IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

ABBVIE INC. and ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED Plaintiffs, v. FRESENIUS KABI USA, LLC and FRESENIUS KABI IPSUM SRL Defendants.	)	Civil Action No. 1:24-cv-4914 **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs AbbVie Inc. ("AbbVie") and Allergan Pharmaceuticals International Limited ("Allergan") (together, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants Fresenius Kabi USA, LLC ("Fresenius USA") and Fresenius Kabi iPSUM SRL ("Fresenius iPSUM") (together, "Fresenius" or "Defendants") and allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 8,471,025 (the "'025 Patent"); 8,835,455 (the "'455 Patent"); 8,969,566 (the "'566 Patent"); 9,284,314 (the "'314 Patent"); and 9,695,122 (the "'122 Patent") (collectively, "the Patents-in-Suit") arising under the United States Patent Laws, Title 35, United States Code, § 1, *et seq.*, and in particular under 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

2. This action is based on Defendants' submission to the FDA of ANDA No. 219325 seeking approval to manufacture and sell a generic version of AVYCAZ® (ceftazidime and avibactam) ("Fresenius's proposed generic AVYCAZ® product") prior to the expiration of the Patents-in-Suit, which are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for AVYCAZ®.

3. This particular action is a protective suit, intended to safeguard Plaintiffs' rights under 21 U.S.C. § 355, particularly to preserve their right for a 30-month stay under 21 U.S.C. § 355(j)(5)(B)(iii), in the event of potential disputes over jurisdiction, venue, and/or the identities of the parties that submitted ANDA No. 219325. On June 6, 2024, Plaintiffs filed a separate suit against, *inter alia*, Fresenius. *See AbbVie Inc. et al. v. Qilu Pharma, Inc. et al.*, C.A. 3:24-cv-06759-ZNQ (D.N.J.). The U.S. District Court for the District of New Jersey, the forum for Plaintiffs' suit against Fresenius, has presided over patent litigation matters wherein Fresenius USA has been a defendant in the past.

4. Defendants have infringed one or more claims of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A) by virtue of their filing of ANDA No. 219325, with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of generic versions of AVYCAZ® prior to the expiration of the Patents-in-Suit, or any extensions thereof.

5. Defendants will infringe one or more claims of the Patents-in-Suit under 35 U.S.C. § 271(a), (b), (c) and/or (g) should they engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic versions of AVYCAZ® prior to the expiration of the Patents-in-Suit, or any extensions thereof.

PARTIES

6. Plaintiff AbbVie is a corporation organized and existing under the laws of the State of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064.

7. AbbVie holds New Drug Application ("NDA") No. 206494 for AVYCAZ®.

8. AbbVie is a global research and development-based biopharmaceutical company committed to developing innovative therapies for some of the world's most complex and critical

conditions. The company's mission is to use its expertise, dedicated people, and unique approach to innovation to markedly improve treatments across therapeutic areas, including the treatment of bacterial infections.

9. AbbVie markets, distributes, and sells therapeutic drug products, including AVYCAZ®, in this judicial district and throughout the United States.

10. Plaintiff Allergan is an Irish company limited by shares having a principal place of business at Clonshaugh Business & Technology Park, Dublin 17, Ireland. Allergan is an indirectly wholly owned subsidiary of AbbVie. Allergan is the assignee of the Patents-in-Suit.

11. Upon information and belief, Defendant Fresenius USA is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

12. Defendant Fresenius USA holds ANDA No. 219325.

13. Upon information and belief, Defendant Fresenius iPSUM is an Italian company, having a principal place of business at Via Roma, 108 - 20051 Cassina De Pecchi, Milan, Italy.

14. Upon information and belief, Defendant Fresenius iPSUM is the holder of FDA Drug Master File No. 20985 for buffered ceftazidime pentahydrate, sterile, FDA Drug Master File No. 38741 for ceftazidime pentahydrate sterile buffered / avibactam sodium sterile (4:1), and FDA Drug Master File No. 39510 for avibactam sodium sterile.

15. Upon information and belief, Defendant Fresenius iPSUM has been and is engaging in activities directed toward infringement of the Patents-in-Suit, including by acting in concert with Defendant Fresenius USA with respect to the development, regulatory approval, commercial manufacture, marketing, sale, offer for sale, and/or distribution of Fresenius's proposed generic AVYCAZ® product prior to the expiration of the Patents-in-Suit.

16. Upon information and belief, Defendants have been acting in concert with respect to the preparation and submission of ANDA No. 219325 and the development of Fresenius's proposed generic AVYCAZ® product described within.

17. Upon information and belief, following any FDA approval of ANDA No. 219325, Defendants will market, distribute, sell, offer for sale, and/or import Fresenius's proposed generic AVYCAZ® product throughout the United States.

JURISDICTION AND VENUE

18. This is a civil action for patent infringement arising under the patent laws of the United States of America, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

19. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

20. This Court has personal jurisdiction over Defendant Fresenius USA because, upon information and belief, Defendant Fresenius USA's principal place of business is located at Three Corporate Drive, Lake Zurich, Illinois 60047.

21. This Court also has personal jurisdiction over Defendant Fresenius USA because, upon information and belief, Fresenius USA claims, "Lake Zurich, Illinois is home to the North America headquarters for Fresenius Kabi, as well as a major global research and development center for medical devices." *Fresenius Kabi – Locations*, https://www.fresenius-kabi.com/us/company/locations (last visited June 10, 2024). Upon information and belief, among Fresenius USA's operations in the Northern District of Illinois, it conducts pharmaceutical research and development, as well as manufacturing and distribution. *Id.*

22. Upon information and belief, Defendant Fresenius USA is registered with the Office of the Illinois Secretary of State as an Illinois Corporation Service Company under File No. 02387301.

23. This Court also has personal jurisdiction over Defendant Fresenius USA because it has had previous patent litigation disputes in the Northern District of Illinois and consented to or did not contest personal jurisdiction in this Court for purposes of those actions, and has asserted counterclaims in those actions, including in at least *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 1:17-cv-07903 (N.D. Ill.); *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 1:16-cv-00651 (N.D. Ill.); *Mylan Pharma Acquisition Ltd. et al v. Fresenius Kabi USA, LLC*, 1:15-cv-06700 (N.D. Ill.).

24. Additionally, this Court has personal jurisdiction over Fresenius iPSUM because, upon information and belief Fresenius iPSUM has continuous and systematic contacts with the State of Illinois, regularly conducts business in the State of Illinois, either directly or through one or more affiliates, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Illinois, and intends to sell Fresenius's proposed generic AVYCAZ® Product in the State of Illinois upon approval of ANDA No. 219325.

25. Defendants have committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to AbbVie, which manufactures and markets AVYCAZ® for sale and use throughout the United States, including in Illinois. Upon information and belief and as indicated in Fresenius's Notice Letter, Defendants prepared and filed ANDA No. 219325 with the intention of seeking to market Fresenius's proposed generic AVYCAZ® product nationwide, including in Illinois.

26. Upon information and belief, Defendants plan to sell Fresenius's proposed generic AVYCAZ® product in the State of Illinois, list Fresenius's proposed generic AVYCAZ® product in the state of Illinois's prescription drug formulary, and seek Medicaid reimbursements for sales

of Fresenius's proposed generic AVYCAZ® product in the State of Illinois, either directly or through one or more of their wholly owned subsidiaries, agents, affiliates, and/or alter egos.

27. Upon information and belief, Defendants know and intend that Fresenius's proposed generic AVYCAZ® product will be distributed and sold in Illinois and will thereby displace sales of AVYCAZ®, causing injury to AbbVie. Defendants intend to take advantage of their established channels of distribution in Illinois for the sale of Fresenius's proposed generic AVYCAZ® product.

28. In the alternative, this Court may exercise jurisdiction over Fresenius iPSUM pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Fresenius iPSUM is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Fresenius iPSUM has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States including this judicial district, such that this Court's exercise of jurisdiction over Fresenius iPSUM satisfies due process.

29. For at least the above reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, it would not be unfair or unreasonable for Defendants to litigate this action in this Court, and Defendants are subject to personal jurisdiction in Illinois.

30. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

31. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because upon information and belief, Fresenius USA's principal place of business is at Three Corporate Drive, Lake Zurich, Illinois 60047.

32. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Fresenius USA is registered to do business in Illinois as an Illinois Corporation Service Company with File No. 02387301.

33. Venue is also proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) because, upon information and belief, Defendants: (1) have sought approval from the FDA to market and sell Fresenius's proposed generic AVYCAZ® product in Illinois; and (2) have engaged in regular and established business contacts with Illinois by, among other things, marketing, making, shipping, using, offering to sell or selling pharmaceutical products in Illinois; and (3) deriving substantial revenue from such activities.

34. Venue is also proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) because, upon information and belief, Defendant Fresenius USA because it has had previous patent litigation disputes in the Northern District of Illinois and consented to or did not contest personal jurisdiction in this Court for purposes of those actions, and has asserted counterclaims in those actions, including in at least *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 1:17-cv-07903 (N.D. Ill.); *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 1:16-cv-00651 (N.D. Ill.); *Mylan Pharma Acquisition Ltd. et al v. Fresenius Kabi USA, LLC*, 1:15-cv-06700 (N.D. Ill.).

35. Upon information and belief, Fresenius USA directly and/or through one or more of its affiliates, agents, and/or alter egos has an extensive network of physicians, medical facilities, wholesalers, and distributors in this judicial district and intends to take advantage of its established channels of distribution in Illinois for the sale of Fresenius's proposed generic AVYCAZ® product.

36. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Defendant Fresenius iPSUM is an Italian corporation and may be sued in any judicial district in the United States.

THE PATENTS-IN-SUIT

37. U.S. Patent No. 8,471,025 entitled "Crystalline forms of trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide sodium salt," was duly and legally issued on June 25, 2013.

38. A true and correct copy of the ’025 Patent is attached hereto as “Exhibit A.”

39. Allergan is the assignee of, and holds all rights, title and interest in the ’025 Patent.

40. The ’025 Patent currently expires on August 12, 2031.

41. U.S. Patent No. 8,835,455 entitled “Crystalline forms of trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide sodium salt” was duly and legally issued on September 16, 2014.

42. A true and correct copy of the ’455 Patent is attached hereto as “Exhibit B.”

43. Allergan is the assignee of, and holds all rights, title and interest in the ’455 Patent.

44. The ’455 Patent currently expires on October 8, 2030.

45. U.S. Patent No. 8,969,566 entitled “Processes for preparing heterocyclic compounds including trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide and salts thereof” was duly and legally issued on March 3, 2015.

46. A true and correct copy of the ’566 Patent is attached hereto as “Exhibit C.”

47. Allergan is the assignee of, and holds all rights, title and interest in the ’566 Patent.

48. The ’566 Patent currently expires on June 15, 2032.

49. U.S. Patent No. 9,284,314 entitled “Processes for preparing heterocyclic compounds including trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide and salts thereof” was duly and legally issued on March 15, 2016.

50. A true and correct copy of the ’314 Patent is attached hereto as “Exhibit D.”

51. Allergan is the assignee of, and holds all rights, title and interest in the ’314 Patent.

52. The ’314 Patent currently expires on June 15, 2032.

53. U.S. Patent No. 9,695,122 entitled “Processes for preparing heterocyclic compounds including trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide and salts thereof” was duly and legally issued on July 4, 2017.

54. A true and correct copy of the '122 Patent is attached hereto as "Exhibit E."

55. Allergan is the assignee of, and holds all rights, title and interest in the '122 Patent.

56. The '122 Patent currently expires on June 15, 2032.

57. All claims of the Patents-in-Suit are valid, enforceable, and not expired.

PLAINTIFFS' AVYCAZ® PRODUCT

58. Antibiotic treatment of bacterial infections is among the greatest success stories in modern medicine. After decades of antibiotic use, however, dangerous drug-resistant bacterial infections spread throughout the community and in hospital-settings. According to a 2013 Centers for Disease Control and Prevention ("CDC") report, as of that date, at least 2 million people per year were becoming infected with antibiotic-resistant bacteria, and at least 23,000 people were dying each year as a direct result of those infections.

59. In 2015, after receiving priority review by FDA, AVYCAZ® was approved as a novel antibiotic treatment for serious infections in patients who had limited or no alternative treatment options: complicated intra-abdominal infections (including pyelonephritis) and complicated urinary tract infections used in combination with metronidazole. Since its original approval, AbbVie has conducted clinical studies establishing the efficacy of AVYCAZ® in the treatment of additional types of bacterial infections, including in pediatric patients, and has obtained approvals for these additional indications.

60. Upon approval, AVYCAZ® received new chemical entity ("NCE"), generating antibiotic incentives now ("GAIN"), and new patient population ("NPP") exclusivities from the FDA. The FDA granted NCE exclusivity to AVYCAZ® because avibactam had not previously been approved for use in a product by the FDA. NCE marketing exclusivity runs through February 25, 2020. The FDA also granted GAIN exclusivity because, as a new antibacterial drug for human use to treat serious or life-threatening infections, AVYCAZ® is a qualified infectious disease

product ("QIDP"). AVYCAZ®'s designation as a QIDP entitled it to a 5-year exclusivity extension to be added on to the NCE exclusivity, extending marketing exclusivity through February 25, 2025. Finally, AVYCAZ® received two NPP exclusivities, through December 20, 2025, and January 26, 2027, to run concurrently with other exclusivities, for new clinical investigations that extended the previously approved active ingredient, ceftazidime, to new patient populations.

61. AbbVie is the holder of NDA No. 206494, which was approved by the FDA on February 25, 2015, for the marketing and sale of ceftazidime and avibactam in the United States under the trade name "AVYCAZ®."

62. AbbVie sells AVYCAZ® in the United States pursuant to NDA No. 206494.

63. AVYCAZ® is an antibacterial combination product including two active pharmaceutical agents: ceftazidime, a cephalosporin, and avibactam, a beta-lactamase inhibitor.

64. AVYCAZ® 2.5 grams (ceftazidime and avibactam) for injection is supplied in a single-dose, clear glass vial containing: ceftazidime 2 grams (equivalent to 2.635 grams of ceftazidime pentahydrate/sodium carbonate) and avibactam 0.5 grams (equivalent to 0.551 grams of avibactam sodium).

65. AVYCAZ® is currently indicated for the treatment of certain infections caused by designated susceptible Gram-negative microorganisms in adult and certain pediatric patients. These infections include complicated Intra-abdominal Infections (cIAI), where AVYCAZ® is used in combination with metronidazole; complicated Urinary Tract Infections (cUTI), including Pyelonephritis; and Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP).

66. The FDA Orange Book for NDA No. 206494 for AVYCAZ® lists U.S. Patent No. 7,112,592 (the "'592 Patent"), U.S. Patent No. 7,612,087 (the "'087 Patent"), the '025 Patent, the '455 Patent, the '566 Patent, the '314 Patent, and the '122 Patent.

67. The Patents-in-Suit were listed in connection with AVYCAZ® in the Orange Book prior to receiving Fresenius's Notice Letter.

FRESENIUS'S PROPOSED GENERIC AVYCAZ® PRODUCT

68. A letter dated April 29, 2024, which was received by AbbVie via Federal Express on April 30, 2024 ("Fresenius's Notice Letter") states that the FDA received ANDA No. 219325 from Fresenius USA pursuant to 21 U.S.C. § 355(j) to obtain FDA approval to engage in the commercial manufacture, use, sale, or importation in the United States of Ceftazidime and Avibactam for Injection, 2 g/0.5 g per vial, Sterile Powder, which is a generic version of AbbVie's AVYCAZ®, before the expiration of the Patents-in-Suit.

69. Fresenius's Notice Letter represents that ANDA No. 219325 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification"), alleging that the claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or importation of Fresenius's proposed generic AVYCAZ® product.

70. Fresenius's Notice Letter does not state or otherwise indicate that Defendants submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '592 and '087 Patents, each of which is listed in the FDA Orange Book for AVYCAZ®. Accordingly, on information and belief, Defendants submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) for the '592 and '087 Patents and informed the FDA that it would not launch at least before November 12, 2026.

71. Upon information and belief, Defendants intend to directly or indirectly engage in the commercial manufacture, use, sale, offer for sale, or importation of Fresenius's proposed generic AVYCAZ® product promptly upon receiving FDA approval to do so.

72. By submitting ANDA No. 219325, and as stated in Fresenius's Notice Letter, Defendants have represented to the FDA that Fresenius's proposed generic AVYCAZ® product has the same active ingredient, dosage form, route of administration, and strength as AVYCAZ®, and is bioequivalent to AVYCAZ®.

73. Defendants have knowledge of the Patents-in-Suit and had knowledge of the Patents-in-Suit when ANDA No. 219325 was submitted to the FDA.

74. Fresenius's Notice Letter contained an Offer of Confidential Access to certain confidential information within ANDA No. 219325 regarding Fresenius's proposed generic AVYCAZ® product. Outside counsel for Plaintiffs negotiated in good faith with outside counsel for Fresenius in an attempt to reach an agreement on reasonable terms of confidential access to ANDA No. 219325. Despite multiple email exchanges, as of June 12, 2024, the parties were unable to reach an agreement. As of June 12, 2024, Plaintiffs have not received access to ANDA No. 219325.

75. This action is being commenced before the expiration of forty-five days from the date of AbbVie's receipt of Fresenius's Notice Letter.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 8,471,025 UNDER 35 U.S.C. § 271(e)(2) BY FRESENIUS

76. Plaintiffs incorporate each of the preceding paragraphs 1 – 75 as if fully set forth herein.

77. Defendants' submission of ANDA No. 219325, with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Fresenius's proposed generic AVYCAZ® product before the expiration of the '025 Patent constituted an act of infringement of one or more claims of the '025 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

78. Upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the preparation, submission and maintenance of ANDA No. 219325 to the FDA.

79. After FDA approval of ANDA No. 219325, Defendants will infringe one or more claims of the '025 Patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Fresenius's proposed generic AVYCAZ® product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 219325 shall be no earlier than the expiration of the '025 Patent and any additional periods of exclusivity.

80. Defendants know, or should know, and intend that healthcare providers will prescribe and patients will take Fresenius's proposed generic AVYCAZ® product, and therefore will infringe at least one claim of the '025 Patent.

81. Defendants know or should know that they will induce direct infringement of at least one of the claims of the '025 Patent, either literally or under the doctrine of equivalents.

82. Defendants know or should know that Fresenius's proposed generic AVYCAZ® product is especially adapted for a use that infringes the '025 Patent, and there is no substantial non-infringing use.

83. Defendants have knowledge and are aware of the '025 Patent, as evidenced by Fresenius's Notice Letter.

84. Unless Defendants are enjoined from directly or indirectly infringing the '025 Patent, AbbVie will suffer substantial and irreparable harm for which AbbVie has no adequate remedy at law.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF

U.S. PATENT NO. 8,471,025 BY FRESENIUS

85. Plaintiffs incorporate each of the preceding paragraphs 1 – 84 as if fully set forth herein.

86. AbbVie's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

87. Upon information and belief, upon FDA approval of ANDA No. 219325, Defendants intend to, and will, infringe one or more claims of the '025 Patent, under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents by the manufacture, use, sale, or importation of Fresenius's proposed generic AVYCAZ® product, unless enjoined by the Court.

88. Upon information and belief, Defendants intend to, and will, actively induce infringement of one or more claims of the '025 Patent, under 35 U.S.C. § 271(b) when ANDA No. 219325 is approved by marketing Fresenius's proposed generic AVYCAZ® product and encouraging doctors and patients to infringe the '025 Patent, unless enjoined by the Court.

89. Defendants have knowledge and are aware of the '025 Patent, as evidenced by Fresenius's Notice Letter.

90. Upon information and belief, Defendants will contribute to infringement of one or more claims of the '025 Patent under 35 U.S.C. § 271(c) when ANDA No. 219325 is approved, unless enjoined by the Court, because Defendants know or should know that Fresenius's proposed generic AVYCAZ® product is especially made or adapted for use in infringing the '025 Patent, and Fresenius's proposed generic AVYCAZ® product is not suitable for substantial noninfringing use.

91. Defendants' infringement is imminent.

92. Defendants have notified AbbVie of the submission of ANDA No. 219325 seeking approval to engage in the manufacture, use, sale, or importation of Fresenius's proposed generic AVYCAZ® product before the expiration of the '025 Patent.

93. Upon information and belief, Defendants' infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Fresenius's proposed generic AVYCAZ® product in the United States, will begin immediately after FDA approval.

94. Thus, a real, substantial, and continuing justiciable controversy exists between the parties hereto as to the infringement of the '025 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

95. Unless Defendants are enjoined from directly or indirectly infringing the '025 Patent, AbbVie will suffer substantial and irreparable harm for which AbbVie has no adequate remedy at law.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 8,835,455
UNDER 35 U.S.C. § 271(e)(2) BY FRESENIUS

96. Plaintiffs incorporate each of the preceding paragraphs 1 – 95 as if fully set forth herein.

97. Defendants' submission of ANDA No. 219325, with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Fresenius's proposed generic AVYCAZ® product before the expiration of the '455 Patent constituted an act of infringement of one or more claims of the '455 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

98. Upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the preparation, submission and maintenance of ANDA No. 219325 to the FDA.

99. After FDA approval of ANDA No. 219325, Defendants will infringe one or more claims of the '455 Patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Fresenius's proposed generic AVYCAZ® product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 219325 shall be no earlier than the expiration of the '455 Patent and any additional periods of exclusivity.

100. Defendants know, or should know, and intend that healthcare providers will prescribe and patients will take Fresenius's proposed generic AVYCAZ® product, and therefore will infringe at least one claim of the '455 Patent.

101. Defendants know or should know that they will induce direct infringement of at least one of the claims of the '455 Patent, either literally or under the doctrine of equivalents.

102. Defendants know or should know that Fresenius's proposed generic AVYCAZ® product is especially adapted for a use that infringes the '455 Patent, and there is no substantial non-infringing use.

103. Defendants have knowledge and are aware of the '455 Patent, as evidenced by Fresenius's Notice Letter.

104. Unless Defendants are enjoined from directly or indirectly infringing the '455 Patent, AbbVie will suffer substantial and irreparable harm for which AbbVie has no adequate remedy at law.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,835,455 BY FRESENIUS

105. Plaintiffs incorporate each of the preceding paragraphs 1 – 104 as if fully set forth herein.

106. AbbVie's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

107. Upon information and belief, upon FDA approval of ANDA No. 219325, Defendants intend to, and will, infringe one or more claims of the '455 Patent, under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents by the manufacture, use, sale, or importation of Fresenius's proposed generic AVYCAZ® product, unless enjoined by the Court.

108. Upon information and belief, Defendants intend to, and will, actively induce infringement of one or more claims of the '455 Patent, under 35 U.S.C. § 271(b) when ANDA No. 219325 is approved by marketing Fresenius's proposed generic AVYCAZ® product and encouraging doctors and patients to infringe the '455 Patent, unless enjoined by the Court.

109. Defendants have knowledge and are aware of the '455 Patent, as evidenced by Fresenius's Notice Letter.

110. Upon information and belief, Defendants will contribute to infringement of one or more claims of the '455 Patent under 35 U.S.C. § 271(c) when ANDA No. 219325 is approved, unless enjoined by the Court, because Defendants know or should know that Fresenius's proposed generic AVYCAZ® product is especially made or adapted for use in infringing the '455 Patent, and Fresenius's proposed generic AVYCAZ® product is not suitable for substantial noninfringing use.

111. Defendants' infringement is imminent.

112. Defendants have notified AbbVie of the submission of ANDA No. 219325 seeking approval to engage in the manufacture, use, sale, or importation of Fresenius's proposed generic AVYCAZ® product before the expiration of the '455 Patent.

113. Upon information and belief, Defendants' infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Fresenius's proposed generic AVYCAZ® product in the United States, will begin immediately after FDA approval.

114. Thus, a real, substantial, and continuing justiciable controversy exists between the parties hereto as to the infringement of the '455 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

115. Unless Defendants are enjoined from directly or indirectly infringing the '455 Patent, AbbVie will suffer substantial and irreparable harm for which AbbVie has no adequate remedy at law.

COUNT V
INFRINGEMENT OF U.S. PATENT NO. 8,969,566
UNDER 35 U.S.C. § 271(e)(2) BY FRESENIUS

116. Plaintiffs incorporate each of the preceding paragraphs 1 – 115 as if fully set forth herein.

117. Defendants' submission of ANDA No. 219325, with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Fresenius's proposed generic AVYCAZ® product before the expiration of the '566 Patent constituted an act of infringement of one or more claims of the '566 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

118. Upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the preparation, submission and maintenance of ANDA No. 219325 to the FDA.

119. After FDA approval of ANDA No. 219325, Defendants will infringe one or more claims of the '566 Patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Fresenius's proposed generic AVYCAZ®

product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 219325 shall be no earlier than the expiration of the '566 Patent and any additional periods of exclusivity.

120. Defendants know, or should know, and intend that healthcare providers will prescribe and patients will take Fresenius's proposed generic AVYCAZ® product, and therefore will infringe at least one claim of the '566 Patent.

121. Defendants know or should know that they will induce direct infringement of at least one of the claims of the '566 Patent, either literally or under the doctrine of equivalents.

122. Defendants know or should know that Fresenius's proposed generic AVYCAZ® product is especially adapted for a use that infringes the '566 Patent, and there is no substantial non-infringing use.

123. Defendants have knowledge and are aware of the '566 Patent, as evidenced by Fresenius's Notice Letter.

124. Unless Defendants are enjoined from directly or indirectly infringing the '566 Patent, AbbVie will suffer substantial and irreparable harm for which AbbVie has no adequate remedy at law.

COUNT VI
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,969,566 BY FRESENIUS

125. Plaintiffs incorporate each of the preceding paragraphs 1 – 124 as if fully set forth herein.

126. AbbVie's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

127. Upon information and belief, upon FDA approval of ANDA No. 219325, Defendants intend to, and will, infringe one or more claims of the '566 Patent, under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents by the manufacture, use, sale, or importation of Fresenius's proposed generic AVYCAZ® product, unless enjoined by the Court.

128. Upon information and belief, Defendants intend to, and will, actively induce infringement of one or more claims of the '566 Patent, under 35 U.S.C. § 271(b) when ANDA No. 219325 is approved by marketing Fresenius's proposed generic AVYCAZ® product and encouraging doctors and patients to infringe the '566 Patent, unless enjoined by the Court.

129. Defendants have knowledge and are aware of the '566 Patent, as evidenced by Fresenius's Notice Letter.

130. Upon information and belief, Defendants will contribute to infringement of one or more claims of the '566 Patent under 35 U.S.C. § 271(c) when ANDA No. 219325 is approved, unless enjoined by the Court, because Defendants know or should know that Fresenius's proposed generic AVYCAZ® product is especially made or adapted for use in infringing the '566 Patent, and Fresenius's proposed generic AVYCAZ® product is not suitable for substantial noninfringing use.

131. Upon information and belief, Defendants will infringe one or more claims of the '566 Patent under 35 U.S.C. § 271(g) when ANDA No. 219325 is approved, unless enjoined by the Court, because Fresenius's proposed generic AVYCAZ® product will be made by a process that infringes the '566 Patent and then imported into the United States.

132. Defendants' infringement is imminent.

133. Defendants have notified AbbVie of the submission of ANDA No. 219325 seeking approval to engage in the manufacture, use, sale, or importation of Fresenius's proposed generic AVYCAZ® product before the expiration of the '566 Patent.

134. Upon information and belief, Defendants' infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Fresenius's proposed generic AVYCAZ® product in the United States, will begin immediately after FDA approval.

135. Thus, a real, substantial, and continuing justiciable controversy exists between the parties hereto as to the infringement of the '566 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

136. Unless Defendants are enjoined from directly or indirectly infringing the '566 Patent, AbbVie will suffer substantial and irreparable harm for which AbbVie has no adequate remedy at law.

COUNT VII
INFRINGEMENT OF U.S. PATENT NO. 9,284,314
UNDER 35 U.S.C. § 271(e)(2) BY FRESENIUS

137. Plaintiffs incorporate each of the preceding paragraphs 1 – 136 as if fully set forth herein.

138. Defendants' submission of ANDA No. 219325, with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Fresenius's proposed generic AVYCAZ® product before the expiration of the '314 Patent constituted an act of infringement of one or more claims of the '314 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

139. Upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the preparation, submission and maintenance of ANDA No. 219325 to the FDA.

140. After FDA approval of ANDA No. 219325, Defendants will infringe one or more claims of the '314 Patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Fresenius's proposed generic AVYCAZ®

product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 219325 shall be no earlier than the expiration of the '314 Patent and any additional periods of exclusivity.

141. Defendants know, or should know, and intend that healthcare providers will prescribe and patients will take Fresenius's proposed generic AVYCAZ® product, and therefore will infringe at least one claim of the '314 Patent.

142. Defendants know or should know that they will induce direct infringement of at least one of the claims of the '314 Patent, either literally or under the doctrine of equivalents.

143. Defendants know or should know that Fresenius's proposed generic AVYCAZ® product is especially adapted for a use that infringes the '314 Patent, and there is no substantial non-infringing use.

144. Defendants have knowledge and are aware of the '314 Patent, as evidenced by Fresenius's Notice Letter.

145. Unless Defendants are enjoined from directly or indirectly infringing the '314 Patent, AbbVie will suffer substantial and irreparable harm for which AbbVie has no adequate remedy at law.

COUNT VIII
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,284,314 BY FRESENIUS

146. Plaintiffs incorporate each of the preceding paragraphs 1 – 145 as if fully set forth herein.

147. AbbVie's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

148. Upon information and belief, upon FDA approval of ANDA No. 219325, Defendants intend to, and will, infringe one or more claims of the '314 Patent, under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents by the manufacture, use, sale, or importation of Fresenius's proposed generic AVYCAZ® product, unless enjoined by the Court.

149. Upon information and belief, Defendants intend to, and will, actively induce infringement of one or more claims of the '314 Patent, under 35 U.S.C. § 271(b) when ANDA No. 219325 is approved by marketing Fresenius's proposed generic AVYCAZ® product and encouraging doctors and patients to infringe the '314 Patent, unless enjoined by the Court.

150. Defendants have knowledge and are aware of the '314 Patent, as evidenced by Fresenius's Notice Letter.

151. Upon information and belief, Defendants will contribute to infringement of one or more claims of the '314 Patent under 35 U.S.C. § 271(c) when ANDA No. 219325 is approved, unless enjoined by the Court, because Defendants know or should know that Fresenius's proposed generic AVYCAZ® product is especially made or adapted for use in infringing the '314 Patent, and Fresenius's proposed generic AVYCAZ® product is not suitable for substantial noninfringing use.

152. Upon information and belief, Defendants intend to, and will, contribute to infringement of one or more claims of the '314 Patent under 35 U.S.C. § 271(g) when ANDA No. 219325 is approved, unless enjoined by the Court, because Fresenius's proposed generic AVYCAZ® product will be made by a process that infringes the '314 Patent and then imported into the United States.

153. Defendants' infringement is imminent.

154. Defendants have notified AbbVie of the submission of ANDA No. 219325 seeking approval to engage in the manufacture, use, sale, or importation of Fresenius's proposed generic AVYCAZ® product before the expiration of the '314 Patent.

155. Upon information and belief, Defendants' infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Fresenius's proposed generic AVYCAZ® product in the United States, will begin immediately after FDA approval.

156. Thus, a real, substantial, and continuing justiciable controversy exists between the parties hereto as to the infringement of the '314 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

157. Unless Defendants are enjoined from directly or indirectly infringing the '314 Patent, AbbVie will suffer substantial and irreparable harm for which AbbVie has no adequate remedy at law.

COUNT IX
INFRINGEMENT OF U.S. PATENT NO. 9,695,122
UNDER 35 U.S.C. § 271(e)(2) BY FRESENIUS

158. Plaintiffs incorporate each of the preceding paragraphs 1 – 157 as if fully set forth herein.

159. Defendants' submission of ANDA No. 219325, with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Fresenius's proposed generic AVYCAZ® product before the expiration of the '122 Patent constituted an act of infringement of one or more claims of the '122 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

160. Upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the preparation, submission and maintenance of ANDA No. 219325 to the FDA.

161. After FDA approval of ANDA No. 219325, Defendants will infringe one or more claims of the '122 Patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Fresenius's proposed generic AVYCAZ® product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 219325 shall be no earlier than the expiration of the '122 Patent and any additional periods of exclusivity.

162. Defendants know, or should know, and intend that healthcare providers will prescribe and patients will take Fresenius's proposed generic AVYCAZ® product, and therefore will infringe at least one claim of the '122 Patent.

163. Defendants know or should know that they will induce direct infringement of at least one of the claims of the '122 Patent, either literally or under the doctrine of equivalents.

164. Defendants know or should know that Fresenius's proposed generic AVYCAZ® product is especially adapted for a use that infringes the '122 Patent, and there is no substantial non-infringing use.

165. Defendants have knowledge and are aware of the '122 Patent, as evidenced by Fresenius's Notice Letter.

166. Unless Defendants are enjoined from directly or indirectly infringing the '122 Patent, AbbVie will suffer substantial and irreparable harm for which AbbVie has no adequate remedy at law.

COUNT X
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,695,122 BY FRESENIUS

167. Plaintiffs incorporate each of the preceding paragraphs 1 – 166 as if fully set forth herein.

168. AbbVie's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

169. Upon information and belief, upon FDA approval of ANDA No. 219325, Defendants intend to, and will, infringe one or more claims of the '122 Patent, under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents by the manufacture, use, sale, or importation of Fresenius's proposed generic AVYCAZ® product, unless enjoined by the Court.

170. Upon information and belief, Defendants intend to, and will, actively induce infringement of one or more claims of the '122 Patent, under 35 U.S.C. § 271(b) when ANDA No. 219325 is approved by marketing Fresenius's proposed generic AVYCAZ® product and encouraging doctors and patients to infringe the '122 Patent, unless enjoined by the Court.

171. Defendants have knowledge and are aware of the '122 Patent, as evidenced by Fresenius's Notice Letter.

172. Upon information and belief, Defendants will contribute to infringement of one or more claims of the '122 Patent under 35 U.S.C. § 271(c) when ANDA No. 219325 is approved, unless enjoined by the Court, because Defendants know or should know that Fresenius's proposed generic AVYCAZ® product is especially made or adapted for use in infringing the '122 Patent, and Fresenius's proposed generic AVYCAZ® product is not suitable for substantial noninfringing use.

173. Defendants' infringement is imminent.

174. Defendants have notified AbbVie of the submission of ANDA No. 219325 seeking approval to engage in the manufacture, use, sale, or importation of Fresenius's proposed generic AVYCAZ® product before the expiration of the '122 Patent.

175. Upon information and belief, Defendants' infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Fresenius's proposed generic AVYCAZ® product in the United States, will begin immediately after FDA approval.

176. Thus, a real, substantial, and continuing justiciable controversy exists between the parties hereto as to the infringement of the '122 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

177. Unless Defendants are enjoined from directly or indirectly infringing the '122 Patent, AbbVie will suffer substantial and irreparable harm for which AbbVie has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that this Court grant the following relief:

178. A judgment that one or more of the claims of the Patents-in-Suit are infringed by Defendants' submission of ANDA No. 219325 under 35 U.S.C. § 271(e)(2)(A);

179. A judgment that Defendants' manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of Fresenius's proposed generic AVYCAZ® product prior to the expiration of the Patents-in-Suit would infringe the Patents-in-Suit, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c), and/or (g);

180. A declaration under 28 U.S.C. § 2201 that if Defendants, their officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities aiding, abetting, acting in concert with it, or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Fresenius's proposed generic AVYCAZ® product prior to the expiration of the Patents-in-Suit, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a), (b), (c), and/or (g);

181. A judgment that the Patents-in-Suit are not invalid or unenforceable;

182. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 219325 shall not be earlier than the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or becomes entitled;

183. An order permanently enjoining Defendants, and their affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with Fresenius, from making, using, offering to sell, selling, or importing Fresenius's proposed generic AVYCAZ® product until after the Patents-in-Suit's expiration, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or becomes entitled in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

184. Damages or other monetary relief, including costs, fees, pre-judgement interest and post-judgment interest to Plaintiffs if Defendants engage in commercial manufacture, use, offers to sell, sale, or importation into the United States of Fresenius's proposed generic AVYCAZ® product prior to the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or becomes entitled;

185. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285; and

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

Dated: June 13, 2024

/s/ Lisa L. Furby

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