

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT HOSPITAL)
PRODUCTS IP LTD.,)
INO THERAPEUTICS LLC, and)
IKARIA, INC.,)
)
Plaintiffs,)
)
v.) C.A. No. 1:15-cv-00170-GMS
)
PRAXAIR DISTRIBUTION, INC. and)
PRAXAIR, INC.,)
)
Defendants.)

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Mallinckrodt Hospital Products IP Ltd. (“Mallinckdrodt IP”), INO Therapeutics LLC (“INOT”), and Ikaria, Inc. (“Ikaria”) (collectively, “Plaintiffs”) for their Complaint against defendants Praxair Distribution, Inc. and Praxair, Inc. (collectively “Praxair” or “Defendants”), hereby allege as follows:

I. THE PARTIES

1. Plaintiff Mallinckrodt IP is a private unlimited company having a share capital and formed under the laws of Ireland with company number 5683516 and having its registered office at Damastown Industrial Estate, Mulhuddart, Dublin 15. In September 2015, Mallinckrodt IP acquired rights in certain regulatory and intellectual property rights related to the INOmax®.

2. Plaintiff INOT is a wholly-owned subsidiary of Mallinckrodt Hospital Products Inc. and is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at Perryville III Corporate Park, P. O. Box 9001, 53 Frontage Road, Third Floor, Hampton, New Jersey 08827-9001.

3. Plaintiff Ikaria is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at Perryville III Corporate Park, P.O. Box 9001, 53 Frontage Road, Third Floor, Hampton, New Jersey 08827-9001.

4. Mallinckrodt Hospital Products Inc. is a research-driven healthcare company that discovers, develops, manufactures and markets innovative products to address the needs of critically ill patients.

5. On information and belief, Praxair Distribution, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its head office at 28 McCandless Ave, Pittsburgh, Pennsylvania 15201.

6. On information and belief, Praxair, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 39 Old Ridgebury Road, Danbury, Connecticut 06810.

7. On information and belief, Praxair Distribution, Inc. is a wholly-owned subsidiary of Praxair, Inc.

8. On information and belief, Praxair Distribution, Inc. assembled and caused to be filed with the United States Food and Drug Administration (“FDA”), pursuant to 21 U.S.C. § 355(j) (Section 505(j) of the Federal Food, Drug and Cosmetic Act), Abbreviated New Drug Application (“ANDA”) No. 207141 (hereinafter “the Praxair ANDA”) concerning a proposed drug product, Noxivent, 100 ppm and 800 ppm nitric oxide for inhalation (“Praxair’s Proposed ANDA Product”).

II. JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. This Court has personal jurisdiction over Praxair Distribution, Inc. On information and belief, Praxair Distribution, Inc. is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Praxair Distribution, Inc. maintains a corporate agent for service of process at 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

11. This Court also has personal jurisdiction over Praxair, Inc. On information and belief, Praxair, Inc. is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Praxair, Inc. maintains a corporate agent for service of process at 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

12. Venue is proper in this Court at least pursuant to 28 U.S.C. §§ 1391 and 1400(b).

III. INOmax[®] (NITRIC OXIDE) FOR INHALATION

13. Mallinckrodt IP owns approved New Drug Application (“NDA”) No. N020845 for nitric oxide 100 and 800 ppm for inhalation to among other things treat neonates with pulmonary hypertension, and is prescribed and sold in the United States under the trademark INOmax[®]. The U.S. Food and Drug Administration (“FDA”) approved NDA No. N020845 on December 23, 1999. INOT is the U.S. agent for Mallinckrodt IP with respect to NDA No. N020845.

14. The approved labeling for INOmax[®] informs the prescribers and users in the Warnings and Precautions section and in section 5.4 that “[i]n patients with pre-existing left

ventricular dysfunction, INOmax may increase pulmonary capillary wedge pressure leading to pulmonary edema.” As such, prescribers and users of INOmax® are cautioned to consider whether INOmax® should be administered to patients with left ventricular dysfunction and the resulting risk of pulmonary edema.

IV. THE PATENTS-IN-SUIT

15. United States Patent No. 8,282,966 (the “’966 patent,” copy attached as Exhibit A) is entitled “Methods of Reducing the Risk of Occurrence of Pulmonary Edema in Children in Need of Treatment with Inhaled Nitric Oxide” and was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on October 9, 2012. The ’966 patent is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) for INOmax® (NDA No. N020845).

16. The ’966 patent is owned by Mallinckrodt IP.

17. United States Patent No. 8,293,284 (the “’284 patent,” copy attached as Exhibit B) is entitled “Methods of Reducing the Risk of Occurrence of Pulmonary Edema in Term or Near-Term Neonates in Need of Treatment with Inhaled Nitric Oxide” and was duly and legally issued by the USPTO on October 23, 2012. The ’284 patent is listed in the FDA’s Orange Book for INOmax® (NDA No. N020845).

18. The ’284 patent is owned by Mallinckrodt IP.

19. United States Patent No. 8,431,163 (the “’163 patent,” copy attached as Exhibit C) is entitled “Methods of Reducing the Risk of Occurrence of Pulmonary Edema Associated with the Inhalation of Nitric Oxide Gas” and was duly and legally issued by the USPTO on April 30, 2013. The ’163 patent is listed in the FDA’s Orange Book for INOmax® (NDA No. N020845).

20. The '163 patent is owned by Mallinckrodt IP.

21. United States Patent No. 8,795,741 (the “’741 patent,” copy attached as Exhibit D) is entitled “Methods For Treating Patients Who Are Candidates For Inhaled Nitric Oxide Treatment” and was duly and legally issued by the USPTO on August 4, 2014. The ’741 patent is listed in the FDA’s Orange Book for INOmax[®] (NDA No. N020845).

22. The ’741 patent is owned by Mallinckrodt IP.

23. United States Patent No. 8,846,112 (the “’112 patent,” copy attached as Exhibit E) is entitled “Methods Of Distributing A Pharmaceutical Product Comprising Nitric Oxide Gas For Inhalation” and was duly and legally issued by the USPTO on September 30, 2014. The ’112 patent is listed in the FDA’s Orange Book for INOmax[®] (NDA No. N020845).

24. The ’966 patent, the ’284 patent, the ’163 patent, and the ’741 patent include claims directed, *inter alia*, to methods for treating or assessing the risk of treating patient populations with hypoxic respiratory failure or pulmonary hypertension with inhaled nitric oxide by, *inter alia*, determining whether patients have left ventricular dysfunction. The instructions and warnings in the approved labeling of INOmax[®] necessarily instruct medical personnel to perform the steps of the claimed methods of these patents. Further, the use of INOmax[®] in accordance with its approved labeling by medical personnel necessarily results in the performance of each of the claimed method steps of these patents.

25. The ’112 patent is owned by Mallinckrodt IP.

26. United States Patent No. 8,291,904 (the “’904 patent,” copy attached as Exhibit F) is entitled “Gas Delivery Device And System” and was duly and legally issued by the USPTO on October 23, 2012. The ’904 patent is listed in the FDA’s Orange Book for INOmax[®] (NDA No. N020845).

27. The '112 patent includes claims directed, *inter alia*, to methods of providing pharmaceutically acceptable nitric oxide gas by, *inter alia*, providing medical providers information that in patients with left ventricular dysfunction, inhaled nitric oxide may lead to pulmonary edema. The instructions and warnings in the approved labeling of INOmax® necessarily include the information included in the claimed methods of the '112 patent. Thus, the distribution of INOmax® with its approved labeling necessarily results in the performance of each of the claimed method steps of the '112 patent.

28. The '904 patent is owned by Mallinckrodt IP.

29. United States Patent No. 8,573,210 (the "'210 patent," copy attached as Exhibit G) is entitled "Nitric Oxide Delivery Device" and was duly and legally issued by the USPTO on November 5, 2013. The '210 patent is listed in the FDA's Orange Book for INOmax® (NDA No. N020845).

30. The '210 patent is owned by Mallinckrodt IP.

31. United States Patent No. 8,573,209 (the "'209 patent," copy attached as Exhibit H) is entitled "Gas Delivery Device And System" and was duly and legally issued by the USPTO on November 5, 2013. The '209 patent is listed in the FDA's Orange Book for INOmax® (NDA No. N020845).

32. The '209 patent is owned by Mallinckrodt IP.

33. United States Patent No. 8,776,794 (the "'794 patent," copy attached as Exhibit I) is entitled "Nitric Oxide Delivery Device" and was duly and legally issued by the USPTO on July 15, 2014. The '794 patent is listed in the FDA's Orange Book for INOmax® (NDA No. N020845).

34. The '794 patent is owned by Mallinckrodt IP.

35. United States Patent No. 8,776,795 (the “’795 patent,” copy attached as Exhibit J) is entitled “Gas Delivery Device and System” and was duly and legally issued by the USPTO on July 15, 2014. The ’795 patent is listed in the FDA’s Orange Book for INOmax® (NDA No. N020845).

36. The ’795 patent is owned by Mallinckrodt IP.

37. The claims of the ’904 patent, ’210 patent, ’209 patent, ’794 patent, and ’795 patent include, *inter alia*, claims to elements of the INOmax DS_{IR} nitric oxide delivery systems. The approved labeling of INOmax® requires that INOmax® be administered with a INOmax DS_{IR} Nitric Oxide Delivery System. Thus, the use of INOmax® in accordance with its approved labeling necessarily results in the use of the claimed elements of these patents.

38. On information and belief, Praxair Distribution, Inc. submitted the Praxair ANDA to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Praxair’s Proposed ANDA Product.

39. On information and belief, the Praxair ANDA seeks FDA approval of Praxair’s Proposed ANDA Product having the same use as INOmax®, which use is covered by the patents in suit. The Praxair ANDA refers to and relies upon INOT’s NDA No. N020845 for INOmax®. The labeling for the Praxair ANDA Product must copy the labeling for INOmax®.

40. On information and belief, Praxair Distribution, Inc. actively collaborated with Praxair, Inc. and/or participated in and/or directed activities related to the submission of the Praxair ANDA and the development of Praxair’s Proposed ANDA Product, was actively involved in preparing the ANDA, and/or intends to directly benefit from and has a financial stake in the approval of the ANDA. On information and belief, upon approval of the Praxair ANDA,

Praxair Distribution, Inc. will be involved in the manufacture, distribution, and/or marketing of Praxair's Proposed ANDA Product.

41. On information and belief, Praxair, Inc. actively collaborated with Praxair Distribution, Inc. and/or participated in and/or directed activities related to the submission of the Praxair ANDA and the development of Praxair's Proposed ANDA Product, was actively involved in preparing the ANDA, and/or intends to directly benefit from and has a financial stake in the approval of the ANDA. On information and belief, upon approval of the Praxair ANDA, Praxair, Inc. will be involved in the manufacture, distribution, and/or marketing of Praxair's Proposed ANDA Product.

42. By letter dated January 6, 2015 (the "January 6 Letter"), and pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), Praxair Distribution, Inc. notified Plaintiffs that it had submitted to the FDA the Praxair ANDA, seeking approval to engage in the commercial manufacture, use, or sale of Praxair's Proposed ANDA Product before the expiration of the '966 patent, the '284 patent, the '163 patent, the '741 patent, the '112 patent, the '904 patent, the '210 patent, the '209 patent, the '794 patent, and the '795 patent. The January 6 Letter was received by Plaintiffs on January 8, 2015.

43. In its January 6 Letter, Praxair Distribution, Inc. notified Plaintiffs, as part of the Praxair ANDA, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") with respect to the '966 patent, the '284 patent, the '163 patent, the '741 patent, the '112 patent, the '904 patent, the '210 patent, the '209 patent, the '794 patent, and the '795 patent. On information and belief, Praxair Distribution, Inc. certified that, the '966 patent, the '284 patent, the '163 patent, the '741 patent, the '112 patent, the '904 patent, the '210 patent, the '209 patent, the '794 patent, and the '795 patent are invalid,

unenforceable and/or will not be infringed by the manufacture, use or sale of Praxair's Proposed ANDA Product.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 8,282,966

44. Plaintiffs repeat and reallege paragraphs 1 through 42 above as if fully set forth herein.

45. By submitting the Praxair ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Praxair's Proposed ANDA Product throughout the United States prior to the expiration of the '966 patent, Defendants committed an act of infringement of the '966 patent under 35 U.S.C. § 271(e)(2). On information and belief, Defendants were aware of the '966 patent at the time the Praxair ANDA was submitted.

46. If Defendants commercially make, use, offer to sell, or sell Praxair's Proposed ANDA Product within the United States, or import Praxair's Proposed ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '966 patent, they would further infringe, for example, claims 1-29 of the '966 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

47. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '966 patent. Plaintiffs do not have an adequate remedy at law.

48. Praxair Distribution, Inc.'s certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '966 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,282,966

49. Plaintiffs repeat and reallege paragraphs 1 through 47 above as if fully set forth herein.

50. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Praxair's Proposed ANDA Product with its proposed labeling immediately following approval of Defendants' ANDA.

51. On information and belief, Defendants' commercial importation, manufacture, use, sale, and/or offer for sale of Praxair's Proposed ANDA Product before the expiration of the '966 patent would infringe one or more claims of the '966 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including at least claims 1-29 of the '966 patent.

52. On information and belief, by seeking approval to distribute Praxair's Proposed ANDA Product with its proposed labeling, Defendants intend to cause others, specifically, for example, medical professionals, to perform acts that Defendants know will infringe one or more claims of the '966 patent.

53. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, actively induce infringement of one or more claims of the '966 patent immediately following approval of Defendants' ANDA, including, for example, claims 1-29 of the '966 patent.

54. On information and belief, Defendants know that Praxair's Proposed ANDA Product and its proposed labeling are especially made or adapted for use in infringing one or more claims of the '966 patent and that Praxair's Proposed ANDA Product and its proposed labeling are not suitable for any substantial noninfringing use.

55. Defendants' commercial manufacture, use, offer for sale, or sale of Praxair's Proposed ANDA Product within the United States will further infringe one or more claims of the '966 patent under 35 U.S.C. § 271(a).

56. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '966 patent. Plaintiffs do not have an adequate remedy at law and those acts will continue unless enjoined by this Court.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 8,293,284

57. Plaintiffs repeat and reallege paragraphs 1 through 55 above as if fully set forth herein.

58. By submitting the Praxair ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Praxair's Proposed ANDA Product throughout the United States prior to the expiration of the '284 patent, Defendants committed an act of infringement of the '284 patent under 35 U.S.C. § 271 (e)(2). On information and belief, Defendants were aware of the '284 patent at the time the Praxair ANDA was submitted.

59. If Defendants commercially make, use, offer to sell, or sell Praxair's Proposed ANDA Product within the United States, or import Praxair's Proposed ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '284 patent, they would further infringe, for example, claims 1-30 of the '284 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

60. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '284 patent. Plaintiffs do not have an adequate remedy at law.

61. Praxair Distribution, Inc.'s certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '284 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,293,284

62. Plaintiffs repeat and reallege paragraphs 1 through 60 above as if fully set forth herein.

63. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Praxair's Proposed ANDA Product with its proposed labeling immediately following approval of Defendants' ANDA.

64. On information and belief, Defendants' commercial importation, manufacture, use, sale, and/or offer for sale of Praxair's Proposed ANDA Product before the expiration of the '284 patent would infringe one or more claims of the '284 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including, for examples, claims 1-30 of the '284 patent.

65. On information and belief, by seeking approval to distribute Praxair's Proposed ANDA Product with its proposed labeling, Defendants intend to cause others, specifically, for example, medical professionals, to perform acts that Defendants know will infringe one or more claims of the '284 patent.

66. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, actively induce infringement of one or more claims of the '284 patent immediately following approval of Defendants' ANDA.

67. On information and belief, Defendants know that Praxair's Proposed ANDA Product and its proposed labeling are especially made or adapted for use in infringing one or

more claims of the '284 patent and that Praxair's Proposed ANDA Product and its proposed labeling are not suitable for any substantial noninfringing use.

68. Defendants' commercial manufacture, use, offer for sale, or sale of Praxair's Proposed ANDA Product within the United States will further infringe one or more claims of the '284 patent under 35 U.S.C. § 271(a).

69. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '284 patent. Plaintiffs do not have an adequate remedy at law and those acts will continue unless enjoined by this Court.

COUNT V
INFRINGEMENT OF U.S. PATENT NO. 8,431,163

70. Plaintiffs repeat and reallege paragraphs 1 through 68 above as if fully set forth herein.

71. By submitting the Praxair ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Praxair's Proposed ANDA Product throughout the United States prior to the expiration of the '163 patent, Defendants committed an act of infringement of the '163 patent under 35 U.S.C. § 271(e)(2). On information and belief, Defendants were aware of the '163 patent at the time the Praxair ANDA was submitted.

72. If Defendants commercially make, use, offer to sell, or sell Praxair's Proposed ANDA Product within the United States, or import Praxair's Proposed ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '163 patent, they would further infringe the '163 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including, for example, claims 1-25 of the '163 patent.

73. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '163 patent. Plaintiffs do not have an adequate remedy at law,

74. Praxair Distribution, Inc.'s certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '163 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

COUNT VI
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,431,163

75. Plaintiffs repeat and reallege paragraphs 1 through 73 above as if fully set forth herein.

76. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Praxair's Proposed ANDA Product with its proposed labeling immediately following approval of Defendants' ANDA.

77. On information and belief, Defendants' commercial importation, manufacture, use, sale, and/or offer for sale of Praxair's Proposed ANDA Product before the expiration of the '163 patent would infringe one or more claims of the '163 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including, for example, claims 1-25 of the '163 patent.

78. On information and belief, by seeking approval to distribute Praxair's Proposed ANDA Product with its proposed labeling, Defendants intend to cause others, specifically, for example, medical professionals, to perform acts that Defendants know will infringe one or more claims of the '163 patent.

79. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, actively induce infringement of one or more claims of the '163 patent immediately following approval of Defendants' ANDA.

80. On information and belief, Defendants know that Praxair's Proposed ANDA Product and its proposed labeling are especially made or adapted for use in infringing one or more claims of the '163 patent, and that Praxair's Proposed ANDA Product and its proposed labeling are not suitable for any substantial noninfringing use.

81. Defendants' commercial manufacture, use, offer for sale, or sale of Defendants' generic product within the United States will further infringe one or more claims of the '163 patent under 35 U.S.C. § 271(a).

82. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '163 patent. Plaintiffs do not have an adequate remedy at law and those acts will continue unless enjoined by this Court.

COUNT VII
INFRINGEMENT OF U.S. PATENT NO. 8,795,741

83. Plaintiffs repeat and reallege paragraphs 1 through 81 above as if fully set forth herein.

84. By submitting the Praxair ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Praxair's Proposed ANDA Product throughout the United States prior to the expiration of the '741 patent, Defendants committed an act of infringement of the '741 patent under 35 U.S.C. § 271(e)(2).

85. If Defendants commercially make, use, offer to sell, or sell Praxair's Proposed ANDA Product within the United States, or import Praxair's Proposed ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '741 patent, they would further infringe the '741 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including, for example, claims 1-44 of the '741 patent.

86. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '741 patent. Plaintiffs do not have an adequate remedy at law.

87. Praxair Distribution, Inc.'s certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '741 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

COUNT VIII
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,795,741

88. Plaintiffs repeat and reallege paragraphs 1 through 86 above as if fully set forth herein.

89. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Praxair's Proposed ANDA Product with its proposed labeling immediately following approval of Defendants' ANDA.

90. On information and belief, Defendants' commercial importation, manufacture, use, sale, and/or offer for sale of Praxair's Proposed ANDA Product before the expiration of the '741 patent would infringe one or more claims of the '741 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including, for example, claims 1-44 of the '741 patent.

91. On information and belief, by seeking approval to distribute Praxair's Proposed ANDA Product with its proposed labeling, Defendants intend to cause others, specifically, for example, medical professionals, to perform acts that Defendants know will infringe one or more claims of the '741 patent.

92. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, actively induce infringement of one or more claims of the '741 patent immediately following approval of Defendants' ANDA.

93. On information and belief, Defendants know that Praxair's Proposed ANDA Product and its proposed labeling are especially made or adapted for use in infringing one or more claims of the '741 patent, and that Praxair's Proposed ANDA Product and its proposed labeling are not suitable for any substantial noninfringing use.

94. Defendants' commercial manufacture, use, offer for sale, or sale of Defendants' generic product within the United States will further infringe one or more claims of the '741 patent under 35 U.S.C. § 271(a).

95. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '741 patent. Plaintiffs do not have an adequate remedy at law and those acts will continue unless enjoined by this Court.

COUNT IX
INFRINGEMENT OF U.S. PATENT NO. 8,846,112

96. Plaintiffs repeat and reallege paragraphs 1 through 94 above as if fully set forth herein.

97. By submitting the Praxair ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Praxair's Proposed ANDA Product throughout the United States prior to the expiration of the '112 patent, Defendants committed an act of infringement of the '112 patent under 35 U.S.C. § 271(e)(2).

98. If Defendants commercially make, use, offer to sell, or sell Praxair's Proposed ANDA Product within the United States, or import Praxair's Proposed ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '112 patent, they would further infringe the '112 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including, for example, claims 1-11 of the '112 patent.

99. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '112 patent. Plaintiffs do not have an adequate remedy at law.

100. Praxair Distribution, Inc.'s certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '112 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

COUNT X
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,846,112

101. Plaintiffs repeat and reallege paragraphs 1 through 99 above as if fully set forth herein.

102. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Praxair's Proposed ANDA Product with its proposed labeling immediately following approval of Defendants' ANDA.

103. On information and belief, Defendants' commercial importation, manufacture, use, sale, and/or offer for sale of Defendants' generic ANDA product before the expiration of the '112 patent would infringe one or more claims of the '112 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including, for example, claims 1-11 of the '112 patent.

104. On information and belief, by seeking approval to distribute Praxair's Proposed ANDA Product with its proposed labeling, Defendants intend to cause others, specifically, for example, medical professionals, to perform acts that Defendants know will infringe one or more claims of the '112 patent.

105. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, actively induce infringement of one or more claims of the '112 patent immediately following approval of Defendants' ANDA.

106. On information and belief, Defendants know that Praxair's Proposed ANDA Product and its proposed labeling are especially made or adapted for use in infringing one or more claims of the '112 patent and that Praxair's Proposed ANDA Product and its proposed labeling are not suitable for any substantial noninfringing use.

107. Defendants' commercial manufacture, use, offer for sale, or sale of Defendants' generic product within the United States will further infringe one or more claims of the '112 patent under 35 U.S.C. § 271(a).

108. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '112 patent. Plaintiffs do not have an adequate remedy at law and those acts will continue unless enjoined by this Court.

COUNT XI
INFRINGEMENT OF U.S. PATENT NO. 8,291,904

109. Plaintiffs repeat and reallege paragraphs 1 through 107 above as if fully set forth herein.

110. By submitting the Praxair ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Praxair's Proposed ANDA Product throughout the United States prior to the expiration of the '904 patent, Defendants committed an act of infringement of the '904 patent under 35 U.S.C. § 271(e)(2). On information and belief, Defendants were aware of the '904 patent at the time the Praxair ANDA was submitted.

111. If Defendants commercially make, use, offer to sell, or sell Praxair's Proposed ANDA Product within the United States, or import Praxair's Proposed ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '904 patent,

they would further infringe the '904 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including, for example, claims 1, 3, 5, and 7 of the '904 patent,

112. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '904 patent. Plaintiffs do not have an adequate remedy at law.

113. Praxair Distribution, Inc.'s certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '904 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

COUNT XII
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,291,904

114. Plaintiffs repeat and reallege paragraphs 1 through 112 above as if fully set forth herein.

115. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Praxair's Proposed ANDA Product with its proposed labeling immediately following approval of Defendants' ANDA.

116. On information and belief, Defendants' commercial importation, manufacture, use, sale, and/or offer for sale of Praxair's Proposed ANDA Product before the expiration of the '904 patent would infringe one or more claims of the '904 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including, for example, claims 1, 3, 5, and 7 of the '904 patent.

117. On information and belief, by seeking approval to distribute Praxair's Proposed ANDA Product with its proposed labeling, Defendants intend to cause others, specifically, for example, medical professionals, to perform acts that Defendants know will infringe one or more claims of the '904 patent.

118. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, actively induce infringement of one or more claims of the '904 patent immediately following approval of Defendants' ANDA.

119. On information and belief, Defendants know that Praxair's Proposed ANDA Product and its proposed labeling are especially made or adapted for use in infringing one or more claims of the '904 patent and that Praxair's Proposed ANDA Product and its proposed labeling are not suitable for any substantial noninfringing use.

120. Defendants' commercial manufacture, use, offer for sale, or sale of Praxair's Proposed ANDA Product within the United States will further infringe one or more claims of the '904 patent under 35 U.S.C. § 271(a).

121. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '904 patent. Plaintiffs do not have an adequate remedy at law and those acts will continue unless enjoined by this Court.

COUNT XIII
INFRINGEMENT OF U.S. PATENT NO. 8,573,210

122. Plaintiffs repeat and reallege paragraphs 1 through 120 above as if fully set forth herein.

123. By submitting the Praxair ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Praxair's Proposed ANDA Product throughout the United States prior to the expiration of the '210 patent, Defendants committed an act of infringement of the '210 patent under 35 U.S.C. § 271(e)(2). On information and belief, Defendants were aware of the '210 patent at the time the Praxair ANDA was submitted.

124. If Defendants commercially make, use, offer to sell, or sell Praxair's Proposed ANDA Product within the United States, or import Praxair's Proposed ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '210 patent, they would further infringe the '210 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including, for example, claims 1-4, 6, 8, and 12-16 of the '210 patent.

125. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '210 patent. Plaintiffs do not have an adequate remedy at law.

126. Praxair Distribution, Inc.'s certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '210 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. §285.

COUNT XIV
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,573,210

127. Plaintiffs repeat and reallege paragraphs 1 through 125 above as if fully set forth herein.

128. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Praxair's Proposed ANDA Product with its proposed labeling immediately following approval of Defendants' ANDA.

129. On information and belief, Defendants' commercial importation, manufacture, use, sale, and/or offer for sale of Praxair's Proposed ANDA Product before the expiration of the '210 patent would infringe one or more claims of the '210 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including, for example, claims 1-4, 6, 8, and 12-16.

130. On information and belief, by seeking approval to distribute Praxair's Proposed ANDA Product with its proposed labeling, Defendants intend to cause others, specifically, for

example, medical professionals, to perform acts that Defendants know will infringe one or more claims of the '210 patent.

131. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, actively induce infringement of one or more claims of the '210 patent immediately following approval of Defendants' ANDA.

132. On information and belief, Defendants know that Praxair's Proposed ANDA Product and its proposed labeling are especially made or adapted for use in infringing one or more claims of the '210 patent, and that Praxair's Proposed ANDA Product and its proposed labeling are not suitable for any substantial noninfringing use.

133. Defendants' commercial manufacture, use, offer for sale, or sale of Praxair's Proposed ANDA Product within the United States will further infringe one or more claims of the '210 patent under 35 U.S.C. § 271(a).

134. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '210 patent. Plaintiffs do not have an adequate remedy at law and those acts will continue unless enjoined by this Court.

COUNT XV
INFRINGEMENT OF U.S. PATENT NO. 8,573,209

135. Plaintiffs repeat and reallege paragraphs 1 through 133 above as if fully set forth herein.

136. By submitting the Praxair ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Praxair's Proposed ANDA Product throughout the United States prior to the expiration of the '209 patent, Defendants committed an act of infringement of the '209 patent under 35 U.S.C. § 271(e)(2), On

information and belief, Defendants were aware of the '209 patent at the time the Praxair ANDA was submitted.

137. If Defendants commercially make, use, offer to sell, or sell Praxair's Proposed ANDA Product within the United States, or import Praxair's Proposed ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '209 patent, they would further infringe the '209 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including, for example, claims 1-3, 6, and 7 of the '209 patent.

138. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '209 patent. Plaintiffs do not have an adequate remedy at law.

139. Praxair Distribution, Inc.'s certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '209 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

COUNT XVI
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,573,209

140. Plaintiffs repeat and reallege paragraphs 1 through 138 above as if fully set forth herein.

141. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Praxair's Proposed ANDA Product with its proposed labeling immediately following approval of Defendants' ANDA.

142. On information and belief, Defendants' commercial importation, manufacture, use, sale, and/or offer for sale of Defendants' generic ANDA product before the expiration of the '209 patent would infringe one or more claims of the '209 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including, for example, claims 1-3, 6, and 7 of the '209 patent.

143. On information and belief, by seeking approval to distribute Praxair's Proposed ANDA Product with its proposed labeling, Defendants intend to cause others, specifically, for example, medical professionals, to perform acts that Defendants know will infringe one or more claims of the '209 patent.

144. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, actively induce infringement of one or more claims of the '209 patent immediately following approval of Defendants' ANDA.

145. On information and belief, Defendants know that Praxair's Proposed ANDA Product and its proposed labeling are especially made or adapted for use in infringing one or more claims of the '209 patent, and that Praxair's Proposed ANDA Product and its proposed labeling are not suitable for any substantial noninfringing use.

146. Defendants' commercial manufacture, use, offer for sale, or sale of Praxair's Proposed ANDA Product within the United States will further infringe one or more claims of the '209 patent under 35 U.S.C. § 271(a).

147. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '209 patent. Plaintiffs do not have an adequate remedy at law and those acts will continue unless enjoined by this Court.

COUNT XVII
INFRINGEMENT OF U.S. PATENT NO. 8,776,794

148. Plaintiffs repeat and reallege paragraphs 1 through 146 above as if fully set forth herein.

149. By submitting the Praxair ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Praxair's Proposed

ANDA Product throughout the United States prior to the expiration of the '794 patent, Defendants committed an act of infringement of the '794 patent under 35 U.S.C. § 271(e)(2).

150. If Defendants commercially make, use, offer to sell, or sell Praxair's Proposed ANDA Product within the United States, or import Praxair's Proposed ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '794 patent, they would further infringe the '794 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including, for example, claims 1-4 and 6-20 of the '794 patent.

151. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '794 patent. Plaintiffs do not have an adequate remedy at law.

152. Praxair Distribution, Inc.'s certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '794 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

COUNT XVIII
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,776,794

153. Plaintiffs repeat and reallege paragraphs 1 through 151 above as if fully set forth herein.

154. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Praxair's Proposed ANDA Product with its proposed labeling immediately following approval of Defendants' ANDA.

155. On information and belief, Defendants' commercial importation, manufacture, use, sale, and/or offer for sale of Praxair's Proposed ANDA Product before the expiration of the '794 patent would infringe one or more claims of the '794 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including, for example, claims 1-4 and 6-20 of the '794 patent.

156. On information and belief, by seeking approval to distribute Praxair's Proposed ANDA Product with its proposed labeling, Defendants intend to cause others, specifically, for example, medical professionals, to perform acts that Defendants know will infringe one or more claims of the '794 patent.

157. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, actively induce infringement of one or more claims of the '794 patent immediately following approval of Defendants' ANDA.

158. On information and belief, Defendants know that Praxair's Proposed ANDA Product and its proposed labeling are especially made or adapted for use in infringing one or more claims of the '794 patent, and that Praxair's Proposed ANDA Product and its proposed labeling are not suitable for any substantial noninfringing use.

159. Defendants' commercial manufacture, use, offer for sale, or sale of Praxair's Proposed ANDA Product within the United States will further infringe one or more claims of the '794 patent under 35 U.S.C. § 271(a).

160. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '794 patent. Plaintiffs do not have an adequate remedy at law and those acts will continue unless enjoined by this Court.

COUNT XIX
INFRINGEMENT OF U.S. PATENT NO. 8,776,795

161. Plaintiffs repeat and reallege paragraphs 1 through 159 above as if fully set forth herein.

162. By submitting the Praxair ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Praxair's Proposed

ANDA Product throughout the United States prior to the expiration of the '795 patent, Defendants committed an act of infringement of the '795 patent under 35 U.S.C. § 271(e)(2).

163. If Defendants commercially make, use, offer to sell, or sell Praxair's Proposed ANDA Product within the United States, or import Praxair's Proposed ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '795 patent, they would further infringe the '795 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including, for example, claims 1-4 and 6-20 of the '795 patent.

164. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '795 patent. Plaintiffs do not have an adequate remedy at law.

165. Praxair Distribution, Inc.'s certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '795 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

COUNT XX
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,776,795

166. Plaintiffs repeat and reallege paragraphs 1 through 164 above as if fully set forth herein.

167. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Praxair's Proposed ANDA Product with its proposed labeling immediately following approval of Defendants' ANDA.

168. On information and belief, Defendants' commercial importation, manufacture, use, sale, and/or offer for sale of Praxair's Proposed ANDA Product before the expiration of the '795 patent would infringe one or more claims of the '795 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including, for example, claims 1-4 and 6-20 of the '795 patent.

169. On information and belief, by seeking approval to distribute Praxair's Proposed ANDA Product with its proposed labeling, Defendants intend to cause others, specifically, for example, medical professionals, to perform acts that Defendants know will infringe one or more claims of the '795 patent.

170. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, actively induce infringement of one or more claims of the '795 patent immediately following approval of Defendants' ANDA.

171. On information and belief, Defendants know that Praxair's Proposed ANDA Product and its proposed labeling are especially made or adapted for use in infringing one or more claims of the '795 patent, and that Praxair's Proposed ANDA Product and its proposed labeling are not suitable for any substantial noninfringing use.

172. Defendants' commercial manufacture, use, offer for sale, or sale of Praxair's Proposed ANDA Product within the United States will further infringe one or more claims of the '795 patent under 35 U.S.C. § 271(a).

173. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '795 patent. Plaintiffs do not have an adequate remedy at law and those acts will continue unless enjoined by this Court.

RESPONSE TO PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Defendants have infringed one or more claims of the '966 patent by filing ANDA No. 207141 relating to Praxair's Proposed ANDA Product before the expiration of the '966 patent;

B. A judgment declaring that the manufacture, use, offer for sale, sale and/or importation of Praxair's Proposed ANDA Product will infringe the '966 patent;

C. A permanent injunction restraining and enjoining Defendants, and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Praxair's Proposed ANDA Product until the expiration of the '966 patent or any later date of exclusivity to which Plaintiffs and/or the '966 patent are or become entitled to;

D. An order that the effective date of any approval of Praxair's ANDA No. 207141 relating to Praxair's Proposed ANDA Product under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of the '966 patent or any later date of exclusivity to which Plaintiffs and/or the '966 patent are or become entitled;

E. A judgment that Defendants have infringed one or more claims of the '284 patent by filing ANDA No. 207141 relating to Praxair's Proposed ANDA Product before the expiration of the '284 patent;

F. A judgment declaring that the manufacture, use, offer for sale, sale and/or importation of Praxair's Proposed ANDA Product will infringe the '284 patent;

G. A permanent injunction restraining and enjoining Defendants, and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Praxair's Proposed ANDA Product until the expiration of

the '284 patent or any later date of exclusivity to which Plaintiffs and/or the '284 patent are or become entitled to;

H. An order that the effective date of any approval of Praxair's ANDA No. 207141 relating to Praxair's Proposed ANDA Product under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of the '284 patent or any later date of exclusivity to which Plaintiffs and/or the '284 patent are or become entitled;

I. A judgment that Defendants have infringed one or more claims of the '163 patent by filing ANDA No. 207141 relating to Praxair's Proposed ANDA Product before the expiration of the '163 patent;

J. A judgment declaring that the manufacture, use, offer for sale, sale and/or importation of Praxair's Proposed ANDA Product will infringe the '163 patent;

K. A permanent injunction restraining and enjoining Defendants, and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Praxair's Proposed ANDA Product until the expiration of the '163 patent or any later date of exclusivity to which Plaintiffs and/or the '163 patent are or become entitled to;

L. An order that the effective date of any approval of Praxair's ANDA No. 207141 relating to Praxair's Proposed ANDA Product under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of the '163 patent or any later date of exclusivity to which Plaintiffs and/or the '163 patent are or become entitled;

M. A judgment that Defendants have infringed one or more claims of the '741 patent by filing ANDA No. 207141 relating to Praxair's Proposed ANDA Product before the expiration of the '741 patent;

N. A judgment declaring that the manufacture, use, offer for sale, sale and/or importation of Praxair's Proposed ANDA Product will infringe the '741 patent;

O. A permanent injunction restraining and enjoining Defendants, and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Praxair's Proposed ANDA Product until the expiration of the '741 patent or any later date of exclusivity to which Plaintiffs and/or the '741 patent are or become entitled to;

P. An order that the effective date of any approval of Praxair's ANDA No. 207141 relating to Praxair's Proposed ANDA Product under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of the '741 patent or any later date of exclusivity to which Plaintiffs and/or the '741 patent are or become entitled;

Q. A judgment that Defendants have infringed one or more claims of the ' 112 patent by filing ANDA No. 207141 relating to Praxair's Proposed ANDA Product before the expiration of the ' 112 patent;

R. A judgment declaring that the manufacture, use, offer for sale, sale and/or importation of Praxair's Proposed ANDA Product will infringe the '112 patent;

S. A permanent injunction restraining and enjoining Defendants, and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging

in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Praxair's Proposed ANDA Product until the expiration of the '112 patent or any later date of exclusivity to which Plaintiffs and/or the '112 patent are or become entitled to;

T. An order that the effective date of any approval of Praxair's ANDA No. 207141 relating to Praxair's Proposed ANDA Product under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of the '112 patent or any later date of exclusivity to which Plaintiffs and/or the '112 patent are or become entitled;

U. A judgment that Defendants have infringed one or more claims of the '904 patent by filing ANDA No. 207141 relating to Praxair's Proposed ANDA Product before the expiration of the '904 patent;

V. A judgment declaring that the manufacture, use, offer for sale, sale and/or importation of Praxair's Proposed ANDA Product will infringe the '904 patent;

W. A permanent injunction restraining and enjoining Defendants, and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Praxair's Proposed ANDA Product until the expiration of the '904 patent or any later date of exclusivity to which Plaintiffs and/or the '904 patent are or become entitled to;

X. An order that the effective date of any approval of Praxair's ANDA No. 207141 relating to Praxair's Proposed ANDA Product under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date

of the '904 patent or any later date of exclusivity to which Plaintiffs and/or the '904 patent are or become entitled;

Y. A judgment that Defendants have infringed one or more claims of the '210 patent by filing ANDA No. 207141 relating to Praxair's Proposed ANDA Product before the expiration of the '210 patent;

Z. A judgment declaring that the manufacture, use, offer for sale, sale and/or importation of Praxair's Proposed ANDA Product will infringe the '210 patent;

AA. A permanent injunction restraining and enjoining Defendants, and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Praxair's Proposed ANDA Product until the expiration of the '210 patent or any later date of exclusivity to which Plaintiffs and/or the '210 patent are or become entitled to;

BB. An order that the effective date of any approval of Praxair's ANDA No. 207141 relating to Praxair's Proposed ANDA Product under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of the '210 patent or any later date of exclusivity to which Plaintiffs and/or the '210 patent are or become entitled;

CC. A judgment that Defendants have infringed one or more claims of the '209 patent by filing ANDA No. 207141 relating to Praxair's Proposed ANDA Product before the expiration of the '209 patent;

DD. A judgment declaring that the manufacture, use, offer for sale, sale and/or importation of Praxair's Proposed ANDA Product will infringe the '209 patent;

EE. A permanent injunction restraining and enjoining Defendants, and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Praxair's Proposed ANDA Product until the expiration of the '209 patent or any later date of exclusivity to which Plaintiffs and/or the '209 patent are or become entitled to;

FF. An order that the effective date of any approval of Praxair's ANDA No. 207141 relating to Praxair's Proposed ANDA Product under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of the '209 patent or any later date of exclusivity to which Plaintiffs and/or the '209 patent are or become entitled;

GG. A judgment that Defendants have infringed one or more claims of the '794 patent by filing ANDA No. 207141 relating to Praxair's Proposed ANDA Product before the expiration of the '794 patent;

HH. A judgment declaring that the manufacture, use, offer for sale, sale and/or importation of Praxair's Proposed ANDA Product will infringe the '794 patent;

II. A permanent injunction restraining and enjoining Defendants, and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Praxair's Proposed ANDA Product until the expiration of the '794 patent or any later date of exclusivity to which Plaintiffs and/or the '794 patent are or become entitled to;

JJ. An order that the effective date of any approval of Praxair's ANDA No. 207141 relating to Praxair's Proposed ANDA Product under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of the '794 patent or any later date of exclusivity to which Plaintiffs and/or the '794 patent are or become entitled;

KK. A judgment that Defendants have infringed one or more claims of the '795 patent by filing ANDA No. 207141 relating to Praxair's Proposed ANDA Product before the expiration of the '795 patent;

LL. A judgment declaring that the manufacture, use, offer for sale, sale and/or importation of Praxair's Proposed ANDA Product will infringe the '795 patent;

MM. A permanent injunction restraining and enjoining Defendants, and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Praxair's Proposed ANDA Product until the expiration of the '795 patent or any later date of exclusivity to which Plaintiffs and/or the '795 patent are or become entitled to;

NN. An order that the effective date of any approval of Praxair's ANDA No. 207141 relating to Praxair's Proposed ANDA Product under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of the '795 patent or any later date of exclusivity to which Plaintiffs and/or the '795 patent are or become entitled;

OO. A declaration that this case is “exceptional” within the meaning of 35 U.S.C. § 285 and an award of reasonable attorney fees, costs, expenses, and disbursements of this action; and

PP. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

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January 28, 2016
9807113

CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2016, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on January 28, 2016, upon the following in the manner indicated:

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