IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT HOSPITAL PRODUCTS IP LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
PRAXAIR DISTRIBUTION, INC. and PRAXAIR, INC.	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Mallinckrodt Hospital Products IP Ltd. ("Mallinckrodt IP" or "Plaintiff") for its Complaint against defendants Praxair Distribution, Inc. and Praxair, Inc. (collectively "Praxair" or "Defendants"), hereby alleges 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 certain regulatory and intellectual property rights related to the INOmax®.

2. 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.

3. 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.

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

5. 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").

6. On or about March 2, 2016, Praxair, Inc. announced that it had acquired NOxBOX Ltd. from Bedfont Scientific Limited. According to Praxair's press release regarding that acquisition, Bedfont was "an existing Praxair supplier," and that NOxBOX Ltd.'s NOxBOXi™ delivery system "provides intelligent nitric oxide delivery with precise real-time monitoring of nitric oxide, nitrogen dioxide and oxygen through a touch screen with step-by-step guided interface to enable ease of use." Praxair stated that the acquisition of NOxBOX Ltd. and its inhaled nitric oxide device product line "is part of [Praxair's] long-term strategy to further broaden our offerings to hospitals and deliver the latest in respiratory healthcare technology to our customers around the world." http://www.praxair.com/news/2016/praxair-acquires-noxbox-ltd-a-leading-developer-of-inhaled-nitric-oxide-delivery-and-monitoring-systems (last accessed on September 28, 2016).

7. On information and belief, Praxair intends to seek approval for its Noxivent product to be administered using the NOxBOXi delivery system, as evidenced by Praxair's acquisition of NOxBOX Ltd.

II. JURISDICTION AND VENUE

8. 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. This action is related to *Mallinckrodt Hospital Prods. IP Ltd., et al. v. Praxair Distrib., Inc., et al.*, Case No. 15-170 (GMS) (D. Del.), which is currently pending.

9. 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.

10. 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.

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

III. INOmax® (NITRIC OXIDE) FOR INHALATION AND INOmax DS_{IR}® DELIVERY DEVICE

12. Mallinckrodt IP owns approved New Drug Application ("NDA") No. N020845 for nitric oxide 100 and 800 ppm for inhalation to 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.

13. The current approved labeling for INOmax®, as revised in October 2015 and supplemented in April 2016, informs physicians that INOmax must be administered "only with an INOmax DS_{IR}® operated by trained personnel." (Ex. 1, INOmax Label, Revised 10/2015.)

The approved labeling further instructs in section 2.2, entitled "Administration," that "INOmax must be administered using a calibrated INOmax DS_{IR} Nitric Oxide Delivery System. Only validated ventilator systems should be used in conjunction with INOmax." (*Id.*)

14. INOmax DS_{IR}® is a therapeutic gas delivery system that delivers Plaintiff's INOmax® inhaled nitric oxide from the supplied gas cylinders. (Ex. 2, INOmax DS_{IR}® Operation Manual at 1.) INOmax DS_{IR}® provides continuous integrated monitoring of inspired O_2, NO_2, and NO and a comprehensive alarm system. (*Id.*) INOmax DS_{IR}® uses a "dual-channel" design to ensure the safe delivery of INOmax®. (*Id.* at 14.) The first channel has a delivery CPU, a flow controller, and an injector module to ensure accurate delivery of nitric oxide, including ensuring the administration of the proper dose of nitric oxide. (*Id.*) The second channel is a monitoring system, which includes a monitor CPU, gas sensors (NO, NO_2, and O_2 sensors) and a user interface, including a display and alarms. (*Id.*) This dual-channel design allows for delivery of INOmax independent of the monitoring, and allows the monitoring system to shut down INOmax delivery if it detects any defects in the delivery system. (*Id.*) The INOmax DS_{IR}® checks to make sure that the INOmax® cylinder has the correct expiration date and cylinder concentration. (*Id.*) The user interface allows for an input of patient information into the delivery system. (*Id.* at 46.)

15. The INOmax DS_{IR}® comprises at least these elements: (1) a drug source, such as the INOmax® gas cylinder; (2) a circuit that includes memory to store drug data such as drug identification, drug expiration date, and drug concentration of the drug source and a processor and transceiver communicating with the memory; and (3) a control module that controls delivery of the gas, which includes separate memory, transceiver, and processor in communication with each other. The INOmax DS_{IR}® further communicates the drug data from the monitoring system

to the delivery system, compares the drug data with the patient information stored in the delivery system, and controls the delivery of the nitric oxide to the patient.

IV. PRAXAIR'S PROPOSED GENERIC INHALED NITRIC OXIDE PRODUCT

16. Praxair is seeking approval from the FDA to market its proposed generic inhaled nitric oxide product prior to the expiration of Mallinckrodt's patents covering the use and administration of Plaintiff's INOmax® product.

17. As part of its ANDA, Praxair must show that "the labeling proposed for the new drug is the same as the labeling approved for the listed drug," except for changes indicating that the drug is produced or distributed by different manufacturers. 21 U.S.C. § 355(j)(2)(A)(v). The FDA may only allow labeling changes such that the change in labeling does not render the generic drug less safe or effective. 21 C.F.R. § 314.93(e)(1)(iv) (stating that the FDA will disapprove a petition if "[a]ny of the proposed changes from the listed drug would jeopardize the safe or effective use of the product so as to necessitate significant labeling changes to address the newly introduced safety or effectiveness problem").

18. The administration of inhaled nitric oxide via the INOmax DS_{IR}® allows for the safe administration of the drug product. Indeed, Praxair has made public statements identifying that the patented features included in the INOmax DS_{IR}® relate to "improv[ing] system safety," "achiev[ing] safety goals," "safety features," "safety checks," and allowing for gases to be "safely delivered" in its filings and arguments before the U.S. Patent and Trademark Office. (*E.g.*, Ex. 3, Praxair IPR Petition for U.S. No. 8,573,210 at 15, 19, 21, 22, 24, 44, 48, 54, 59.)

19. For the foregoing reasons, on information and belief, Praxair will have to include in its label for its Proposed ANDA Product the language requiring that Praxair's Proposed ANDA Product be administered using the INOmax DS_{IR}® in at least the "Dosage and

Administration" section of Praxair's Proposed ANDA Label. Such labeling will infringe and/or induce infringement of Plaintiff's patents covering the INOmax DS_{IR}®.

20. The inclusion of language indicating that Praxair's Proposed ANDA Product must be administered using a calibrated INOmax DS_{IR} Nitric Oxide Delivery System would evidence specific intent to induce physicians to infringe Plaintiff's patents covering the INOmax DS_{IR}®.

21. To the extent that the label for Praxair's Proposed ANDA Product does not precisely replicate the language in the INOmax labeling reciting that the product "must be administered using a calibrated INOmax DS_{IR} Nitric Oxide Delivery System," Praxair nonetheless will infringe and/or induce infringement of Plaintiff's patents covering the INOmax DS_{IR}® because Praxair's Proposed ANDA Product must be delivered with a device that is substantially equivalent to INOmax DS_{IR}® such that it possesses the safety features thereof.

22. Praxair's Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use.

V. THE PATENT-IN-SUIT

23. United States Patent No. 9,408,993 ("the '993 patent," copy attached as Exhibit 4) is entitled "Nitric Oxide Delivery Device" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on August 9, 2016. The '993 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for INOmax® (NDA No. N020845). The '993 patent claims read on the INOmax DS_{IR}®.

24. The '993 patent, including all rights to sue for infringement thereof, is owned by Mallinckrodt IP.

25. By way of a notice letter dated January 6, 2015, Praxair notified Plaintiffs that it had 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.

26. The 2015 Praxair notice letter recites that the Praxair ANDA seeks FDA approval of Praxair's Proposed ANDA Product having the same indication as INOmax® and that the Praxair ANDA refers to and relies upon Plaintiff's NDA No. N020845 for INOmax®.

27. Pursuant to pertinent regulations, as set forth *supra*, the labeling for the Praxair ANDA Product must copy the labeling for INOmax®, which includes the instruction that INOmax® must be delivered using the INOmax DS_{IR}®.

28. As set forth *supra*, to the extent that the labeling for the Praxair ANDA Product does not include the instruction that it must be delivered using the INOmax DS_{IR}®, the Praxair ANDA Product must be delivered with a device that is substantially equivalent to INOmax DS_{IR}®, including the various safety features thereof.

29. 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.

30. 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.

31. By letter dated August 30, 2016 (the "August 30 Letter"), Praxair, Inc. notified Plaintiff that it had amended its ANDA to include 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 '993 patent. In the August 30 Letter, Praxair, Inc. informed Plaintiff that it had certified that the '993 patent is invalid, unenforceable, or will not be infringed by Praxair's Proposed ANDA Product.

32. Praxair's August 30 Letter triggered the statutory 45-day period in which Plaintiff may bring suit with regard to the '993 patent.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 9,408,993

33. Plaintiff repeats and realleges paragraphs 1 through 32 above as if fully set forth herein.

34. 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 '993 patent, Defendants committed an act of infringement of the '993 patent under 35 U.S.C. § 271(e)(2). On information and belief, Defendants were aware of the '993 patent at the time the amendment to the Praxair ANDA was submitted.

35. 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 '993 patent,

they would further infringe, for example, claims 1-11 of the '993 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

36. The INOmax DS_{IR}® is an embodiment of one or more claims of the '993 patent. The use of the INOmax DS_{IR}® to deliver nitric oxide falls within one or more claims of the '993 patent.

37. As part of its ANDA, Praxair must show that "the labeling proposed for the new drug is the same as the labeling approved for the listed drug," except for changes indicating that the drug is produced or distributed by different manufacturers. 21 U.S.C. § 355(j)(2)(A)(v). The FDA may only allow labeling changes such that the change in labeling does not render the generic drug less safe or effective. 21 C.F.R. § 314.93(e)(1)(iv) (stating that the FDA will disapprove a petition if "[a]ny of the proposed changes from the listed drug would jeopardize the safe or effective use of the product so as to necessitate significant labeling changes to address the newly introduced safety or effectiveness problem").

38. The administration of inhaled nitric oxide via the INOmax DS_{IR}® allows for the safe administration of the drug product. Indeed, Praxair has made public statements identifying that the patented features included in the INOmax DS_{IR}® relate to "improv[ing] system safety," "achiev[ing] safety goals," "safety features," "safety checks," and allowing for nitric oxide to be "safely delivered" in its filings and arguments before the U.S. Patent and Trademark Office. (*E.g.*, Ex. 3, Praxair IPR Petition for U.S. No. 8,573,210 at 15, 19, 21, 22, 24, 44, 48, 54, 59.)

39. For the foregoing reasons, on information and belief, Praxair will have to include in its label for its Proposed ANDA Product the language requiring that Praxair's Proposed ANDA Product be administered using the INOmax DS_{IR}® in at least the "Dosage and

Administration" section of Praxair's Proposed ANDA Label. Such labeling will infringe and/or induce infringement of at least claims 1 and 6 of the '993 patent.

40. The inclusion of language indicating that Praxair's Proposed ANDA Product must be administered using a calibrated INOmax DS_{IR}® Nitric Oxide Delivery System would evidence specific intent to induce physicians to infringe at least claim 6 of the '993 patent.

41. To the extent that the label for Praxair's Proposed ANDA Product does not precisely replicate the language in the INOmax labeling reciting that the product "must be administered using a calibrated INOmax DS_{IR} Nitric Oxide Delivery System," Praxair nonetheless will infringe and/or induce infringement of Plaintiff's patents covering the INOmax DS_{IR}® because Praxair's Proposed ANDA Product must be delivered with a device that is substantially equivalent to INOmax DS_{IR}® such that it possesses the safety features thereof. The use of a device that is substantially equivalent to the INOmax DS_{IR}® with regard to safety features to administer Noxivent will infringe at least claim 1 of the '993 patent and induce infringement of at least claim 6 of the '993 patent, and also will reflect a specific intent to induce said infringement.

42. 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 '993 patent and that Praxair's Proposed ANDA Product and its proposed labeling are not suitable for any substantial noninfringing use.

43. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing and inducing infringement of the '993 patent. Plaintiff does not have an adequate remedy at law.

44. Praxair Distribution, Inc.'s certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '993 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. 9,408, 993

45. Plaintiff repeats and realleges paragraphs 1 through 44 above as if fully set forth herein.

46. 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.

47. 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 '993 patent would infringe one or more claims of the '993 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), including at least claims 1-11 of the '993 patent.

48. 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 '993 patent.

49. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, actively infringe and/or induce infringement of one or more claims of the '993 patent immediately following approval of Defendants' ANDA, including, for example, claims 1-11 of the '993 patent.

50. 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 '993 patent and that Praxair's Proposed ANDA Product and its proposed labeling are not suitable for any substantial noninfringing use.

51. 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 '993 patent under 35 U.S.C. § 271(a), (b), and/or (c), including, for example, claims 1-11 of the '993 patent.

52. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing and inducing infringement of the '993 patent. Plaintiff does not have an adequate remedy at law and those acts will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. A judgment that Defendants have infringed one or more claims of the '993 patent by filing ANDA No. 207141 relating to Praxair's Proposed ANDA Product before the expiration of the '993 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 '993 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 ’993 patent or any later date of exclusivity to which Plaintiff and/or the ’993 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 ’993 patent or any later date of exclusivity to which Plaintiff and/or the ’993 patent are or become entitled;

E. 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

F. 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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