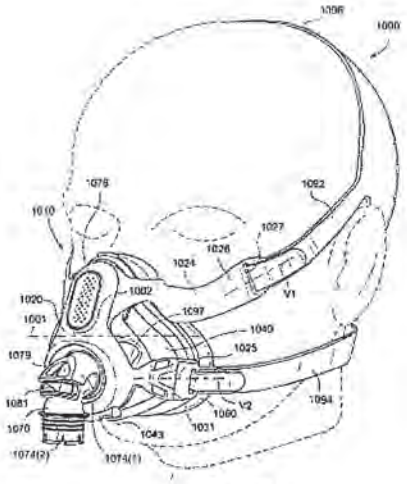

Fig. 1B

5.14 The non-technical description above is limited in nature. Note that in addition to the description above, the patented invention includes all elements of a CPAP treatment.

3. Foreign Counterparts to the '931 Patent

5.15 The foreign counterparts to the '931 patent are listed in Exhibit 7. No other foreign patents or patent applications corresponding to the '931 patent have been filed, withdrawn, or rejected.

VI. THE DOMESTIC INDUSTRY

6.1 A domestic industry exists, as defined by 19 U.S.C. §§ 1337(a)(3)(A), (B), and/or (C), based on ResMed's significant investment in plant and equipment; significant employment of labor or capital; and substantial investment in the exploitation of the Asserted Patents.

6.2 ResMed's Patented Products use the inventions claimed in its Asserted Patents and ResMed has made, continues to make and will make in the future, significant domestic

investments in these products, as described in the accompanying Confidential Declaration of Andrew Price, attached to this Complaint as Confidential Exhibit 8, which provides an identification and allocation of qualified expenses, investments, and sales related to the Patented Products.

6.3 ResMed has sold and continues to sell in the United States mask systems that practice ResMed's Asserted Patents, including, for example, the Quattro™ FX and Quattro™ FX for Her mask systems that practice both the '196 and '931 patents; the Quattro™ Air and Quattro™ Air for Her mask systems that practice the '196 patent; and the AirFit™ F10 and AirFit™ F10 for Her mask systems that practice the '196 patent. During Fiscal Years 2015 and 2016, ResMed sold a substantial number of Patented Products in the United States. *See* Ex. 8 at ¶ 17. As described below in greater detail, each of these Patented Products practices one or both of the Asserted Patents. ResMed's domestic investments and expenditures related to these Patented Products are significant, on-going and increasing.

6.4 ResMed's significant investment in plant and equipment; significant employment of labor or capital; and substantial investment in the exploitation of the Asserted Patents includes facilities in Atlanta, Georgia; Denver, Colorado; and its U.S. and Global Headquarters in San Diego, California. ResMed's investment in its domestic industry further includes the significant employment of people in the United States, and plant and equipment to support these employees. *See* Ex. 8 at ¶ 9. Many of these employees work either full- or part-time to support various activities related to the Patented Products. *See* Ex. 8 at ¶¶ 9-14.

6.5 ResMed's activities in the United States with respect to the Patented Products constitute a domestic industry for purposes of Section 337. *See* Ex. 8.

A. Technical Prong

6.6 ResMed uses its Asserted Patents in various sleep-disordered breathing treatment mask systems and these mask systems incorporate the inventions claimed in the Asserted Patents. Examples of ResMed's use of its Asserted Patents are described above and detailed below in the Exhibits 11, 12, 15 and 18.

6.7 ResMed's Quattro™ FX and Quattro™ FX for Her mask systems practice at least claim 73 of the '196 patent. Photographs of the Quattro™ FX and Quattro™ FX for Her mask systems are attached as Exhibit 9. A copy of the user manual for the Quattro™ FX and Quattro™ FX for Her mask systems is attached as Exhibit 10. An exemplary claim chart demonstrating how the Quattro™ FX and Quattro™ FX for Her mask systems embody claim 73 of the '196 patent is attached as Exhibit 11.

6.8 The Quattro™ FX and Quattro™ FX for Her mask systems also practice at least claim 1 of the '931 patent. An exemplary claim chart demonstrating how the Quattro™ FX and Quattro™ FX for Her mask systems embody claim 1 of the '931 patent is attached as Exhibit 12.

6.9 ResMed's Quattro™ Air and Quattro™ Air for Her mask systems practice at least claim 73 of the '196 patent. Photographs of the Quattro™ Air and Quattro™ Air for Her mask systems are attached as Exhibit 13. A copy of the user manual for the Quattro™ Air and Quattro™ Air for Her mask systems is attached as Exhibit 14. An exemplary claim chart demonstrating how the Quattro™ Air and Quattro™ Air for Her mask systems embody claim 73 of the '196 patent is attached as Exhibit 15.

6.10 ResMed's AirFit™ F10 and AirFit™ F10 for Her mask systems practice at least claim 73 of the '196 patent. Photographs of the AirFit™ F10 and AirFit™ F10 for Her mask systems are attached as Exhibit 16. A copy of the user manual for the AirFit™ F10 and AirFit™ F10 for Her mask systems is attached as Exhibit 17. An exemplary claim chart demonstrating

how the AirFit™ F10 and AirFit™ F10 for Her mask systems embody claim 73 of the '196 patent is attached as Exhibit 18.

B. Economic Prong

6.11 ResMed conducts significant domestic industry activities in the United States relating to the Patented Products. *See* Ex. 8.

6.12 A domestic industry exists under 19 U.S.C. §§ 1337(a)(3)(A) at least because ResMed had made and continues to make significant investment in plant and equipment in the United States, including its existing facilities in San Diego, California; Atlanta, Georgia; and Denver, Colorado. *See* Ex. 8 at ¶¶ 10, 14 and 22. In the San Diego facility, which serves as ResMed's United States and global headquarters, ResMed conducts substantial activities related to the Patented Products. *See* Ex. 8 at ¶ 11. In the Atlanta facility, ResMed additionally conducts substantial activities related to the Patented Products. *See id.* at ¶ 19. The Denver facility provides additional substantial activities related to the Patented Products. *See id.* at ¶ 14. Confidential Exhibit 8 provides details concerning ResMed's investment in plant and equipment.

6.13 A domestic industry exists under 19 U.S.C. §§ 1337(a)(3)(B) at least because ResMed has employed and continues to employ significant labor or capital in the United States related to the Patented Products. *See* Ex. 8 at ¶ 9. ResMed's employees, at its California, Georgia, and Colorado facilities, devote substantial personnel-hours toward various activities relating to the Patented Products. *See id.* at ¶ 9. Additionally, ResMed employees in San Diego and throughout the United States devote substantial personnel-hours toward various activities relating to the Patented Products. *See id.* at ¶ 12. ResMed has made substantial investments in capital and infrastructure to support these employees and their activities. Confidential Exhibit 8 provides details concerning ResMed's employment of labor or capital.

6.14 A domestic industry exists under 19 U.S.C. §§ 1337(a)(3)(C) at least because ResMed has invested and continues to invest substantially in the exploitation of the Asserted Patents through the Patented Products, including, by example, ResMed's investment in engineering. ResMed has made substantial investments in capital and infrastructure to support these employees and their activities. Confidential Exhibit 8 provides details concerning ResMed's exploitation of the Asserted Patents. A copy of ResMed Inc.'s Form 10-K and Annual Report for the fiscal year ending June 30, 2015, which further describes ResMed's domestic investments, is attached as Exhibit 19.

VII. UNLAWFUL AND UNFAIR ACTS OF PROPOSED RESPONDENTS

7.1 Proposed Respondents have engaged in unlawful and unfair acts including the sale for importation into the United States, importation into the United States, sale within the United States after importation, and/or use within the United States after importation of the Accused Products that infringe one or more of the following claims (independent claims in bold):

	'196 patent:	**'931 patent:**
Simplus	**23**-31, 32-40, **41**-48, 49-56, **57**-72, **73**-86	**1**, 5-8, 11-14, 18-22, 25, 26, 28-31, **33**, 34-37, 40, 41, **43**, 46, 48, 49, **51**, 53-55, **57**, 58, 60-65, 69, 70, 71, 77, 78
Eson	**23**, 27-30, 32-36, 38-40, **41**, 42-46, 48-52, 54-**57**, 59-62, 64-69, 71-**73**, 75-78, 80-82, 84-86	**33**-37, 40, 41, **57**, 58, 60-64, 69, 71, 77, 78
Eson 2	**23**, 27-30, 33-36, 38-40, **41**, 42-46, 49-52, 54-**57**, 59-62, 65-69, 71-**73**, 75-78, 80-82, 84-86.	**33**-37, 40, 41, **57**, 58, 60, 61, 69, 71, 77, 78

A. Infringement of the '196 Patent

7.1 Proposed Respondents' Simplus™ mask system directly infringes at least claims 23-31, 32-40, 41-48, 49-56, 57-72, and 73-86 of the '196 patent. Proposed Respondents' Eson™ mask system directly infringes at least claims 23, 27-30, 32-36, 38-40, 41, 42-46, 48-52, 54-57, 59-62, 64-69, 71-73, 75-78, 80-82, and 84-86 of the '196 patent. Proposed Respondents' Eson™

2 mask system directly infringes at least claims 23, 27-30, 33-36, 38-40, 41, 42-46, 49-52, 54-57, 59-62, 65-69, 71-73, 75-78, 80-82, and 84-86 of the '196 patent. On information and belief as to the Eson™ 2 mask system, the Accused Products are manufactured, assembled, packaged, and/or tested overseas, specifically, at least in New Zealand. These same products are then imported into the United States, sold for importation into the United States, and/or sold after importation into the United States by Proposed Respondents. Further discovery may reveal that Proposed Respondents infringe additional claims of the '196 patent.

7.2 Further discovery may also reveal additional FPH products and/or models that infringe the '196 patent. Photographs of a representative FPH Simplus™ and Eson™ and mask systems are attached to this Complaint as Exhibits 20 and 23, respectively. A copy of the user manual for the representative Simplus™ mask system is attached to this Complaint as Exhibit 23. A copy of the user manual for the representative Eson™ mask system is attached to this Complaint as Exhibit 24. A copy of the user manual for the representative Eson™ 2 mask system is attached to this Complaint as Exhibit 25. Claim charts demonstrating how the asserted claims of the '196 patent is infringed by the Simplus™ Eson™ and Eson™ 2 mask systems are attached as Exhibits 31, 32 and 33, respectively.

B. Infringement of the '931 Patent

7.3 Upon information and belief, Proposed Respondents' Simplus™ mask systems directly infringes at least claims 1, 5-8, 11-14, 18-22, 25, 26, 28-31, 33, 34-37, 40, 41, 43, 46, 48, 49, 51, 53-55, 57, 58, 60-65, 69, 70, 71, 77, 78 of the '931 patent. Upon information and belief, Proposed Respondents' Eson™ mask systems directly infringes at least claims 33-37, 40, 41, 57, 58, 60-64, 69, 71, 77, 78 of the '931 patent. Upon information and belief, Proposed Respondents' Eson™ 2 mask systems directly infringes at least claims 33-37, 40, 41, 57, 58, 60, 61, 69, 71, 77, 78 of the '931 patent. Upon information and belief as to the Eson™ 2 mask

system, the Accused Products are manufactured, assembled, packaged, and/or tested overseas, specifically, at least in New Zealand. These same products are then imported into the United States, sold for importation into the United States, and/or sold after importation into the United States by Proposed Respondents. Further discovery may reveal that Proposed Respondents infringe additional claims of the '931 patent.

7.4 Further discovery may also reveal additional FPH products and/or models that infringe the '931 patent. Photographs of a representative FPH Simplus™ and Eson™ mask systems are attached to this Complaint as Exhibits 20 and 21, respectively. A copy of the user manual for the representative Simplus™ mask system is attached to this Complaint as Exhibit 23. A copy of the user manual for the representative Eson™ mask system is attached to this Complaint as Exhibit 24. A copy of the user manual for the representative Eson™ 2 mask system is attached to this Complaint as Exhibit 25. Claim charts demonstrating how the asserted claims of the '931 patent is infringed by the Simplus™, Eson™, and Eson™ 2 mask systems are attached as Exhibits 34, 35 and 36, respectively.

VIII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

A. FPH

8.1 Complainants purchased representative FPH Simplus™ and Eson™ mask systems in the United States. Attached as Exhibit 22 are photographs depicting the packaging in which the FPH Simplus™ and Eson™ mask systems, respectively, were shipped. Exhibit 22 also shows labels on the devices and/or product packaging for representative FPH devices, which indicate that the Accused Products were manufactured in New Zealand. In June 2016, FPH displayed an Eson™ 2 Nasal Mask at the SLEEP 2016 conference in Denver, Colorado. *See* Ex. 37 at ¶¶ 3, 4.

8.2 On October 2, 2012, the FPH Eson™ Nasal Mask was granted 510(k) clearance for marketing K121597 by the United States Food and Drug Administration under the Food Drug and Cosmetic Act. 21 U.S.C. § 360 *et seq.*; 21 CFR § 807.92. On June 5, 2013, the FPH Simplus™ Full Face Mask was granted 510(k) clearance for marketing K130328 by the United States Food and Drug Administration under the Food Drug and Cosmetic Act. 21 U.S.C. § 360 et seq.; 21 CFR § 807.92. The Eson™ 2 Nasal Mask is pending FDA approval. *See* Ex. 37 at ¶ 4. Spec sheets for the accused Simplus™, Eson™ and Eson™ 2 mask systems are attached as Exhibits 26, 27 and 28, respectively. The Simplus™ and Eson™ mask systems are marketed directly on FPH's website, pages of which are attached as Exhibits 29 and 30, respectively.[4]

B. HTSUS

8.3 The Accused Products are believed to fall within at least the following classifications of the Harmonized Tariff Schedules of the United States: 9019.20.00. This classification is intended for illustrative purposes only and is not intended to restrict the scope or type of accused product.

IX. LICENSEES

9.1 ResMed has licensed the Asserted Patents. Pursuant to Commission Rule 210.12, ResMed states that for the Asserted Patents ResMed Ltd has granted ResMed Inc. an exclusive license with the right to sublicense. ResMed Inc. has granted an exclusive license to the Asserted Patents to ResMed Corp. Copies of these licenses can be found in Confidential Exhibits 38 and 39. A list of all licensees can be found in Confidential Exhibit 40.

X. RELATED LITIGATION

10.1 The alleged unfair acts, and the subject matter thereof, are not nor have been the subject of any court or agency litigation.

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[4] *See*, https://www.fphcare.com/sleep-apnea/masks/.

XI. REQUESTED RELIEF

11.1 WHEREFORE, by reason of the foregoing, ResMed requests that the United States International Trade Commission:

(a) institute an immediate Investigation, pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to violations of Section 337 based on the Proposed Respondents' unlawful importation into the United States, sale for importation into the United States, and/or sale within the United States after importation of certain sleep-disordered breathing treatment mask systems and components thereof, which infringe one or more claims of the Asserted Patents;

(b) schedule and conduct a hearing on the unlawful acts and, following the hearing, determine that there has been a violation of Section 337;

(c) issue a permanent limited exclusion order, pursuant to Section 337(d) of the Tariff Act of 1930, as amended, excluding from entry into the United States all of the Proposed Respondents' sleep-disordered breathing treatment mask systems and components thereof which infringe one or more claims of the Asserted Patents;

(d) issue permanent cease and desist orders, pursuant to Section 337(f) of the Tariff Act of 1930, as amended, directing the Proposed Respondents to cease and desist from the importation, marketing, advertising, demonstrating, warehousing inventory for distribution, sale and use of certain sleep-disordered breathing treatment mask systems and components thereof that infringe one or more claims of the Asserted Patents;

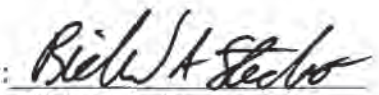
(e) impose a bond, pursuant to Section 337(j), upon importation of any sleep-disordered breathing treatment mask systems and components thereof that infringe one or more claims of the Asserted Patents during the Presidential Review Period; and

(f) grant such other and further relief as the Commission deems just and proper based on the facts determined by the Investigation and the authority of the Commission.

Respectfully submitted,

FISH & RICHARDSON P.C.

Dated: August 17, 2016

By: 

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Counsel for Complainants ResMed Ltd, ResMed Inc., and ResMed Corp.

VERIFICATION OF COMPLAINT

I, Jon Yerbury, declare under the penalty of perjury under the laws of the United States of America, and in accordance with 19 C.F.R. §§ 210.4(c) and 210.2(a), that the following is true and correct:

1. I am currently the Vice President of Marketing-Americas at ResMed Corp.
2. I am duly authorized to verify the foregoing Complaint on behalf of ResMed Corp, ResMed Inc. and ResMed Ltd.;
3. I have read the complaint and I am aware of its contents;
4. The complaint is not being presented for any improper purpose, such as to harass or to cause unnecessary delay or needlessly increase the cost of the investigation or related proceeding;
5. To the best of my knowledge, information, and belief founded upon reasonable inquiry, the claims and legal contentions of this complaint are warranted by existing law or by a nonfrivolous argument for the extension, modification or reversal of existing law or the establidhment of new law; and
6. To the best of my knowledge, information and belief founded upon reasonable inquiry, the allegations and other factual contentions in the complaint have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.

Executed on August 17, 2016

Jon Yerbury