

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BAXTER HEALTHCARE CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No.
PAR STERILE PRODUCTS, LLC, ENDO	)	
PHARMACEUTICALS, INC., NEVAKAR	)	
INC., and NEVAKAR INJECTABLES INC.,	)	
	)	
Defendants.	)	

**COMPLAINT FOR DECLARATORY JUDGMENT**

Plaintiff Baxter Healthcare Corporation (“Baxter”), by and through the undersigned attorneys and for its Complaint against Par Sterile Products, LLC (“Par”), Endo Pharmaceuticals, Inc. (“Endo”), Nevakar Inc. (“Nevakar”), and Nevakar Injectables Inc. (“Nevakar Injectables”) (collectively, “Defendants”), alleges as follows:

1. Baxter brings this action to obtain declaratory relief against Defendants, 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. 10,159,657 (“the ‘657 patent”); 10,226,436 (“the ‘436 patent”); 10,420,735 (“the ‘735 patent”); 10,471,026 (“the ‘026 patent”); 10,568,850 (“the ‘850 patent”); and 10,646,458 (“the ‘458 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 Par is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

8. On information and belief, Defendant Endo is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355.

9. On information and belief, Defendant Nevakar 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.

10. 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**

11. 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 does not and will not infringe the Patents at Issue, and/or that the Patents at Issue are invalid.

12. 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, Defendants have 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.

13. 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.

14. An actual and justiciable controversy exists between Baxter and Defendants, 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.

15. 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.

16. This Court has personal jurisdiction over Par. On information and belief, Par conducts substantial business in, and has regular systematic contact with, this District. On information and belief, Par 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, Par, directly or indirectly, researches, develops, manufactures, markets, and/or sells pharmaceutical products throughout the United States, including in Delaware.

17. On information and belief, Par 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.

18. On information and belief, Par is a limited liability company organized and existing under the laws of Delaware.

19. On information and belief, Par is registered to do business in Delaware.

20. On information and belief, Par 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: *Par Pharmaceutical, Inc. et al. v. Fresenius Kabi USA, LLC*, 1:19-cv-01985; *Par Pharmaceutical, Inc. et al. v. American Regent, Inc.*, 1:19-cv-01490; and *Par Pharmaceutical Inc. et al. v. Amneal Pharmaceuticals Company GmbH et al.*, 1:19-cv-00712.

21. This Court has personal jurisdiction over Endo. On information and belief, Endo conducts substantial business in, and has regular systematic contact with, this District. On

information and belief, Endo 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, Endo, directly or indirectly, researches, develops, manufactures, markets, and/or sells pharmaceutical products throughout the United States, including in Delaware.

22. On information and belief, Endo 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.

23. On information and belief, Endo is a corporation organized and existing under the laws of Delaware.

24. On information and belief, Endo is registered to do business in Delaware.

25. On information and belief, Endo 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: *Endo Pharmaceuticals Inc. v. Perrigo UK FINCO Limited Partnership*, 1:19-cv-00437; *Endo Pharmaceuticals Inc. et al. v. Actavis, Inc. n/k/a Actavis LLC et al.*, 1:14-cv-01381; and *Endo Pharmaceuticals Inc. et al. v. Amneal Pharmaceuticals LLC et al.*, 1:14-cv-01382.

26. This Court has personal jurisdiction over Nevakar. On information and belief, Nevakar conducts substantial business in, and has regular systematic contact with, this District. On information and belief, Nevakar 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, directly or indirectly,

researches, develops, manufactures, markets, and/or sells pharmaceutical products throughout the United States, including in Delaware.

27. On information and belief, Nevakar 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.

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

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

30. 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, Inc. v. Leiutis Pharmaceuticals Pvt Ltd et al.*, 1:21-cv-00133.

31. 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.

32. 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.

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

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

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

### **FACTUAL BACKGROUND**

#### **A. The Drug Approval Process.**

36. 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).

37. 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).

38. 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.

39. 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.**

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

41. 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 FDCA to raise blood pressure in adult patients with severe, acute hypotension.

42. Baxter intends on commercially marketing and launching its Norepinephrine Bitartrate Products in short order, as it is lawfully entitled to do in view of FDA's approval of NDA No. 214313.

43. Baxter's Norepinephrine Bitartrate Products will be 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.



44. Baxter's Norepinephrine Bitartrate Products are the only ready-to-use norepinephrine bitartrate products approved by FDA and will 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.**

45. On its face, the '657 patent is titled "NOREPINEPHRINE COMPOSITIONS AND METHODS THEREFOR," and indicates it was issued by the United States Patent and Trademark Office ("PTO") on December 25, 2018. A true and correct copy of the '657 patent is attached as Exhibit A.

46. The '657 patent lists Vivek Yadav, Sriramy Garapati, Tushar Hingorani, Iouri V. Ilitchev, Prem Sagar Akasapu, Kumaresh Soppimath, and Navneet Puri as the purported named inventors.

47. According to the face of the '657 patent, Nevakar is the assignee of the '657 patent; however, according to the PTO's online records, Nevakar Injectables is the assignee of the '657 patent.

48. On information and belief, Par is an exclusive licensee of the '657 patent and Par and Endo have the ability to assert the '657 patent.

49. According to online records at the PTO, the '657 patent purportedly will expire on or about January 30, 2038.

50. Baxter's Norepinephrine Bitartrate Product does not infringe any valid or enforceable claim of the '657 patent, either literally or under the doctrine of equivalents.

51. On its face, the '436 patent is titled "NOREPINEPHRINE COMPOSITIONS AND METHODS THEREFOR," and indicates it was issued by the PTO on March 12, 2019. A true and correct copy of the '436 patent is attached as Exhibit B.

52. The '436 patent lists Navneet Puri, Kumaresh Soppimath, Prem Sagar Akasapu, Vivek Yadav, Iouri V. Ilitchev, Sriramy Garapati, and Tushar Hingorani as the purported named inventors.

53. According to the face of the '436 patent and the PTO's online records, Nevakar is the assignee of the '436 patent.

54. On information and belief, Par is an exclusive licensee of the '436 patent and Par and Endo have the ability to assert the '436 patent.

55. According to online records at the PTO, the '436 patent purportedly will expire on or about January 30, 2038.

56. Baxter's Norepinephrine Bitartrate Product does not infringe any valid or enforceable claim of the '436 patent, either literally or under the doctrine of equivalents.

57. 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 C.

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

59. According to the face of the '735 patent and the PTO's online records, Nevakar is the assignee of the '735 patent.

60. On information and belief, Par is an exclusive licensee of the '735 patent and Par and Endo have the ability to assert the '735 patent.

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

62. 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.

63. 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 D.

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

65. According to the face of the '026 patent and the PTO's online records, Nevakar is the assignee of the '026 patent.

66. On information and belief, Par is an exclusive licensee of the '026 patent and Par and Endo have the ability to assert the '026 patent.

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

68. 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.

69. 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 E.

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

71. According to the face of the '850 patent and the PTO's online records, Nevakar is the assignee of the '850 patent.

72. On information and belief, Par is an exclusive licensee of the '850 patent and Par and Endo have the ability to assert the '850 patent.

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

74. Baxter's Norepinephrine Bitartrate Product does not infringe any valid or enforceable claim of the '080 patent, either literally or under the doctrine of equivalents.

75. 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 F.

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

77. According to the face of the '458 patent, Nevakar is the assignee of the '458 patent; however, according to the PTO's online records, Nevakar Injectables is the assignee of the '458 patent.

78. On information and belief, Par is an exclusive licensee of the '458 patent and Par and Endo have the ability to assert the '458 patent.

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

80. 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.

**D. Defendant Endo's Threats of Litigation.**

81. There is a substantial and continuing controversy between Baxter and Defendants and a declaration of rights is both necessary and appropriate to establish that Baxter does not infringe any valid or enforceable claim of the Patents at Issue and allow Baxter to bring its Norepinephrine Bitartrate Products to market.

82. On February 19, 2021, Defendant 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, Defendant Endo specifically asserted that Defendant Par "develops, manufactures, and markets a broad portfolio of sterile injectable products." In this letter, Defendant Endo asserted that Defendant 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 Patents at Issue, and asserted that Par is "an exclusive licensee" of the Patents at Issue. In this letter, Defendants Par and Endo not only specifically notified Baxter about the Patents at Issue, but also threatened litigation if Baxter launched its proposed Norepinephrine Bitartrate Products and failed to respect and take into account the Patents at Issue. (See Exhibit G, 2/19/21 Endo Ltr. To Baxter). On information and belief, Defendant Endo was authorized to make the representations set forth in the February 19, 2021 letter on behalf of Defendants Par, Nevakar, and Nevakar Injectables.

83. On August 11, 2021, Defendant 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, Defendant Endo asserted that if "Baxter is preparing to launch" Baxter's Norepinephrine Bitartrate Products, Defendant Endo threatened that "such a launch would infringe our subsidiary Par's intellectual property" as previously set forth in the letter

of February 19, 2021 (Exhibit H, 8/11/21 Endo E-mail to Baxter). Furthermore, in this August 11 email, Defendant Endo demanded an answer by August 13, 2021, as to whether Baxter intended to launch Baxter's Norepinephrine Bitartrate Products. In this electronic mail, Defendant Endo specifically threatened litigation involving the Patents at Issue, 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 H, 8/11/21 Endo Email to Baxter). On information and belief, Defendant Endo was authorized to make the representations set forth in the August 11, 2021 letter on behalf of Defendants Par, Nevakar, and Nevakar Injectables.

84. On August 12, 2021, Baxter, through its Counsel, Derek Johnson, responded to Defendant Endo's "threat letters" (Exhibit J, 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 Patents at Issue, found no basis for a claim of infringement, and further stated that there are good faith grounds to challenge the validity of the Patents at Issue, including obviousness. Baxter, in this August 12, 2021 letter, offered to discuss the Patents at Issue at a "mutually convenient" time.

85. On August 17, 2021, Derek Johnson, counsel for Baxter, and Gina R. Gencarelli, counsel for Defendant Endo, participated in a telephone call to discuss the Patents at Issue, among other things. During this call, Ms. Gencarelli repeated the assertion that Baxter's Norepinephrine

Bitartrate Products infringe the Patents at Issue, that Defendant Endo did not need any additional documentation or any internal Baxter data to further assess infringement, and that Defendants 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 Defendants 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, Defendant Endo was authorized to participate in the August 17, 2021 telephone call on behalf of Defendants Par, Nevakar, and Nevakar Injectables.

86. 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 Defendants’ extensive history of bringing of patent infringement matters and asserting their patents, Defendants pose an immediate and real threat of litigation against Baxter.

87. 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.

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

89. 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.

90. The totality of the circumstances gives rise to an actual and justiciable controversy between Defendants and Baxter as to the non-infringement and invalidity of the Patents at Issue.

Absent a declaration of non-infringement and invalidity, Defendants' continued wrongful assertions of infringement will cause Baxter harm.

91. 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.

92. Baxter desires to bring Baxter's Norepinephrine Bitartrate Products to market to allow the public and payors to enjoy and reap the benefits of competition for this product at the earliest possible date in view of its NDA approval.

**COUNT I**  
**DECLARATORY JUDGMENT OF NO PATENT INFRINGEMENT**  
**OF U.S. PATENT NO. 10,159,657**

93. Baxter realleges and incorporates by reference the allegations of paragraphs 1-92, above, as if fully set forth herein.

94. Baxter seeks a judgment from this Court that Baxter's Norepinephrine Bitartrate Products do not infringe any valid or enforceable claim of the '657 patent.

95. A present, genuine, and justiciable controversy exists between Baxter and Defendants 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 '657 patent.

96. 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 '657 patent.



**COUNT II**  
**DECLARATORY JUDGMENT OF INVALIDITY**  
**OF U.S. PATENT NO. 10,159,657**

97. Baxter realleges and incorporates by reference the allegations of paragraphs 1-96, above, as if fully set forth herein.

98. Baxter seeks a judgment from this Court that the '657 patent is invalid.

99. A present, genuine, and justiciable controversy exists between Baxter and Defendants concerning, *inter alia*, the validity of the '657 patent.

100. Baxter is entitled to a declaratory judgment that the claims of the '657 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. 10,226,436**

101. Baxter realleges and incorporates by reference the allegations of paragraphs 1-100, above, as if fully set forth herein.

102. Baxter seeks a judgment from this Court that Baxter's Norepinephrine Bitartrate Products do not infringe any valid or enforceable claim of the '436 patent.

103. A present, genuine, and justiciable controversy exists between Baxter and Defendants 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 '436 patent.

104. 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 '436 patent.

**COUNT IV**  
**DECLARATORY JUDGMENT OF INVALIDITY**  
**OF U.S. PATENT NO. 10,226,436**

105. Baxter realleges and incorporates by reference the allegations of paragraphs 1-104, above, as if fully set forth herein.

106. Baxter seeks a judgment from this Court that the '436 patent is invalid.

107. A present, genuine, and justiciable controversy exists between Baxter and Defendants concerning, *inter alia*, the validity of the '436 patent.

108. Baxter is entitled to a declaratory judgment that the claims of the '436 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. 10,420,735**

109. Baxter realleges and incorporates by reference the allegations of paragraphs 1-108, above, as if fully set forth herein.

110. 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.

111. A present, genuine, and justiciable controversy exists between Baxter and Defendants 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.

112. 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 VI**  
**DECLARATORY JUDGMENT OF INVALIDITY**  
**OF U.S. PATENT NO. 10,420,735**

113. Baxter realleges and incorporates by reference the allegations of paragraphs 1-112, above, as if fully set forth herein.

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

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

116. 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 VII**  
**DECLARATORY JUDGMENT OF NO PATENT INFRINGEMENT**  
**OF U.S. PATENT NO. 10,471,026**

117. Baxter realleges and incorporates by reference the allegations of paragraphs 1-116, above, as if fully set forth herein.

118. 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.

119. A present, genuine, and justiciable controversy exists between Baxter and Defendants 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.

120. 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 VIII**  
**DECLARATORY JUDGMENT OF INVALIDITY**  
**OF U.S. PATENT NO. 10,471,026**

121. Baxter realleges and incorporates by reference the allegations of paragraphs 1-120, above, as if fully set forth herein.

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

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

124. 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 IX**  
**DECLARATORY JUDGMENT OF NO PATENT INFRINGEMENT**  
**OF U.S. PATENT NO. 10,568,850**

125. Baxter realleges and incorporates by reference the allegations of paragraphs 1-124, above, as if fully set forth herein.

126. 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.

127. A present, genuine, and justiciable controversy exists between Baxter and Defendants 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.

128. 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 X**  
**DECLARATORY JUDGMENT OF INVALIDITY**  
**OF U.S. PATENT NO. 10,568,850**

129. Baxter realleges and incorporates by reference the allegations of paragraphs 1-128, above, as if fully set forth herein.

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

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

132. 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 XI**  
**DECLARATORY JUDGMENT OF NO PATENT INFRINGEMENT**  
**OF U.S. PATENT NO. 10,646,458**

133. Baxter realleges and incorporates by reference the allegations of paragraphs 1-132, above, as if fully set forth herein.

134. 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.

135. A present, genuine, and justiciable controversy exists between Baxter and Defendants 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.

136. 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 XII**  
**DECLARATORY JUDGMENT OF INVALIDITY**  
**OF U.S. PATENT NO. 10,646,458**

137. Baxter realleges and incorporates by reference the allegations of paragraphs 1-136, above, as if fully set forth herein.

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

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

140. 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 will not infringe any valid and enforceable claim of the '657 patent;
- B. Declaring that the '657 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 will not infringe any valid and enforceable claim of the '436 patent;
- D. Declaring that the '436 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 will not infringe any valid and enforceable claim of the '735 patent;
- F. Declaring that the '735 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 will not infringe any valid and enforceable claim of the '026 patent;
- H. Declaring that the '026 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 will not infringe any valid and enforceable claim of the '850 patent;
- J. Declaring that the '850 patent is invalid;
- K. Declaring that the manufacture, use, offer for sale, sale, and/or importation into the United States of Baxter's Norepinephrine Bitartrate Products will not infringe any valid and enforceable claim of the '458 patent;
- L. Declaring that the '458 patent is invalid;
- M. Declaring that Baxter's launch of Baxter's Norepinephrine Bitartrate Products prior to January 30, 2038 does not constitute infringement of the '657 patent;
- N. Declaring that Baxter's launch of Baxter's Norepinephrine Bitartrate Products prior to January 30, 2038 does not constitute infringement of the '436 patent;

- O. Declaring that Baxter's launch of Baxter's Norepinephrine Bitartrate Products prior to January 30, 2038 does not constitute infringement of the '735 patent;
- P. Declaring that Baxter's launch of Baxter's Norepinephrine Bitartrate Products prior to January 30, 2038 does not constitute infringement of the '026 patent;
- Q. Declaring that Baxter's launch of Baxter's Norepinephrine Bitartrate Products prior to January 30, 2038 does not constitute infringement of the '850 patent;
- R. Declaring that Baxter's launch of Baxter's Norepinephrine Bitartrate Products prior to January 30, 2038 does not constitute infringement of the '458 patent;
- S. Entering final judgment that Baxter's Norepinephrine Bitartrate Products do not infringe any valid or enforceable claim of the '657 patent;
- T. Entering final judgment that Baxter's Norepinephrine Bitartrate Products do not infringe any valid or enforceable claim of the '436 patent;
- U. Entering final judgment that Baxter's Norepinephrine Bitartrate Products do not infringe any valid or enforceable claim of the '735 patent;
- V. Entering final judgment that Baxter's Norepinephrine Bitartrate Products do not infringe any valid or enforceable claim of the '026 patent;
- W. Entering final judgment that Baxter's Norepinephrine Bitartrate Products do not infringe any valid or enforceable claim of the '850 patent;
- X. Entering final judgment that Baxter's Norepinephrine Bitartrate Products do not infringe any valid or enforceable claim of the '458 patent;
- Y. Awarding Baxter its costs, expenses and reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and
- Z. Such other and further relief as the Court may deem just and proper.



POTTER ANDERSON & CORROON LLP

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

Dated: August 18, 2021  
7336362

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

*Attorneys for Plaintiff*