IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAXTER HEALTHCARE CORPORATION, *Plaintiff*, v. NEVAKAR INJECTABLES, INC., *Defendant*.	C.A. No. 21-1184-CJB

BAXTER HEALTHCARE CORPORATION'S
FIRST SUPPLEMENTAL COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Baxter Healthcare Corporation ("Baxter"), by and through the undersigned attorneys and for its Complaint against Nevakar Injectables, Inc. ("Nevakar Injectables") (collectively, "Defendant"), alleges as follows:

1. Baxter brings this action to obtain declaratory relief against Nevakar Injectables, under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that Baxter's Norepinephrine Bitartrate in 5% Dextrose Injection, 0.016 mg/mL and 0.032 mg/mL products ("Baxter's Norepinephrine Bitartrate Products") do not infringe U.S. Patent Nos. 10,420,735 ("the '735 patent"); 10,471,026 ("the '026 patent"); 10,568,850 ("the '850 patent"); 10,646,458 ("the '458 patent"); and 11,602,508 ("the '508 patent") (collectively the "Patents at Issue"), and/or that such patents are invalid.

2. Baxter is a healthcare company that develops, manufactures, and markets, among other things, quality intravenous drug products, including ready-to-use intravenous drug products.

3. Baxter is considered an innovator and leader in the field of ready-to-use intravenous drug products.

4. Baxter introduced its first ready-to-use intravenous drug product in 1974 and has since invested significantly in research and development to bring these important products to market.

PARTIES

5. Plaintiff Baxter is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015.

6. Baxter is the holder of New Drug Application No. 214313 for Norepinephrine Bitartrate in 5% Dextrose Injection, which has been approved to raise blood pressure in adult patients with severe, acute hypotension.

7. On information and belief, Defendant Nevakar Injectables is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1019 US Highway 202-206, Building K, NJ Center of Excellence, Bridgewater, New Jersey 08807.

JURISDICTION AND VENUE

8. Baxter brings this declaratory judgment action under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties for a declaration that Baxter's Norepinephrine Bitartrate Products that are the subject of Baxter's 505(b)(2) NDA do not and will not infringe the Patents at Issue, and/or that the Patents at Issue are invalid.

9. This Court has original subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a); and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Baxter seeks a declaration that the manufacture, use, sale, offer for sale, and/or importation of

Baxter's Norepinephrine Bitartrate Products do not constitute infringement of the Patents at Issue, and/or that the Patents at Issue are invalid, which on information and belief, Defendant has the right to enforce. Pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, this Court is authorized to provide declaratory relief relating to the subject matter of this action, and Baxter is entitled to a judgment from this Court with respect to the subject matter of this action.

10. This is an action for declaratory judgment in a case of actual controversy pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

11. An actual and justiciable controversy exists between Baxter and Nevakar Injectables, at the very least, concerning the issue of whether Baxter's manufacture, use, offer for sale, sale, and/or importation of Baxter's Norepinephrine Bitartrate Products would infringe any valid or enforceable claim of the Patents at Issue.

12. A judicial declaration confirming that the manufacture, use, offer for sale, sale, and/or importation of Baxter's Norepinephrine Bitartrate Products would not, and does not, constitute infringement of any valid or enforceable claim of the Patents at Issue, is necessary and appropriate to resolve this controversy.

13. This Court has personal jurisdiction over Nevakar Injectables. On information and belief, Nevakar Injectables conducts substantial business in, and has regular systematic contact with, this District. On information and belief, Nevakar Injectables is in the business of, among other things, researching, developing, manufacturing, marketing, and/or selling pharmaceutical products throughout the United States, including in Delaware. On information and belief, Nevakar Injectables, directly or indirectly, researches, develops, manufactures, markets, and/or sells pharmaceutical products throughout the United States, including in Delaware.

14. On information and belief, Nevakar Injectables purposefully has conducted, and continues to conduct, substantial business in this District, including but not limited to the manufacture and sale of pharmaceutical products to Delaware residents; and it regularly solicits business from, does business with, and derives revenue from such goods provided to customers in Delaware.

15. On information and belief, Nevakar Injectables is a corporation organized and existing under the laws of Delaware.

16. On information and belief, Nevakar Injectables is registered to do business in Delaware.

17. On information and belief, Nevakar has purposely availed itself of the jurisdiction of this Court, including, but not limited to, by filing suit in, or removing actions to, this District: *Nevakar Injectables, Inc. v. Baxter Healthcare Corporation*, 1:21-cv-01186 (CJB).

18. Venue is proper in this District pursuant to 28 U.S.C. § 1391.

FACTUAL BACKGROUND

A. The Drug Approval Process.

19. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the FDA, typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a). The sponsor of the NDA generally must submit, among other things, technical data on the composition of the drug, the means for manufacturing it, clinical trial results to establish the safety and efficacy of the drug, and labeling for use of the drug for which approval is requested. *See* 21 U.S.C. § 355(b)(1).

20. On the other hand, a company seeking FDA approval to market a generic version of a previously approved drug is not required to submit a full NDA. For example, the company

may submit an NDA under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), known as the "505(b)(2) pathway." *See* 21 U.S.C. § 355(b)(2).

21. Under the 505(b)(2) pathway, an applicant may submit an NDA for a change to or modification of a reference listed drug ("RLD") that FDA has found to be safe and effective. *See id.* A 505(b)(2) NDA contains clinical data demonstrating safety and effectiveness of the drug, but differs from a full or stand-alone NDA because some of the safety and/or efficacy data are not generated by or at the request of the applicant, but are found in the RLD application or scientific literature. The sponsor typically must provide additional data to ensure that differences from the RLD do not compromise safety and effectiveness. Based on the data and information provided by a 505(b)(2) applicant, the FDA will make a determination as to whether or not the application may be approved.

22. As such, the 505(b)(2) pathway offers companies an important option for gaining a more rapid determination that its product is safe and effective and ultimately providing critical alternative treatments to patients in need.

B. Baxter's Norepinephrine Bitartrate in 5% Dextrose Injection NDA.

23. On March 16, 2020, Baxter submitted an NDA pursuant to section 505(b)(2) of the FFDCA seeking approval for Baxter's Norepinephrine Bitartrate Products. FDA assigned Baxter's NDA No. 214313.

24. On or about January 15, 2021, after undergoing regulatory review, the FDA approved Baxter's NDA No. 214313 for the use of Baxter's Norepinephrine Bitartrate Products under § 505(b)(2) of the FFDCA to raise blood pressure in adult patients with severe, acute hypotension.

25. On or about September 23, 2021, Baxter announced FDA's approval of NDA No. 214313 and the commercial launch of its Norepinephrine Bitartrate Products in short order, as it is lawfully entitled to do in view of FDA's approval of NDA No. 214313.

26. Baxter's Norepinephrine Bitartrate Products is used to raise blood pressure in adult patients with severe, acute hypotension or shock, including for patients with COVID-19 in an intensive care unit setting.

27. Baxter's Norepinephrine Bitartrate Products are the only ready-to-use norepinephrine bitartrate products commercially available on the U.S. market,and provide an important new and safe treatment option for patients, including for patients with COVID-19 in an intensive care unit setting.

C. The Patents At Issue.

28. On its face, the '735 patent is titled "NOREPINEPHRINE COMPOSITIONS AND METHODS THEREFOR," and indicates it was issued by the PTO on September 24, 2019. A true and correct copy of the '735 patent is attached as Exhibit A.

29. The '735 patent lists Tushar Hingorani, Prem Sagar Akasapu, and Kumaresh Soppimath as the purported named inventors.

30. According to the face of the '735 patent and the PTO's online records, Nevakar Inc. is the assignee of the '735 patent. Based on information and belief, Nevakar Inc. assigned its rights in the '735 patent to Nevakar on July 31, 2021.

31. According to online records at the PTO, the '735 patent purportedly will expire on or about January 30, 2038.

32. Baxter's Norepinephrine Bitartrate Product does not infringe any valid or enforceable claim of the '735 patent, either literally or under the doctrine of equivalents.

33. On its face, the '026 patent is titled "NOREPINEPHRINE COMPOSITIONS AND METHODS THEREFOR," and indicates it was issued by the PTO on November 12, 2019. A true and correct copy of the '026 patent is attached as Exhibit B.

34. The '026 patent lists Tushar Hingorani, Prem Sagar Akasapu, and Kumaresh Soppimath as the purported named inventors.

35. According to the face of the '026 patent and the PTO's online records, Nevakar Inc. is the assignee of the '026 patent. Based on information and belief, Nevakar Inc. assigned its rights in the '026 patent to Nevakar on July 31, 2021.

36. According to online records at the PTO, the '026 patent purportedly will expire on or about January 30, 2038.

37. Baxter's Norepinephrine Bitartrate Product does not infringe any valid or enforceable claim of the '026 patent, either literally or under the doctrine of equivalents.

38. On its face, the '850 patent is titled "NOREPINEPHRINE COMPOSITIONS AND METHODS THEREFOR," and indicates it was issued by the PTO on February 25, 2020. A true and correct copy of the '850 patent is attached as Exhibit C.

39. The '850 patent lists Tushar Hingorani, Prem Sagar Akasapu, and Kumaresh Soppimath as the purported named inventors.

40. According to the face of the '850 patent and the PTO's online records, Nevakar Inc. is the assignee of the '850 patent. Based on information and belief, Nevakar Inc. assigned its rights in the '850 patent to Nevakar on July 31, 2021.

41. According to online records at the PTO, the '850 patent purportedly will expire on or about January 30, 2038.

42. Baxter's Norepinephrine Bitartrate Product does not infringe any valid or enforceable claim of the '850 patent, either literally or under the doctrine of equivalents.

43. On its face, the '458 patent is titled "NOREPINEPHRINE COMPOSITIONS AND METHODS THEREFOR," and indicates it was issued by the PTO on May 12, 2020. A true and correct copy of the '458 patent is attached as Exhibit D.

44. The '458 patent lists Tushar Hingorani, Prem Sagar Akasapu, and Kumaresh Soppimath as the purported named inventors.

45. According to the face of the '458 patent, Nevakar Inc. is the assignee of the '458 patent; however, according to the PTO's online records, Nevakar Injectables is the assignee of the '458 patent. Based on information and belief, Nevakar Inc. assigned its rights in the '458 patent to Nevakar on July 31, 2021.

46. According to online records at the PTO, the '458 patent purportedly will expire on or about January 30, 2038.

47. Baxter's Norepinephrine Bitartrate Product does not infringe any valid or enforceable claim of the '458 patent, either literally or under the doctrine of equivalents.

48. On its face, the '508 patent is titled "NOREPINEPHRINE COMPOSITIONS AND METHODS THEREFOR," and indicates it was issued by the PTO on March 14, 2023. A true and correct copy of the '508 patent is attached as Exhibit E.

49. The '508 patent lists Tushar Hingorani and Kumaresh Soppimath as the purported named inventors.

50. According to the face of the '508 patent, Nevakar Injectables is the assignee of the '508 patent.

51. According to online records at the PTO, the '508 patent purportedly will expire on or about January 30, 2038.

52. Baxter's Norepinephrine Bitartrate Product does not infringe any valid or enforceable claim of the '508 patent, either literally or under the doctrine of equivalents.

D. Defendant Nevakar's Threats of Litigation.

53. There is a substantial and continuing controversy between Baxter and Nevakar Injectables and a declaration of rights is both necessary and appropriate to establish that Baxter does not infringe any valid or enforceable claim of the '735, '026, '850, '458 and '508 patents and allow Baxter to bring its Norepinephrine Bitartrate Products to market.

54. On February 19, 2021, Endo Pharmaceuticals, Inc. ("Endo"), through Endo's counsel, Matthew Maletta, sent an initial "threat letter" to Baxter asserting an intent to file a patent infringement suit. In this letter, Endo specifically asserted that Par Sterile Products, LLC ("Par") "develops, manufactures, and markets a broad portfolio of sterile injectable products." In this letter, Endo asserted that Par "invested significant resources in developing technology relating to ready-to-administer Norepinephrine" and that "[t]his technology is protected by a number of patents," specifically identified the '735, '026, '850 and '458 patents, and asserted that Par is "an exclusive licensee" of the '735, '026, '850 and '458 patents, amongst others. In this letter, Par and Endo not only specifically notified Baxter about the '735, '026, '850 and '458 patents, but also threatened litigation if Baxter launched its proposed Norepinephrine Bitartrate Products and failed to respect and take into account the '735, '026, '850 and '458 patents. (*See* Exhibit F, 2/19/21 Endo Ltr. To Baxter). On information and belief, Endo was authorized to make the representations set forth in the February 19, 2021 letter on behalf of Defendant Nevakar Injectables.

55. On August 11, 2021, Endo, through Endo's counsel, Matthew Maletta, sent a second "threat letter" via electronic mail to Baxter, again asserting an intent to file a patent infringement suit. In this August 11 email, Endo asserted that if "Baxter is preparing to launch" Baxter's Norepinephrine Bitartrate Products, "such a launch would infringe our subsidiary Par's intellectual property" as previously set forth in the letter of February 19, 2021 (Exhibit G, 8/11/21 Endo E-mail to Baxter). Furthermore, in this August 11 email, Endo demanded an answer by August 13, 2021, as to whether Baxter intended to launch Baxter's Norepinephrine Bitartrate Products. In this electronic mail, Endo specifically threatened litigation involving the '735, '026, '850 and '458 patents, and threatened that it will take "prompt legal action to defend its intellectual property rights" if Baxter did not respond by August 13, 2021, about its intent to launch. (*See* Exhibit G, 8/11/21 Endo Email to Baxter). On information and belief, Endo was authorized to make the representations set forth in the August 11, 2021 letter on behalf of Defendant Nevakar Injectables.

56. On August 12, 2021, Baxter, through its Counsel at that time, Derek Johnson, responded to Endo's "threat letters" (Exhibit H, 8/12/21 Baxter Ltr.). In this letter, Baxter began by noting that it is in fact the "innovator and leader in the field of ready-to-use products," such as Baxter's Norepinephrine Bitartrate Products, since 1974 and has invested significant resources in bringing these products to market. In this letter, Baxter also noted that Baxter's Norepinephrine Bitartrate Products are the only ready-to-use Norepinephrine Bitrate products approved by FDA and will provide an important new and safe treatment option to patients. In this letter, Baxter further stated that it not only respects the intellectual property rights of others, but also has assessed the '735, '026, '850 and '458 patents, and found no basis for a claim of infringement, and further stated that there are good faith grounds to challenge the validity of the '735, '026, '850 and '458

patents, including obviousness. Baxter, in this August 12, 2021 letter, offered to discuss the '735, '026, '850 and '458 patents at a "mutually convenient" time.

57. On August 17, 2021, Derek Johnson, counsel for Baxter at that time, and Gina R. Gencarelli, counsel for Endo, participated in a telephone call to discuss the '735, '026, '850 and '458 patents, among other things. During this call, Ms. Gencarelli repeated the assertion that Baxter's Norepinephrine Bitartrate Products infringe the '735, '026, '850 and '458 patents, that Endo did not need any additional documentation or any internal Baxter data to further assess infringement, and that Endo, Par, and Nevakar Injectables were prepared to file a complaint along with a request for a preliminary injunction and temporary restraining order, but would delay doing so if Baxter would consider settlement. Ms. Gencarelli also confirmed during this call that Endo, Par, and/or Nevakar Injectables do not have competing ready-to-use Norepinephrine Bitartrate products on the market. (*See* Exhibit I, 8/18/21 Declaration of Derek Johnson). On information and belief, Endo was authorized to participate in the August 17, 2021 telephone call on behalf of Defendant Nevakar Injectables.

58. On August 18, 2021, Endo Ventures Limited ("Endo"), Par Sterile Products, LLC ("Par"), and Nevakar Injectables filed suit against Baxter in this District alleging, *inter alia*, infringement of the '735, '026, '850 and '458 patents, amongst other patents ("Nevakar Injectable's Complaint").

59. On March 2, 2023, Defendant Nevakar Injectables, through Nevakar Injectables' counsel, Alexandra Haner, sent an e-mail to Baxter asserting an intent to amend or supplement Nevakar Injectable's Complaint to add the '508 patent to the litigation once the patent had issued. (Exhibit J, 3/2/23 Nevakar E-mail).

60. In view of at least the threats of litigation in the "threat letters" of February 19 and August 11, 2021, as well as the threats of litigation explicitly communicated during the telephone call of August 17, 2021 and the e-mail of March 2, 2023, and Nevakar Injectables' history of bringing patent infringement matters and asserting its patents, Nevakar Injectables poses an immediate and real threat of litigation against Baxter.

61. To avoid legal uncertainty and to protect Baxter's substantial investment (and anticipated future investment) in Baxter's Norepinephrine Bitartrate Products, Baxter respectfully seeks declaratory relief with respect to the Patents at Issue.

62. Baxter has not stipulated to or otherwise consented to the validity, infringement, or enforceability of the Patents at Issue.

63. The totality of the circumstances support that a case or controversy exists with respect to the non-infringement and invalidity of the Patents at Issue.

64. The totality of the circumstances gives rise to an actual and justiciable controversy between Nevakar Injectables and Baxter as to the non-infringement and invalidity of the Patents at Issue. Absent a declaration of non-infringement and invalidity, Nevakar Injectables' continued wrongful assertions of infringement will cause Baxter harm.

65. In proving that Baxter does not infringe any valid or enforceable claim of the Patents at Issue, such a judgment will remove any existing uncertainty that precludes commercial manufacture, use, importation, offer for sale, and/or sale of Baxter's Norepinephrine Bitartrate Products before the expiration of the Patents at Issue.

66. Baxter brought Baxter's Norepinephrine Bitartrate Products to market to allow the public and payors to enjoy and reap the benefits of competition for this product in view of its NDA approval.

COUNT I
DECLARATORY JUDGMENT OF NO PATENT INFRINGEMENT
OF U.S. PATENT NO. 10,420,735

67. Baxter realleges and incorporates by reference the allegations of paragraphs 1-66, above, as if fully set forth herein.

68. Baxter seeks a judgment from this Court that Baxter's Norepinephrine Bitartrate Products do not infringe any valid or enforceable claim of the '735 patent.

69. A present, genuine, and justiciable controversy exists between Baxter and Defendant concerning, *inter alia*, the issue of whether Baxter's manufacture, use, offer for sale, sale, and/or importation of Baxter's Norepinephrine Bitartrate Products would infringe any valid or enforceable claim of the '735 patent.

70. Pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, Baxter is entitled to a judgment from this Court that Baxter's manufacture, use, sale, offer for sale, and/or importation of Baxter's Norepinephrine Bitartrate Products would not infringe any valid or enforceable claim of the '735 patent.

COUNT II
DECLARATORY JUDGMENT OF INVALIDITY
OF U.S. PATENT NO. 10,420,735

71. Baxter realleges and incorporates by reference the allegations of paragraphs 1-70, above, as if fully set forth herein.

72. Baxter seeks a judgment from this Court that the '735 patent is invalid.

73. A present, genuine, and justiciable controversy exists between Baxter and Defendant concerning, *inter alia*, the validity of the '735 patent.

74. Baxter is entitled to a declaratory judgment that the claims of the '735 patent are invalid for failing to comply with one or more of the conditions and requirements for patentability

under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112 and/or non-statutory double patenting.

COUNT III
DECLARATORY JUDGMENT OF NO PATENT INFRINGEMENT
OF U.S. PATENT NO. 10,471,026

75. Baxter realleges and incorporates by reference the allegations of paragraphs 1-74, above, as if fully set forth herein.

76. Baxter seeks a judgment from this Court that Baxter's Norepinephrine Bitartrate Products do not infringe any valid or enforceable claim of the '026 patent.

77. A present, genuine, and justiciable controversy exists between Baxter and Defendant concerning, *inter alia*, the issue of whether Baxter's manufacture, use, offer for sale, sale, and/or importation of Baxter's Norepinephrine Bitartrate Products would infringe any valid or enforceable claim of the '026 patent.

78. Pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, Baxter is entitled to a judgment from this Court that Baxter's manufacture, use, sale, offer for sale, and/or importation of Baxter's Norepinephrine Bitartrate Products would not infringe any valid or enforceable claim of the '026 patent.

COUNT IV
DECLARATORY JUDGMENT OF INVALIDITY
OF U.S. PATENT NO. 10,471,026

79. Baxter realleges and incorporates by reference the allegations of paragraphs 1-78, above, as if fully set forth herein.

80. Baxter seeks a judgment from this Court that the '026 patent is invalid.

81. A present, genuine, and justiciable controversy exists between Baxter and Defendant concerning, *inter alia*, the validity of the '026 patent.

82. Baxter is entitled to a declaratory judgment that the claims of the '026 patent are invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112 and/or non-statutory double patenting.

COUNT V
DECLARATORY JUDGMENT OF NO PATENT INFRINGEMENT
OF U.S. PATENT NO. 10,568,850

83. Baxter realleges and incorporates by reference the allegations of paragraphs 1-82, above, as if fully set forth herein.

84. Baxter seeks a judgment from this Court that Baxter's Norepinephrine Bitartrate Products do not infringe any valid or enforceable claim of the '850 patent.

85. A present, genuine, and justiciable controversy exists between Baxter and Defendant concerning, *inter alia*, the issue of whether Baxter's manufacture, use, offer for sale, sale, and/or importation of Baxter's Norepinephrine Bitartrate Products would infringe any valid or enforceable claim of the '850 patent.

86. Pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, Baxter is entitled to a judgment from this Court that Baxter's manufacture, use, sale, offer for sale, and/or importation of Baxter's Norepinephrine Bitartrate Products would not infringe any valid or enforceable claim of the '850 patent.

COUNT VI
DECLARATORY JUDGMENT OF INVALIDITY
OF U.S. PATENT NO. 10,568,850

87. Baxter realleges and incorporates by reference the allegations of paragraphs 1-86, above, as if fully set forth herein.

88. Baxter seeks a judgment from this Court that the '850 patent is invalid.

89. A present, genuine, and justiciable controversy exists between Baxter and Defendant concerning, *inter alia*, the validity of the '850 patent.

90. Baxter is entitled to a declaratory judgment that the claims of the '850 patent are invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112 and/or non-statutory double patenting.

COUNT VII
DECLARATORY JUDGMENT OF NO PATENT INFRINGEMENT
OF U.S. PATENT NO. 10,646,458

91. Baxter realleges and incorporates by reference the allegations of paragraphs 1-90, above, as if fully set forth herein.

92. Baxter seeks a judgment from this Court that Baxter's Norepinephrine Bitartrate Products does not infringe any valid or enforceable claim of the '458 patent.

93. A present, genuine, and justiciable controversy exists between Baxter and Defendant concerning, *inter alia*, the issue of whether Baxter's manufacture, use, offer for sale, sale, and/or importation of Baxter's Norepinephrine Bitartrate Products would infringe any valid or enforceable claim of the '458 patent.

94. Pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, Baxter is entitled to a judgment from this Court that Baxter's manufacture, use, sale, offer for sale, and/or importation of Baxter's Norepinephrine Bitartrate Products would not infringe any valid or enforceable claim of the '458 patent.

COUNT VIII
DECLARATORY JUDGMENT OF INVALIDITY
OF U.S. PATENT NO. 10,646,458

95. Baxter realleges and incorporates by reference the allegations of paragraphs 1-94, above, as if fully set forth herein.

96. Baxter seeks a judgment from this Court that the '458 patent is invalid.

97. A present, genuine, and justiciable controversy exists between Baxter and Defendant concerning, *inter alia*, the validity of the '458 patent.

98. Baxter is entitled to a declaratory judgment that the claims of the '458 patent are invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112 and/or non-statutory double patenting.

COUNT IX
DECLARATORY JUDGMENT OF NO PATENT INFRINGEMENT
OF U.S. PATENT NO. 11,602,508

99. Baxter realleges and incorporates by reference the allegations of paragraphs 1-98, above, as if fully set forth herein.

100. Baxter seeks a judgment from this Court that Baxter's Norepinephrine Bitartrate Products does not infringe any valid or enforceable claim of the '508 patent.

101. A present, genuine, and justiciable controversy exists between Baxter and Defendant concerning, *inter alia*, the issue of whether Baxter's manufacture, use, offer for sale, sale, and/or importation of Baxter's Norepinephrine Bitartrate Products would infringe any valid or enforceable claim of the '508 patent.

102. Pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, Baxter is entitled to a judgment from this Court that Baxter's manufacture, use, sale, offer for sale, and/or

importation of Baxter's Norepinephrine Bitartrate Products would not infringe any valid or enforceable claim of the '508 patent.

COUNT X
DECLARATORY JUDGMENT OF INVALIDITY
OF U.S. PATENT NO. 11,602,508

103. Baxter realleges and incorporates by reference the allegations of paragraphs 1-102, above, as if fully set forth herein.

104. Baxter seeks a judgment from this Court that the '508 patent is invalid.

105. A present, genuine, and justiciable controversy exists between Baxter and Defendant concerning, *inter alia*, the validity of the '508 patent.

106. Baxter is entitled to a declaratory judgment that the claims of the '458 patent are invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112 and/or non-statutory double patenting.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Baxter Healthcare Corporation respectfully requests the following relief:

A. Declaring that the manufacture, use, offer for sale, sale, and/or importation into the United States of Baxter's Norepinephrine Bitartrate Products does not infringe any valid and enforceable claim of the '735 patent;

B. Declaring that the '735 patent is invalid;

C. Declaring that the manufacture, use, offer for sale, sale, and/or importation into the United States of Baxter's Norepinephrine Bitartrate Products does not infringe any valid and enforceable claim of the '026 patent;

D. Declaring that the '026 patent is invalid;

E. Declaring that the manufacture, use, offer for sale, sale, and/or importation into the United States of Baxter's Norepinephrine Bitartrate Products does not infringe any valid and enforceable claim of the '850 patent;

F. Declaring that the ‘850 patent is invalid;

G. Declaring that the manufacture, use, offer for sale, sale, and/or importation into the United States of Baxter’s Norepinephrine Bitartrate Products does not infringe any valid and enforceable claim of the ‘458 patent;

H. Declaring that the ‘458 patent is invalid;

I. Declaring that the manufacture, use, offer for sale, sale, and/or importation into the United States of Baxter’s Norepinephrine Bitartrate Products does not infringe any valid and enforceable claim of the ‘508 patent;

J. Declaring that the ‘508 patent is invalid;

K. Declaring that Baxter’s launch of Baxter’s Norepinephrine Bitartrate Products prior to January 30, 2038 does not constitute infringement of the ‘735 patent;

L. Declaring that Baxter’s launch of Baxter’s Norepinephrine Bitartrate Products prior to January 30, 2038 does not constitute infringement of the ‘026 patent;

M. Declaring that Baxter’s launch of Baxter’s Norepinephrine Bitartrate Products prior to January 30, 2038 does not constitute infringement of the ‘850 patent;

N. Declaring that Baxter’s launch of Baxter’s Norepinephrine Bitartrate Products prior to January 30, 2038 does not constitute infringement of the ‘458 patent;

O. Declaring that Baxter’s launch of Baxter’s Norepinephrine Bitartrate Products prior to January 30, 2038 does not constitute infringement of the ‘508 patent;

P. Entering final judgment that Baxter’s Norepinephrine Bitartrate Products do not infringe any valid or enforceable claim of the ‘735 patent;

Q. Entering final judgment that Baxter’s Norepinephrine Bitartrate Products do not infringe any valid or enforceable claim of the ‘026 patent;

R. Entering final judgment that Baxter’s Norepinephrine Bitartrate Products do not infringe any valid or enforceable claim of the ‘850 patent;

S. Entering final judgment that Baxter’s Norepinephrine Bitartrate Products do not infringe any valid or enforceable claim of the ‘458 patent;

T. Entering final judgment that Baxter’s Norepinephrine Bitartrate Products do not infringe any valid or enforceable claim of the ‘508 patent;

U. Awarding Baxter its costs, expenses and reasonable attorneys’ fees pursuant to 35 U.S.C. § 285; and

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

Of Counsel:

William A. Rakoczy
Paul J. Molino
Tara M. Raghavan
Steven J. Birkos
Conly S. Wythers
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, IL 60654
(312) 222-6300
wrakoczy@rmmslegal.com
pmolino@rmmslegal.com
traghavan@rmmslegal.com
sbirkos@rmmslegal.com
cwythers@rmmslegal.com

Dated: April 26, 2023

POTTER ANDERSON & CORROON LLP

By: */s/ Philip A. Rovner*
Philip A. Rovner (#3215)
Jonathan A. Choa (#5319)
Hercules Plaza
P.O. Box 951
Wilmington, Delaware 19899
Telephone: (302) 984-6000
provner@potteranderson.com
jchoa@potteranderson.com