IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

)
)
)
) C.A. No.
)
) JURY TRIAL DEMANDED
)
)
)
)
)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Fresenius Kabi USA, LLC and Fresenius Kabi Deutschland GmbH (together, "Fresenius"), by and through their attorneys, for their complaint against Defendant Natco Pharma USA LLC ("Natco"), hereby allege as follows:

THE PARTIES

1. Plaintiff Fresenius Kabi USA, LLC is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 3 Corporate Drive, Lake Zurich, Illinois 60047.

 Plaintiff Fresenius Kabi Deutschland GmbH is a corporation organized and existing under the laws of Germany, with its principal place of business at Else-Kröner-Straβe 1, 61352 Bad Homburg, Germany.

3. On information and belief, Natco, formerly known as Dash Pharmaceuticals LLC, is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 300 Interpace Pkwy, Ste C100, Parsippany, NJ 07054. In its Financial Report

for Fiscal year 2022-2023, Natco Pharma USA LLC reported that Dash Pharmaceuticals LLC had been acquired by Natco Pharma, Inc. and Dash Pharmaceuticals LLC had changed its name to Natco Pharma USA LLC. Natco Pharma Limited announced that Dash Pharmaceuticals LLC had officially transitioned to Natco Pharma USA LLC as of January 2, 2024.

JURISDICTION AND VENUE

4. This is an action for patent infringement under 35 U.S.C. § 271 *et seq*.

5. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338 because all claims in this action arise under the patent laws of the United States.

6. This Court has personal jurisdiction over Natco as a corporation organized and existing under the laws of the State of Delaware.

7. Venue in this District is proper under 28 U.S.C. §§ 1391 and 1400 at least because Natco is incorporated in this District, this Court has personal jurisdiction over Natco, and, upon information and belief, infringement has occurred in this District.

THE ASSERTED PATENTS

8. On August 15, 2017, the United States Patent and Trademark Office (the "USPTO") duly and legally issued United States Patent No. 9,731,082 ("the '082 patent"), entitled "Drug Container." A copy of the '082 patent is attached as <u>Exhibit 1</u>.

9. On May 26, 2020, the USPTO duly and legally issued United States Patent No. 10,661,018 ("the '018 patent"), entitled "Drug Container." A copy of the '018 patent is attached as <u>Exhibit 2</u>.

10. On August 30, 2022, the USPTO duly and legally issued United States Patent No. 11,426,522 ("the '522 patent"), entitled "Drug Container." A copy of the '522 patent is attached as <u>Exhibit 3</u>.

Case 1:24-cv-00472-UNA Document 1 Filed 04/12/24 Page 3 of 18 PageID #: 3

11. The '082 patent, the '018 patent, and the '522 patent (together, "the Asserted Patents") claim priority to the same international patent application, No. PCT/IB2008/003736.

12. The Asserted Patents relate generally to "an injection device having a distal tip on which is mounted an adaptor element, such as a Luer lock adaptor" and a "means for preventing the rotation of the adaptor with respect to the distal tip." '082 patent (Exhibit 1) at 1:1-7; *see* '018 patent (Exhibit 2) at 1:16-20 (same); '522 patent (Exhibit 3) at 1:18-22 (same). In hospital and emergency settings, medications are often administered by intravenous ("IV") push or injection. In certain IV preparations, an injection device containing the required dose of a medication is fitted into an IV connector using an adaptor. A secure and reliable connection between the IV connector, adaptor, and injection device is key to prevent leaks and ensure correct dosage.

13. The Asserted Patents teach and claim injection devices that ensure a secure connection with, for example, an IV connector. *See* '082 patent (Exhibit 1) at 1:16-59; '018 patent (Exhibit 2) at 1:29-2:5; '522 patent (Exhibit 3) at 1:31-2:8. The Asserted Patents also teach and claim injection devices with film coatings that enhance the stability of the device and allow for the labeling of the container.

14. The '082 patent discloses and claims certain novel injection devices and methods for manufacturing those injection devices. For example, claim 1 of the '082 patent recites:

1. An assembly comprising:

an injection device comprising a container for a product, said container comprising a distal tip encompassing a channel providing a passageway for transfer of said product;

an adaptor comprising a ring mounted onto said distal tip, said ring including an internally threaded portion and an inner projection extending radially inwardly, wherein said ring of said adaptor is mounted on said distal tip by friction between said inner projection and said distal tip and wherein said distal tip extends into said internally threaded portion of said adaptor with a distal end of said distal tip being disposed beyond a distal end of said adaptor; and

a heat-shrinkable film covering at least part of said container and at least part of said adaptor, said heat-shrinkable film not covering a distal end of said ring so as to allow access to said internal thread without removal of any portion of said heat-shrinkable film covering at least part of said container and at least part of said adaptor, said heat-shrinkable film maintaining said adaptor blocked in rotation and in translation with respect to said container when said heat-shrinkable film is in its heat-shrunk condition.

'082 patent (Exhibit 1) at 5:46-6:2.

15. The '018 patent discloses and claims certain novel injection devices. For example,

claim 1 of the '018 patent recites:

1. An assembly comprising:

an injection device comprising a container for a product, said container comprising a distal tip encompassing a channel providing a passageway for transfer of said product;

an adaptor comprising a ring mounted onto said distal tip, said ring including an internally threaded portion and an inner projection extending radially inwardly, wherein said ring of said adaptor is mounted on said distal tip by friction between said inner projection and said distal tip and wherein said distal tip extends into said internally threaded portion of said adaptor with a distal end of said distal tip being disposed beyond a distal end of said adaptor;

a plug mounted on said adapter; and

a heat-shrinkable film covering at least part of said container, said adaptor, and at least part of said plug, said heat-shrinkable film maintaining said adaptor blocked in rotation and in translation with respect to said container when said heat-shrinkable film is in its heat-shrunk condition.

'018 patent (Exhibit 2) at 6:6-26.

16. The '522 patent discloses and claims certain novel injection devices. For example,

claim 1 of the '522 patent recites:

1. An assembly comprising:

a container having a reservoir configured to contain a product and a distal tip having a channel configured to transfer the product;

an adaptor mounted onto the distal tip and having an internal thread, wherein the distal tip extends into the adaptor and a distal end of the distal tip extends beyond a distal end of the adaptor; and

a sheet fixing the adaptor with respect to the container.

'522 patent (Exhibit 3) at 6:5-14.

17. Fresenius Kabi Deutschland GmbH is the owner and assignee of all right, title, and interest in and to the Asserted Patents.

18. Fresenius Kabi USA, LLC is the entity responsible for manufacturing, marketing, selling, and distributing Fresenius' Simplist[®] Diazepam Injection product in the United States, which practices the inventions of the Asserted Patents.

FRESENIUS' PRACTICING PRODUCT

19. Fresenius markets, sells, and distributes its Simplist[®] Diazepam Injection product in the United States.

20. Diazepam is a pharmaceutical compound that is indicated to treat, among other things, anxiety and muscle spasms. For example, it may be administered to patients prior to surgical procedures or cardioversion in order to relieve anxiety and tension.

21. Fresenius' Simplist[®] Diazepam Injection is available in Fresenius' proprietary line of Simplist[®] ready-to-administer prefilled syringes. The syringes require no assembly at point of care, with Luer-LokTM connectivity, seal, and twist off cap.

22. The Fresenius Simplist[®] Diazepam Injection product is explicitly marked in its Package Insert as practicing the '082 and '018 patents.

DEFENDANT'S INFRINGING PRODUCT AND ACTIVITIES

23. On information and belief, Natco markets, sells, and distributes the Dash Pharmaceuticals LLC Diazepam Injection prefilled syringe device in the United States (the "Dash Diazepam Product").

24. "Natco Pharma USA LLC" is the name of the entity that appears on the package insert for the Dash Diazepam Product which is marketed under National Drug Codes ("NDC")

beginning NDC 69339-136.

25. "Natco Pharma USA LLC" is the entity listed as the "Labeler" on the United StatesFood & Drug Administration's website based on a search of NDC Codes beginning NDC 69339-136.

26. The Dash Diazepam Product package insert includes the following images:



27. The Dash Diazepam Product has been marketed to consumers in a video that appeared on the Dash Pharmaceuticals LLC website.



28. The Dash Diazepam Product video claims that Dash is introducing "a new tamper evident seal for its diazepam injection single-dose prefilled syringes."

29. The Dash Diazepam Product video also claims that the new syringes have been "reengineered to connect seamlessly for IV or IM administration." On information and belief, the Dash Diazepam Product video is referring to intravenous (IV) or intramuscular (IM) administration.

30. The Dash Diazepam Product video concludes by instructing that the viewer should "contact Dash Pharmaceuticals or your wholesale distributor for ordering information."

31. The product that appears in the Dash Diazepam Product video bears an NDC Code of 69339-136-34.

32. The Natco website lists a pre-filled syringe Diazepam Injection having an NDC Code as 69339-136-34 in Natco's product catalog.

FIRST CAUSE OF ACTION

(Infringement of the '082 Patent)

33. Fresenius incorporates by reference paragraphs 1-32.

34. On information and belief, the Dash Diazepam Product satisfies each and every limitation, either literally or under the doctrine of equivalents, of one or more claims of the '082 patent, including at least claim 1, as described below.

35. To the extent the preamble is limiting, on information and belief, the Dash Diazepam Product comprises an assembly at least because it is a prefilled syringe. *See, e.g.*, Dash Diazepam Product Video.

36. On information and belief, the Dash Diazepam Product is an injection device comprising a container for a product, said container comprising a distal tip encompassing a channel providing a passageway for transfer of said product. On information and belief, the Dash Diazepam Product is an injection device comprising a prefilled syringe that contains diazepam and has a distal tip that provides a channel through which the diazepam can be transferred. *See id.*

37. On information and belief, the Dash Diazepam Product has an adaptor comprising a ring mounted onto said distal tip. *See id.*

38. On information and belief, the ring adaptor of the Dash Diazepam Product includes an internally threaded portion and an inner projection extending radially inwardly and the ring of the adaptor is mounted on the distal tip by friction between the inner projection of the adaptor and the distal tip of the Dash Diazepam Product. *See id.*

39. On information and belief, the distal tip of the Dash Diazepam Product extends into the internally threaded portion of the adaptor and the distal end of the distal tip is disposed beyond the distal end of the adaptor. *See id.*

40. On information and belief, the Dash Diazepam Product has a heat-shrinkable film

Case 1:24-cv-00472-UNA Document 1 Filed 04/12/24 Page 9 of 18 PageID #: 9

that covers at least part of the syringe of the Dash Diazepam Product and at least part of the adaptor of the Dash Diazepam Product. *See id.*

41. On information and belief, the heat-shrinkable film covering portions of the Dash Diazepam Product does not cover the distal end of the ring and allows access to the internal threading of the adaptor without removal of any portion of the heat-shrinkable film covering at least part of the syringe and at least part of the adaptor. *See id.*

42. On information and belief, the heat-shrinkable film covering portions of the Dash Diazepam Product maintains the adaptor blocked in rotation and in translation with respect to the syringe when the heat-shrinkable film is in its heat-shrunk condition. *See id.*

43. On information and belief, Natco has made, used, offered for sale, sold, distributed and/or imported, and continues to make, use, offer for sale, sell, distribute, and/or import, the infringing Dash Diazepam Product in the United States. Such conduct constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '082 patent under 35 U.S.C. § 271(a).

44. On information and belief, prior to this Complaint and at least as of the filing date of this Complaint, Natco knew, should have known, or was willfully blind to the existence of the '082 patent and, further, that its manufacturing, using, offering for sale, selling, distribution and/or importation of the Dash Diazepam Product would infringe the '082 patent, at least based on Fresenius' prior distribution and sales of its Simplist[®] Diazepam Injection product, marked as practicing the '082 patent.

45. On information and belief, Natco has no reasonable basis for believing that it does not infringe the '082 patent, that the '082 patent is invalid, or that the '082 patent is otherwise unenforceable.

Case 1:24-cv-00472-UNA Document 1 Filed 04/12/24 Page 10 of 18 PageID #: 10

46. On information and belief, despite Natco's knowledge of and/or willful blindness to the '082 patent and Natco's knowledge and/or willful blindness regarding the Dash Diazepam Product's infringement of the '082 patent, Natco has actively distributed for sale and encouraged medical care providers, healthcare professionals and/or other customers to use the Dash Diazepam Product, through at least its Package Insert instructions and its marketing of the product on its website. On information and belief, the medical care providers, healthcare professionals, and/or other customers that Natco has encouraged, and continues to encourage, directly infringe one or more claims of the '082 patent by using the Dash Diazepam Product in response to Natco's encouragement. As a result of these actions Natco's conduct constitutes infringement of one or more claims of the '082 patent under 35 U.S.C. § 271(b).

47. On information and belief, Natco manufactures, uses, offers to sell, sells, distributes, and/or imports into the United States the Dash Diazepam Product for distribution, sale, and use by medical care providers, healthcare professionals, and/or other customers, knowing that the Dash Diazepam Product is especially made or adapted for use in a manner that infringes the '082 patent, with the Dash Diazepam Product constituting a material part of the claimed invention and not a staple article of commerce capable of substantial non-infringing use. On information and belief, the medical care providers, healthcare professionals and/or other customers that have used and use the Dash Diazepam Product directly infringe one or more claims of the '082 patent. Natco's conduct thus constitutes infringement of one or more claims of the '082 patent under 35 U.S.C. § 271(c).

48. On information and belief, Natco imports, sells, offers to sell, distributes and uses the Dash Diazepam Product, which is manufactured abroad by the process patented in at least claim 14 of the '082 patent. Such conduct constitutes infringement of one or more claims of the

'082 patent under 35 U.S.C. § 271(g).

49. Natco's unlawful infringement activities have caused and will continue to cause Fresenius substantial and irreparable harm.

50. The harm Fresenius has suffered and will continue to suffer is irreparable and cannot be sufficiently compensated through monetary damages. This harm includes, but is not limited to, loss of business opportunities, loss of market share, price erosion, loss of goodwill, and direct and indirect competition for its Simplist[®] Diazepam Injection product in the United States. Accordingly, Fresenius is entitled to preliminary and permanent injunctive relief. The public interest would not be disserved by injunctive relief.

51. On information and belief, Natco's infringement of the '082 patent was, and remains, willful, justifying the assessment of treble damages pursuant to 35 U.S.C. § 284.

SECOND CAUSE OF ACTION

(Infringement of the '018 Patent)

52. Fresenius incorporates by reference paragraphs 1-51.

53. On information and belief, Natco's Dash Diazepam Product satisfies each and every limitation, either literally or under the doctrine of equivalents, of one or more claims of the '018 patent, including at least claim 1 as follows.

54. To the extent the preamble is limiting, on information and belief, the Dash Diazepam Product comprises an assembly at least because it is a prefilled syringe. *See, e.g.*, Dash Diazepam Product Video.

55. On information and belief, the Dash Diazepam Product is an injection device comprising a container for a product, said container comprising a distal tip encompassing a channel providing a passageway for transfer of said product. On information and belief, the Dash Diazepam Product is an injection device comprising a prefilled syringe that contains diazepam and

Case 1:24-cv-00472-UNA Document 1 Filed 04/12/24 Page 12 of 18 PageID #: 12

that has a distal tip that provides a channel through which the diazepam can be transferred. See id.

56. On information and belief, the Dash Diazepam Product has an adaptor comprising a ring mounted onto said distal tip. *See id.*

57. On information and belief, the ring adaptor of the Dash Diazepam Product includes an internally threaded portion and an inner projection extending radially inwardly and the ring of the adaptor is mounted on the distal tip by friction between the inner projection of the adaptor and the distal tip of the Dash Diazepam Product. *See id.*

58. On information and belief, the distal tip of the Dash Diazepam Product extends into the internally threaded portion of the adaptor and the distal end of the distal tip is disposed beyond the distal end of the adaptor. *See id.*

59. On information and belief, the Dash Diazepam Product has a plug mounted on its adaptor. *See id.*

60. On information and belief, the Dash Diazepam Product has a heat-shrinkable film covering at least part of the syringe of the Dash Diazepam Product, the adaptor of the Dash Diazepam Product, and at least part of the plug of the Dash Diazepam Product. *See id.*

61. On information and belief, the heat-shrinkable film covering portions of the Dash Diazepam Product maintains the adaptor blocked in rotation and in translation with respect to the syringe when the heat-shrinkable film is in its heat-shrunk condition. *See id.*

62. On information and belief, Natco has made, used, offered for sale, sold, distributed and/or imported, and continues to make, use, offer for sale, sell, distribute, and/or import, the infringing Dash Diazepam Product in the United States. Such conduct constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '018 patent under 35 U.S.C. § 271(a).

Case 1:24-cv-00472-UNA Document 1 Filed 04/12/24 Page 13 of 18 PageID #: 13

63. On information and belief, prior to this Complaint and at least as of the filing date of this Complaint, Natco knew, should have known, or was willfully blind to the existence of the '018 patent and, further, that its manufacturing, using, offering for sale, selling, distribution and/or importation of the Dash Diazepam Product would infringe the '018 patent, at least based on Fresenius' prior distribution and sales of its Simplist[®] Diazepam Injection product, marked as practicing the '018 patent.

64. On information and belief, Natco has no reasonable basis for believing that it does not infringe the '018 patent, that the '018 patent is invalid, or that the '018 patent is otherwise unenforceable.

65. On information and belief, despite Natco's knowledge of and/or willful blindness to the '018 patent and Natco's knowledge and/or willful blindness regarding the Dash Diazepam Product's infringement of the '018 patent, Natco has actively distributed for sale and encouraged medical care providers, healthcare professionals and/or other customers to use the Dash Diazepam Product, through at least its Package Insert instructions and its marketing of the product on its website. On information and belief, the medical care providers, healthcare professionals, and/or other customers that Natco has encouraged, and continues to encourage, directly infringe one or more claims of the '018 patent by using the Dash Diazepam Product in response to Natco's encouragement. As a result of these actions Natco's conduct constitutes infringement of one or more claims of the '018 patent under 35 U.S.C. § 271(b).

66. On information and belief, Natco manufactures, uses, offers to sell, sells, distributes, and/or imports into the United States the Dash Diazepam Product for distribution, sale, and use by medical care providers, healthcare professionals, and/or other customers, knowing that the Dash Diazepam Product is especially made or adapted for use in a manner that infringes the

Case 1:24-cv-00472-UNA Document 1 Filed 04/12/24 Page 14 of 18 PageID #: 14

'018 patent, with the Dash Diazepam Product constituting a material part of the claimed invention and not a staple article of commerce capable of substantial non-infringing use. On information and belief, the medical care providers, healthcare professionals, and/or other customers that have used and use the Dash Diazepam Product directly infringe one or more claims of the '018 patent. Natco's conduct thus constitutes infringement of one or more claims of the '018 patent under 35 U.S.C. § 271(c).

67. Natco's unlawful infringement activities have caused and will continue to cause Fresenius substantial and irreparable harm.

68. The harm Fresenius has suffered and will continue to suffer is irreparable and cannot be sufficiently compensated through monetary damages. This harm includes, but is not limited to, loss of business opportunities, loss of market share, price erosion, loss of goodwill, and direct and indirect competition for its Simplist[®] Diazepam Injection product in the United States. Accordingly, Fresenius is entitled to preliminary and permanent injunctive relief. The public interest would not be disserved by injunctive relief.

69. On information and belief, Natco's infringement of the '018 patent was, and remains, willful, justifying the assessment of treble damages pursuant to 35 U.S.C. § 284.

THIRD CAUSE OF ACTION

(Infringement of the '522 Patent)

70. Fresenius incorporates by reference paragraphs 1-69.

71. On information and belief, Natco's Dash Diazepam Product satisfies each and every limitation, either literally or under the doctrine of equivalents, of one or more claims of the '522 patent, including at least claim 1, as follows.

72. To the extent the preamble is limiting, on information and belief, the Dash Diazepam Product comprises an assembly at least because it is a prefilled syringe. *See, e.g.*, Dash

Diazepam Product Video.

73. On information and belief, the Dash Diazepam Product is a container having a reservoir configured to contain a product and a distal tip having a channel configured to transfer the product. On information and belief, the Dash Diazepam Product is a prefilled syringe having a reservoir configured to contain a product, namely a diazepam injection, and a distal tip having a channel configured to transfer the product (i.e., the diazepam injection). *See id.*

74. On information and belief, the Dash Diazepam Product has an adaptor mounted onto its distal tip.

75. On information and belief, the adaptor mounted onto the distal tip of the Dash Diazepam Product has an internal thread.

76. On information and belief, the distal tip of the Dash Diazepam Product extends into the adaptor and the distal end of the distal tip extends beyond the distal end of the adaptor. *See id.*

77. On information and belief, the Dash Diazepam Product has a sheet fixing the adaptor of the Dash Diazepam Product with respect to the syringe. *See id.*

78. On information and belief, Natco has made, used, offered for sale, sold, distributed and/or imported, and continues to make, use, offer for sale, sell, distribute, and/or import, the infringing Dash Diazepam Product in the United States. Such conduct constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '522 patent under 35 U.S.C. § 271(a).

79. On information and belief, prior to this Complaint and at least as of the filing date of this Complaint, Natco knew, should have known, or was willfully blind to the existence of the '522 patent and, further, that its manufacturing, using, offering for sale, selling, distribution and/or importation of the Dash Diazepam Product would infringe the '522 patent, at least based on

Case 1:24-cv-00472-UNA Document 1 Filed 04/12/24 Page 16 of 18 PageID #: 16

Fresenius' prior distribution and sales of its Simplist[®] Diazepam Injection product, marked as practicing the '082 and '018 patents which are the grandparent and parent patents, respectively, to the '522 patent.

80. On information and belief, Natco has no reasonable basis for believing that it does not infringe the '522 patent, that the '522 patent is invalid, or that the '522 patent is otherwise unenforceable.

81. On information and belief, despite Natco's knowledge of and/or willful blindness to the '522 patent and Natco's knowledge and/or willful blindness regarding the Dash Diazepam Product's infringement of the '522 patent, Natco has actively distributed for sale and encouraged medical care providers, healthcare professionals and/or other customers to use the Dash Diazepam Product, through at least its Package Insert instructions and its marketing of the product on its website. On information and belief, the medical care providers, healthcare professionals, and/or other customers that Natco has encouraged, and continues to encourage, directly infringe one or more claims of the '522 patent by using the Dash Diazepam Product in response to Natco's encouragement. As a result of these actions Natco's conduct constitutes infringement of one or more claims of the '522 patent under 35 U.S.C. § 271(b).

82. On information and belief, Natco manufactures, uses, offers to sell, sells, distributes, and/or imports into the United States the Dash Diazepam Product for distribution, sale, and use by medical care providers, healthcare professionals, and/or other customers, knowing that the Dash Diazepam Product is especially made or adapted for use in a manner that infringes the '522 patent, with the Dash Diazepam Product constituting a material part of the claimed invention and not a staple article of commerce capable of substantial non-infringing use. On information and belief, the medical care providers, healthcare professionals and/or other customers that have

Case 1:24-cv-00472-UNA Document 1 Filed 04/12/24 Page 17 of 18 PageID #: 17

used and use the Dash Diazepam Product directly infringe one or more claims of the '522 patent. Natco's conduct thus constitutes infringement of one or more claims of the '522 patent under 35 U.S.C. § 271(c).

83. Natco's unlawful infringement activities have caused and will continue to cause Fresenius substantial and irreparable harm.

84. The harm Fresenius has suffered and will continue to suffer is irreparable and cannot be sufficiently compensated through monetary damages. This harm includes, but is not limited to, loss of business opportunities, loss of market share, price erosion, loss of goodwill, and direct and indirect competition for its Simplist[®] Diazepam Injection product in the United States. Accordingly, Fresenius is entitled to preliminary and permanent injunctive relief. The public interest would not be disserved by injunctive relief.

85. On information and belief, Natco's infringement of the '522 patent was, and remains, willful, justifying the assessment of treble damages pursuant to 35 U.S.C. § 284.

DEMAND FOR RELIEF

WHEREFORE, Fresenius respectfully requests the following relief:

a) That this Court adjudge and decree that Natco has infringed the Asserted Patents in violation of 35 U.S.C. § 271(a), (b), (c), and/or (g);

b) That this Court enter preliminary and permanent injunctions against Natco, barring and enjoining Natco and its officers, employees, agents, servants, and those in privity with them from continuing to infringe the Asserted Patents;

c) That this Court order Natco to pay damages to Fresenius to compensate Fresenius for Natco's infringement of the Asserted Patents, together with pre- and post-judgment interest and costs pursuant to 35 U.S.C. § 284, including any supplemental damages that accrue between

the close of fact discovery and the date a final judgment is entered in this litigation;

d) That this Court determine that Natco's infringement was willful and award Fresenius enhanced damages for such infringement in accordance with 35 U.S.C. § 284;

e) That this Court enter an order for a post-judgment equitable accounting of damage pursuant to 35 U.S.C. § 283;

f) That this Court determine that this patent infringement case is exceptional under 35

U.S.C. § 285 and award Fresenius its costs and attorneys' fees incurred in this action; and

g) That this Court award such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Fresenius respectfully requests a trial by jury on all issues triable thereby.

OF COUNSEL: John T. Bennett ALLEN & OVERY LLP One Beacon Street Boston, MA 02108 (847) 353-4500

Christopher P. Galligan Megan M. Ines ALLEN & OVERY LLP 1101 New York Avenue, NW Washington, D.C. 20005 (202) 683-3800

Dated: April 12, 2024

/s/ Karen E. Keller

Karen E. Keller (No. 4489) Nathan R. Hoeschen (No. 6232) Emily S. DiBenedetto (No. 6779) SHAW KELLER LLP I.M. Pei Building 1105 North Market Street, 12th Floor Wilmington, DE 19801 (302) 298-0700 kkeller@shawkeller.com nhoeschen@shawkeller.com edibenedetto@shawkeller.com *Attorneys for Plaintiffs*