

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

**In the Matter of Certain Obstructive Sleep Apnea
Treatment Mask Systems and Components
Thereof**

Investigation No. 337-TA-_____
Docket No.

**COMPLAINT UNDER SECTION 337 OF
THE TARIFF ACT OF 1930, AS AMENDED**

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3	Foreign counterpart patents and applications to U.S. Patent No. 9,333,315
4	Certified Copy of U.S. Patent No. 9,517,317
5	Certified Assignment Documents for U.S. Patent No 9,517,317
6	Listing of All Foreign Patents and All Foreign Patent Applications Corresponding to U.S. Patent No. 9,517,317
7	Certified Copy of U.S. Patent No. 9,539,405
8	Certified Assignment Documents for U.S. Patent No. 9,539,405
9	Foreign counterpart patents and applications to U.S. Patent No. 9,539,405
10	Uncertified Copy of U.S. Patent No. 9,907,925
11	Certified Assignment Documents for U.S. Patent No. 9,907,925
12	Foreign counterpart patents and applications to U.S. Patent No. 9,907,925
13	Uncertified Copy of U.S. Patent No. 9,974,914
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LIST OF PHYSICAL EXHIBITS

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LIST OF APPENDICES

Appendix	Description
A	Certified File History for U.S. Patent No. 9,333,315
B	References Cited in File History of U.S. Patent No. 9,333,315
C	Certified File History for U.S. Patent No. 9,517,317
D	References Cited in File History of U.S. Patent No. 9,517,317
E	Certified File History for U.S. Patent No. 9,539,405
F	References Cited in File History of U.S. Patent No. 9,539,405
G	Certified File History for U.S. Patent No. 9,907,925
H	References Cited in File History of U.S. Patent No. 9,907,925
I	Uncertified File History for U.S. Patent No. 9,974,914
J	References Cited in File History of U.S. Patent No. 9,974,914

I. INTRODUCTION

1. Fisher & Paykel Healthcare Limited (“Fisher & Paykel Healthcare,” “FPH” or “Complainant”) requests 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 of articles covered by valid and enforceable United States patents owned by Fisher & Paykel Healthcare, namely United States Patent Nos. 9,333,315 (the “’315 Patent”), 9,517,317 (the “’317 Patent”), 9,539,405 (the “’405 Patent”), 9,907,925 (the “’925 Patent”), and 9,974,914 (the “’914 Patent”) (collectively, the “Asserted Patents”).

2. The Respondents are ResMed Inc., ResMed Corp., and ResMed Limited (collectively, “Respondents” or “ResMed”). Respondents have engaged in unfair acts in violation of Section 337 through the unlawful and unauthorized importation into the United States, sale for importation into the United States, and/or sale within the United States after importation, of certain obstructive sleep apnea treatment mask systems and components thereof covered by one or more claims of each of the Asserted Patents.

3. Certified copies of the ’315 Patent, ’317 Patent, and ’405 Patent are attached hereto as **Exhibits 1, 4, and 7** respectively. Uncertified copies of the ’925 Patent and ’914 Patent are attached as **Exhibits 10 and 13** respectively.¹ Fisher & Paykel Healthcare owns by assignment the entire right, title, and interest in and to the Asserted Patents. Certified copies of the ’315 Patent, ’317 Patent, and ’405 Patent, and ’925 Patent assignment documents are attached hereto as **Exhibits 2, 5, 8 and 11**, respectively. An uncertified copy of the ’914 Patent

¹ Certified copies of the ’925 Patent and ’914 Patent have been ordered and will be submitted upon receipt in a supplemental filing.

assignment documents is attached hereto as **Exhibit 14**.²

4. Respondents, through their unlawful importation, sale for importation, and/or sale after importation, infringe at least the following patent claims:

<u>U.S. Patent</u>	<u>Asserted Claims</u>
'315 Patent	1, 2, 3, 4, 6, 7, 8, 9, 11, 12, 13, 14, 15, 17, 18, 19
'317 Patent	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20
'405 Patent	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20
'925 Patent	4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20
'914 Patent	1, 2, 3, 5, 6, 7, 8, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 22, 25, 26, 27

Further discovery may reveal that Respondents infringe additional claims.

5. Specifically, Respondents' AirFit™ P10/AirFit™ P10 for Her mask systems infringe claims 1-4, 6-9, 11-15, and 17-19 of the '315 Patent. The AirFit™ P10/AirFit™ P10 for Her mask systems infringe claims 1-20 of the '317 Patent. The AirFit™ P10/AirFit™ P10 for Her mask systems infringe claims 1-20 of the '405 Patent. The AirFit™ P10/AirFit™ P10 for Her mask systems infringe claims 4-20 of the '925 Patent. The AirFit™ P10/AirFit™ P10 for Her mask systems infringe claims 1-3, 5-8, 11-20, 22, and 25-27 of the '914 Patent.

6. The AirFit™ P10 for AirMini™ mask system infringes claims 6-9, 11-14 and 17-19 of the '315 Patent. The AirFit™ P10 for AirMini™ mask system infringes claims 1-20 of the '317 Patent. The AirFit™ P10 for AirMini™ mask system infringes claims 8-13 and 16-20 of the '405 Patent. The AirFit™ P10 for AirMini™ mask system infringes claims 4-20 of the '925 Patent. The AirFit™ P10 for AirMini™ mask system infringes claims 1-3, 5-7, 11, 12, 15-20, 22, 25-27 of the '914 Patent.

7. As required by Section 337(a)(2), and defined by Section 337(a)(3), an industry exists in the United States, and is in the process of being further established in the United States,

² Certified copies of the '914 Patent assignments have been ordered and will be submitted upon receipt in a supplemental filing.

relating to articles protected by each of the Asserted Patents.

8. Fisher & Paykel Healthcare 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 Respondents' obstructive sleep apnea treatment mask systems covered by one or more claims of the '315 Patent, '317 Patent, '405 Patent, '925 Patent and/or '914 Patent, and components of Respondents' covered mask systems. Fisher & Paykel Healthcare also seeks a permanent cease and desist order, pursuant to Section 337(f), directing Respondents to immediately cease and desist from importing, marketing, advertising, demonstrating, warehousing inventory for distribution, distributing, offering for sale, selling, and using any such excluded products in the United States.

II. COMPLAINANT

9. Complainant Fisher & Paykel Healthcare is a New Zealand corporation having a principal place of business at 15 Maurice Paykel Place, East Tamaki, Auckland 2013, PO Box 14 348, Panmure, Auckland 1741, New Zealand. Fisher & Paykel Healthcare is engaged in the business of designing, manufacturing, and marketing medical devices including obstructive sleep apnea treatment mask systems and components thereof. Fisher & Paykel Healthcare owns the Asserted Patents. *See Exhibits 1-14.*

10. For nearly five decades, Fisher & Paykel Healthcare has developed and commercialized products for improved respiratory care. Fisher & Paykel Healthcare employs over 4,100 people in 37 countries in order to bring its innovative therapies and products to treat an estimated 13 million patients a year in over 120 countries.

III. RESPONDENTS

11. On information and belief, Respondent ResMed Limited is a corporation organized under the laws of Australia, having its principal place of business in Bella Vista, New South Wales, Australia.

12. On information and belief, ResMed Limited is principally responsible for ResMed's production/assembly and manufacturing operations, which are located in various places around the world.

13. On information and belief, Respondent ResMed Corp. is a corporation organized under the laws of the state of Minnesota, with its principal place of business in San Diego, California.

14. On information and belief, Respondent ResMed Inc. is a corporation organized under the laws of the state of Delaware, with its principal place of business in San Diego, California.

15. ResMed Corp. and ResMed Limited are, respectively, direct and indirect subsidiaries of ResMed Inc. The three Respondents, ResMed Limited, ResMed Inc., and ResMed Corp., are collectively referred to as "ResMed" or "Respondents."

16. On information and belief, Respondents manufacture, assemble and/or package their products outside of the United States, at least in Australia. Respondents' products are then imported into the United States, sold for importation into the United States, and/or sold after importation into the United States.

IV. PRODUCTS AND TECHNOLOGY AT ISSUE

17. The products at issue are mask systems used in the treatment of sleep apnea. Obstructive Sleep Apnea (OSA) is a sleep disorder that is estimated to affect up to 9% of the

population. With OSA, muscles that normally hold the airway open instead relax and ultimately collapse, thereby sealing a patient's airway. The sleep pattern of an OSA sufferer is characterized by repeated sequences of snoring, breathing difficulty, lack of breathing, waking with a start and then returning to sleep. Often the sufferer is unaware of this pattern occurring. Sufferers of OSA usually experience daytime drowsiness and irritability due to a lack of continuous sleep.

18. To treat OSA sufferers, a technique known as Continuous Positive Airway Pressure (CPAP) can be employed. A CPAP device consists of a gas supply (or blower) with a conduit connected to supply pressurized gas to a patient. The pressurized air supplied to the patient effectively assists the muscles to keep the patient's airway open, eliminating the typical OSA sleep pattern.

19. The procedure for administering CPAP treatment has been well documented in both the technical and patent literature. Briefly stated, CPAP treatment acts as a pneumatic splint of the airway by the provision of a positive pressure. The air is supplied to the airway by a blower whose outlet passes via an air delivery hose to a nose and/or mouth mask. Below is an image of a Fisher & Paykel Healthcare Opus™ 360 CPAP mask system in use.



Fisher & Paykel Healthcare Opus™ 360 CPAP Mask System in Use

V. THE ASSERTED PATENTS

A. U.S. Patent No. 9,333,315

1. Identification of the Patent and Ownership by Complainant

20. The '315 Patent is entitled "Breathing Assistance Apparatus," and issued on May 10, 2016. *See Exhibit 1.* Fisher and Paykel Healthcare owns by assignment the entire right, title, and interest in the '315 Patent. The '315 Patent issued from United States Patent Application Serial No. 14/846,226, filed on September 4, 2015. The '315 Patent is a continuation of United States Patent Application Serial No. 14/333,134, filed on July 16, 2014, which is a continuation of United States Patent Application Serial No. 10/598,026, filed as Application Serial No. PCT/NZ2005/000023 on February 18, 2005, now United States Patent No. 8,783,257.

21. The named inventors of the '315 Patent are Alastair Edwin McAuley, Craig Robert Prentice, and Oliver Gleeson. The named inventors of the '315 Patent assigned to Fisher

& Paykel Healthcare the entire right, title, and interest in the invention described and claimed in United States Patent Application Serial No. 10/598,026, and all divisions and continuations thereof, which includes the '315 Patent. *See Exhibit 2.* The '315 Patent is valid, enforceable, and is currently in full force and effect.

22. Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by: (1) a certified copy and three additional copies of the prosecution history of the '315 Patent, and (2) four copies of each reference document mentioned in the prosecution history. These materials are included in **Appendices A and B**, respectively.

2. Non-Technical Description of the Patented Invention

23. The '315 patent generally discloses a mask system for treatment of obstructive sleep apnea via the delivery of a supply of air at positive pressure into the patient's airway. *See Exhibit 1* at 2:45-67; 3:1-4. The masks are secured onto a patient through headgear. Conventional masks used for administering CPAP are considered uncomfortable and cumbersome. The comfort, ease of use and performance of the mask is improved by various features, including the interconnectivity of the components and shape of the mask system. The mask system of the '315 patent improves patient comfort and is more convenient to use. *See id.* at 2:1-4; 2:41-44.

24. The foregoing non-technical description of the patented technology is not intended to limit, define, or otherwise affect the scope of the claimed inventions, nor is the non-technical description in any way intended to construe or define any word, phrase, term, or limitation recited in any claim of the '315 Patent.

3. Foreign Counterparts to the '315 Patent

25. The foreign counterparts to the '315 Patent are listed in **Exhibit 3**.

B. U.S. Patent No. 9,517,317

1. Identification of the Patent and Ownership by Complainant

26. The '317 Patent is entitled "Breathing Assistance Apparatus," and issued on December 13, 2016. *See Exhibit 4.* Fisher & Paykel Healthcare owns by assignment the entire right, title, and interest in the '317 Patent. The '317 Patent issued from United States Application Serial No. 15/088,628, which was filed on April 1, 2016. This application is a continuation application of United States Patent Application Serial No. 14/887,212, filed on October 19, 2015, now United States Patent No. 9,320,866, which is a continuation of United States Application Serial No. 14/812,167, filed on July 29, 2015, now United States Patent No. 9,339,624, which is a continuation of United States Application Serial No. 12/633,135, filed on December 8, 2009, now United States Patent No. 9,138,555, which is a continuation of United States Application Serial No. 12/307,993, filed as Application Serial No. PCT/NZ2007/000185 on July 13, 2007, now United States Patent No. 8,443,807.

27. The named inventors of the '317 Patent are Alastair Edwin McAuley, Oliver Gleeson, Evan Stuart Erstich, Simon Eric Freeman, Neil Glen Davies, Stephen John Schoenberg, Kamman Law, and Craig Robert Prentice. The named inventors of the '317 Patent assigned to Fisher & Paykel Healthcare the entire right, title, and interest in the invention ultimately disclosed and claimed in United States Application Nos. 12/663,135, 12/307,993, 14/812,167, and all divisions and continuations thereof, which includes the '317 Patent. *See Exhibit 5.* The '317 Patent is valid, enforceable, and is currently in full force and effect.

28. Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by: (1) a certified copy and three additional copies of the

prosecution history of the '317 Patent, and (2) four copies of each reference document mentioned in the prosecution history. These materials are included in **Appendices C** and **D**, respectively.

2. Non-Technical Description of the Patented Invention

29. The '317 patent generally discloses a mask system for treatment of obstructive sleep apnea via the delivery of a supply of air at positive pressure into the patient's airway. *See Exhibit 4* at 1:24-27. The masks are secured onto a patient through headgear. Conventional masks used for administering CPAP are considered uncomfortable and cumbersome. The comfort, ease of use and performance of the mask is improved by various features, including the interconnectivity of the components and shape of the mask system. The mask system of the '317 patent improves component interconnectivity making the system easier to use and more reliable. *See id.* at 2:9-18; 38-48; 3:6-9.

30. The foregoing non-technical description of the patented technology is not intended to limit, define, or otherwise affect the scope of the claimed inventions, nor is the non-technical description in any way intended to construe or define any word, phrase, term, or limitation recited in any claim of the '317 Patent.

3. Foreign Counterparts to the '317 Patent

31. The foreign counterparts to the '317 Patent are listed in **Exhibit 6**.

C. U.S. Patent No. 9,539,405

1. Identification of the Patent and Ownership by Complainant

32. The '405 Patent is entitled "Breathing Assistance Apparatus," and issued on January 10, 2017. *See Exhibit 7*. Fisher & Paykel Healthcare owns by assignment the entire right, title, and interest in the '405 Patent. The '405 Patent issued from United States Application Serial No. 15/087,775, which was filed on March 31, 2016. This application is a

continuation of United States Application Serial No. 14/887,200, filed on October 19, 2015, which is a continuation of United States Application Serial No. 14/791,142, filed on July 2, 2015, now United States Patent No. 9,339,622, which is a continuation of U.S. Application Serial No. 14/333,134 filed on July 16, 2014, which is a continuation of U.S. Application Serial No. 10/598,026, filed as PCT Application Serial No. PCT/NZ2005/000023 on February 18, 2005, now United States Patent No. 8,783,257.

33. The named inventors of the '405 Patent are Alastair Edwin McAuley, Craig Robert Prentice, and Oliver Gleeson. The named inventors of the '405 Patent assigned to Fisher & Paykel Healthcare the entire right, title, and interest in the invention described and claimed in Application Serial No. 14/887,200, and all divisions and continuations thereof, which includes the '405 Patent. *See Exhibit 8.* The '405 Patent is valid, enforceable, and is currently in full force and effect.

34. Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by: (1) a certified copy and three additional copies of the prosecution history of the '405 Patent, and (2) four copies of each reference document mentioned in the prosecution history. These materials are included in **Appendices E and F**, respectively.

2. Non-Technical Description of the Patented Invention

35. The '405 patent generally discloses a mask system for treatment of obstructive sleep apnea via the delivery of a supply of air at positive pressure into the patient's airway. *See Exhibit 7* at 1:14-16; 2:46-49. The masks are secured onto a patient through headgear. Conventional masks used for administering CPAP are considered uncomfortable and cumbersome. The comfort, ease of use and performance of the mask is improved by various features, including the interconnectivity of the components and shape of the mask system. The

mask system of the '405 patent improves patient comfort and is more convenient to use. *See id.* at 2:4-15; 46-49.

36. The foregoing non-technical description of the patented technology is not intended to limit, define, or otherwise affect the scope of the claimed inventions, nor is the non-technical description in any way intended to construe or define any word, phrase, term, or limitation recited in any claim of the '405 Patent.

3. Foreign Counterparts to the '405 Patent

37. The foreign counterparts to the '405 Patent are listed in **Exhibit 9**.

D. U.S. Patent No. 9,907,925

4. Identification of the Patent and Ownership by Complainant

38. The '925 Patent is entitled "Nasal Pillows for a Patient Interface," and issued on March 6, 2018. *See Exhibit 10*. Fisher & Paykel Healthcare owns by assignment the entire right, title, and interest in the '925 Patent. The '925 Patent issued from United States Application Serial No. 13/123,503, which was filed on October 9, 2009. This application is a continuation of United States Application Serial No. 14/887,200, filed as PCT Application Serial No. PCT/NZ2009/000219 on October 9, 2009, now United States Patent No. 9,901,700.

39. The named inventors of the '925 Patent are Alastair Edwin McAuley, Craig Robert Prentice, Rory Alexander Monro, Isaac Tristram Tane Mason, and Nadjean Maurice Gabriel Geslain. The named inventors of the '925 Patent assigned to Fisher & Paykel Healthcare the entire right, title, and interest in the invention described and claimed in Application Serial No. 13,123,503, and all divisions and continuations thereof, which includes the '925 Patent. *See Exhibit 11*. The '925 Patent is valid, enforceable, and is currently in full force and effect.

40. Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by: (1) a certified copy and three additional copies of the prosecution history of the '925 Patent, and (2) four copies of each reference document mentioned in the prosecution history. These materials are included in **Appendices G and H**, respectively.

5. Non-Technical Description of the Patented Invention

41. The '925 patent generally discloses nasal pillows for use with a mask system for treatment of obstructive sleep apnea via the delivery of a supply of air at positive pressure into the patient's airway. *See Exhibit 10* at 1:16-24; 2:30-34. Conventional masks used for administering CPAP are considered uncomfortable and cumbersome. The comfort of the mask is improved through the features of the nasal pillows. The nasal pillows of the '925 patent improve patient comfort while providing a substantial seal against the nares of a user. *See id.* at 2:4-6; 26-29.

42. The foregoing non-technical description of the patented technology is not intended to limit, define, or otherwise affect the scope of the claimed inventions, nor is the non-technical description in any way intended to construe or define any word, phrase, term, or limitation recited in any claim of the '925 Patent.

6. Foreign Counterparts to the '925 Patent

43. The foreign counterparts to the '925 Patent are listed in **Exhibit 12**.

E. U.S. Patent No. 9,974,914

7. Identification of the Patent and Ownership by Complainant

44. The '914 Patent is entitled "Breathing Assistance Apparatus," and issued on May 22, 2018. *See Exhibit 13*. Fisher & Paykel Healthcare owns by assignment the entire right, title, and interest in the '914 Patent. The '914 Patent issued from United States Application Serial No.

14/333,134, which was filed on July 16, 2014. This application is a continuation of United States Application Serial No. 10/598,026, filed as PCT Application Serial No. PCT/NZ2005/000023 on Feb. 18, 2005, now United States Patent No. 8,783,257.

45. The named inventors of the '914 Patent are Alastair Edwin McAuley, Craig Robert Prentice, and Oliver Gleeson. The named inventors of the '914 Patent assigned to Fisher & Paykel Healthcare the entire right, title, and interest in the invention described and claimed in Application Serial No. 10/598,026, and all divisions and continuations thereof, which includes the '914 Patent. *See Exhibit 14*. The '914 Patent is valid, enforceable, and is currently in full force and effect.

46. Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by: (1) a certified copy and three additional copies of the prosecution history of the '914 Patent, and (2) four copies of each reference document mentioned in the prosecution history. These materials are included in **Appendices I and J**, respectively.

8. Non-Technical Description of the Patented Invention

47. The '914 patent generally discloses nasal pillows for use with a mask system for treatment of obstructive sleep apnea via the delivery of a supply of air at positive pressure into the patient's airway. *See Exhibit 13* at 1:15-17; 2:45-48. Conventional masks used for administering CPAP are considered uncomfortable and cumbersome. The comfort of the mask is improved through various features, such as an inwardly curved surface that limits contact with a user's upper lip. *See Fig. 12*. The mask of the '914 Patent improves patient comfort. *See id.* at 2:45-48.

48. The foregoing non-technical description of the patented technology is not intended to limit, define, or otherwise affect the scope of the claimed inventions, nor is the non-

technical description in any way intended to construe or define any word, phrase, term, or limitation recited in any claim of the '914 Patent.

9. Foreign Counterparts to the '914 Patent

49. The foreign counterparts to the '914 Patent are listed in **Exhibit 15**.

VI. DOMESTIC INDUSTRY

50. In accordance with Section 337(a)(2) and Section 337(a)(3), a domestic industry exists in the United States and also is in the process of being further established in the United States in connection with each of the Asserted Patents.

51. Fisher & Paykel Healthcare's Opus™ 360 product is protected by each of the Asserted Patents, and all units for the worldwide sales of the Opus™ 360 are manufactured in the United States. That domestic manufacturing has established, and is in the process of further establishing, the domestic industry in the United States with respect to the articles protected by each of the Asserted Patents.

52. The domestic manufacture of Opus™ 360 includes significant investment in plant and equipment under Section 337(a)(3)(A), and/or significant employment of labor or capital under Section 337(a)(3)(B). Those domestic investments and employments are both quantitatively and qualitatively significant. Jesse Dijkstra, Fisher & Paykel Healthcare's Program Manager for Opus™ 360, provides a detailed description of those significant domestic investments and employments in his Confidential Declaration attached as **Exhibit 42**.

A. Technical Prong

53. Fisher & Paykel Healthcare's Opus™ 360 obstructive sleep apnea treatment mask system practices the Asserted Patents, as detailed in **Exhibits 16-23**.

54. In particular, Fisher & Paykel Healthcare's Opus™ 360 mask system practices at least claims 6, 11-14, and 17 of the '315 Patent. Photographs of the Opus™ 360 system are attached as **Exhibit 16**. A copy of the user manual for the Opus™ 360 is attached as **Exhibit 17**. A copy of instructions for use for the Opus™ 360 is attached as **Exhibit 18**. A claim chart demonstrating how the Opus™ 360 embodies exemplary claim 17 of the '315 patent is attached as **Exhibit 19**.

55. The Opus™ 360 mask system also practices at least claims 1, 3-4, 6-10, and 12-19 of the '317 Patent. A claim chart demonstrating how the Opus™ 360 embodies exemplary claim 12 of the '317 Patent is attached as **Exhibit 20**.

56. The Opus™ 360 mask system also practices at least claims 8, 9-12, and 16-20 of the '405 Patent. A claim chart demonstrating how the Opus™ 360 embodies exemplary claim 16 of the '405 Patent is attached as **Exhibit 21**.

57. The Opus™ 360 mask system also practices at least claims 11-18 of the '925 Patent. A claim chart demonstrating how the Opus™ 360 embodies exemplary claim 11 of the '925 Patent is attached as **Exhibit 22**.

58. The Opus™ 360 mask system also practices at least claims 9, 10, 15-19, 22-28 of the '914 Patent. A claim chart demonstrating how the Opus™ 360 embodies exemplary claim 9 of the '914 Patent is attached as **Exhibit 23**.

B. Economic Prong

59. All units for the worldwide sales of Fisher & Paykel Healthcare's Opus™ 360, including its spare parts, are manufactured in the United States and are labeled "Made in the USA." See **Exhibit 42** (Dijkstra Decl.) at ¶ 13. Beginning in 2017, Fisher & Paykel Healthcare relocated its Opus™ 360 manufacturing to the United States. See *id.* at ¶ 14. Opus™ 360 is

manufactured using the following steps, each of which occurs in the United States: (1) silicone, polycarbonate, and nylon injection-molding for its nasal pillow seal, swivel snap, elbow joint, and frame components, (2) foam and fabric manufacture for its headgear component, (3) polycarbonate manufacture for its flexible tubing component, (4) printing for its instructions, and (5) assembly, packaging, and labeling of the completed Opus™ 360 mask system. *See id.* at ¶¶ 14-23; **Exhibit 43**.

60. For each unit of Opus™ 360, Fisher & Paykel Healthcare spends over 80% of the unit's manufacturing costs, on a recurring cost-of-goods-sold basis, on United States manufacturing expenditures. *See id.* at ¶¶ 24-27; **Exhibit 44**.

61. Furthermore, Fisher & Paykel Healthcare has invested in retooling its Opus™ 360 manufacturing equipment for use in the United States. Fisher & Paykel Healthcare has also invested in new Opus™ 360 manufacturing equipment in the United States, and is in the process of continuing to invest in the United States in additional new Opus™ 360 manufacturing equipment. Mr. Dijkstra's declaration provides details of Fisher & Paykel Healthcare's investments in manufacturing Opus™ 360 in the United States. *See, e.g., id.* at ¶¶ 28-30.

VII. UNLAWFUL AND UNFAIR ACTS OF RESPONDENTS

62. 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 the '315 Patent, '317 Patent, '405 Patent, '925 Patent, and '914 Patent.

63. The Accused Products include products sold under the names AirFit P10 (Part No. 62900), AirFit™ P10 for Her (Part No. 62910), and AirFit P10™ for AirMini™ (Part No. 38824). These products include a headgear (Part No. 62935 or 62936), a frame (Part No. 62938)

and may include pillows of the following sizes: extra small (Part No. 62930); small (Part No. 62931); medium (Part No. 62932); and large (Part No. 62933).

64. Respondents' AirFit™ P10 mask system directly infringes at least claims 1-4, 6-9, 11-15, 17-19 of the '315 Patent; claims 1-20 of the '317 Patent; claims 1-20 of the '405 Patent; claims 4-20 of the '925 Patent; and claims 1-3, 5-8, 11-20, 22, 25-27 of the '914 Patent. Respondents' AirFit™ P10 for AirMini mask system directly infringes at least claims 6-9, 11-14, 17-19 of the '315 Patent; 1-20 of the '317 Patent; 8-13, 16-20 of the '405 Patent; 4-20 of the '925 Patent; and claims 1-3, 5-7, 11, 12, 15-20, 22, 25-27 of the '914 Patent.

65. Further discovery may also reveal additional ResMed products and/or models that infringe the '315, '317, '405, '925, and '914 Patents. Photographs of an AirFit™ P10 are attached to this Complaint as **Exhibit 24**. A copy of a user guide for the AirFit™ P10 mask system is attached to this Complaint as **Exhibit 25**. A printout of an excerpt of the AirFit™ P10 Product Webpage is attached to this Complaint as **Exhibit 26**. Photographs of an AirFit™ P10 for Her are attached to this Complaint as **Exhibit 27**. A printout of an excerpt of the AirFit™ P10 for Her Product Webpage is attached to this Complaint as **Exhibit 28**.

66. Photographs of an AirFit™ P10 for AirMini™ are attached to this Complaint as **Exhibit 34**. A copy of a user guide for the AirFit™ P10 for AirMini™ is attached to this Complaint as **Exhibit 35**. A printout of an excerpt of the AirFit™ P10 for AirMini™ Product Webpage is attached to this Complaint as **Exhibit 36**. Claim charts demonstrating how the asserted claims of the '315 Patent, '317 Patent, '405 Patent, '925 Patent, and '914 Patent are infringed are attached as **Exhibits 29-33, 37-41**.

VIII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

67. Complainant previously purchased ResMed's AirFit™ P10, AirFit™ P10 for Her and AirFit™ P10 for AirMini™ mask systems in the United States. Attached as **Exhibit 24** are photographs depicting the packaging in which the AirFit™ P10 mask systems were shipped. **Exhibit 24** also shows labels on the devices and/or product packaging for ResMed devices, which indicate that the Accused Products were manufactured in Australia. Attached as **Exhibit 27** are photographs depicting the packaging in which the AirFit™ P10 for Her mask systems were shipped. **Exhibit 27** also shows labels on the devices and/or product packaging for ResMed devices, which indicate that the Accused Products were manufactured in Australia. Attached as **Exhibit 34** are photographs depicting the packaging in which the AirFit™ P10 for AirMini™ mask systems were shipped. **Exhibit 34** also shows labels on the devices and/or product packaging for ResMed devices, which indicate that the Accused Products were manufactured in Australia.

IX. CLASSIFICATION OF THE INFRINGING PRODUCTS UNDER THE HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES

68. Upon information and belief, the Accused Products may be classified under at least the following heading of the Harmonized Tariff Schedules of the United States: 9019.20.00.

X. LICENSEES

69. There are no licenses to any of the Asserted Patents.

XI. RELATED LITIGATION

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

XII. REQUESTED RELIEF

71. WHEREFORE, by reason of the foregoing, Fisher & Paykel Healthcare requests that the United States International Trade Commission:

- a) institute an immediate investigation pursuant to 19 U.S.C. § 1337 into the violations of that section based on Respondents' unlawful importation into the United States, sale for importation into the United States, and/or sale in the United States after importation of certain obstructive sleep apnea treatment mask systems and components thereof that 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 19 U.S.C. § 1337(d), excluding from entry into the United States all of Respondents' certain obstructive sleep apnea treatment mask systems and components thereof that infringe one or more claims of the Asserted Patents;
- d) issue permanent cease and desist orders, pursuant to 19 U.S.C. § 1337(f), directing Respondents to cease and desist from importing, marketing, advertising, demonstrating, warehousing of inventory for distribution, sale, and use of certain obstructive sleep apnea treatment mask systems and components thereof that infringe one or more claims of the Asserted Patents;
- e) impose a bond upon Respondents, pursuant to 19 U.S.C. § 1337(j), upon importation of any obstructive sleep apnea 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 appropriate and just under the law, based on the facts complained of herein, and determined by the Investigation and the authority of the Commission.

Respectfully submitted,

Dated: September 7, 2018

By:  _____

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