UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEW YORK UNIVERSITY Plaintiff, v. RESMED INC. Defendant.	Case No. Jury Trial Demanded

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff New York University ("Plaintiff"), by and through its counsel, files this Complaint against ResMed Inc. ("ResMed" or "Defendant") for infringement of United States Patent Nos. 9,867,955 ("the '955 patent"), 6,988,994 ("the '944 patent"), 9,168,344 ("the '344 patent"), 9,108,009 ("the '009 patent"), 9,427,539 ("the '539 patent"), 9,533,115 ("the '115 patent"), and 10,384,024 ("the '024 patent"), (collectively, the "patents-in-suit"), and alleges as follows:

NATURE OF THE ACTION

1. This is an action for infringement of the patents-in-suit arising under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.* Specifically, this action relates to patents directed to systems and methods for diagnosing and treatment of a breathing pattern of a patient, and a positive airway pressure system and method for treatment of sleeping disorders in a patient.

PARTIES

2. Plaintiff New York University is a research university organized as a corporation under the laws of the State of New York and having a place of business at 550 First Avenue, New York, New York, 10016.

3. On information and belief, Defendant ResMed Inc. is a corporation duly organized and existing under the laws of the State of Delaware with its principal place of business at 9001 Spectrum Center Blvd., San Diego, CA 92123.

4. ResMed distributes, sells, and/or imports products for the entire United States market and does business in every state, including Delaware, either directly or indirectly.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this is a patent infringement action that arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c), (d) and/or 1400(b) because, among other things, Defendant is incorporated in the State of Delaware and, therefore, resides in this judicial district.

PERSONAL JURISDICTION OVER RESMED

7. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

8. This Court has personal jurisdiction over Defendant in part because a substantial part of the events giving rise to the claims alleged in this Complaint for which Defendant is responsible occurred in Delaware.

9. Specifically, Defendant's products are used and/or sold within and throughout the United States, including in Delaware. On information and belief, AirSense™ 10 AutoSet™ systems are prescribed by medical professionals practicing in Delaware, sold by distributors located within Delaware, and used by patients in Delaware. Each of these activities has a substantial effect within Delaware, as they constitute infringement, directly and indirectly, of the patents-in-suit.

10. Additionally, Defendant sells other products and does business throughout the United States, including Delaware.

11. Thus, Defendant has purposefully availed itself of the privileges of conducting business in Delaware and within this judicial district; has established sufficient minimum contacts in Delaware and within this judicial district such that it should reasonably and fairly anticipate being involved in court in Delaware and in this judicial district; has purposefully directed activities at residents of Delaware and this judicial district; and at least a portion of the patent infringement claims alleged herein arise out of or are related to one or more of the foregoing activities.

12. Accordingly, this Court has personal jurisdiction over Defendant who, on information and belief: (1) has committed acts of patent infringement, individually, in active concert or jointly in the State of Delaware and in this judicial district; (2) has substantial, regularly conducted and systematic business contacts in the State of

Delaware and in this judicial district; (3) owns, manages, and markets products in the State of Delaware and in this judicial district; and (4) enjoys substantial income from the sale of products in the State of Delaware and in this judicial district.

BACKGROUND

The Patents-in-Suit

13. David M. Rapoport, M.D. is the foremost expert in sleep technology.

14. Dr. Rapoport has an undergraduate degree in Physics from Massachusetts Institute of Technology, an MD from Albert Einstein College of Medicine, Internal Medicine training at the Roosevelt Hospital, and a Pulmonary Fellowship at New York University Medical Center/Bellevue.

15. Dr. Rapoport has been involved in clinical research in Sleep Medicine for over 30 years and currently serves as Director of the Sleep Medicine Research Program at Mount Sinai.

16. Dr. Rapoport holds multiple U.S. and European patents for improvements on nasal CPAP.

17. Dr. Rapoport is also the founder and President of the Foundation for Research in Sleep Disorders and is a member of the Board of Directors of the American Sleep Apnea Association.

United States Patent No. 9,867,955

18. U.S. Patent No. 9,867,955, entitled "System and method for diagnosis and treatment of a breathing pattern of a patient," (attached as Exhibit 1), was duly and legally issued on January 16, 2018.

19. The '955 patent will expire on March 21, 2024, per the 35 U.S.C. § 154(b) patent term adjustment.

20. The inventors named on the '955 patent are David M. Rapoport and Robert G. Norman.

21. The '955 patent covers a system including a sensor and a processing arrangement.

22. The claims of the '955 patent are valid, enforceable, and not expired.

23. The '955 patent ultimately claims priority to U.S. Application No. 10/642,459, filed August 14, 2003, now U.S. Patent No. 6,988,994.

24. All rights, title and interests in the '955 patent are owned by and assigned to New York University.

United States Patent No. 6,988,994

25. U.S. Patent No. 6,988,994, entitled "Positive airway pressure system and method for treatment of sleeping disorder in patient," (attached as Exhibit 2), was duly and legally issued on January 24, 2006.

26. The '994 patent will expire on September 5, 2023.

27. The inventors named on the '994 patent are David M. Rapoport and Robert G. Norman.

28. The claims of the '994 patent are valid, enforceable, and not expired.

29. All rights, title and interests in the '994 patent are owned by and assigned to New York University.

United States Patent No. 9,168,344

30. U.S. Patent No. 9,168,344, entitled "System and method for diagnosis and treatment of a breathing pattern of a patient," (attached as Exhibit 3), was duly and legally issued on October 27, 2015.

31. The '344 patent will expire on August 14, 2023.

32. The inventors named on the '344 patent are David M. Rapoport and Robert G. Norman.

33. The '344 patent covers a system including a sensor and a processing arrangement.

34. The claims of the '344 patent are valid, enforceable, and not expired.

35. The '344 patent ultimately claims priority to U.S. Application No. 10/642,459, filed August 14, 2003, now U.S. Patent No. 6,988,994.

36. All rights, title and interests in the '344 patent are owned by and assigned to New York University.

United States Patent No. 9,108,009

37. U.S. Patent No. 9,108,009, entitled "System and method for diagnosis and treatment of a breathing pattern of a patient," (attached as Exhibit 4), was duly and legally issued on August 18, 2015.

38. The '009 patent will expire on August 14, 2023.

39. The inventors named on the '009 patent are David M. Rapoport and Robert G. Norman.

40. The '009 patent covers a system including a sensor and a processing arrangement.

41. The claims of the '009 patent are valid, enforceable, and not expired.

42. The '009 patent ultimately claims priority to U.S. Application No. 10/642,459, filed August 14, 2003, now U.S. Patent No. 6,988,994.

43. All rights, title and interests in the '009 patent are owned by and assigned to New York University.

United States Patent No. 9,427,539

44. U.S. Patent No. 9,427,539, entitled "System and method for diagnosis and treatment of a breathing pattern of a patient," (attached as Exhibit 5), was duly and legally issued on August 30, 2016.

45. The '539 patent will expire on February 27, 2035.

46. The inventors named on the '539 patent are David M. Rapoport and Robert G. Norman.

47. The '539 patent covers a system including a sensor and a processing arrangement.

48. The claims of the '539 patent are valid, enforceable, and not expired.

49. The '539 patent ultimately claims priority to U.S. Application No. 10/642,459, filed August 14, 2003, now U.S. Patent No. 6,988,994.

50. All rights, title and interests in the '539 patent are owned by and assigned to New York University.

United States Patent No. 9,533,115

51. U.S. Patent No. 9,533,115, entitled "System and method for diagnosis and treatment of a breathing pattern of a patient," (attached as Exhibit 6), was duly and legally issued on January 3, 2017.

52. The '115 patent will expire on February 27, 2035.

53. The inventors named on the '115 patent are David M. Rapoport and Robert G. Norman.

54. The '115 patent covers a system including a sensor and a processing arrangement.

55. The claims of the '115 patent are valid, enforceable, and not expired.

56. The '115 patent ultimately claims priority to U.S. Application No. 10/642,459, filed August 14, 2003, now U.S. Patent No. 6,988,994.

57. All rights, title and interests in the '115 patent are owned by and assigned to New York University.

United States Patent No. 10,384,024

58. U.S. Patent No. 10,384,024, entitled "System and method for diagnosis and treatment of a breathing pattern of a patient," (attached as Exhibit 7), was duly and legally issued on August 20, 2019.

59. The '024 patent will expire on January 3, 2031.

60. The inventors named on the '024 patent are David M. Rapoport and Robert G. Norman.

61. The '024 patent covers a system including a sensor and a processing arrangement.

62. The claims of the '024 patent are valid, enforceable, and not expired.

63. The '024 patent ultimately claims priority to U.S. Application No. 10/642,459, filed August 14, 2003, now U.S. Patent No. 6,988,994.

64. All rights, title and interests in the '024 patent are owned by and assigned to New York University.

AirSense™ 10 AutoSet™

65. On information and belief, ResMed manufactures, sells and distributes the AirSense™ 10 AutoSet™ series of positive airway pressure machines throughout the United States. *See generally* ResMed Air Solutions product brochure, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf, attached as Exhibit 8.

66. The AirSense™ 10 AutoSet™ series is indicated for the treatment of sleeping disorders and is a complete system. Further, the AirSense™ 10 AutoSet™ is a positive airway pressure system, providing air pressure to a patient's airways. *Id.*

67. The AirSense™ 10 AutoSet™ system contains the AutoRamp™ feature with sleep onset detection. The AutoRamp™ starts by delivering a low pressure; once the AutoRamp™ detects that the patient is asleep, it increases the pressure to the prescribed level. *Id.* at 7.

68. Further, the AirSense™ 10 AutoSet™ system detects when a patient is asleep and adjusts the treatment pressure accordingly. *See* ResMed sleep blog, https://www.resmed.com/en-us/sleep-apnea/sleep-blog/fall-asleep-faster-with-lower-cpap-pressure/, attached as Exhibit 9.

69. The AirSense™ 10 AutoSet™ system also has the AutoSet algorithm, which continually monitors each patient's unique breathing pattern and assesses each breathing event to determine and deliver the ideal pressure to treat the event. *See* Apnea board, http://www.apneaboard.com/wiki/index.php/CPAP_Algorithms, attached as Exhibit 10.

Notice of the Patents-in-Suit

70. ResMed has had notice and been aware of the patents-in-suit, when Plaintiff sent correspondence on June 1, 2021, which was received on June 2, 2021, to the Chief Executive Officer of ResMed informing him of the existence of these patents and the infringement of same by ResMed. *See* Notice letter, attached as Exhibit 11.

71. Plaintiff's letter instructed ResMed to immediately cease and desist from engaging in any further conduct that would lead to infringing activity. On information and belief, ResMed has not altered its conduct in response to the letter from Plaintiff.

72. ResMed has thus induced infringement of the patents-in-suit in violation of 35 USC § 271(b) by providing to the public, at a minimum, the AirSense™ 10 AutoSet™ CPAP product and product specifications and directions which provide instructions on how to use the AirSense™ 10 AutoSet™ in a manner that directly infringes the patents-in-suit.

PATENT INFRINGEMENT

Count I: Infringement of United States Patent No. 9,867,955 by ResMed

73. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

74. On information and belief, and without authority, consent, right, or license, ResMed makes, uses, sells, offers to sell and/or imports positive airway pressure devices in the United States. In doing so, ResMed infringes one or more claims, including claims 1-6, 8, 11-12, 16-26, and 30-31 of the '955 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing the AirSense™ 10 AutoSet™ systems, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c) by providing to the public, at a minimum, the AirSense™ 10 AutoSet™ system specifications and directions, which provide instructions on how to use the AirSense™ 10 AutoSet™ systems in a manner that infringes directly the '955 patent.

75. ResMed commits acts of patent infringement through the manufacture, use, offer for sale, sale and/or importation of at least ResMed's AirSense™ 10 AutoSet™ systems that include the AutoSet ™ algorithm and AutoRamp™ features, including, but not limited to, the AirSense™ 10 AutoSet™ series of systems.

76. For example, claim 1 of the '955 patent covers:

> A positive airway pressure system for delivery of a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure delivered to an entrance of a patient's airways in order to assist in treating

a sleeping disorder in a patient, the positive airway pressure system comprising:

a flow generator which supplies a positive treatment pressure flow of breathable gases to the entrance of a tube, the tube directing the flow of breathable gases to the airway of a patient to provide the patent with the positive treatment pressure flow of breathable gases;

a flow sensor located in a flow path of the positive treatment pressure flow of breathable gases, the flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patient's breathing patterns; and

a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data to determine the patient's breathing patterns,

the processing arrangement also determines whether to alter the pressure supplied to the airway of the patient based, at least in part, on the determined breathing patterns of the patient,

wherein the processing arrangement applies a greater positive treatment pressure in an asleep state and a lesser positive treatment pressure in an awake state,

wherein when the processor determines that the patient has transitioned between at least an awake state and an asleep state, the processing arrangement automatically controls the flow generator to increase a positive treatment pressure supplied to the entrance of the tube using a ramp system.

77. The AirSense™ 10 AutoSet™ systems meet the claim element for "[a] positive airway pressure system for delivery of a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure delivered to an entrance of a patient's airways in order to assist in treating a sleeping disorder in a patient…" The AirSense™ 10 AutoSet™ system is a positive airway pressure system that delivers a flow of breathable gas to an entrance of a patient's airways to treat a sleeping disorder,

as shown by the product brochure. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf.

78. The AirSense™ 10 AutoSet™ systems meet the claim element for "a flow generator which supplies a positive treatment pressure flow of breathable gases to the entrance of a tube, the tube directing the flow of breathable gases to the airway of a patient to provide the patent with the positive treatment pressure flow of breathable gases." As shown by the user guide, The AirSense™ 10 AutoSet™ system uses a flow generator (blower) to supply the positive treatment pressure flow of breathable gases through a tube attached to a mask. *See* Exhibit 12, AirSense™ 10 user guide, p. 19, https://document.resmed.com/en-us/documents/products/machine/airsense-series/user-guide/airsense-10-device-with-humidifier_user-guide_amer_eng.pdf; *see also* https://www.resmed.com/en-us/sleep-apnea/cpap-products/cpap-masks/.

79. The AirSense™ 10 AutoSet™ systems meet the claim element for "a flow sensor located in a flow path of the positive treatment pressure flow of breathable gases, the flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patient's breathing patterns," as shown by the user guide indicating the presence of a flow sensor. *See* Exhibit 12, p. 19.

80. The AirSense™ 10 AutoSet™ systems meet the claim element for "a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data to determine the patient's breathing patterns…" As shown by the product brochure, the AirSense™ Autoset™

algorithm (processing arrangement) receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data to determine the patient's breathing patterns. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf; *see also* Exhibit 10, http://www.apneaboard.com/wiki/index.php/CPAP_Algorithms.

81. The AirSense™ 10 AutoSet™ systems meet the claim element for "the processing arrangement also determines whether to alter the pressure supplied to the airway of the patient based, at least in part, on the determined breathing patterns of the patient…" As explained by the product brochure, the AirSense™ AutoRamp™ processing arrangement determines whether to alter the pressure supplied to the airway of the patient based, at least in part, on the determined breathing patterns of the patient. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf.

82. The AirSense™ 10 AutoSet™ systems meet the claim element for "wherein the processing arrangement applies a greater positive treatment pressure in an asleep state and a lesser positive treatment pressure in an awake state…" The AirSense™ AutoRamp™ processing arrangement applies a greater positive treatment pressure when the patient is asleep, and a lesser pressure when the patient is awake. *Id.*

83. The AirSense™ 10 AutoSet™ systems meet the claim element for "wherein when the processor determines that the patient has transitioned between at

least an awake state and an asleep state, the processing arrangement automatically controls the flow generator to increase a positive treatment pressure supplied to the entrance of the tube using a ramp system." The AutoRamp™ processing arrangement increases the pressure through a ramp system once the processor determines that the patient has transitioned from an awake state to an asleep state. *Id*.

84. Since the AirSense™ 10 AutoSet™ systems meet each and every claim limitation, ResMed is directly infringing one or more claims of the '955 patent in violation of 35 U.S.C. § 271(a).

85. ResMed, acting without authority, consent, right, or license of the '955 patent, has induced, and continues to induce, medical professionals and patients to administer and use the AirSense™ 10 AutoSet™ systems, which directly infringe one or more claims of the '955 patent resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(b) and 35 U.S.C. § 271(c). More specifically, patients and medical professionals directly infringe (literally and/or under the doctrine of equivalents) at least claims 1-6, 8, 11-12, 16-26, and 30-31 of the '955 patent by using the AirSense™ 10 AutoSet™ systems, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(a).

86. At least since the date of receipt of the notice letter, *see* Exhibit 11, ResMed knew of the '955 patent, knowingly induced the use by medical professionals and patients of the AirSense™ 10 AutoSet™ systems by keeping these products in the market place and the stream of commerce, and possessed a specific intent to encourage

direct infringement of the '955 patent, due to the failure to remove these goods from the stream of commerce.

87. ResMed possessed, and continues to possess, specific intent to induce infringement by providing to the public, at a minimum, product specifications and the option to purchase and/or use the AirSense™ 10 AutoSet™ systems, which directly infringe the '955 patent.

88. ResMed has actively induced and encouraged, and continues to actively induce and encourage, medical professionals to prescribe the AirSense™ 10 AutoSet™ systems, and patients to use the AirSense™ 10 AutoSet™ systems, by marketing, promoting and advertising the infringing use of the AirSense™ 10 AutoSet™ systems.

89. Upon information and belief, ResMed knows that the AirSense™ 10 AutoSet™ systems are especially made or adapted for use in infringing the '955 patent, that the AirSense™ 10 AutoSet™ systems are not staple articles or commodities of commerce, and that the AirSense™ 10 AutoSet™ systems are not suitable for substantial noninfringing use, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(c). More specifically, patients or medical professionals directly infringe (literally and/or under the doctrine of equivalents) at least claims 1-6, 8, 11-12, 16-26, and 30-31 of the '955 patent by using the AirSense™ 10 AutoSet™ systems, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(a).

90. ResMed's foregoing actions constitute and/or will constitute infringement of the '955 patent, active inducement of infringement of the '955 patent, and contribution to the infringement by others of the '955 patent.

91. Plaintiff reserves the right to assert additional claims of the '955 patent that ResMed infringes.

92. Plaintiff has been damaged as a result of ResMed's infringing conduct. ResMed is, thus, liable to Plaintiff in an amount that adequately compensates for its infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

Count II Infringement of United States Patent No. 6,988,994 by ResMed

93. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

94. On information and belief, and without authority, consent, right, or license, ResMed makes, uses, sells, offers to sell and/or imports positive airway pressure systems in the United States. In doing so, ResMed infringes one or more claims, including claims 1, 6-7, 10-14, 19-20, 23-30, and 32 of the '994 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing the AirSense™ 10 AutoSet™ series, and/or by actively inducing infringement by others under § 271(b) by providing to the public, at a minimum, the AirSense™ 10 AutoSet™ product specifications and directions, which

provide instructions on how to use the AirSense™ 10 AutoSet™ series in a manner that directly infringes the '994 patent.

95. ResMed commits acts of patent infringement through the manufacture, use, offer for sale, sale and/or importation of at least the AirSense™ 10 AutoSet™ line of systems that include the AutoSet ™ algorithm and AutoRamp™ feature, including, but not limited to, the AirSense™ 10 AutoSet™ series.

96. For example, claim 1 of the '994 patent covers:

> A positive airway pressure system for treatment of a sleeping disorder in a patient, comprising:
>
> a generator supplying airflow and applying a pressure to an airway of a patient;
>
> a sensor measuring data corresponding to patient's breathing patterns; and
>
> a processing arrangement analyzing the breathing patterns to determine whether the breathing patterns are indicative of one of the following patient's states: (i) a regular breathing state, (ii) a sleep disorder breathing state, (iii) a REM sleep state and (iv) a troubled wakefulness state, the processing arrangement adjusting the applied pressure as a function of the patient's state,
>
> wherein, when the breathing patterns indicate one of states (i) and (ii) and (iii), the processing arrangement controls the generator to adjust the pressure to a first value and
>
> wherein, when the breathing patterns indicate state (iv), the processing arrangement controls the generator to adjust the pressure to a second value.

97. The AirSense™ 10 AutoSet™ systems meet the claim element for "A positive airway pressure system for treatment of a sleeping disorder in a patient" because ResMed makes, uses, sells, offers to sell and/or imports the AirSense™ 10

AutoSet™ system for treatment of a sleeping disorder. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf

98. The AirSense™ 10 AutoSet™ systems meet the claim element for "a generator supplying airflow and applying a pressure to an airway of a patient," as evidenced by product schematics within the user guide showing the presence of a flow generator (blower). *See* Exhibit 12, p. 19, https://document.resmed.com/en-us/documents/products/machine/airsense-series/user-guide/airsense-10-device-with-humidifier_user-guide_amer_eng.pdf.

99. The AirSense™ 10 AutoSet™ systems meet the claim element for "a sensor measuring data corresponding to patient's breathing patterns," as evidenced by product schematics within the user guide showing the presence of a sensor. *Id*.

100. The AirSense™ 10 AutoSet™ systems meet the claim element for "a processing arrangement analyzing the breathing patterns to determine whether the breathing patterns are indicative of one of the following patient's states: (i) a regular breathing state, (ii) a sleep disorder breathing state, (iii) a REM sleep state and (iv) a troubled wakefulness state, the processing arrangement adjusting the applied pressure as a function of the patient's state," as evidenced by the AutoSet™ algorithm and AutoRamp™ features which analyze the patient's breathing patterns. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf

101. The AirSense™ 10 AutoSet™ systems meet the claim element for " wherein, when the breathing patterns indicate one of states (i) and (ii) and (iii), the processing arrangement controls the generator to adjust the pressure to a first value…" When the breathing patterns indicate one of states (i) (a regular breathing state) and (ii) (a sleep disorder breathing state) and (iii) (a REM sleep state), the AirSense™ Autoset™ algorithm (processing arrangement), through its AutoRamp™ feature, controls the generator to adjust the pressure to a first value, i.e. the prescribed treatment pressure level. *Id.*; *see also* Exhibit 9, https://www.resmed.com/en-us/sleep-apnea/sleep-blog/fall-asleep-faster-with-lower-cpap-pressure/

102. The AirSense™ 10 AutoSet™ systems meet the claim element for "wherein, when the breathing patterns indicate state (iv), the processing arrangement controls the generator to adjust the pressure to a second value." When the breathing patterns indicate a troubled wakefulness state (state iv), the AirSense™ 10 AutoSet™ AutoSet™ algorithm (processing arrangement), and/or the AutoRamp™ feature, controls the generator to adjust the pressure to a second value, i.e. it decreases the pressure upon waking up. *Id.*

103. Since the AirSense™ 10 AutoSet™ systems meet each and every claim limitation, ResMed is directly infringing one or more claims of the '994 patent in violation of 35 U.S.C. § 271(a).

104. ResMed, acting without authority, consent, right, or license of the '994 patent, has induced, and continues to induce, medical professionals and patients to administer and use the AirSense™ 10 AutoSet™ systems, which directly infringe one

or more claims of the '994 patent resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(b) and/or contributing to infringement under § 271(c). More specifically, patients and medical professionals directly infringe (literally and/or under the doctrine of equivalents) at least claims 1, 6-7, 10-14, 19-20, 23-30, and 32 of the of the '994 patent by using the AirSense™ 10 AutoSet™ systems, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(a).

105. At least as of the date of receipt of the notice letter, *see* Exhibit 11, ResMed knew of the '994 patent, knowingly induced the use by medical professionals and patients of the AirSense™ 10 AutoSet™ systems by keeping these products in the market place and the stream of commerce, and possessed a specific intent to encourage direct infringement of the '994 patent, due to the failure to remove these goods from the stream of commerce.

106. ResMed possessed, and continues to possess, specific intent to induce infringement by providing to the public, at a minimum, product specifications and the option to purchase and/or use the AirSense™ 10 AutoSet™ systems, which products directly infringe the '994 patent.

107. ResMed has actively induced and encouraged, and continues to actively induce and encourage, medical professionals to prescribe the AirSense™ 10 AutoSet™ systems to patients, and patients to use the AirSense™ 10 AutoSet™ systems, by marketing, promoting and advertising the infringing use of the AirSense™ 10 AutoSet™ systems.

108. Upon information and belief, ResMed knows that its AirSense™ 10 AutoSet™ systems are especially made or adapted for use in infringing the '994 patent, that AirSense™ 10 AutoSet™ systems are not staple articles or commodities of commerce, and that the AirSense™ 10 AutoSet™ systems are not suitable for substantial noninfringing use, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(c). More specifically, patients or medical professionals directly infringe (literally and/or under the doctrine of equivalents) at least claims 1, 6-7, 10-14, 19-20, 23-30, and 32 of the '994 patent by using the AirSense™ 10 AutoSet™ systems, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(a).

109. ResMed's foregoing actions constitute and/or will constitute infringement of the '994 patent, active inducement of infringement of the '994 patent, and contribution to the infringement by others of the '994 patent.

110. Plaintiff reserves the right to assert additional claims of the '994 patent that ResMed infringes.

111. Plaintiff has been damaged as a result of ResMed's infringing conduct. ResMed is, thus, liable to Plaintiff in an amount that adequately compensates for its infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

Count III: Infringement of United States Patent No. 9,168,344 by ResMed

112. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

113. On information and belief, and without authority, consent, right, or license, ResMed makes, uses, sells, offers to sell and/or imports the AirSense™ 10 AutoSet™ systems in the United States. In doing so, ResMed infringes one or more claims, including claims 1, 3, 7, 9, 11, and 13 of the '344 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing the AirSense™ 10 AutoSet™ systems, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c) by providing to the public, at a minimum, the AirSense™ 10 AutoSet™ system specifications and directions, which provide instructions on how to use the systems in a manner that directly infringes the '344 patent.

114. ResMed commits acts of patent infringement through the manufacture, use, offer for sale, sale and/or importation of at least the AirSense™ 10 AutoSet™ systems that include the AutoSet™ and AutoRamp™ features, including, but not limited to, the AirSense™ 10 AutoSet™ systems.

115. For example, claim 1 of the '344 patent covers:

A system, comprising:

> a flow sensor provided in an airflow path and measuring data corresponding to a patient's breathing patterns; and

> a processing arrangement configured to analyze the breathing patterns to determine whether the breathing patterns are indicative of a troubled wakefulness state; and
>
> a generator configured to supply an airflow to an airway of the patient and to reduce a pressure of the airflow supplied to an airway of the patient from a first pressure to a second pressure when the processing arrangement determines that the breathing patterns are indicative of the troubled wakefulness state, the second pressure being lower than the first pressure.

116. The AirSense™ 10 AutoSet™ systems meet the claim element for "[a] system, comprising: a flow sensor provided in an airflow path and measuring data corresponding to a patient's breathing patterns." Product schematics within the AirSense™ 10 user guide show the presence of a sensor which measures data corresponding to a patient's breathing patterns. *See* Exhibit 12, p. 19, https://document.resmed.com/en-us/documents/products/machine/airsense-series/user-guide/airsense-10-device-with-humidifier_user-guide_amer_eng.pdf.

117. The AirSense™ 10 AutoSet™ systems meet the claim element for "a processing arrangement configured to analyze the breathing patterns to determine whether the breathing patterns are indicative of a troubled wakefulness state..." The AirSense™ 10 AutoSet™ algorithm and/or the AutoRamp™ feature are configured to analyze the breathing patterns to determine whether the breathing patterns are indicative of a troubled wakefulness state; as indicated by the product brochure, the AutoRamp™ feature analyzes the troubled wakefulness state. *See* Exhibit 8, p. 7, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf.

118. The AirSense™ 10 AutoSet™ systems meet the claim element for "a generator configured to supply an airflow to an airway of the patient and to reduce a pressure of the airflow supplied to an airway of the patient from a first pressure to a second pressure when the processing arrangement determines that the breathing patterns are indicative of the troubled wakefulness state, the second pressure being lower than the first pressure." Per the user guide, the AirSense™ 10 AutoSet™ has a generator (blower) configured to supply an airflow to an airway of the patient. *See* Exhibit 12, p. 19, https://document.resmed.com/en-us/documents/products/machine/airsense-series/user-guide/airsense-10-device-with-humidifier_user-guide_amer_eng.pdf. Further, this pressure is reduced from a first pressure, i.e. the prescribed treatment pressure, to a second pressure, i.e. a lower pressure upon waking up, as shown by the troubled wakefulness state. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf.

119. As such, since the AirSense™ 10 AutoSet™ systems meet each and every claim limitation, ResMed is directly infringing one or more claims of the '344 patent in violation of 35 U.S.C. § 271(a).

120. ResMed, acting without authority, consent, right, or license of the '344 patent, has induced, and continues to induce, medical professionals and patients to administer and use the AirSense™ 10 AutoSet™ systems, which directly infringe one or more claims of the '344 patent resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(b) and 35 U.S.C. § 271(c). More specifically,

patients and medical professionals directly infringe (literally and/or under the doctrine of equivalents) at least claims 1, 3, 7, 9, 11, and 13 of the '344 patent by using the AirSense™ 10 AutoSet™ systems, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(a).

121. At least as of the date of receipt of the notice letter, *see* Exhibit 11, ResMed knew of the '344 patent, knowingly induced the use by medical professionals and patients of the AirSense™ 10 AutoSet™ systems by keeping these products in the market place and the stream of commerce, and possessed a specific intent to encourage direct infringement of the '344 patent, due to the failure to remove these goods from the stream of commerce.

122. ResMed possessed, and continues to possess, specific intent to induce infringement by providing to the public, at a minimum, product specifications and the option to purchase and/or use the AirSense™ 10 AutoSet™ systems, which systems directly infringe the '344 patent.

123. ResMed has actively induced and encouraged, and continues to actively induce and encourage, medical professionals to prescribe the AirSense™ 10 AutoSet™ systems to patients, and patients to use the AirSense™ 10 AutoSet™ systems, by marketing, promoting and advertising the infringing use of the AirSense™ 10 AutoSet™ systems.

124. Upon information and belief, ResMed knows that the AirSense™ 10 AutoSet™ systems are especially made or adapted for use in infringing the '344 patent, that the the AirSense™ 10 AutoSet™ systems are not staple articles or commodities of

commerce, and that the the AirSense™ 10 AutoSet™ systems are not suitable for substantial noninfringing use, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(c). More specifically, patients or medical professionals directly infringe (literally and/or under the doctrine of equivalents) at least claims 1, 3, 7, 9, 11, and 13 of the '344 patent by using the AirSense™ 10 AutoSet™ systems, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(a).

125. ResMed's foregoing actions constitute and/or will constitute infringement of the '344 patent, active inducement of infringement of the '344 patent, and contribution to the infringement by others of the '344 patent.

126. Plaintiff reserves the right to assert additional claims of the '344 patent that ResMed infringes.

127. Plaintiff has been damaged as a result of ResMed's infringing conduct. ResMed is, thus, liable to Plaintiff in an amount that adequately compensates for its infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

Count IV: Infringement of United States Patent No. 9,108,009 by ResMed

128. Plaintiff incorporates each of the preceding paragraphs as if fully set forth here.

129. On information and belief, and without authority, consent, right, or license, ResMed makes, uses, sells, offers to sell and/or imports positive airway

pressure devices in the United States. In doing so, ResMed infringes one or more claims, including claims 1-30 of the '009 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing the AirSense™ 10 AutoSet™ systems, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c) by providing to the public, at a minimum, the AirSense™ 10 AutoSet™ systems' product specifications and directions, which provide instructions on how to use the AirSense™ 10 AutoSet™ systems in a manner that infringes directly the '009 patent.

130. ResMed commits acts of patent infringement through the manufacture, use, offer for sale, sale and/or importation of at least the AirSense™ 10 AutoSet™ line of systems that include the AutoSet™ and AutoRamp™ features including, but not limited to, the AirSense™ 10 AutoSet™ series of systems.

131. For example, claim 1 of the '009 patent covers:

> A positive airway pressure system for delivery of a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure delivered to an entrance of a patient's airways in order to assist in treating a sleeping disorder in a patient, the positive airway pressure system comprising:
>
> a flow generator which supplies a positive treatment pressure flow of breathable gases to be supplied to a patient;
>
> a flow sensor located in a flow path of the positive treatment pressure flow of breathable gases, the flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patient's breathing patterns; and
>
> a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data to determine the patient's breathing patterns,

> the processing arrangement also determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part, on the determined breathing patterns of the patient,
>
> wherein the processing arrangement automatically delays the onset of a pressure increase to the patient when the processing arrangement determines that the patient is in an awake state,
>
> wherein the delay lasts at least until the processing arrangement determines that the patient is in an asleep state,
>
> wherein the processing arrangement determines the patient has transitioned between an awake state and an asleep state when a combination of obstructions are detected.

132. The AirSense™ 10 AutoSet™ systems meet the claim element for "A positive airway pressure system for delivery of a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure delivered to an entrance of a patient's airways in order to assist in treating a sleeping disorder in a patient…" because ResMed makes, uses, sells, offers to sell and/or imports the AirSense™ 10 AutoSet™ system for treatment of a sleeping disorder. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf

133. The AirSense™ 10 AutoSet™ systems meet the claim element for "a flow generator which supplies a positive treatment pressure flow of breathable gases to be supplied to a patient." The AirSense™ contains a flow generator (blower) which supplies a positive treatment pressure flow of breathable gases to a patient. *See* Exhibit 12, p. 19, https://document.resmed.com/en-

us/documents/products/machine/airsense-series/user-guide/airsense-10-device-with-humidifier_user-guide_amer_eng.pdf.

134. The AirSense™ 10 AutoSet™ systems meet the claim element for "a flow sensor located in a flow path of the positive treatment pressure flow of breathable gases, the flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patient's breathing patterns." As shown by product schematics within the user guide, the AirSense™ contains a flow sensor located in a flow path of the positive treatment pressure flow of breathable gases, the flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patient's breathing pattern. *Id.*

135. The AirSense™ 10 AutoSet™ systems meet the claim element for "a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data to determine the patient's breathing patterns…" The AirSense™ 10 AutoSet™ has an Autoset™ algorithm (processing arrangement) that receives the measured data corresponding to the flow of breathable gases from the flow sensor. This algorithm analyzes the data to determine the patient's breathing patterns. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf.

136. The AirSense™ 10 AutoSet™ systems meet the claim element for "the processing arrangement also determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part, on the determined

breathing patterns of the patient…" As shown by the product brochure, ResMed sleep blog, and other sources, the AirSense™ 10 AutoSet™ system determines whether to alter the pressure based in part on the determined breathing patterns of the patient. *Id.; see also* Exhibit 9, https://www.resmed.com/en-us/sleep-apnea/sleep-blog/fall-asleep-faster-with-lower-cpap-pressure/; Exhibit 10, http://www.apneaboard.com/wiki/index.php/CPAP_Algorithms.

137. The AirSense™ 10 AutoSet™ systems meet the claim element for "wherein the processing arrangement automatically delays the onset of a pressure increase to the patient when the processing arrangement determines that the patient is in an awake state…" Through its AutoRamp ™ feature, the AirSense ™ processing arrangement delays the onset of pressure increase to the patient if the patient is still awake. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf.

138. The AirSense™ 10 AutoSet™ systems meet the claim element for "wherein the delay lasts at least until the processing arrangement determines that the patient is in an asleep state…" Through its AutoRamp ™ feature, the AirSense ™ processing arrangement delays the onset of pressure increase to the patient until the patient is asleep. *Id.*

139. The AirSense™ 10 AutoSet™ systems meet the claim element for "wherein the processing arrangement determines the patient has transitioned between an awake state and an asleep state when a combination of obstructions are detected."

Per the ResMed sleep blog entry, the AirSense™ 10 determines the patient is asleep when it detects a combination of obstructions. *See* Exhibit 9, https://www.resmed.com/en-us/sleep-apnea/sleep-blog/fall-asleep-faster-with-lower-cpap-pressure/.

140. Since the AirSense™ 10 AutoSet™ systems meet each and every claim limitation, ResMed is directly infringing one or more claims of the '009 patent in violation of 35 U.S.C. § 271(a).

141. ResMed, acting without authority, consent, right, or license of the '009 patent, has induced, and continues to induce, medical professionals and patients to administer and use the AirSense™ 10 AutoSet™ systems, which directly infringe one or more claims of the '009 patent resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(b) and 35 U.S.C. § 271(c). More specifically, patients and medical professionals directly infringe (literally and/or under the doctrine of equivalents) at least claims 1-30 of the '009 patent by using the AirSense™ 10 AutoSet™ systems, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(a).

142. At least since the date of receipt of the notice letter, *see* Exhibit 11, ResMed knew of the '009 patent, knowingly induced the use by medical professionals and patients of the AirSense™ 10 AutoSet™ systems by keeping these products in the market place and the stream of commerce, and possessed a specific intent to encourage direct infringement of the '009 patent, due to the failure to remove these goods from the stream of commerce.

143. ResMed possessed, and continues to possess, specific intent to induce infringement by providing to the public, at a minimum, product specifications and the option to purchase and/or use the AirSense™ 10 AutoSet™ systems which directly infringe the ’009 patent.

144. ResMed has actively induced and encouraged, and continues to actively induce and encourage, medical professionals to prescribe the AirSense™ 10 AutoSet™ systems to patients, and patients to use the AirSense™ 10 AutoSet™ systems, by marketing, promoting and advertising the infringing use of the AirSense™ 10 AutoSet™ systems.

145. Upon information and belief, ResMed knows that its AirSense™ 10 AutoSet™ systems are especially made or adapted for use in infringing the '009 patent, that the AirSense™ 10 AutoSet™ systems are not staple articles or commodities of commerce, and that the AirSense™ 10 AutoSet™ systems are not suitable for substantial noninfringing use, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(c). More specifically, patients or medical professionals directly infringe (literally and/or under the doctrine of equivalents) claims 1- 30 of the ’009 patent by using the AirSense™ 10 AutoSet™ systems, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(a).

146. ResMed’s foregoing actions constitute and/or will constitute infringement of the ’009 patent, active inducement of infringement of the ’009 patent, and contribution to the infringement by others of the ’009 patent.

147. Plaintiff reserves the right to assert additional claims of the '009 patent that ResMed infringes.

148. Plaintiff has been damaged as a result of ResMed's infringing conduct. ResMed is, thus, liable to Plaintiff in an amount that adequately compensates for its infringement, which, by law, cannot be less than a reasonable royalty, together with interest.

Count V: Infringement of United States Patent No. 9,427,539 by ResMed

149. Plaintiff incorporates each of the preceding paragraphs as if fully set forth here.

150. On information and belief, and without authority, consent, right, or license, ResMed makes, uses, sells, offers to sell and/or imports positive airway pressure devices in the United States. In doing so, ResMed infringes one or more claims, including claims 1-2, 5-11, 13, and 15-30 of the '539 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing the AirSense™ 10 AutoSet™ systems, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c) by providing to the public, at a minimum, the AirSense™ 10 AutoSet™ systems' product specifications and directions, which provide instructions on how to use the AirSense™ 10 AutoSet™ systems in a manner that infringes directly the '539 patent.

151. ResMed commits acts of patent infringement through the manufacture, use, offer for sale, sale and/or importation of at least the AirSense™ 10 AutoSet™ line

of systems that include the AutoSet and AutoRamp™ features including, but not limited to, the AirSense™ 10 AutoSet™ series of systems.

152. For example, claim 1 of the '539 patent covers:

> A positive airway pressure system for treatment of a sleeping disorder in a patient, the system comprising:
>
> a generator supplying airflow to an airway of a patient;
>
> one or more flow sensors measuring data corresponding to the supplied airflow; and
>
> at least one hardware processor,
>
> wherein the hardware processor receives the measured data from the one or more flow sensors and provides operational control signals to the generator,
>
> wherein the hardware processor analyzes the measured data to determine whether a patient breathing pattern indicative at least one transition between an awake state and an asleep state has occurred,
>
> the hardware processor providing instructions to the generator to adjust the applied pressure in response to the breathing patterns indicative of the at least one transition.

153. The AirSense™ 10 AutoSet™ systems meet the claim element for "A positive airway pressure system for treatment of a sleeping disorder in a patient." The AirSense™ 10 AutoSet™ system is a positive airway pressure system that treats sleeping disorders. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf.

154. The AirSense™ 10 AutoSet™ systems meet the claim element for "a generator supplying airflow to an airway of a patient." Per the user guide, this system

has a generator (blower) which supplies airflow to an airway of a patient. *See* Exhibit 12, p. 19, https://document.resmed.com/en-us/documents/products/machine/airsense-series/user-guide/airsense-10-device-with-humidifier_user-guide_amer_eng.pdf.

155. The AirSense™ 10 AutoSet™ systems meet the claim element for "one or more flow sensors measuring data corresponding to the supplied airflow…" Per the user guide, this system has a flow sensor to measure data corresponding to the supplied airflow. Per product schematics within the user guide, this system has a generator (blower) which supplies airflow to an airway of a patient. *Id.*

156. The AirSense™ 10 AutoSet™ systems meet the claim element for "at least one hardware processor…" Per the product brochure, the AirSense™ has at least one hardware processor, i.e. the Autoset™ algorithm (processing arrangement), which receives the measured data from the one or more flow sensors and provides operational control signals to the generator. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf.

157. The AirSense™ 10 AutoSet™ systems meet the claim element for "wherein the hardware processor receives the measured data from the one or more flow sensors and provides operational control signals to the generator…" The AirSense™ hardware processor, i.e. the Autoset™ algorithm, receives the measured data from the one or more flow sensors and provides operational control signals to the generator. *See* Exhibit 8, https://document.resmed.com/en-

us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf.; see also Exhibit 10, http://www.apneaboard.com/wiki/index.php/CPAP_Algorithms.

158. The AirSense™ 10 AutoSet™ systems meet the claim element for "wherein the hardware processor analyzes the measured data to determine whether a patient breathing pattern indicative at least one transition between an awake state and an asleep state has occurred…" Per the product brochure, the AirSense™ hardware processor, i.e. the Autoset™ algorithm (processing arrangement), through its AutoRamp™ feature, analyzes the measured data to determine whether a patient breathing pattern indicative at least one transition between an awake state and an asleep state has occurred. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf.

159. The AirSense™ 10 AutoSet™ systems meet the claim element for "the hardware processor providing instructions to the generator to adjust the applied pressure in response to the breathing patterns indicative of the at least one transition." The AirSense™ hardware processor, i.e. the Autoset™ algorithm, through its AutoRamp™ feature, provides instructions to the generator to adjust the applied pressure in response to the patient's breathing patterns indicative of the at least one transition. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-

overview_brochure_anz_eng.pdf; *see also* Exhibit 9, https://www.resmed.com/en-us/sleep-apnea/sleep-blog/fall-asleep-faster-with-lower-cpap-pressure/.

160. Since the AirSense™ 10 AutoSet™ systems meet each and every claim limitation, ResMed is directly infringing one or more claims of the '539 patent in violation of 35 U.S.C. § 271(a).

161. ResMed, acting without authority, consent, right, or license of the '539 patent, has induced, and continues to induce, medical professionals and patients to administer and use the AirSense™ 10 AutoSet™ systems, which directly infringe one or more claims of the '539 patent resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(b) and 35 U.S.C. § 271(c). More specifically, patients and medical professionals directly infringe (literally and/or under the doctrine of equivalents) at least claims 1-2, 5-11, 13, and 15-30 of the '539 patent by using the AirSense™ 10 AutoSet™ systems, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(a).

162. At least since the date of receipt of the notice letter, *see* Exhibit 11, ResMed knew of the '539 patent, knowingly induced the use by medical professionals and patients of the AirSense™ 10 AutoSet™ systems by keeping these products in the market place and the stream of commerce, and possessed a specific intent to encourage direct infringement of the '539 patent, due to the failure to remove these goods from the stream of commerce.

163. ResMed possessed, and continues to possess, specific intent to induce infringement by providing to the public, at a minimum, product specifications and the

option to purchase and/or use the AirSense™ 10 AutoSet™ systems which directly infringe the '539 patent.

164. ResMed has actively induced and encouraged, and continues to actively induce and encourage, medical professionals to prescribe the AirSense™ 10 AutoSet™ systems to patients, and patients to use the AirSense™ 10 AutoSet™ systems, by marketing, promoting and advertising the infringing use of the AirSense™ 10 AutoSet™ systems.

165. Upon information and belief, ResMed knows that its AirSense™ 10 AutoSet™ systems are especially made or adapted for use in infringing the '539 patent, that the AirSense™ 10 AutoSet™ systems are not staple articles or commodities of commerce, and that the AirSense™ 10 AutoSet™ systems are not suitable for substantial noninfringing use, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(c). More specifically, patients or medical professionals directly infringe (literally and/or under the doctrine of equivalents) claims 1-2, 5-11, 13, and 15-30 of the '539 patent by using the AirSense™ 10 AutoSet™ systems, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(a).

166. The foregoing actions of ResMed constitute and/or will constitute infringement of the '539 patent, active inducement of infringement of the '539 patent, and contribution to the infringement by others of the '539 patent.

167. Plaintiff reserves the right to assert additional claims of the '539 patent that ResMed infringes.

168. Plaintiff has been damaged as a result of ResMed's infringing conduct. ResMed is, thus, liable to Plaintiff in an amount that adequately compensates for its infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

Count VI: Patent Infringement of United States Patent No. 9,533,115 by ResMed

169. Plaintiff incorporates each of the preceding paragraphs as if fully set forth here.

170. On information and belief, and without authority, consent, right, or license, ResMed makes, uses, sells, offers to sell and/or imports positive airway pressure devices in the United States. In doing so, ResMed infringes one or more claims, including claims 1, 3-6, 9-12, 14-24, 26, 28-29 of the '115 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing the AirSense™ 10 AutoSet™ systems, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c) by providing to the public, at a minimum, the AirSense™ 10 AutoSet™ systems' product specifications and directions, which provide instructions on how to use the AirSense™ 10 AutoSet™ systems in a manner that infringes directly the '115 patent.

171. ResMed commits acts of patent infringement through the manufacture, use, offer for sale, sale and/or importation of at least the AirSense™ 10 AutoSet™ line of systems that include the AutoSet™ and AutoRamp™ features including, but not limited to, the AirSense™ 10 AutoSet™ series of systems.

172. For example, claim 1 of the '115 patent covers:

> A positive airway pressure system which delivers of a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure to an entrance of a patient's airways in order to assist in treating a sleeping disorder, the positive airway pressure system comprising:
>
> a flow generator which generates a flow of breathable gases to be supplied to a patient;
>
> a flow sensor measuring data indicative of the patient's breathing patterns; and
>
> at least one hardware processor which receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data,
>
> the hardware processor determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part, on the indication of the patient's breathing patterns,
>
> wherein the hardware processor automatically increases a pressure supplied to the patient when the hardware processor determines that an indication of the patient's breathing patterns representative of a change from an awake state to an asleep state has occurred,
>
> the indication of the patient's breathing patterns representative of a change from an awake state to an asleep state including at least one of a regularity of breathing or a regular period of obstructions.

173. The AirSense™ 10 AutoSet™ systems meet the claim element for "A positive airway pressure system which delivers of a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure to an entrance of a patient's airways in order to assist in treating a sleeping disorder, the positive airway pressure system..." As shown by the product brochure, the AirSense™ 10 AutoSet™ system is a

positive airway pressure system which delivers a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure to an entrance of a patient's airways in order to assist in treating a sleeping disorder. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf.

174. The AirSense™ 10 AutoSet™ systems meet the claim element for "a flow generator which generates a flow of breathable gases to be supplied to a patient." The AirSense™ contains a flow generator (blower) which generates a flow of breathable gases to be supplied to a patient, as shown by product schematics in the user guide. *See* Exhibit 12, p. 19, https://document.resmed.com/en-us/documents/products/machine/airsense-series/user-guide/airsense-10-device-with-humidifier_user-guide_amer_eng.pdf.

175. The AirSense™ 10 AutoSet™ systems meet the claim element for "at least one hardware processor which receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data…" The AirSense™ 10 has the AutoSet™ algorithm, which receives and measures the data from the flow sensor. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf.

176. The AirSense™ 10 AutoSet™ systems meet the claim element for "the hardware processor determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part, on the indication of the

patient's breathing patterns…" The AirSense™ 10 has the AutoSet™ algorithm, which determines whether to alter the pressure based upon the patient's breathing patterns. *Id.; see also* Exhibit 10, http://www.apneaboard.com/wiki/index.php/CPAP_Algorithms.

177. The AirSense™ 10 AutoSet™ systems meet the claim element for "wherein the hardware processor automatically increases a pressure supplied to the patient when the hardware processor determines that an indication of the patient's breathing patterns representative of a change from an awake state to an asleep state has occurred…" As indicated by the product brochure, through its AutoRamp™ feature, the processor of the AirSense™ 10 automatically increases the pressure when the patient has fallen asleep. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf; *see also* Exhibit 9, https://www.resmed.com/en-us/sleep-apnea/sleep-blog/fall-asleep-faster-with-lower-cpap-pressure/.

178. The AirSense™ 10 AutoSet™ systems meet the claim element for "indication of the patient's breathing patterns representative of a change from an awake state to an asleep state including at least one of a regularity of breathing or a regular period of obstructions." Per the ResMed sleep apnea blog, the AutoRamp™ feature determines that the patient has fallen asleep based on these factors. *See* Exhibit 9, https://www.resmed.com/en-us/sleep-apnea/sleep-blog/fall-asleep-faster-with-lower-cpap-pressure/.

179. Since the AirSense™ 10 AutoSet™ systems meet each and every claim limitation, ResMed is directly infringing one or more claims of the '115 patent in violation of 35 U.S.C. § 271(a).

180. ResMed, acting without authority, consent, right, or license of the '115 patent, has induced, and continues to induce, medical professionals and patients to administer and use the AirSense™ 10 AutoSet™ systems, which directly infringe one or more claims of the '115 patent resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(b) and 35 U.S.C. § 271(c). More specifically, patients and medical professionals directly infringe (literally and/or under the doctrine of equivalents) at least claims 1, 3-6, 9-12, 14-24, 26, 28-29 of the '115 patent by using the AirSense™ 10 AutoSet™ systems, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(a).

181. At least since the date of receipt of the notice letter, *see* Exhibit 11, ResMed knew of the '115 patent, knowingly induced the use by medical professionals and patients of the AirSense™ 10 AutoSet™ systems by keeping these products in the market place and the stream of commerce, and possessed a specific intent to encourage direct infringement of the '115 patent, due to the failure to remove these goods from the stream of commerce.

182. ResMed possessed, and continues to possess, specific intent to induce infringement by providing to the public, at a minimum, product specifications and the option to purchase and/or use the AirSense™ 10 AutoSet™ systems which directly infringe the '115 patent.

183. ResMed has actively induced and encouraged, and continues to actively induce and encourage, medical professionals to prescribe the AirSense™ 10 AutoSet™ systems to patients, and patients to use the AirSense™ 10 AutoSet™ systems, by marketing, promoting and advertising the infringing use of the AirSense™ 10 AutoSet™ systems.

184. Upon information and belief, ResMed knows that its AirSense™ 10 AutoSet™ systems are especially made or adapted for use in infringing the '115 patent, that the AirSense™ 10 AutoSet™ systems are not staple articles or commodities of commerce, and that the AirSense™ 10 AutoSet™ systems are not suitable for substantial noninfringing use, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(c). More specifically, patients or medical professionals directly infringe (literally and/or under the doctrine of equivalents) claims 1, 3-6, 9-12, 14-24, 26, 28-29 of the '115 patent by using the AirSense™ 10 AutoSet™ systems, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(a).

185. ResMed's foregoing actions constitute and/or will constitute infringement of the '115 patent, active inducement of infringement of the '115 patent, and contribution to the infringement by others of the '115 patent.

186. Plaintiff reserves the right to assert additional claims of the '115 patent infringed by ResMed.

187. Plaintiff has been damaged as a result of ResMed's infringing conduct. ResMed is, thus, liable to Plaintiff in an amount that adequately compensates for its

infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

Count VII: Infringement of United States Patent No. 10,384,024 by ResMed

188. Plaintiff incorporates each of the preceding paragraphs as if fully set forth here.

189. On information and belief, and without authority, consent, right, or license, ResMed makes, uses, sells, offers to sell and/or imports positive airway pressure devices in the United States. In doing so, ResMed infringes one or more claims, including claims 1-14 of the '024 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing the AirSense™ 10 AutoSet™ systems, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c) by providing to the public, at a minimum, the AirSense™ 10 AutoSet™ systems' product specifications and directions, which provide instructions on how to use the AirSense™ 10 AutoSet™ systems in a manner that directly infringes the '024 patent.

190. ResMed commits acts of patent infringement through the manufacture, use, offer for sale, sale and/or importation of at least the AirSense™ 10 AutoSet™ line of systems that include the AutoSet™ and AutoRamp™ features including, but not limited to, the AirSense™ 10 AutoSet™ series of systems.

191. For example, claim 1 of the '024 patent covers:

> A positive airway pressure system for delivery of a flow of breathable gas at a positive treatment pressure with respect to ambient air

pressure delivered to an entrance of a patient's airways in order to assist in treating a sleeping disorder in a patient, the positive airway pressure system comprising:

a flow generator which supplies a positive treatment pressure flow of breathable gases to be supplied to a patient;

a flow sensor located in a flow path of the positive treatment pressure flow of breathable gases, the flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patient's breathing patterns; and

a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data to determine the patient's breathing patterns,

the processing arrangement also determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part, on the determined breathing patterns of the patient,

wherein the processing arrangement automatically delays the onset of a pressure increase to the patient when the processing arrangement determines that the patient is in an awake state,

wherein the delay lasts at least until the processing arrangement determines that the patient is in an asleep state.

192. The AirSense™ 10 AutoSet™ systems meet the claim element for "A positive airway pressure system for delivery of a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure delivered to an entrance of a patient's airways in order to assist in treating a sleeping disorder in a patient…" The AirSense™ 10 AutoSet™ system is a positive airway pressure system that treats sleeping disorders. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf.

193. The AirSense™ 10 AutoSet™ systems meet the claim element for "a flow generator which supplies a positive treatment pressure flow of breathable gases to be supplied to a patient…" Per product schematics within the user guide, AirSense™ 10 AutoSet™ systems contain a flow generator (blower) to supply a positive treatment pressure flow of breathable gases. *See* Exhibit 12, p. 19, https://document.resmed.com/en-us/documents/products/machine/airsense-series/user-guide/airsense-10-device-with-humidifier_user-guide_amer_eng.pdf.

194. The AirSense™ 10 AutoSet™ systems meet the claim element for "a flow sensor located in a flow path of the positive treatment pressure flow of breathable gases, the flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patient's breathing patterns…" This system has a sensor to measure data corresponding to the flow of breathable gases and indicative of the patient's breathing patterns, as shown by product schematics within the user guide. *Id.*

195. The AirSense™ 10 AutoSet™ systems meet the claim element for "a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data to determine the patient's breathing patterns…" The AirSense™ AutoSet™ systems have a processing arrangement, i.e. the Autoset™ algorithm, which receive the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data to determine the patient's breathing patterns. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-

series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf; *See also* Exhibit 10, http://www.apneaboard.com/wiki/index.php/CPAP_Algorithms

196. The AirSense™ 10 AutoSet™ systems meet the claim element for "the processing arrangement also determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part, on the determined breathing patterns of the patient…" The AirSense™ processing arrangement, i.e. the Autoset™ algorithm, determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part, on the determined breathing patterns of the patient. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf; *See also* Exhibit 10, http://www.apneaboard.com/wiki/index.php/CPAP_Algorithms.

197. The AirSense™ 10 AutoSet™ systems meet the claim element for "wherein the processing arrangement automatically delays the onset of a pressure increase to the patient when the processing arrangement determines that the patient is in an awake state…" The AirSense™ processing arrangement, i.e. Autoset™ algorithm, through its AutoRamp™ feature, automatically delays the onset of a pressure increase when the processing arrangement determines that the patient is in an awake state. *See* Exhibit 8, https://document.resmed.com/en-us/documents/products/machine/aircurve-series/product-brochure/1018639_ras-overview_brochure_anz_eng.pdf

198. The AirSense™ 10 AutoSet™ systems meet the claim element for "wherein the delay lasts at least until the processing arrangement determines that the patient is in an asleep state." The AirSense™ processing arrangement, i.e. the Autoset™ algorithm, through the AutoRamp™ feature, delays the onset of a pressure increase until the processing arrangement determines that the patient is in an asleep state. *Id.*

199. Since the AirSense™ 10 AutoSet™ systems meet each and every claim limitation, ResMed is directly infringing one or more claims of the '024 patent in violation of 35 U.S.C. § 271(a).

200. ResMed, acting without authority, consent, right, or license of the '024 patent, has induced, and continues to induce, patients to administer and use the AirSense™ 10 AutoSet™ systems, which directly infringe one or more claims of the '024 patent resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(b) and 35 U.S.C. § 271(c). More specifically, patients and medical professionals directly infringe (literally and/or under the doctrine of equivalents) at least claims 1-14 of the '024 patent by using the AirSense™ 10 AutoSet™ systems, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(a).

201. At least since the date of receipt of the notice letter, *see* Exhibit 11, ResMed knew of the '024 patent, knowingly induced the use by medical professionals and patients of the AirSense™ 10 AutoSet™ systems by keeping these products in the market place and the stream of commerce, and possessed a specific intent to encourage

direct infringement of the '024 patent, due to the failure to remove these goods from the stream of commerce.

202. ResMed possessed, and continues to possess, specific intent to induce infringement by providing to the public, at a minimum, product specifications and the option to purchase and/or use the AirSense™ 10 AutoSet™ systems which directly infringe the '024 patent.

203. ResMed has actively induced and encouraged, and continues to actively induce and encourage, medical professionals to prescribe the AirSense™ 10 AutoSet™ systems to patients, and patients to use the AirSense™ 10 AutoSet™ systems, by marketing, promoting and advertising the infringing use of the AirSense™ 10 AutoSet™ systems.

204. Upon information and belief, ResMed knows that its AirSense™ 10 AutoSet™ systems are especially made or adapted for use in infringing the '024 patent, that the AirSense™ 10 AutoSet™ systems are not staple articles or commodities of commerce, and that the AirSense™ 10 AutoSet™ systems are not suitable for substantial noninfringing use, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(c). More specifically, patients or medical professionals directly infringe (literally and/or under the doctrine of equivalents) claims 1-14 of the '024 patent by using the AirSense™ 10 AutoSet™ systems, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(a).

205. ResMed's foregoing actions constitute and/or will constitute infringement of the '024 patent, active inducement of infringement of the '024 patent, and contribution to the infringement by others of the '024 patent.

206. Plaintiff reserves the right to assert additional claims of the '024 patent that ResMed infringes.

207. Plaintiff has been damaged as a result of ResMed's infringing conduct. ResMed is, thus, liable to Plaintiff in an amount that adequately compensates for its infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

JURY DEMANDED

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff requests a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the Court to enter judgment in its favor and against ResMed as follows:

a. finding that ResMed has infringed, contributed to and induced infringement of one or more claims of the patents-in-suit;

b. awarding Plaintiff damages under 35 U.S.C. § 284, or otherwise permitted by law, and damages for any continued post-verdict infringement;

c. awarding Plaintiff damages for the unjust enrichment of ResMed;

d. awarding Plaintiff pre-judgment and post-judgment interest on the damages award and costs;

e. declaring this case exceptional pursuant to 35 U.S.C. § 285;

f. awarding costs of this action and attorney fees pursuant to 35 U.S.C. § 285, or as otherwise permitted by the law; and

g. awarding such other costs and further relief the Court determines to be just and equitable.

Dated: June 2, 2021

Respectfully submitted,

/s/ Stamatios Stamoulis

Stamatios Stamoulis (#4606)
Richard C. Weinblatt (#5080)
800 N. Street, Third Floor
Wilmington, DE 19801
(302) 999-1540
stamoulis@swdelaw.com
weinblatt@swdelaw.com

Of Counsel:
Christopher J. Belter (*pro hac vice pending*)
Michael A. Siem (*pro hac vice pending*)
GOLDBERG SEGALLA LLP
cbelter@goldbergsegalla.com
msiem@goldbergsegalla.com
711 Third Avenue, Suite 1900
New York, New York 10017
Telephone: (646) 292-8700

Lynn Lehnert (*pro hac vice pending*)
llehnert@goldbergsegalla.com
GOLDBERG SEGALLA LLP
8000 Maryland Avenue, Suite 640
St. Louis, Missouri 63105
Telephone: (314) 446-3359

Attorneys for Plaintiff New York University