IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT PLC, MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED, MALLINCKRODT HOSPITAL PRODUCTS IP UNLIMITED COMPANY, INO THERAPEUTICS LLC, Plaintiffs, v. AIRGAS THERAPEUTICS LLC, AIRGAS USA LLC, and AIR LIQUIDE S.A. Defendants.	C.A. No. 22-1648-RGA-LDH **JURY TRIAL DEMANDED**

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Mallinckrodt plc, Mallinckrodt Pharmaceuticals Ireland Limited ("Mallinckrodt Ireland"), Mallinckrodt Hospital Products IP Unlimited Company ("Mallinckrodt Hospital") and INO Therapeutics LLC ("INO Therapeutics") (collectively, "Mallinckrodt"), by their undersigned attorneys, bring this action against Defendants Airgas Therapeutics LLC ("Airgas"), Airgas USA LLC ("Airgas USA"), and Air Liquide S.A. ("Air Liquide") (collectively, "Defendants") and hereby allege as follows:

NATURE OF THIS ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, arises both (1) from Defendants' submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 203144 ("Defendants' ANDA") seeking approval to market a generic version of Mallinckrodt's highly successful INOmax® therapy, currently marketed by Defendants as Ulspira

and administered to patients by Defendants' nitric oxide delivery device, Ulspira TS, before the expiration of Mallinckrodt's U.S. Patent Nos. 8,795,741 ("'the '741 patent"), 8,776,794 ("the '6,794 patent"), 8,776,795 ("the '795 patent"), 9,279,794 ("the '9,794 patent") ("Orange Book Patents"), which Mallinckrodt lists in the FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, and (2) from Defendants' infringement of the Orange Book Patents and U.S. Patent Nos. 10,773,046 ("the '046 patent") and 9,919,118 ("the '118 patent") (collectively, the "Patents-in-Suit") through the manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and/or Ulspira TS following FDA approval of Defendants' ANDA.

THE PARTIES

2. Plaintiff Mallinckrodt plc is a company organized and existing under the laws of Ireland, having a registered address of College Business & Technology Park, Cruiserath Road, Blanchardstown, Dublin 15, D15 TX2V, Ireland.

3. Plaintiff Mallinckrodt Ireland is a company organized and existing under the laws of Ireland, having a registered address of College Business & Technology Park, Cruiserath Road, Blanchardstown, Dublin 15, D15 TX2V, Ireland. Mallinckrodt Ireland is a wholly-owned, indirect subsidiary of Mallinckrodt plc. Mallinckrodt Ireland is the assignee of the Patents-in-Suit.

4. Plaintiff Mallinckrodt Hospital is a company organized and existing under the laws of Ireland, having a registered address of College Business & Technology Park, Cruiserath Road, Blanchardstown, Dublin 15, D15 TX2V, Ireland. Mallinckrodt Hospital is a wholly-owned, indirect subsidiary of Mallinckrodt plc. As set forth herein, FDA records show that Mallinckrodt Hospital is the holder of New Drug Application ("NDA") No. 020845 for INOmax®, 800 ppm ("the NDA Product").

5. Plaintiff INO Therapeutics is a company organized and existing under the laws of Delaware, with a principle place of business at 675 McDonnell Blvd., St. Louis, MO 63042. INO Therapeutics is a wholly owned indirect subsidiary of Mallinckrodt plc. INO Therapeutics commercializes the NDA Product.

6. On information and belief, Defendant Airgas is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 6141 Easton Rd. Building 3, Plumsteadville, PA 18949.

7. On information and belief, Airgas is in the business of manufacturing and supplying specialty medical gases, including nitric oxide, and systems and equipment for the same, for sale and/or use throughout the United States, including in this Judicial District.

8. On information and belief, and as supported by Airgas's website, Airgas holds itself out as an Air Liquide company.

9. On information and belief, Defendant Airgas USA is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 259 N. Radnor Chester Road, Suite 100, Radnor, PA 19087. Upon information and belief, Airgas is a wholly-owned subsidiary of Airgas USA.

10. On information and belief, Airgas USA is leading single-source supplier and distributor of medical and other specialty gases.

11. On information and belief, and as supported by Airgas USA's website, Airgas USA holds itself out as an Air Liquide company.

12. On information and belief, Defendant Air Liquide is a corporation organized and exiting under the laws of France, with a principal place of business at 75 Quai D Orsay, Paris Cedex 07, Paris, 75321. Upon information and belief, Airgas and Airgas USA are wholly-owned

subsidiaries of Air Liquide.

13. On information and belief, Air Liquide is in the business of producing and preserving pharmaceutical products, as well as pharmaceutical formulation, packaging and distribution.

14. On information and belief, Defendants are agents of one another and/or operate in concert as integrated parts of the same business group.

15. On information and belief, Airgas, itself and/or through Airgas USA and/or Air Liquide, is in the business of developing, manufacturing, marketing, and/or selling medical gases and/or equipment for the same throughout the United States, including in this Judicial District.

16. On information and belief, Airgas USA, itself and/or through Airgas and/or Air Liquide, is in the business of developing, manufacturing, marketing, and/or selling medical gases and/or equipment for the same throughout the United States, including in this Judicial District.

17. On information and belief, Air Liquide, itself and/or through Airgas and/or Airgas USA, is in the business of developing, manufacturing, marketing, and/or selling medical gases and/or equipment for the same throughout the United States, including in this Judicial District.

18. On information and belief, and as described in Defendants' written notification of Defendants' ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certifications received November 18, 2022 ("Defendants' Paragraph IV Notice Letter"), Defendants caused Defendants' ANDA to be submitted to FDA and seek FDA approval of Defendants' ANDA prior to the expiration of the Orange Book Patents.

19. On information and belief, Defendants are, or intend to, commercially manufacture, use, offer for sale, sell, and/or import into the United States Ulspira and/or Ulspira TS, including in the State of Delaware.

JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 1291, 1400, and 2201(a).

21. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, upon information and belief, Defendants having availed themselves of the rights and benefits of the laws of the State of Delaware by engaging in substantial, continuous, and systematic contacts with the State of Delaware and because Defendants are, or intend to indirectly or directly make, use, offer for sale, sell, and/or import specialty medical gases and/or systems for the use thereof, including Ulspira and Ulspira TS, to residents of the State of Delaware. Accordingly, Defendants should reasonably anticipate being hauled into court in this Judicial District.

22. On information and belief, Airgas, Airgas USA, and/or Air Liquide, acting in concert and/or as agents of one another, prepared and/or submitted and/or approved of Defendants' ANDA.

23. On information and belief, the acts of Airgas, including the research and development, commercialization, and sale and marketing of Ulspira and Ulspira TS, as well as the preparation and submission of Defendants' ANDA, complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation or assistance of, or at least in part for the benefits of Airgas USA and Air Liquide.

24. On information and belief, Airgas, Airgas USA, and/or Air Liquide, acting in concert and/or as agents of one another, have or will market, distribute, and/or sell Ulspira and/or Ulspira TS in the United States, including in the State of Delaware, and will derive substantial revenue from the sale of Ulspira and/or Ulspira TS.

25. On information and belief, Ulspira and/or Ulspira TS is or will be used within and throughout the United States, including the State of Delaware.

26. On information and belief, Ulspira and/or Ulspira TS is or will be prescribed by physicians and/or health care providers and/or will be used by patients in the State of Delaware.

27. This Court also has personal jurisdiction over Defendants by virtue of, *inter alia*, the fact that they have committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271 that has led to and/or will lead to foreseeable harm and injury to Mallinckrodt.

28. This Court has personal jurisdiction over Airgas and Airgas USA by virtue of the fact that Airgas and Airgas USA are at home in Delaware as reflected by the fact that they are incorporated in Delaware, regularly do and/or solicit business in Delaware, engage in other persistent courses of conduct in Delaware, and/or derive substantial revenue from services or things used or consumed in Delaware, including by distributing its specialty medical gases, equipment, and/or systems in Delaware and, therefore, can reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, upon information and belief, Airgas and Airgas USA conduct marketing and sales activities in the State of Delaware, including, but not limited to, distribution, marketing, and/or sales of specialty medical gases, equipment, and/or systems to Delaware residents that are continuous and systemic. Additionally, upon information and belief, Airgas and Airgas USA intend to distribute, market, and/or sell Ulspira and/or Ulspira TS in the State of Delaware.

29. This Court has personal jurisdiction over Air Liquide pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Air Liquide is a foreign defendant who appears not to be subject to personal jurisdiction in the courts of any state; and (c) Air Liquide has sufficient contacts with the United States as a whole, including, but not limited to, submitting various ANDAs to the FDA, and manufacturing, selling, and/or distributing medical

gases and/or equipment throughout the United States, such that this Court's exercise of jurisdiction over Air Liquide satisfies due process.

30. Venue is proper in this Court for Airgas and Airgas USA pursuant to 28 U.S.C. § 1400(b) because, upon information and belief, *inter alia*, Airgas and Airgas USA are limited liability companies organized under the laws of the State of Delaware and, therefore, reside in this Judicial District.

31. Venue is proper in this Judicial District for Air Liquide pursuant to 28 U.S.C. §§ 1391 and/or 1400 because, upon information and belief, *inter alia*, Air Liquide is a company organized and existing under the laws of France, and may be sued in any judicial district pursuant to 28 U.S.C. § 1391(c) and Ulspira and/or Ulspira TS is or will be prescribed by physicians and/or health care providers and/or will be used by patients in the State of Delaware. Each of these activities would have a substantial effect within the State of Delaware and constitutes an act of infringement.

32. Venue is further proper against Defendants as they are the alter egos and/or agents of each other (which are all individually also subject to venue in this Judicial District) in connection with the submission of Defendants' ANDA.

INOMAX® AND BACKGROUND OF THE INVENTIONS

33. FDA records show that Mallinckrodt Hospital holds approved NDA No. 020845 for its Nitric Oxide Gas for Inhalation, 800 ppm product. FDA approved NDA No. 020845 in December 1999 for administration by inhalation to neonates and children suffering from hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension. Mallinckrodt's nitric oxide 800 ppm for inhalation product is sold in the United States under the trademark INOmax®. FDA records also show Mallinckrodt obtained approval for

a specialized, highly sophisticated delivery system called INOmax® DS, INOmax® DSIR, and INOmax® DSIR Plus, which were approved by FDA starting in December 2006. Since their approval by FDA, INOmax®, INOmax® DS, INOmax® DSIR, and INOmax® DSIR Plus have becomes highly successful, life-sustaining therapies.

34. Mallinckrodt has obtained a number of patents directed to inventions related to the administration and delivery of nitric oxide, associated systems, devices, and processes, and methods of treatment, for INOmax®.

35. Certain of the Patents-in-Suit are broadly directed to systems and devices for the administration of nitric oxide, and associated methods and processes. The remainder of the Patents-in-Suit are broadly directed to methods of treating patients with nitric oxide while reducing the risks of adverse events or serious adverse events ("SAEs") associated with nitric oxide treatment. The method of treatment patents disclose a solution to the previously unknown problem that neonates and children suffering from hypoxic respiratory failure who also suffer from pre-existing left ventricular dysfunction ("LVD") have a high risk of experiencing SAEs such as pulmonary edema if they are administered nitric oxide. These patents recite methods of reducing the risks of SAEs associated with administering nitric oxide by determining whether the patients have pre-existing LVD, and adjusting the administration of nitric oxide based on the patient's LVD status.

36. The invention of the Patents-in-Suit are embodied in at least Mallinckrodt's INOmax® drug product, and one or more of the associated delivery systems, and their methods and conditions of use. The FDA approved labeling for INOmax® reflects the inventions of the Patents-in-Suit, and is covered by the claims of the Patents-in-Suit, in that it informs the prescribers, health care providers, and/or patients that "[i]n patients with pre-existing [LVD],

[INOmax®] may increase pulmonary capillary wedge pressure leading to pulmonary edema." INOmax® Label at 1, attached as Exhibit 1. Consequently, prescribers, health care providers, and/or patients of INOmax® are instructed to identify patients with LVD, and to affirmatively and actively adjust the dosing of INOmax® based on whether patients have LVD and the resulting risk of pulmonary edema. *See id*. at 1; *see also id.* at 3.

37. Certain of the Patents-in-Suit, inter alia the '741 patent, '6,794 patent, '795 patent, and '9,794 patent, were previously asserted against an unrelated generic inhaled nitric oxide product in *Mallinckrodt Hospital Products IP LTD. v. Praxair Distribution, Inc.*, C.A. No. 1:15-cv-00170-RGA (D. Del.) ("*Praxair* litigation"). Defendants' Ulspira and Ulspira TS were not at issue in the *Praxair* litigation. There, the District Court of Delaware entered a judgment that only claims 1, 4, 7, 9, and 18 of the '741 patent were invalid under 35 U.S.C. § 101. *Id.* at D.I. 322.

38. At least claims 24-30, and 33 of the '741 patent are not invalid in light of the prior judgment in the *Praxair* litigation because they were not subject to the judgment in the *Praxair* litigation and they include an affirmative treatment step, including adjusting the administration of nitric oxide based on the patient's LVD status.

THE PATENTS-IN-SUIT

39. On August 5, 2014, the PTO duly and legally issued the '741 patent, titled "Methods for treating patients who are candidates for inhaled nitric oxide treatment." At least claims 2, 3, 5, 6, 8, 10-16, and 19-44 of the '741 patent are valid and enforceable. A true and correct copy of the '741 patent is attached as Exhibit 2.

40. The '741 patent is assigned to Mallinckrodt Ireland.

41. The '741 patent is listed in FDA's Orange Book for INOmax®.

42. Claim 24 of the '741 patent recites:

> A method of treating patients who are candidates for inhaled nitric oxide treatment, which method reduces the risk of inducing an increase in PCWP leading to pulmonary edema in neonatal patients with hypoxic respiratory failure, the method comprising:
>
> identifying a plurality of term or near-term neonatal patients who have hypoxic respiratory failure and are candidates for 20 ppm inhaled nitric oxide treatment;
>
> determining that a first patient of the plurality does not have pre-existing left ventricular dysfunction;
>
> administering a first treatment regimen to the first patient, wherein the first treatment regimen comprises administration of 20 ppm inhaled nitric oxide for 14 days or until the first patient's hypoxia has resolved;
>
> determining that a second patient of the plurality has pre-existing left ventricular dysfunction, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide; and
>
> administering a second treatment regimen to the second patient, wherein the second treatment regimen does not comprise either (i) administration of inhaled nitric oxide for 14 days or (ii) administration of inhaled nitric oxide until the second patient's hypoxia has resolved.

(Exhibit 2).

43. At least claim 24 of the ’741 patent, and the claims that depend therefrom, are materially different from the claims in the *Praxair* litigation because claim 24 recites an affirmative step of treating the patient that suffers from pre-existing left ventricular dysfunction, including adjusting the dose of inhaled nitric oxide treatment in the patient.

44. On July 15 2014, the PTO duly and legally issued the ’6,794 patent, titled “Nitric oxide delivery device.” Each and every claim of the ’6,794 patent is valid and enforceable. A true and correct copy of the ’6,794 patent is attached as Exhibit 3.

45. The ’6,794 patent is assigned to Mallinckrodt Ireland.

46. The ’6,794 patent is listed in FDA’s Orange Book for INOmax®.

47. Claim 1 of the '6,794 patent recites:

> A gas delivery device comprising:
>
> a gas source to provide therapy gas comprising nitric oxide;
>
> a valve attachable to the gas source, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas through the valve to a control module that delivers the therapy gas comprising nitric oxide in an amount effective to treat or prevent hypoxic respiratory failure; and
>
> a circuit including:
>
> a memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration; and
>
> a processor and a transceiver in communication with the memory to send and receive signals to communicate the gas data to the control module that controls gas delivery to a subject and to verify one or more of the gas identification, the gas concentration and that the gas is not expired.

(Exhibit 3).

48. On July 15, 2014, the PTO duly and legally issued the '795 patent, titled "Gas delivery device and system." Each and every claim of the '795 patent is valid and enforceable. A true and correct copy of the '795 patent is attached as Exhibit 4.

49. The '795 patent is assigned to Mallinckrodt Ireland.

50. The '795 patent is listed in FDA's Orange Book for INOmax®.

51. Claim 1 of the '795 patent recites:

> A gas delivery device to administer therapy gas from a gas source, the gas delivery device comprising:
>
> a valve attachable to the gas source, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas through the valve; and

> a circuit including:
>
> a memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration; and
>
> a processor and a transceiver in communication with the memory to send and receive signals to communicate the gas data to a control module that controls gas delivery to a subject and to verify one or more of the gas identification, the gas concentration and that the gas is not expired.

(Exhibit 4).

52. On March 8, 2016, the PTO duly and legally issued the '9,794 patent, titled "Systems and methods for compensating long term sensitivity drift of electrochemical gas sensors exposed to nitric oxide." Each and every claim of the '9,794 patent is valid and enforceable. A true and correct copy of the '9,794 patent is attached as Exhibit 5.

53. The '9,794 patent is assigned to Mallinckrodt Ireland.

54. The '9,794 patent is listed in FDA's Orange Book for INOmax®.

55. Claim 1 of the '9,794 patent recites:

> A method for compensating for output drift of an electrochemical gas sensor exposed to nitric oxide in a controlled environment comprising:
>
> establishing, via a setting in a system controller, a dosage of a nitric oxide to be delivered to a patient;
>
> delivering, via a flow control valve, a therapeutic gas comprising nitric oxide to a breathing circuit for delivery to the patient;
>
> identifying a change in the setting the system controller;
>
> identifying, via the system controller, a sensor recalibration schedule stored in a system controller memory in response to the identified change;
>
> identifying, via the system controller, a time for executing a

> calibration from the sensor recalibration schedule stored in the system controller memory;
>
> detecting, via the system controller, if an alarm is active or has been active within a predetermined timeframe at the time the calibration is to be executed, wherein the calibration is postponed if the active alarm is detected or has been detected within the predetermined timeframe, and the calibration is executed if the active alarm is not detected or has not been detected within the predetermined timeframe;
>
> implementing, via the system controller, the sensor recalibration schedule identified;
>
> continuously measuring, via a first nitric oxide sensor, a concentration of the nitric oxide in the breathing circuit;
>
> communicating a signal representative of the nitric oxide concentration from the first nitric oxide sensor to the system controller over a communication path; and
>
> determining a response by the first nitric oxide sensor to the nitric oxide concentration after the change in the setting in the system controller.

(Exhibit 5).

56. On September 15, 2020, the PTO duly and legally issued the ’046 patent, titled “Apparatus and method for monitoring nitric oxide delivery.” Each and every claim of the ’046 patent is valid and enforceable. A true and correct copy of the ’046 patent is attached as Exhibit 6.

57. The ’046 patent is assigned to Mallinckrodt Hospital Products IP Unlimited.

58. Claim 1 of the ’046 patent recites:

> An apparatus to deliver therapeutic gas to a patient, the apparatus comprising:
>
> a therapeutic gas supply comprising nitric oxide;
>
> a therapeutic gas injector module comprising a first inlet in fluid communication with the therapeutic gas supply, a second inlet in fluid communication with a breathing gas delivery system that provides a breathing gas, and an outlet in fluid communication with the first inlet and the second inlet to supply a mixture of the breathing gas and the therapeutic gas to the patient, the therapeutic

> gas injector module in communication with the therapeutic gas supply to control the flow of therapeutic gas to the patient and achieve a desired dose of therapeutic gas administered to the patient;
>
> a flow sensor operable to measure the flow of the breathing gas;
>
> a display in communication with the therapeutic gas injector module; and
>
> a control circuit in communication with the therapeutic gas injector module and the display, the control circuit operable to calculate a delivery concentration of the therapeutic gas and operable to send data to the display to produce an indicator to inform the user of the apparatus when the calculated delivery concentration is in one of a target delivery region, an under-delivery of nitric oxide region, and an over-delivery of nitric oxide region.

(Exhibit 6).

59. On March 20, 2018, the PTO duly and legally issued the '118 patent, titled "Systems and methods for compensating long term sensitivity drift of electrochemical gas sensors exposed to nitric oxide." Each and every claim of the '118 patent is valid and enforceable. A true and correct copy of the '118 patent is attached as Exhibit 7.

60. The '118 patent is assigned to Mallinckrodt Hospital Products UP Unlimited.

61. Claim 1 of the '118 patent recites:

> A method for delivering notifications of a calibration status for a sensor associated with a therapeutic gas delivery device, the method comprising:
>
> storing in memory a baseline calibration value, slope, and calibration schedule;
>
> monitoring a patient intake of therapeutic gas with a sensor;
>
> delivering, via a therapeutic gas delivery device, a predetermined dosage of therapeutic gas to the patient;
>
> measuring a concentration of therapeutic gas from the delivered predetermined dosage;

> retrieving, from memory, the baseline calibration value, slope and calibration schedule;
>
> performing a calibration according to the calibration schedule, wherein the calibration includes exposing the sensor to a zero concentration of the therapeutic gas and adjusting the baseline calibration value according to a sensor output value during the calibration;
>
> notifying a user, during the performance of the calibration, that the calibration is currently in effect, wherein the notifying includes displaying a notification that the measuring of therapeutic gas concentration is off-line; and
>
> upon completion of the calibration, determining an actual concentration of therapeutic gas delivered in the predetermined dosage to compensate for sensor drift by adjusting the value of the measured concentration based on the adjusted baseline value and the slope.

(Exhibit 7).

DEFENDANTS' ACTS OF INFRINGEMENT

62. Defendants submitted Defendants' ANDA to FDA in order to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira, as a purported generic version of INOmax® prior to the expiration of the patents listed on the Orange Book.

63. On information and belief, Ulspira must be administered to patients through an FDA-cleared nitric oxide delivery system.

64. Defendants submitted 510(k) No. K212409 to FDA in order to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants nitric oxide delivery system Ulspira TS, which is purported to be equivalent of INOmax DSIR®.

65. Defendants submitted and continue to maintain Defendants' ANDA to FDA under 21 U.S.C. § 355(j).

66. Defendants' Paragraph IV Notice Letter states that "[Defendants seek] to obtain approval to engage in the commercial manufacture, use or sale of [Ulspira], 800 ppm, before the expiration of [Orange Book Patents], all of which are listed in the Patent and Exclusivity Information Addendum of FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as 'the Orange Book') … FDA is aware that Airgas Therapeutics is only seeking approval for the 800 ppm strength."

67. By filing Defendants' ANDA, Defendants certified to FDA that Defendants' Proposed ANDA Product has the same active pharmaceutical ingredient as INOmax®.

68. By filing Defendants' ANDA, Defendants certified to FDA that Defendants' Proposed ANDA Product has the same dosage form and strength as INOmax®.

69. By filing Defendants' ANDA, Defendants certified to FDA that Defendants' Proposed ANDA Product is bioequivalent to INOmax®.

70. Defendants sought and received approval to market Ulspira for the same approved indication as INOmax®.

71. Defendants' ANDA contains either the same or substantially similar proposed product labeling as INOmax®.

72. Defendants have infringed, are infringing, and will infringe at least one of the Patents-in-Suit.

73. Defendants' Paragraph IV Notice Letter represents that Defendants' ANDA contains a certification under 21 U.S.C. § 355(j)(2)(B)(iv)(II) (the "Paragraph IV certification") alleging that the claims of the Orange Book Patents are invalid or would not be infringed by the commercial manufacture, use, offer for sale, sale, or importation of Ulspira and/or Ulspira TS.

74. Defendants' submission of Defendants' ANDA to FDA, including their Paragraph

IV certification, constitutes an act of infringement under 35 U.S.C. § 271(e)(2)(A). Upon FDA approval, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and/or Ulspira TS would constitute infringement under 35 U.S.C. § 271(a), and Defendants would induce and/or contribute to such conduct and therefore be liable for infringement under 35 U.S.C. § 271(b) and/or (c).

75. Defendants' filing of its ANDA infringes at least the Orange Book Patents.

76. On information and belief, FDA approved Defendants' ANDA on July 27, 2023.

77. On information and belief, following FDA's approval of Defendants' ANDA on July 27, 2023, Defendants began commercially manufacturing, using, offering for sale, selling, and/or importing Ulspira and Ulspira TS in the United States.

78. On information and belief, the manufacture, use, offer for sale, sale, and/or importation of Ulspira and/or Ulspira TS infringe the Asserted Patents.

79. The FDA-approved labeling for Ulspira ("the Ulspira Label") has or will induce or contribute to the infringement of at least one claim of the Patents-in-Suit.

80. The Ulspira Label instructs medical practitioners to perform the steps of (a) determining which patients have LVD and are at an increased risk of increased pulmonary capillary wedge pressure ("PCWP") leading to pulmonary edema; (b) for patients without LVD, administering the recommended 20 ppm dose for 14 days or until hypoxia is resolved; and (c) for patients with LVD who exhibit a risk of increased PCWP leading to adverse events like pulmonary edema, administering a different, safer iNO treatment regimen, including a treatment where the iNO dose is downtitrated in view of increased PCWP leading to adverse events.

81. The Ulspira Label instructs medical practitioners that Ulspira is to be used in neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence

of pulmonary hypertension.

82. The Ulspira Label instructs medical practitioners that the recommended dose is 20 ppm, maintained for up to 14 days or until the underlying oxygen desaturation is resolved.

83. The Ulspira Label instructs medical practitioners that patients with left ventricular dysfunction treated with Ulspira may experience pulmonary edema, increased pulmonary capillary wedge pressure.

84. The Ulspira Label instructs medical practitioners to discontinue Ulspira while providing symptomatic care.

85. The Ulspira Label instructs medical practitioners to avoid abrupt discontinuation of Ulspira.

86. The Ulspira Label instructs medical practitioners to wean Ulspira, and downtitrate in several steps.

87. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS contains each and every limitation of at least one claim of the Patents-in-Suit.

88. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS is connected to Airgas' iNO gas cylinders *via* a valve, allowing the gas to flow through to a control module that delivers a desired dose of the gas to the patient.

89. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS contains a therapeutic gas injector module in communication with the iNO gas cylinders and with a breathing gas delivery system that functions to deliver a desired dose of the gas to the patient.

90. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS contains a flow sensor operable to measure the flow of the breathing gas.

91. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS contains a circuit to store, calculate, and communicate the gas concentration data to the control module and to verify the gas concentration data, to enable the device to titrate the proper therapeutic concentration of NO gas for the patient.

92. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS also contains a circuit operable to calculate a delivery concentration of the therapeutic gas and to send data to a display

93. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS contains a display to receive data and produce an indicator to inform the user of the apparatus when the calculated delivery concentration is in one of a target delivery region, an under-delivery of nitric oxide region, and an over-delivery of nitric oxide region. *See,* D.I. 96, Exhibit Q at Exhibit 4.

94. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, one of the main functionalities of Ulspira TS is the administration and monitoring of nitric oxide gas concentrations into a respiratory device circuit.

95. On information and belief, and as shown by documents produced in this case and

by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS establishes a dose of nitric oxide gas using a setting in a system controller.

96. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS delivers nitric oxide gas to a breathing circuit for delivery through a flow control valve.

97. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS identifies a change in the setting the system controller.

98. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS identifies a sensor recalibration schedule stored in a system controller memory in response to an identified change, using a system controller.

99. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS identifies a time for executing a calibration from the sensor recalibration schedule, using a system controller.

100. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS detects whether an alarm is active or has been active within a predetermined timeframe and postpones calibration is the alarm is active or has been within a predetermined timeframe, or executes calibration is not, using a system controller.

101. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS

implements a sensor recalibration schedule identified using a system controller.

102. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS continuously measures a concentration of nitric oxide in the breathing circuit using a nitric oxide sensor.

103. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS communicate a signal representative of the nitric oxide concentration for the nitric oxide sensor to a system controller over a communication path.

104. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS determines a response by the nitric oxide sensor to the nitric oxide concentration after the change in the setting in the system controller.

105. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS delivers a notification of a calibration status for a sensor associated with the Ulspira TS.

106. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS stores in a memory a baseline calibration value, slope, and calibration schedule.

107. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS monitors a patient intake of therapeutic gas with a sensor.

108. On information and belief, and as shown by documents produced in this case and

by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS delivers via a therapeutic gas delivery device, a predetermined dosage of therapeutic gas to the patient.

109. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS measures a concentration of therapeutic gas from the delivered predetermined dosage.

110. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS retrieves from memory, the baseline calibration value, slope and calibration schedule.

111. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS performs a calibration according to the calibration schedule, wherein the calibration includes exposing the sensor to a zero concentration of the therapeutic gas and adjusting the baseline calibration value according to a sensor output value during the calibration.

112. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS notifies a user, during the performance of the calibration, that the calibration is currently in effect, wherein the notifying includes displaying a notification that the measuring of therapeutic gas concentration is off-line.

113. On information and belief, and as shown by documents produced in this case and by the Ulspira TS device and/or source code inspection performed by Plaintiffs, Ulspira TS determined, upon completion of the calibration, an actual concentration of therapeutic gas delivered in the predetermined dosage to compensate for sensor drift by adjusting the value of the

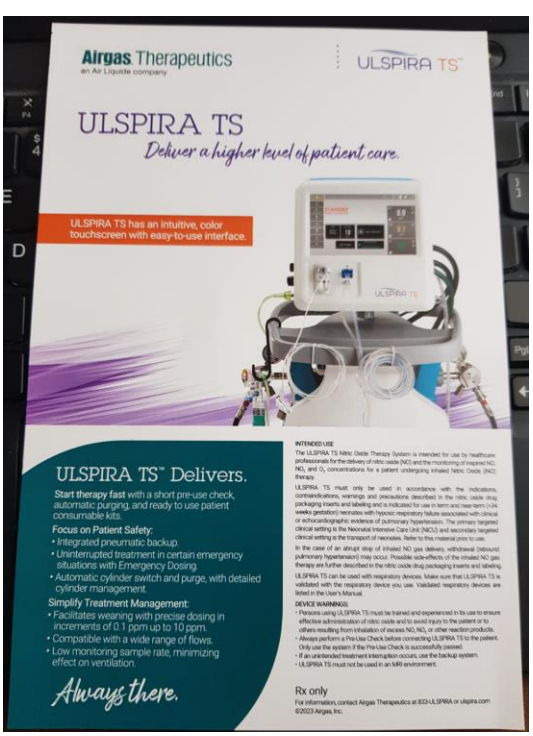
measured concentration based on the adjusted baseline value and the slope.

114. On information and belief, and as shown by documents produced in this case, Defendants have assembled technical, sales, marketing, and support teams in order to enter the commercial inhaled nitric oxide market with Ulspira and Ulspira TS. Upon information and belief, and as shown by documents produced in this case, the buildout of Defendants' inhaled nitric oxide team includes hiring former Mallinckrodt employees, for example Patricia-Ann Therriault, to commercialize Ulspira and Ulspira TS.

115. During the American Association for Respiratory Care Congress 2023 ("AARC Congress"), which was held in Nashville, Tennessee from November 5, 2023 to November 8, 2023, Defendants had a booth to display Ulspira and Ulspira TS. Publicly available pictures of Defendants' display booth for Ulspira and Ulspira TS are shown below:

116. On information and belief, at the AARC Congress, Defendants displayed Ulspira and Ulspira TS.

117. During the AARC Congress, Defendants distributed and/or displayed marketing materials concerning Ulspira and Ulspira TS to prospective purchasers. A copy of a marketing brochure distributed by Defendants at the AARC Congress is attached as Exhibit 8 and reproduced below:



(Exhibit 8).

118. On information and belief, Defendants solicited offers to sell Ulspira and/or Ulspira TS at the AARC Congress.

119. On information and belief, the manufacture of Ulspira and/or Ulspira TS on display at the AARC Congress was not reasonably related to FDA approval.

120. On information and belief, and as shown by documents produced in this case, Ulspira and/or Ulspira TS are assembled inside of the United States and/or are imported into the United States with the intent to sell to the public.

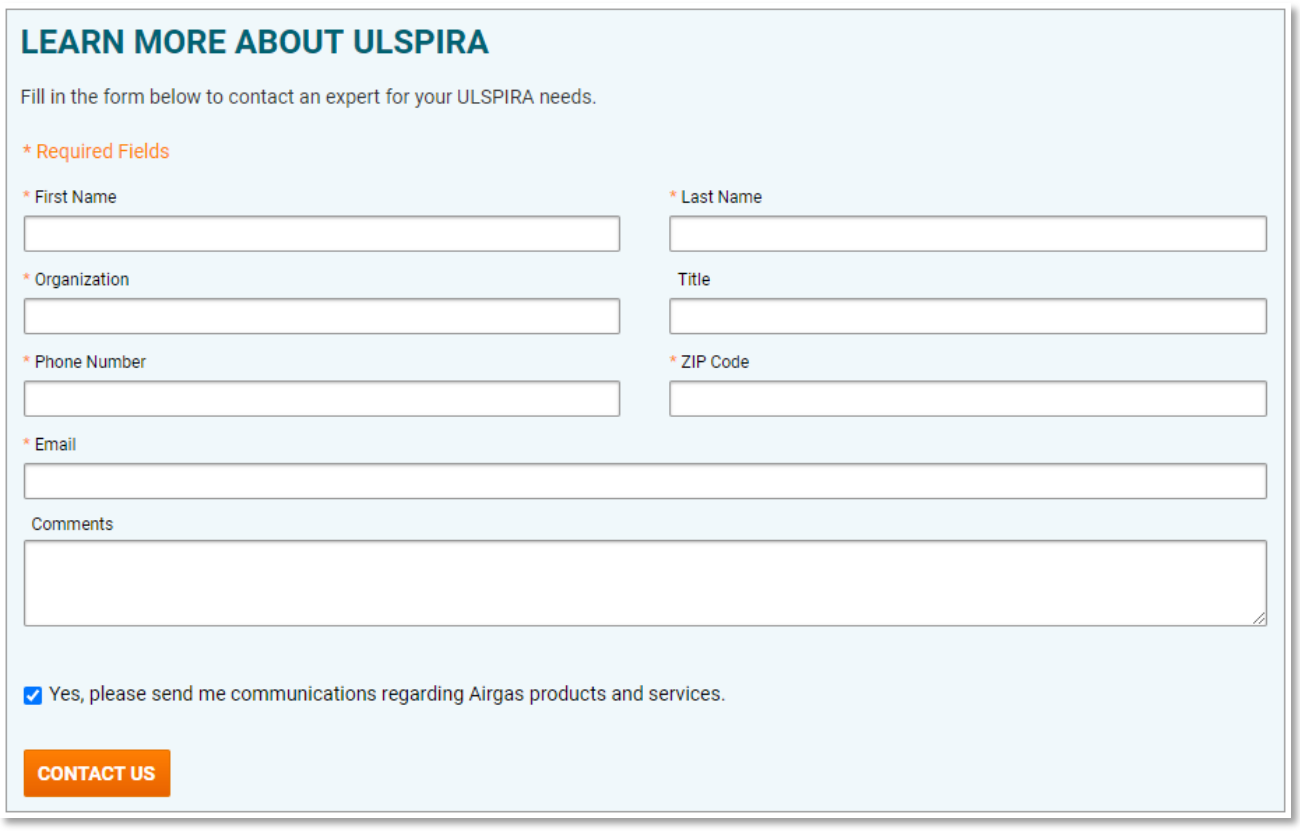
121. On information and belief, Ulspira and Ulspira TS on display at the AARC Congress were assembled and/or imported into the United States with the intent to sell to the public.

122. On information and belief, the manufacture and importation of Ulspira and Ulspira TS on display at the AARC Congress were not reasonably related to FDA approval.

123. On information and belief, and as shown by documents produced in this case, Defendants have manufactured and/or imported into the United States additional quantities of Ulspira and/or Ulspira TS to support Defendants' commercial operations.

124. On information and belief, the manufacture and/or importation of these additional commercial quantities of Ulspira and/or Ulspira TS were not reasonably related to FDA approval.

125. As of November 16, 2023, Defendants caused to be available to the public the url www.airgas.com/ulspira ("the Ulspira website"), which contains information about Ulspira and Ulspira TS, and invites the public to submit their contact information to learn more about Ulspira and/or Ulspira TS, as shown in the screenshot below:



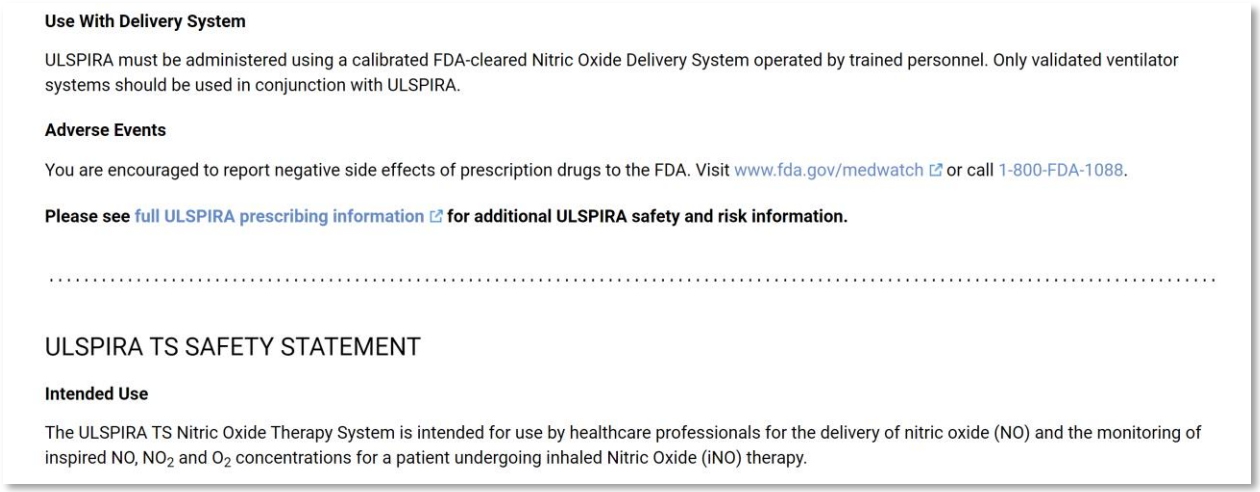
126. On information and belief, prospective purchasers can solicit information about Ulspira and/or Ulspira TS through the Ulspira website, as well as initiate the purchase, lease, acquisition, and/or installation of Ulspira and/or Ulspira TS. Upon information and belief, the

Ulspira website is in furtherance of Defendants' commercial activities, including the commercial manufacture, use, offer for sale, sale, and/or importation of Ulspira and/or Ulspira TS.

127. The Ulspira website provides the following guidance and instruction to current and/or prospective purchasers of Ulspira and/or Ulspira TS:

- "ULSPIRA (nitric oxide) gas, for inhalation, is a vasodilator indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents."
- "Heart Failure: In patients with pre-existing left ventricular dysfunction, ULSPIRA may increase pulmonary capillary wedge pressure, leading to pulmonary edema."
- "ULSPIRA TS must only be used in accordance with the indications, contraindications, warnings and precautions described in the nitric oxide drug packaging inserts and labeling, and is indicated for use in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension. The primary targeted clinical setting is the Neonatal Intensive Care Unit (NICU) and secondary targeted clinical setting is the transport of neonates. Refer to this material prior to use."
- "In the case of an abrupt stop of inhaled NO gas delivery, withdrawal (rebound pulmonary hypertension) may occur. Possible side-effects of the inhaled NO gas therapy are further described in the nitric oxide drug packaging inserts and labeling."

128. The Ulspira TS website links to the prescribing information for Ulspira, as shown in the screenshot below:



Use With Delivery System

ULSPIRA must be administered using a calibrated FDA-cleared Nitric Oxide Delivery System operated by trained personnel. Only validated ventilator systems should be used in conjunction with ULSPIRA.

Adverse Events

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full ULSPIRA prescribing information for additional ULSPIRA safety and risk information.

ULSPIRA TS SAFETY STATEMENT

Intended Use

The ULSPIRA TS Nitric Oxide Therapy System is intended for use by healthcare professionals for the delivery of nitric oxide (NO) and the monitoring of inspired NO, NO_2 and O_2 concentrations for a patient undergoing inhaled Nitric Oxide (iNO) therapy.

129. On information and belief, Defendants' actions associated with the AARC Congress and/or the Ulspira website are in furtherance of Defendants' present and future infringement of the Patents-in-Suit through the manufacture, use, offer to sell, sale, and/or important into the United States of Ulspira and/or Ulspira TS.

130. On information and belief, Defendants' manufacture, use, offer for sale, sale, and/or importation into the United States, including by and through their actions associated with the AARC Congress and/or the Ulspira website, infringes the Patents-in-Suit.

131. On information and belief, and as shown by documents produced in this case, Defendants are actively pursuing commercial contracts with prospective customers for the purchase, lease, acquisition, and/or installation of Ulspira and/or Ulspira TS.

132. Upon information and belief, and as shown by documents produced in this case, Defendants have pursued contracts for the purchase, lease, acquisition, and/or installation of Ulspira and/or Ulspira TS, including instructing employees of Defendants to send contracts and pricing terms to prospective customers. Upon information and belief, Defendants have sent

contracts and pricing terms to prospective customers.

133. On information and belief, and as shown by documents produced in this case, in furtherance of their commercial activities Defendants have and/or will manufacture and/or import and stockpile commercial quantities in the United States Ulspira and/or Ulspira TS for commercial use, offer for sale, or sale in the United States.

134. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and/or Ulspira TS constitutes infringement under 35 U.S.C. § 271(a), and Defendants induce and/or contribute to such conduct and therefore are liable for infringement under 35 U.S.C. § 271(b) and/or (c).

135. Upon information and belief, Defendants were aware, and had notice, of the Orange Book Patents prior to filing Defendants' ANDA. Upon information and belief, Defendants were aware, and had notice, of the Orange Book Patents, as well as Plaintiffs' allegations of infringement as to those patents, prior to Defendants' commercial activities described herein. Defendants have no reasonable basis to believe that Ulspira and Ulspira TS did not infringe the Orange Books Patents. Defendants knew or should have known that Ulspira and Ulspira TS infringed the Orange Book Patents. Defendants' filing of Defendants' ANDA and/or Defendants' commercial activities are willful, wanton, malicious, deliberate, in bad faith consciously wrong, and flagrant, rendering this an exceptional case under 35 U.S.C. § 285.

136. The acts of infringement by Defendants set forth above will cause Mallinckrodt irreparable harm for which they have no adequate remedy at all, and will continue unless enjoined by this Court.

137. Mallinckrodt has filed its original complaint within 45 days of receiving Defendants' Paragraph IV Notice Letter.

COUNT I FOR PATENT INFRINGEMENT

(Infringement of the '6,794 Patent)

138. Plaintiffs incorporate by reference paragraphs 1-135 as if fully set forth herein.

139. On information and belief, Defendants submitted Defendants' ANDA and 510(k) to FDA seeking marketing approval for Ulspira and Ulspira TS.

140. Ulspira and Ulspira TS infringe one or more claims of the '6,794 patent.

141. Defendants have infringed one or more claims of the '6,794 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA and thereby seeking FDA approval of a generic version of INOmax®, prior to the expiration of the '6,794 patent.

142. On information and belief, Defendants' commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and/or Ulspira TS prior to the expiration of the '6,794 Patent infringes one or more claims of the '6,794 patent under 35 U.S.C. § 271(a), and/or Defendants induce and/or contribute to the infringement of one or more claims of the '6,794 patent under 35 U.S.C. § 271(b) and/or (c).

143. On information and belief, Defendants have knowledge of the '6,794 patent and filed Defendants' ANDA seeking approval to, and thereafter entered the commercial market through their, commercial manufacture, use, offer for sale, sell, and/or importation into the United States of Ulspira and Ulspira TS. Upon information and belief, physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '6,794 patent, literally or under the doctrine of equivalents.

144. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS with the instructions

and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '6,794 patent with the requisite intent under 35 U.S.C. § 271(b).

145. On information and belief, because of FDA's approval of Defendants' ANDA, Defendants will sell or offer to sell Ulspira and Ulspira TS specifically labeled for use in practicing one or more of the claims of the '6,794 patent, wherein Ulspira and Ulspira TS are a material part of the inventions claimed in the '6,794 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS for one or more of the inventions claimed in the '6,794 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '6,794 patent under 35 U.S.C. § 271(c).

146. Upon information and belief, Defendants had actual and/or constructive notice of the '6,794 patent since its publication on July 15, 2014. Upon information and belief, Defendants had actual notice of the '6,794 patent, as well as Mallinckrodt's allegations of infringement thereto, as of the filing date of the original complaint in this action. Nonetheless, Defendants maintained Defendants' ANDA and thereafter entered the commercial market upon FDA approval despite knowing that the manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and Ulspira TS prior to the expiration of the '6,794 patent would constitute an act of infringement. Accordingly, Defendants have willfully infringed and continue to willfully infringe one or more claims of the '6,794 patent pursuant to 35 U.S.C. § 284.

147. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and/or Ulspira TS prior to the expiration of the '6,794 Patent has caused Mallinckrodt injury entitling Mallinckrodt to monetary damages, including enhanced monetary damages under 35 U.S.C. § 284.

148. Mallinckrodt is being irreparably harmed by Defendants' infringement, and active induced or contributory infringement of, the '6,794 patent. Mallinckrodt does not have an adequate remedy at law and, considering the balance of hardships between Mallinckrodt and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

149. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '6,794 patent, actively inducing infringement of the '6,794 patent, and/or contributing to the infringement by others of the '6,794 patent.

150. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT II FOR DECLARATORY JUDGMENT

(Declaratory Judgement of Patent Infringement of the '6,794 Patent)

151. Plaintiffs incorporate by reference paragraphs 1-148 as if fully set forth herein.

152. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

153. On information and belief, because of FDA's approval of Ulspira and Ulspira TS for use and sale in the United States, Defendants will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '6,794 patent under 35 U.S.C. § 271(a), in violation of Mallinckrodt's patent rights, by making, using, offering to sell, selling, and/or importing Ulspira and Ulspira TS for use and sale within the United States.

154. The manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed ANDA Product so labeled, as approved by FDA, induces and/or contributes to the infringement of one or more claims of the '6,794 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Mallinckrodt's patent rights.

155. On information and belief, Defendants have knowledge of the '6,794 patent and filed Defendants' ANDA seeking authorization to commercially manufacture, use, offer for sale, sell, and/or import into the United States of Ulspira and Ulspira TS. Upon information and belief, physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '6,794 patent.

156. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '6,794 patent with the requisite intent under 35 U.S.C. § 271(b).

157. On information and belief, because of FDA's approval of Defendants' ANDA, Defendants will sell or offer to sell Ulspira and Ulspira TS specifically labeled for use in practicing one or more of the claims of the '6,794 patent, wherein Ulspira and Ulspira TS are a material part of the inventions claimed in the '6,794 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS for one or more of the inventions claimed in the '6,794 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '6,794 patent under 35 U.S.C. § 271(c).

158. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mallinckrodt and Defendants as to liability for the infringement of the '6,794 patent claims. Defendants' actions have created in Mallinckrodt a reasonable apprehension of irreparable harm and loss.

159. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation

into the United States of Ulspira and/or Ulspira TS prior to the expiration of the '6,794 patent will cause Mallinckrodt injury entitling Mallinckrodt to monetary damages, including enhanced monetary damages under 35 U.S.C. § 284.

160. Upon information and belief, Defendants had actual and/or constructive notice of the '6,794 patent since its publication on July 15, 2014. Upon information and belief, Defendants had actual notice of the '6,794 patent, as well as Mallinckrodt's allegations of infringement thereto, as of the filing date of the original complaint in this action. Nonetheless, Defendants maintained Defendants' ANDA and thereafter entered the commercial market upon FDA approval despite knowing that the manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and Ulspira TS prior to the expiration of the '6,794 patent would constitute an act of infringement. Accordingly, Defendants have willfully infringed and continue to willfully infringe one or more claims of the '6,794 patent pursuant to 35 U.S.C. § 284.

161. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '6,794 patent, actively inducing infringement of the '6,794 patent, and/or contributing to the infringement by others of the '6,794 patent.

162. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT III FOR PATENT INFRINGEMENT

(Infringement of the '795 Patent)

163. Plaintiffs incorporate by reference paragraphs 1-160 as if fully set forth herein.

164. On information and belief, Defendants submitted Defendants' ANDA and 510(k) to FDA seeking marketing approval for Ulspira and Ulspira TS.

165. Ulspira and Ulspira TS infringe one or more claims of the '795 patent.

166. Defendants have infringed one or more claims of the '795 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA and thereby seeking FDA approval of a generic

version of INOmax®, prior to the expiration of the '795 patent.

167. On information and belief, Defendants' commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and Ulspira TS prior to the expiration of the '795 Patent infringes one or more claims of the '795 patent under 35 U.S.C. § 271(a), and/or Defendants induce and/or contribute to the infringement of one or more claims of the '795 patent under 35 U.S.C. § 271(b) and/or (c).

168. On information and belief, Defendants have knowledge of the '795 patent and filed Defendants' ANDA seeking approval to, and thereafter entered the commercial market through their, commercial manufacture, use, offer for sale, sell, and/or importation into the United States of Ulspira and Ulspira TS. Upon information and belief, physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '795 patent, literally or under the doctrine of equivalents.

169. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '795 patent with the requisite intent under 35 U.S.C. § 271(b).

170. On information and belief, because of FDA's approval of Defendants' ANDA, Defendants will sell or offer to sell Ulspira and Ulspira TS specifically labeled for use in practicing one or more of the claims of the '795 patent, wherein Ulspira and Ulspira TS are a material part of the inventions claimed in the '795 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS for one or more of the inventions claimed in the '795 patent, and wherein nitric oxide delivery systems are not a staple

article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '795 patent under 35 U.S.C. § 271(c).

171. Upon information and belief, Defendants had actual and/or constructive notice of the '795 patent since its publication on July 15, 2014. Upon information and belief, Defendants had actual notice of the '795 patent, as well as Mallinckrodt's allegations of infringement thereto, as of the filing date of the original complaint in this action. Nonetheless, Defendants maintained Defendants' ANDA and thereafter entered the commercial market upon FDA approval despite knowing that the manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and Ulspira TS prior to the expiration of the '795 patent would constitute an act of infringement. Accordingly, Defendants have willfully infringed and continue to willfully infringe one or more claims of the '795 patent pursuant to 35 U.S.C. § 284.

172. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and/or Ulspira TS prior to the expiration of the '795 Patent has caused Mallinckrodt injury entitling Mallinckrodt to monetary damages, including enhanced monetary damages under 35 U.S.C. § 284.

173. Mallinckrodt is being irreparably harmed by Defendants infringement and active induced or contributory infringement of, the '795 patent. Mallinckrodt does not have an adequate remedy at law and, considering the balance of hardships between Mallinckrodt and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

174. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '795 patent, actively inducing infringement of the '795 patent, and/or contributing to the infringement by others of the '795 patent.

175. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT IV FOR DECLARATORY JUDGMENT

(Declaratory Judgement of Patent Infringement of the '795 Patent)

176. Plaintiffs incorporate by reference paragraphs 1-173 as if fully set forth herein.

177. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

178. On information and belief, because of FDA's approval of Ulspira and Ulspira TS for use and sale in the United States, Defendants will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '795 patent under 35 U.S.C. § 271(a), in violation of Mallinckrodt's patent rights, by making, using, offering to sell, selling, and/or importing Ulspira and Ulspira TS for use and sale within the United States.

179. The manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed ANDA Product so labeled, as approved by FDA, induces and/or contributes to the infringement of one or more claims of the '795 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Mallinckrodt's patent rights.

180. On information and belief, Defendants have knowledge of the '795 patent and filed Defendants' ANDA seeking authorization to commercially manufacture, use, offer for sale, sell, and/or import into the United States Ulspira and Ulspira TS. Upon information and belief, physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '795 patent.

181. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS with the instructions

and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '795 patent with the requisite intent under 35 U.S.C. § 271(b).

182. On information and belief, because of FDA's approval of Defendants' ANDA, Defendants will sell or offer to sell Ulspira and Ulspira TS specifically labeled for use in practicing one or more of the claims of the '795 patent, wherein Ulspira and Ulspira TS are a material part of the inventions claimed in the '795 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS for one or more of the inventions claimed in the '795 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '795 patent under 35 U.S.C. § 271(c).

183. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mallinckrodt and Defendants as to liability for the infringement of the '795 patent claims. Defendants' actions have created in Mallinckrodt a reasonable apprehension of irreparable harm and loss.

184. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and/or Ulspira TS prior to the expiration of the '795 patent will cause Mallinckrodt injury entitling Mallinckrodt to monetary damages, including enhanced monetary damages under 35 U.S.C. § 284.

185. Upon information and belief, Defendants had actual and/or constructive notice of the '795 patent since its publication on July 15, 2014. Upon information and belief, Defendants had actual notice of the '795 patent, as well as Mallinckrodt's allegations of infringement thereto, as of the filing date of the original complaint in this action. Nonetheless, Defendants maintained Defendants' ANDA and thereafter entered the commercial market upon FDA approval despite

knowing that the manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and Ulspira TS prior to the expiration of the '795 patent would constitute an act of infringement. Accordingly, Defendants have willfully infringed and continue to willfully infringe one or more claims of the '795 patent pursuant to 35 U.S.C. § 284.

186. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '795 patent, actively inducing infringement of the '795 patent, and/or contributing to the infringement by others of the '795 patent.

187. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT V FOR PATENT INFRINGEMENT

(Infringement of the '9,794 Patent)

188. Plaintiffs incorporate by reference paragraphs 1-185 as if fully set forth herein.

189. On information and belief, Defendants submitted Defendants' ANDA and 510(k) to FDA seeking marketing approval for Ulspira and Ulspira TS.

190. Ulspira and Ulspira TS infringe one or more claims of the '9,794 patent.

191. Defendants have infringed one or more claims of the '9,794 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA and thereby seeking FDA approval of a generic version of INOmax®, prior to the expiration of the '9,794 patent.

192. On information and belief, Defendants' commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and Ulspira TS prior to the expiration of the '9,794 Patent infringes one or more claims of the '9,794 patent under 35 U.S.C. § 271(a), and/or Defendants induce and/or contribute to the infringement of one or more claims of the '9,794 patent under 35 U.S.C. § 271(b) and/or (c).

193. On information and belief, Defendants have knowledge of the '9,794 patent and

filed Defendants' ANDA seeking approval to, and thereafter entered the commercial market through their, commercial manufacture, use, offer for sale, sell, and/or importation into the United States of Ulspira and Ulspira TS. Upon information and belief, physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '9,794 patent, literally or under the doctrine of equivalents.

194. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '9,794 patent with the requisite intent under 35 U.S.C. § 271(b).

195. On information and belief, because of FDA's approval of Defendants' ANDA, Defendants will sell or offer to sell Ulspira and Ulspira TS specifically labeled for use in practicing one or more of the claims of the '9,794 patent, wherein Ulspira and Ulspira TS are a material part of the inventions claimed in the '9,794 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS for one or more of the inventions claimed in the '9,794 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '9,794 patent under 35 U.S.C. § 271(c).

196. Upon information and belief, Defendants had actual and/or constructive notice of the '9,794 patent since its publication on March 8, 2016. Upon information and belief, Defendants had actual notice of the '9,794 patent, as well as Mallinckrodt's allegations of infringement thereto, as of the filing date of the original complaint in this action. Nonetheless, Defendants maintained Defendants' ANDA and thereafter entered the commercial market upon FDA approval despite

knowing that the manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and Ulspira TS prior to the expiration of the '9,794 patent would constitute an act of infringement. Accordingly, Defendants have willfully infringed and continue to willfully infringe one or more claims of the '9,794 patent pursuant to 35 U.S.C. § 284.

197. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and/or Ulspira TS prior to the expiration of the '9,794 Patent has caused Mallinckrodt injury entitling Mallinckrodt to monetary damages, including enhanced monetary damages under 35 U.S.C. § 284.

198. Mallinckrodt is being irreparably harmed by infringement, and active induced or contributory infringement of, the '9,794 patent. Mallinckrodt does not have an adequate remedy at law and, considering the balance of hardships between Mallinckrodt and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

199. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '9,794 patent, actively inducing infringement of the '9,794 patent, and/or contributing to the infringement by others of the '9,794 patent.

200. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT VI FOR DECLARATORY JUDGMENT

(Declaratory Judgement of Patent Infringement of the '9,794 Patent)

201. Plaintiffs incorporate by reference paragraphs 1-198 as if fully set forth herein.

202. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

203. On information and belief, because of FDA's approval of Ulspira and Ulspira TS

for use and sale in the United States, Defendants will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '9,794 patent under 35 U.S.C. § 271(a), in violation of Mallinckrodt's patent rights, by making, using, offering to sell, selling, and/or importing Ulspira and Ulspira TS for use and sale within the United States.

204. The manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed ANDA Product so labeled, as approved by FDA, induces and/or contributes to the infringement of one or more claims of the '9,794 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Mallinckrodt's patent rights.

205. On information and belief, Defendants have knowledge of the '9,794 patent and filed Defendants' ANDA seeking authorization to commercially manufacture, use, offer for sale, sell, and/or import into the United States Ulspira and Ulspira TS. Upon information and belief, physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '9,794 patent.

206. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '9,794 patent with the requisite intent under 35 U.S.C. § 271(b).

207. On information and belief, because of FDA's approval of Defendants' ANDA, Defendants will sell or offer to sell Ulspira and Ulspira TS specifically labeled for use in practicing one or more of the methods of the '9,794 patent, wherein Ulspira and Ulspira TS is a material part of the methods claimed in the '9,794 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS for one or more of the

methods claimed in the '9,794 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '9,794 patent under 35 U.S.C. § 271(c).

208. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mallinckrodt and Defendants as to liability for the infringement of the '9,794 patent claims. Defendants' actions have created in Mallinckrodt a reasonable apprehension of irreparable harm and loss.

209. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and/or Ulspira TS prior to the expiration of the '9,794 patent will cause Mallinckrodt injury entitling Mallinckrodt to monetary damages, including enhanced monetary damages under 35 U.S.C. § 284.

210. Upon information and belief, Defendants had actual and/or constructive notice of the '9,794 patent since its publication on March 8, 2016. Upon information and belief, Defendants had actual notice of the '9,794 patent, as well as Mallinckrodt's allegations of infringement thereto, as of the filing date of the original complaint in this action. Nonetheless, Defendants maintained Defendants' ANDA and thereafter entered the commercial market upon FDA approval despite knowing that the manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and Ulspira TS prior to the expiration of the '9,794 patent would constitute an act of infringement. Accordingly, Defendants have willfully infringed and continue to willfully infringe one or more claims of the '9,794 patent pursuant to 35 U.S.C. § 284.

211. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '9,794 patent, actively inducing infringement of the '9,794 patent, and/or contributing to the infringement by others of the '9,794 patent.

212. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT VII FOR PATENT INFRINGEMENT

(Infringement of the '741 Patent)

213. Plaintiffs incorporate by reference paragraphs 1-210 as if fully set forth herein.

214. On information and belief, Defendants submitted Defendants' ANDA and 510(k) to FDA seeking marketing approval for Ulspira and Ulspira TS.

215. Claims 24, 26, 29-30, and 33 of the '741 patent were not subject to the judgment in the *Praxair* litigation.

216. Ulspira and Ulspira TS infringe one or more of claims 24, 26, 29-30, and 33of the '741 patent.

217. Defendants have infringed one or more of claims 24, 26, 29-30, and 33 of the '741 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA and thereby seeking FDA approval of a generic version of INOmax®, prior to the expiration of the '741 patent.

218. On information and belief, Defendants' commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and Ulspira TS prior to the expiration of the '741 Patent infringes one or more of claims 24, 26, 29-30, and 33 of the '741 patent under 35 U.S.C. § 271(a), and/or Defendants induce and/or contribute to the infringement of one or more of claims 24, 26, 29-30, and 33 of the '741 patent under 35 USC § 271(b) and/or (c).

219. On information and belief, Defendants have knowledge of the '741 patent and filed Defendants' ANDA seeking approval to, and thereafter entered the commercial market through their, commercial manufacture, use, offer for sale, sell, and/or importation into the United States of Ulspira and Ulspira TS. Upon information and belief, physicians, health care providers, and/or

patients will prescribe and/or use Ulspira and Ulspira TS in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more of claims 24, 26, 29-30, and 33 of the '741 patent.

220. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of claims 24, 26, 29-30, and 33 of the '741 patent with the requisite intent under 35 U.S.C. § 271(b).

221. On information and belief, because of FDA's approval of Defendants' ANDA, Defendants will sell or offer to sell Ulspira and Ulspira TS specifically labeled for use in practicing one or more of claims 24, 26, 29-30, and 33 of the '741 patent, wherein Ulspira and Ulspira TS are a material part of the inventions claimed in claims 24, 26, 29-30, and 33 of the '741 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS for one or more of the inventions claimed in claims 24, 26, 29-30, and 33 of the '741 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of one or more of claims 24, 26, 29-30, and 33 of the '741 patent under 35 U.S.C. § 271(c).

222. Upon information and belief, Defendants had actual and/or constructive notice of the '741 patent since its publication on August 5, 2014. Upon information and belief, Defendants had actual notice of the '741 patent, as well as Mallinckrodt's allegations of infringement thereto, as of the filing date of the original complaint in this action. Nonetheless, Defendants maintained Defendants' ANDA and thereafter entered the commercial market upon FDA approval despite knowing that the manufacture, use, offer for sale, sale, and/or importation into the United States

of Ulspira and Ulspira TS prior to the expiration of the '741 patent would constitute an act of infringement. Accordingly, Defendants have willfully infringed and continue to willfully infringe one or more claims of the '741 patent pursuant to 35 U.S.C. § 284.

223. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and/or Ulspira TS prior to the expiration of the '741 Patent has caused Mallinckrodt injury entitling Mallinckrodt to monetary damages, including enhanced monetary damages under 35 U.S.C. § 284.

224. Mallinckrodt is being irreparably harmed by Defendants infringement and active induced or contributory infringement of, one or more of claims 24, 26, 29-30, and 33 of the '741 patent. Mallinckrodt does not have an adequate remedy at law and, considering the balance of hardships between Mallinckrodt and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

225. Defendants acted without a reasonable basis for believing that they would not be liable for infringing one or more of claims 24, 26, 29-30, and 33 of the '741 patent, actively inducing infringement of one or more of claims 24, 26, 29-30, and 33 of the '741 patent, and/or contributing to the infringement by others of one or more of claims 24, 26, 29-30, and 33 of the '741 patent.

226. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT IIX FOR DECLARATORY JUDGMENT

(Declaratory Judgement of Patent Infringement of the '741 Patent)

227. Plaintiffs incorporate by reference paragraphs 1-224 as if fully set forth herein.

228. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

229. On information and belief, because of FDA's approval of Ulspira and Ulspira TS for use and sale in the United States, Defendants will directly infringe, literally and/or through the doctrine of equivalents, one or more of claims 24, 26, 29-30, and 33of the '741 patent under 35 U.S.C. § 271(a), in violation of Mallinckrodt's patent rights, by making, using, offering to sell, selling, and/or importing Ulspira and Ulspira TS for use and sale within the United States.

230. The manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed ANDA Product so labeled, as approved by FDA, induces and/or contributes to the infringement of one or more of claims 24, 26, 29-30, and 33 of the '741 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Mallinckrodt's patent rights.

231. On information and belief, Defendants have knowledge of the '741 patent and filed Defendants' ANDA seeking authorization to commercially manufacture, use, offer for sale, sell, and/or import into the United States Ulspira and Ulspira TS. Upon information and belief, physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more of claims 24, 26, 29-30, and 33 of the '741 patent.

232. On information and belief, Defendants knows and intends that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of claims 24, 26, 29-30, and 33 of the '741 patent with the requisite intent under 35 U.S.C. § 271(b).

233. On information and belief, because of FDA's approval of Defendants' ANDA, Defendants will sell or offer to Ulspira and Ulspira TS specifically labeled for use in practicing one or more of claims 24, 26, 29-30, and 33 of the '741 patent, wherein Ulspira and Ulspira TS

are a material part of the methods claimed in one or more of claims 24, 26, 29-30, and 33 of the '741 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS for one or more of the methods claimed in one or more of claims 24, 26, 29-30, and 33 of the '741 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of one or more of claims 24, 26, 29-30, and 33 of the '741 patent under 35 U.S.C. § 271(c).

234. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mallinckrodt and Defendants as to liability for the infringement of one or more of claims 24, 26, 29-30, and 33 of the '741 patent claims. Defendants' actions have created in Mallinckrodt a reasonable apprehension of irreparable harm and loss.

235. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and/or Ulspira TS prior to the expiration of the '741 patent will cause Mallinckrodt injury entitling Mallinckrodt to monetary damages, including enhanced monetary damages under 35 U.S.C. § 284.

236. Upon information and belief, Defendants had actual and/or constructive notice of the '741 patent since its publication on August 5, 2014. Upon information and belief, Defendants had actual notice of the '741 patent, as well as Mallinckrodt's allegations of infringement thereto, as of the filing date of the original complaint in this action. Nonetheless, Defendants maintained Defendants' ANDA and thereafter entered the commercial market upon FDA approval despite knowing that the manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and Ulspira TS prior to the expiration of the '741 patent would constitute an act of infringement. Accordingly, Defendants have willfully infringed and continue to willfully infringe

one or more claims of the '741 patent pursuant to 35 U.S.C. § 284.

237. Defendants acted without a reasonable basis for believing that they would not be liable for infringing one or more of claims 24, 26, 29-30, and 33 of the '741 patent, actively inducing infringement of one or more of claims 24, 26, 29-30, and 33 of the '741 patent, and/or contributing to the infringement by others of one or more of claims 24, 26, 29-30, and 33 of the '741 patent.

238. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT IX FOR PATENT INFRINGEMENT

(Infringement of the '046 Patent)

239. Plaintiffs incorporate by reference paragraphs 1-236 as if fully set forth herein.

240. Ulspira and Ulspira TS infringe one or more claims of the '046 patent.

241. The manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and Ulspira TS prior to the expiration of the '046 patent infringes one or more claims of the '046 patent under 35 U.S.C. § 271(a), and/or Defendants induce and/or contribute to the infringement of one or more claims of the '046 patent under 35 U.S.C. § 271(b) and/or (c).

242. On information and belief, Defendants have knowledge of the '046 patent and filed Defendants' ANDA seeking approval to, and thereafter entered the commercial market through their, commercial manufacture, use, offer for sale, sell, and/or importation into the United States of Ulspira and Ulspira TS. Upon information and belief, physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '046 patent, literally or under the doctrine of equivalents.

243. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS with the instructions

and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '046 patent with the requisite intent under 35 U.S.C. § 271(b).

244. On information and belief, because of FDA's approval of Defendants' ANDA, Defendants will sell or offer to sell Ulspira and Ulspira TS specifically labeled for use in practicing one or more of the claims of the '046 patent, wherein Ulspira and Ulspira TS are a material part of the inventions claimed in the '046 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS for one or more of the inventions claimed in the '046 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '046 patent under 35 U.S.C. § 271(c).

245. Upon information and belief, Defendants had actual and/or constructive notice of the '046 patent since its publication on December 22, 2017, and nonetheless continued its infringing activities despite knowing that the manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and Ulspira TS prior to the expiration of the '046 patent would constitute an act of infringement. Accordingly, Defendants have willfully infringed the '046 patent. Additionally, Defendants have actual notice of Mallinckrodt's infringement allegations with respect to the '046 patent as of this complaint, and therefore Defendants' continued commercial activities will constitute willful infringement one or more claims of the '046 patent pursuant to 35 U.S.C. § 284.

246. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and/or Ulspira TS prior to the expiration of the '046 Patent has caused Mallinckrodt injury entitling Mallinckrodt to monetary damages, including enhanced monetary damages under 35 U.S.C. § 284.

247. Mallinckrodt is being irreparably harmed by infringement, and active induced or contributory infringement of, the '046 patent. Mallinckrodt does not have an adequate remedy at law and, considering the balance of hardships between Mallinckrodt and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

248. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '046 patent, actively inducing infringement of the '046 patent, and/or contributing to the infringement by others of the '046 patent.

249. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT X FOR DECLARATORY JUDGMENT

(Declaratory Judgement of Patent Infringement of the '046 Patent)

250. Plaintiffs incorporate by reference paragraphs 1-247 as if fully set forth herein.

251. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

252. On information and belief, because of FDA's approval of Ulspira and Ulspira TS for use and sale in the United States, Defendants will directly infringed, literally and/or through the doctrine of equivalents, one or more claims of the '046 patent under 35 U.S.C. § 271(a), in violation of Mallinckrodt's patent rights, by making, using, offering to sell, selling, and/or importing Ulspira and Ulspira TS for use and sale within the United States.

253. The manufacture, use, offer for sale, sale, and/or importation of Ulspira and Ulspira TS so labeled, as approved by FDA, induces and/or contributes to the infringement of one or more claims of the '046 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Mallinckrodt's patent rights.

254. On information and belief, physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '9,794 patent.

255. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '046 patent with the requisite intent under 35 U.S.C. § 271(b).

256. On information and belief, because of FDA's approval of Defendants' ANDA, Defendants will sell or offer to sell Ulspira and Ulspira TS specifically labeled for use in practicing one or more of the methods of the '046 patent, wherein Ulspira and Ulspira TS is a material part of the methods claimed in the '046 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS for one or more of the methods claimed in the '046 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '046 patent under 35 U.S.C. § 271(c).

257. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mallinckrodt and Defendants as to liability for the infringement of the '046 patent claims. Defendants' actions have created in Mallinckrodt a reasonable apprehension of irreparable harm and loss.

258. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and/or Ulspira TS prior to the expiration of the '046 patent will cause Mallinckrodt injury entitling Mallinckrodt to monetary damages, including enhanced monetary damages under 35 U.S.C. § 284.

259. Upon information and belief, Defendants had actual and/or constructive notice of the '046 patent since its publication on December 22, 2017, and nonetheless continued its infringing activities despite knowing that the manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and Ulspira TS prior to the expiration of the '046 patent would constitute an act of infringement. Accordingly, Defendants have willfully infringed the '046 patent. Additionally, Defendants have actual notice of Mallinckrodt's infringement allegations with respect to the '046 patent as of this complaint, and therefore Defendants' continued commercial activities will constitute willful infringement one or more claims of the '046 patent pursuant to 35 U.S.C. § 284.

260. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '046 patent, actively inducing infringement of the '046 patent, and/or contributing to the infringement by others of the '046 patent.

261. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT XI FOR PATENT INFRINGEMENT

(Infringement of the '118 Patent)

262. Plaintiffs incorporate by reference paragraphs 1-259 as if fully set forth herein.

263. Ulspira and Ulspira TS infringe one or more claims of the '118 patent.

264. The manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and Ulspira TS prior to the expiration of the '118 patent infringes one or more claims of the '118 patent under 35 U.S.C. § 271(a), and/or Defendants induce and/or contribute to the infringement of one or more claims of the '118 patent under 35 U.S.C. § 271(b) and/or (c).

265. On information and belief, Defendants have knowledge of the '118 patent and filed Defendants' ANDA seeking approval to, and thereafter entered the commercial market through their, commercial manufacture, use, offer for sale, sell, and/or importation into the United States

of Ulspira and Ulspira TS. Upon information and belief, physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '118 patent, literally or under the doctrine of equivalents.

266. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '118 patent with the requisite intent under 35 U.S.C. § 271(b).

267. On information and belief, because of FDA's approval of Defendants' ANDA, Defendants will sell or offer to sell Ulspira and Ulspira TS specifically labeled for use in practicing one or more of the claims of the '118 patent, wherein Ulspira and Ulspira TS are a material part of the inventions claimed in the '118 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS for one or more of the inventions claimed in the '118 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '118 patent under 35 U.S.C. § 271(c).

268. Upon information and belief, Defendants had actual and/or constructive notice of the '118 patent since its publication on March 16, 2017, and nonetheless continued its infringing activities despite knowing that the manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and Ulspira TS prior to the expiration of the '118 patent would constitute an act of infringement. Accordingly, Defendants have willfully infringed the '118 patent. Additionally, Defendants have actual notice of Mallinckrodt's infringement allegations with respect to the '118 patent as of this complaint, and therefore Defendants' continued

commercial activities will constitute willful infringement one or more claims of the '118 patent pursuant to 35 U.S.C. § 284.

269. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and/or Ulspira TS prior to the expiration of the '118 Patent has caused Mallinckrodt injury entitling Mallinckrodt to monetary damages, including enhanced monetary damages under 35 U.S.C. § 284.

270. Mallinckrodt is being irreparably harmed by infringement, and active induced or contributory infringement of, the '118 patent. Mallinckrodt does not have an adequate remedy at law and, considering the balance of hardships between Mallinckrodt and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

271. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '118 patent, actively inducing infringement of the '118 patent, and/or contributing to the infringement by others of the '118 patent.

272. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT XII FOR DECLARATORY JUDGMENT

(Declaratory Judgement of Patent Infringement of the '118 Patent)

273. Plaintiffs incorporate by reference paragraphs 1-270 as if fully set forth herein.

274. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

275. On information and belief, because of FDA's approval of Ulspira and Ulspira TS for use and sale in the United States, Defendants will directly infringed, literally and/or through the doctrine of equivalents, one or more claims of the '118 patent under 35 U.S.C. § 271(a), in

violation of Mallinckrodt's patent rights, by making, using, offering to sell, selling, and/or importing Ulspira and Ulspira TS for use and sale within the United States.

276. The manufacture, use, offer for sale, sale, and/or importation of Ulspira and Ulspira TS so labeled, as approved by FDA, induces and/or contributes to the infringement of one or more claims of the '118 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Mallinckrodt's patent rights.

277. On information and belief, physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '9,794 patent.

278. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '118 patent with the requisite intent under 35 U.S.C. § 271(b).

279. On information and belief, because of FDA's approval of Defendants' ANDA, Defendants will sell or offer to sell Ulspira and Ulspira TS specifically labeled for use in practicing one or more of the methods of the '118 patent, wherein Ulspira and Ulspira TS is a material part of the methods claimed in the '118 patent, wherein Defendants know that physicians, health care providers, and/or patients will prescribe and/or use Ulspira and Ulspira TS for one or more of the methods claimed in the '118 patent, and wherein nitric oxide delivery systems are not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '118 patent under 35 U.S.C. § 271(c).

280. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mallinckrodt and Defendants as to liability for the infringement

of the '118 patent claims. Defendants' actions have created in Mallinckrodt a reasonable apprehension of irreparable harm and loss.

281. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and/or Ulspira TS prior to the expiration of the '118 patent will cause Mallinckrodt injury entitling Mallinckrodt to monetary damages, including enhanced monetary damages under 35 U.S.C. § 284.

282. Upon information and belief, Defendants had actual and/or constructive notice of the '118 patent since its publication on March 16, 2017, and nonetheless continued its infringing activities despite knowing that the manufacture, use, offer for sale, sale, and/or importation into the United States of Ulspira and Ulspira TS prior to the expiration of the '118 patent would constitute an act of infringement. Accordingly, Defendants have willfully infringed the '118 patent. Additionally, Defendants have actual notice of Mallinckrodt's infringement allegations with respect to the '118 patent as of this complaint, and therefore Defendants' continued commercial activities will constitute willful infringement one or more claims of the '118 patent pursuant to 35 U.S.C. § 284.

283. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '118 patent, actively inducing infringement of the '118 patent, and/or contributing to the infringement by others of the '118 patent.

284. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Defendants have infringed one or more claims of one or more of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A);

B. A Judgment that Defendants will infringe one or more claims of one or more of the

Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A);

C. A Judgment and Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Defendants' ANDA shall be no be earlier than the expiration date of the latest to expire of any Patents-in-Suit adjudged to be infringed by Defendants, including the expiration of any applicable extensions or regulatory exclusivities;

D. A Judgment and Order that Defendants, their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, are permanently enjoined from commercially manufacturing, using, offering to sell, selling, marketing, distributing, or importing Ulspira and Ulspira TS and any other product that infringes or induces or contributes to the infringement of the Patents-in-Suit, prior to the expiration of any of the Patents-in-Suit adjudged to be infringed, including any exclusivities or extensions to which Plaintiffs are or become entitled;

E. A Judgment declaring that making, using, selling, offering to sell, or importing Ulspira and/or Ulspira TS, or inducing or contributing to such conduct, would constitute infringement of the Patents-in-Suit pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

F. A Judgment that Defendants' manufacture, use, sale, offer for sale, or importation of Ulspira and/or Ulspira TS, or inducement or contribution to such conduct, constitutes infringement of the Patents-in-Suit pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

G. A Judgment that Defendants have and/or will willfully infringe the Patents-in-Suit;

H. A declaration under 28 U.S.C. § 2201 that, if Defendants, their officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with them or on their behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Ulspira and Ulspira TS, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

I. A declaration under 28 U.S.C. § 2201 that, that Defendants, their officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with them or on their behalf, engaged in the commercial manufacture, use, offer for sale, sale or importation of Ulspira and Ulspira TS, constituting an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

J. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), due to Defendants' commercial manufacture, use, offer for sale, sale, and/or importation of Ulspira and Ulspira TS, or any product that infringes the Patents-in-Suit, or induces or contributes to such conduct, prior to the expiration of any of the Patents-in-Suit adjudged to be infringed, including the expiration of any additional exclusivity period applicable to that patent;

K. An award of damages or other relief arising from the infringement of the Patents-in-Suit adequate to compensate Mallinckrodt for Defendants' past, present, and future infringement, including enhanced damages, pursuant to 35 U.S.C. § 284, and prejudgment and post-judgment interest;

L. An award of enhanced damages pursuant to 35 U.S.C. § 284;

M. A finding that this case is an exceptional case and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

N. Costs and expenses in this action; and

O. Such other and further relief as this Court deems just and proper.

DATED: February 12, 2024

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