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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ABBVIE INC. and ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED, Plaintiffs, v. QILU PHARMA, INC., QILU ANTIBIOTICS PHARMACEUTICAL CO., LTD., APOTEX INC., FRESENIUS KABI USA, LLC, and FRESENIUS KABI IPSUM SRL, Defendants.	C. A. No. 3:24-cv-06759 (ZNQ)(TJB) ***Document Filed Electronically***

FRESENIUS KABI USA, LLC AND FRESENIUS KABI IPSUM SRL'S
ANSWER, DEFENSES, AND COUNTERCLAIMS TO COMPLAINT

In light of the Transfer Order issued by the MDL Panel (MDL No. 3134, Dkt. 21), Defendants Fresenius Kabi USA, LLC ("Fresenius USA") and Fresenius Kabi iPSUM S.r.l. ("Fresenius iPSUM") (together, "Fresenius" or "Defendants"), by and through their undersigned counsel, hereby submit the following Answer, Defenses, and Counterclaims in response to the Complaint for Patent Infringement ("Complaint") filed by Plaintiffs AbbVie Inc. ("AbbVie") and Allergan Pharmaceuticals International Limited ("Allergan") (together, "Plaintiffs").

Pursuant to Federal Rule of Civil Procedure 8(b)(3), Fresenius denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts. All allegations not specifically admitted are denied. Fresenius denies that Plaintiffs are entitled to the relief requested or any other relief. Fresenius responds to the Complaint 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.

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that the Complaint is for alleged patent infringement and for declaratory judgement of alleged 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"), but denies that Plaintiffs are entitled to any relief. Fresenius denies any and all remaining allegations contained in Paragraph 1.

2. This action is based on the Qilu Defendants' submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 219392 and the Fresenius Defendants' submission to the FDA of ANDA No. 219325, each seeking approval to manufacture and sell a generic version of AVYCAZ® (ceftazidime and avibactam) ("Qilu's proposed generic AVYCAZ® product" and "Fresenius's proposed generic AVYCAZ® product," respectively) 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®.

ANSWER: Paragraph 2 contains legal conclusions to which no answer is required. No response is required from Fresenius to the extent that the allegations in Paragraph 2 are directed to a Defendant other than Fresenius. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA submitted Abbreviated New Drug Application ("ANDA") No. 219325 to the U.S. Food and Drug Administration ("FDA") for Ceftazidime and Avibactam for Injection, 2 g/0.5 g per vial, Sterile Powder ("Fresenius USA's ANDA Product"). Fresenius denies any and all remaining allegations contained in Paragraph 2.

3. 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 Nos. 219392 and 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.

ANSWER: No response is required from Fresenius to the extent that the allegations in Paragraph 3 are directed to a Defendant other than Fresenius. To the extent that Fresenius is required to answer, denied.

4. 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.

ANSWER: No response is required from Fresenius to the extent that the allegations in Paragraph 4 are directed to a Defendant other than Fresenius. To the extent that Fresenius is required to answer, denied.

PARTIES

5. 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.

ANSWER: Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 5 and therefore denies those allegations.

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

ANSWER: Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 6 and therefore denies those allegations.

7. 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.

ANSWER: Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 7 and therefore denies those allegations.

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

ANSWER: Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 8 and therefore denies those allegations.

9. 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.

ANSWER: Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 9 and therefore denies those allegations.

Qilu Defendants

10. Upon information and belief, Defendant Qilu Pharma is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 101 Lindenwood Drive, Suite 225, Malvern, PA 19355.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 10 and therefore denies those allegations.

11. Defendant Qilu Pharma holds ANDA No. 219392.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 11 and therefore denies those allegations.

12. Upon information and belief, Defendant Qilu Antibiotics is a Chinese company, having a principal place of business at No. 849 Dongjia Town, Licheng District, Jinan City, Shandong Province, 250105, China.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 12 and therefore denies those allegations.

13. Upon information and belief, Qilu Antibiotics is the holder of FDA Drug Master File No. 20481 for ceftazidime for injection and FDA Drug Master File No. 38569 for sterile avibactam sodium.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 13 and therefore denies those allegations.

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

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 14 and therefore denies those allegations.

15. Upon information and belief, Defendant Apotex is a Canadian company, having a principal place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 15 and therefore denies those allegations.

16. In a letter dated April 22, 2024, which was received by AbbVie via Federal Express on April 23, 2024 ("Qilu's Notice Letter"), Qilu informed Plaintiffs that Apotex Inc. should be provided with notice of this Complaint.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 16 and therefore denies those allegations.

17. On May 20, 2024, Qilu represented in writing that Apotex holds the rights to market the product described in ANDA No. 219392.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 17 and therefore denies those allegations.

18. Upon information and belief, the Qilu Defendants have been acting in concert with respect to the preparation and submission of ANDA No. 219392 and the development of Qilu's proposed generic AVYCAZ® product described within.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 18 and therefore denies those allegations.

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

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 19 and therefore denies those allegations.

20. Upon information and belief, following any FDA approval of ANDA No. 219392, the Qilu Defendants will market, distribute, sell, offer for sale, and/or import Qilu's proposed generic AVYCAZ® product throughout the United States.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 20 and therefore denies those allegations.

Fresenius Defendants

21. 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.

ANSWER: Admitted.

22. Defendant Fresenius USA holds ANDA No. 219325.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA submitted ANDA No. 219325 to FDA. Fresenius denies any and all remaining allegations contained in Paragraph 22.

23. 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.

ANSWER: Admitted.

24. 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.

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius iPSUM submitted Drug Master File ("DMF") No. 20985, DMF No. 38741, and DMF No. 39510 to FDA. Fresenius denies any and all remaining allegations contained in Paragraph 24.

25. 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.

ANSWER: Denied.

26. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

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

ANSWER: Denied.

JURISDICTION AND VENUE

28. 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.

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that the Complaint is for alleged patent infringement and for declaratory judgment of alleged patent infringement, but denies that Plaintiffs are entitled to any relief. Fresenius denies any and all remaining allegations contained in Paragraph 28.

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

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, for the limited purposes of this action only, Fresenius does not contest subject matter jurisdiction over the claims solely directed against Fresenius USA under 35 U.S.C. § 271(e)(2)(A). Fresenius denies any and all remaining allegations contained in Paragraph 29.

Qilu Defendants

30. This Court has personal jurisdiction over the Qilu Defendants for this action because the Qilu Defendants, through their counsel, consented to personal jurisdiction in the District of New Jersey for purposes of this action prior to the filing of this Complaint.

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 30 and therefore denies those allegations.

31. This Court also has personal jurisdiction over Defendant Qilu Pharma because it has created a presence in New Jersey through its registration with the New Jersey Department of

the Treasury as a Foreign For-Profit Corporation in Princeton, NJ under Entity Identification No. 0400704255.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 31 and therefore denies those allegations.

32. Upon information and belief, Qilu Pharma maintains a regular and established place of business at 108 Carnegie Center, Suite 208, Princeton, New Jersey 08540.

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 32 and therefore denies those allegations.

33. This Court also has personal jurisdiction over Defendant Qilu Pharma because it has had previous patent litigation disputes in the District of New Jersey and consented to or did not contest personal jurisdiction in this Court for purposes of those actions including in at least *Boehringer Ingelheim Pharms. Inc. v. Qilu Pharm. Co. Ltd., et al.*, No. 3:21-cv-01732 (D.N.J.); *Helsinn Healthcare S.A., et al. v. Qilu Pharm. Co., Ltd., et al.*, No. 2:15-cv-08132 (D.N.J.).

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 33 and therefore denies those allegations.

34. Upon information and belief, Defendant Qilu Pharma has also affirmatively invoked this Court's jurisdiction by asserting counterclaims in cases that it has litigated in New Jersey. For example, Qilu Pharma asserted counterclaims in at least *Boehringer Ingelheim Pharms. Inc. v. Qilu Pharm. Co. Ltd., et al.*, No. 3:21-cv-01732 (D.N.J.); *Helsinn Healthcare S.A., et al. v. Qilu Pharm. Co., Ltd., et al.*, No. 2:15-cv-08132 (D.N.J.).

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or

information to form a belief as to the allegations of Paragraph 34 and therefore denies those allegations.

35. Additionally, this Court has personal jurisdiction over Qilu Antibiotics because, upon information and belief, it has continuous and systematic contacts with the State of New Jersey, regularly conducts business in the State of New Jersey, 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 New Jersey, and intends to sell Qilu's proposed generic AVYCAZ® Product in the State of New Jersey upon approval of ANDA No. 219392.

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 35 and therefore denies those allegations.

36. In the alternative, this Court may exercise jurisdiction over Qilu Antibiotics pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Qilu Antibiotics is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Qilu Antibiotics 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 Qilu Antibiotics satisfies due process.

ANSWER: Paragraph 36 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 36 and therefore denies those allegations.

37. This Court has personal jurisdiction over Apotex because, upon information and belief, it has continuous and systematic contacts with the State of New Jersey, regularly conducts business in the State of New Jersey, 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 New Jersey, and intends to sell Qilu's proposed generic AVYCAZ® Product in the State of New Jersey upon approval of ANDA No. 219392.

ANSWER: Paragraph 37 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or

information to form a belief as to the allegations of Paragraph 37 and therefore denies those allegations.

38. This Court also has personal jurisdiction over Defendant Apotex because it has had previous patent litigation disputes in the District of New Jersey and consented to or did not contest personal jurisdiction in this Court for purposes of those actions including in at least *Oyster Point Pharma, Inc. v. Apotex Inc.*, No. 2:23-cv-03860 (D.N.J); *Amgen Inc. v. Apotex Inc.*, No. 3:22-cv-03827 (D.N.J.); *Supernus Pharms., Inc. v. Apotex Inc., et al.*, No. 3:20-cv-07870 (D.N.J.).

ANSWER: Paragraph 38 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 38 and therefore denies those allegations.

39. Upon information and belief, Defendant Apotex has also affirmatively invoked this Court's jurisdiction by asserting counterclaims in cases that it has litigated in New Jersey. For example, Apotex asserted counterclaims in *Oyster Point Pharma, Inc. v. Apotex Inc.*, No. 2:23-cv-03860 (D.N.J); *Amgen Inc. v. Apotex Inc.*, No. 3:22-cv-03827 (D.N.J.); *Supernus Pharms., Inc. v. Apotex Inc., et al.*, No. 3:20-cv-07870 (D.N.J.).

ANSWER: Paragraph 39 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 39 and therefore denies those allegations.

40. In the alternative, this Court may exercise jurisdiction over Apotex pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Apotex is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Apotex 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 Apotex satisfies due process.

ANSWER: Paragraph 40 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 40 and therefore denies those allegations.

41. The Qilu 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 New Jersey. Upon information and belief and as indicated in Qilu's Notice Letter, the Qilu Defendants prepared and filed ANDA No. 219392 with the intention of seeking to market Qilu's proposed generic AVYCAZ® product nationwide, including in New Jersey.

ANSWER: Paragraph 41 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 41 and therefore denies those allegations.

42. Upon information and belief, the Qilu Defendants plan to sell Qilu's proposed generic AVYCAZ® product in the State of New Jersey, list Qilu's proposed generic AVYCAZ® product in the state of New Jersey's prescription drug formulary, and seek Medicaid reimbursements for sales of Qilu's proposed generic AVYCAZ® product in the State of New Jersey, either directly or through one or more of their wholly owned subsidiaries, agents, affiliates, and/or alter egos.

ANSWER: Paragraph 42 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 42 and therefore denies those allegations.

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

ANSWER: Paragraph 43 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 43 and therefore denies those allegations.

44. 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 the Qilu Defendants

to litigate this action in this Court, and the Qilu Defendants are subject to personal jurisdiction in New Jersey.

ANSWER: Paragraph 44 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 44 and therefore denies those allegations.

45. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Paragraph 45 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 45 and therefore denies those allegations.

46. Venue is proper in this Court because, among other things, the Qilu Defendants, through their counsel, consented to venue in the District of New Jersey for purposes of this action prior to the filing of this Complaint.

ANSWER: Paragraph 46 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 46 and therefore denies those allegations.

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

ANSWER: Paragraph 47 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 47 and therefore denies those allegations.

48. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Qilu Pharma is registered to do business in New Jersey and, upon information and belief, maintains a regular and established place of business at 108 Carnegie Center, Suite 208, Princeton, New Jersey 08540.

ANSWER: Paragraph 48 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 48 and therefore denies those allegations.

49. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Defendant Qilu Antibiotics is a Chinese corporation and may be sued in any judicial district in the United States.

ANSWER: Paragraph 49 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 49 and therefore denies those allegations.

50. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Defendant Apotex is a Canadian corporation and may be sued in any judicial district in the United States.

ANSWER: Paragraph 50 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 50 and therefore denies those allegations.

Fresenius Defendants

51. This Court has personal jurisdiction over Defendant Fresenius Kabi USA because, upon information and belief, it has created a presence in New Jersey through its registration with the New Jersey Department of the Treasury as a Foreign Limited Liability Company under Entity Identification No. 0600313148.

ANSWER: Denied.

52. Upon information and belief, Defendant Fresenius USA is registered with the State of New Jersey's Department of Health as a wholesaler under Registration No. 5003710.

ANSWER: Paragraph 52 contains legal conclusions to which no answer is required. To the extent Fresenius is required to answer, Fresenius admits that the online records of the New Jersey Department of Health lists "FRESENIUS KABI USA, LLC" under Registration No. 5003710. (*See* https://healthapps.nj.gov/fooddrug/OneRecord.aspx?id=5003710 (last accessed February 13, 2025)). Fresenius denies any and all remaining allegations contained in Paragraph 52.

53. This Court also has personal jurisdiction over Defendant Fresenius USA because it has had previous patent litigation disputes in the District of New Jersey 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 *Merck Sharp & Dohme BV, et al. v. Fresenius Kabi USA, LLC, et al.*, No. 2:20-cv-02892 (D.N.J.); *Boehringer Ingelheim Pharmaceuticals, Inc., et al., v. Fresenius Kabi USA, LLC, et al.*, No. 3:18-cv-03244 (D.N.J.).

ANSWER: Denied.

54. This Court also has personal jurisdiction over Defendant Fresenius USA because it has affirmatively invoked this Court's jurisdiction by filing patent litigation complaints in the District of New Jersey, including in at least *Fresenius Kabi USA, LLC v. Accord Healthcare, Inc.*, 1:24-cv-05674 (D.N.J.); *Fresenius Kabi USA LLC v. Amneal Pharmaceuticals LLC, et al.*, 2:23-cv-04343 (D.N.J.); *Fresenius Kabi USA, LLC v. Zydus Pharmaceuticals (USA) Inc.*, No. 3:22-cv-01702 (D.N.J.).

ANSWER: Denied.

55. 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 New Jersey, regularly conducts business in the State of New Jersey, 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 New Jersey, and intends to sell Fresenius's proposed generic AVYCAZ® Product in the State of New Jersey upon approval of ANDA No. 219325.

ANSWER: Denied.

56. The Fresenius 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 New Jersey. Upon information and belief and as indicated in Fresenius's Notice Letter, the Fresenius Defendants prepared and filed ANDA No. 219325 with

the intention of seeking to market Fresenius's proposed generic AVYCAZ® product nationwide, including in New Jersey.

ANSWER: Denied.

57. Upon information and belief, the Fresenius Defendants plan to sell Fresenius's proposed generic AVYCAZ® product in the State of New Jersey, list Fresenius's proposed generic AVYCAZ® product in the state of New Jersey's prescription drug formulary, and seek Medicaid reimbursements for sales of Fresenius's proposed generic AVYCAZ® product in the State of New Jersey, either directly or through one or more of their wholly owned subsidiaries, agents, affiliates, and/or alter egos.

ANSWER: Denied.

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

ANSWER: Denied.

59. 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.

ANSWER: Denied.

60. 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 the Fresenius Defendants to litigate this action in this Court, and the Fresenius Defendants are subject to personal jurisdiction in New Jersey.

ANSWER: Denied.

61. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Denied.

62. Venue is also proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b) because, upon information and belief, the Fresenius Defendants: (1) have sought approval from the FDA to market and sell Fresenius's proposed generic AVYCAZ® product in New Jersey; and (2) have engaged in regular and established business contacts with New Jersey by, among other

things, marketing, making, shipping, using, offering to sell or selling pharmaceutical products in New Jersey; and (3) deriving substantial revenue from such activities.

ANSWER: Denied.

63. 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 New Jersey under Entity Identification No. 0600313148, registered with the State of New Jersey's Department of Health as a wholesaler under Registration No. 5003710 and has repeatedly consented to and/or invoked the venue of this Court as a litigant.

ANSWER: Denied.

64. On 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 New Jersey for the sale of Fresenius's proposed generic AVYCAZ® product.

ANSWER: Denied.

65. On information and belief, Fresenius USA has a regular and established place of business in New Jersey. On information and belief, Fresenius USA maintains an office at 100 Charles Ewing Blvd, Trenton, NJ 08628-6454 and has employees located in the state of New Jersey.

ANSWER: Denied.

66. 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.

ANSWER: Paragraph 66 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius iPSUM does not contest venue in this Court solely for the purposes of this action only and reserves the right to contest venue in any other case. Fresenius denies any and all remaining allegations contained in Paragraph 66.

THE PATENTS-IN-SUIT

67. 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.

ANSWER: Paragraph 67 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that, according to the online records of the United States Patent and Trademark Office ("USPTO"), the '025 patent, titled "Crystalline Forms Of Trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide Sodium Salt," issued on or about June 25, 2013. Answering further, Fresenius denies that the '025 patent was duly or legally issued. Fresenius denies any and all remaining allegations contained in Paragraph 67.

68. A true and correct copy of the '025 Patent is attached hereto as "Exhibit A."

ANSWER: Paragraph 68 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that what purports to be a copy of the '025 patent is attached to the Complaint as Exhibit A. Fresenius denies any and all remaining allegations contained in Paragraph 68.

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

ANSWER: Paragraph 69 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that, according to the electronic records of the USPTO, "ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED" is identified as the current assignee of the '025 patent. Fresenius lacks knowledge or information sufficient to form a belief as to truth of the remaining allegations of Paragraph 69, and therefore denies any and all remaining allegations of Paragraph 69.

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

ANSWER: Paragraph 70 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, denied.

71. 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.

ANSWER: Paragraph 71 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that, according to the online records of the USPTO, the ’455 patent, titled “Crystalline Forms Of Trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide Sodium Salt,” issued on or about September 16, 2014. Answering further, Fresenius denies that the ’455 patent was duly or legally issued. Fresenius denies any and all remaining allegations contained in Paragraph 71.

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

ANSWER: Paragraph 72 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that what purports to be a copy of the ’455 patent is attached to the Complaint as Exhibit B. Fresenius denies any and all remaining allegations contained in Paragraph 72.

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

ANSWER: Paragraph 73 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that, according to the electronic records of the USPTO, “ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED” is identified as the current assignee of the ’455 patent. Fresenius lacks knowledge or information sufficient to form a belief as to truth of the remaining allegations of Paragraph 73, and therefore denies any and all remaining allegations of Paragraph 73.

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

ANSWER: Paragraph 74 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, denied.

75. 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.

ANSWER: Paragraph 75 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that, according to the online records of the USPTO, the ’566 patent, titled “Processes For Preparing Heterocyclic Compounds Including Trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide And Salts Thereof,” issued on or about March 3, 2015. Answering further, Fresenius denies that the ’566 patent was duly or legally issued. Fresenius denies any and all remaining allegations contained in Paragraph 75.

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

ANSWER: Paragraph 76 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that what purports to be a copy of the ’566 patent is attached to the Complaint as Exhibit C. Fresenius denies any and all remaining allegations contained in Paragraph 76.

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

ANSWER: Paragraph 77 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that, according to the electronic records of the USPTO, “ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED” is identified as the current assignee of the ’566 patent. Answering further, Fresenius lacks knowledge or information sufficient to form a belief as to truth of the remaining allegations of Paragraph 77, and therefore denies any and all remaining allegations of Paragraph 77.

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

ANSWER: Paragraph 78 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, denied.

79. 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.

ANSWER: Paragraph 79 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that, according to the online records of the USPTO, the ’314 patent, titled “Processes For Preparing Heterocyclic Compounds Including Trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide And Salts Thereof,” issued on or about March 15, 2016. Answering further, Fresenius denies that the ’314 patent was duly or legally issued. Fresenius denies any and all remaining allegations contained in Paragraph 79.

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

ANSWER: Paragraph 80 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that what purports to be a copy of the ’314 patent is attached to the Complaint as Exhibit D. Fresenius denies any and all remaining allegations contained in Paragraph 80.

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

ANSWER: Paragraph 81 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that, according to the electronic records of the USPTO, “ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED” is identified as the current assignee of the ’314 patent. Answering further, Fresenius lacks knowledge or information sufficient to form a belief as to truth of the remaining allegations of Paragraph 81, and therefore denies any and all remaining allegations of Paragraph 81.

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

ANSWER: Paragraph 82 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, denied.

83. 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.

ANSWER: Paragraph 83 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that, according to the online records of the USPTO, the ’122 patent, titled “Processes For Preparing Heterocyclic Compounds Including Trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide And Salts Thereof,” issued on or about July 4, 2017. Answering further, Fresenius denies that the ’122 patent was duly or legally issued. Fresenius denies any and all remaining allegations contained in Paragraph 83.

84. A true and correct copy of the ’122 Patent is attached hereto as “Exhibit E.”

ANSWER: Paragraph 84 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that what purports to be a copy of the ’122 patent is attached to the Complaint as Exhibit E. Fresenius denies any and all remaining allegations contained in Paragraph 84.

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

ANSWER: Paragraph 85 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that, according to the electronic records of the USPTO, “ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED” is identified as the current assignee of the ’122 patent. Answering further, Fresenius lacks knowledge or information sufficient to form a belief as to truth of the remaining allegations of Paragraph 85, and therefore denies any and all remaining allegations of Paragraph 85.

86. The ’122 Patent currently expires on June 15, 2032.

ANSWER: Paragraph 86 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, denied.

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

ANSWER: Denied.

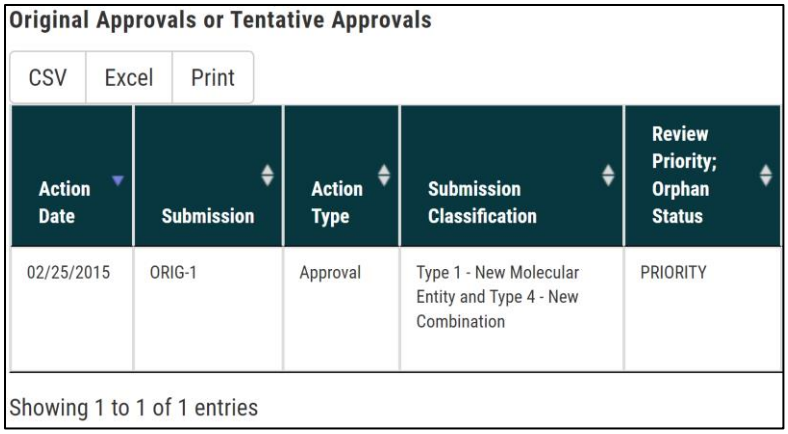
PLAINTIFFS’ AVYCAZ® PRODUCT

88. 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.

ANSWER: Fresenius lacks knowledge or information sufficient to form a belief as to truth of the allegations of Paragraph 88, and therefore denies any and all remaining allegations of Paragraph 88.

89. 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.

ANSWER: Paragraph 89 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that online FDA records state as follows for New Drug Application (“NDA”) No. 206494:



Original Approvals or Tentative Approvals

CSV | Excel | Print

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status
02/25/2015	ORIG-1	Approval	Type 1 - New Molecular Entity and Type 4 - New Combination	PRIORITY

Showing 1 to 1 of 1 entries

(https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206494 (last accessed February 13, 2025)). Fresenius lacks knowledge or information sufficient to form a belief as to truth of the remaining allegations of Paragraph 89, and therefore denies any and all remaining allegations of Paragraph 89.

90. 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.

ANSWER: Paragraph 90 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that the electronic version of FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") identifies the following in connection with NDA No. 206494 for AVYCAZ®:

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
001	NCE	02/25/2020
001	NCE *GAIN	02/25/2025
001	NPP	12/20/2025
001	NPP	01/26/2027

(https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=206494&Appl_type=N (last accessed February 13, 2025)). Fresenius lacks knowledge or information sufficient to form a belief as to truth of the remaining allegations of Paragraph 90, and therefore denies any and all remaining allegations of Paragraph 90.

91. 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®."

ANSWER: Paragraph 91 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that the Orange Book identifies the following in connection with NDA No. 206494 for AVYCAZ®:

Application Number: N206494
Product Number: 001
Approval Date: Feb 25, 2015
Applicant Holder Full Name: ABBVIE INC

(https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=206494#21544 (last accessed February 13, 2025)). Fresenius denies any and all remaining allegations contained in Paragraph 91.

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

ANSWER: Paragraph 92 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that the Orange Book identifies the following in connection with NDA No. 206494 for AVYCAZ®:

Application Number: N206494
Product Number: 001
Approval Date: Feb 25, 2015
Applicant Holder Full Name: ABBVIE INC

(https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=206494#21544 (last accessed February 13, 2025)). Fresenius denies any and all remaining allegations contained in Paragraph 92.

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

ANSWER: Paragraph 93 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that the current FDA-approved prescribing information for AVYCAZ® states in part as follows:

----------INDICATIONS AND USAGE----------
AVYCAZ is a combination of ceftazidime, a cephalosporin, and avibactam, a beta-lactamase inhibitor, indicated for the treatment of the following infections caused by designated susceptible Gram-negative microorganisms in adult and pediatric patients (at least 31 weeks gestational age):

(AVYCAZ® Prescribing Information (Revised: 1/2024) (available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/206494s012lbl.pdf (last accessed February 13, 2025))). Fresenius denies any and all remaining allegations contained in Paragraph 93.

94. 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).

ANSWER: Paragraph 94 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that the current FDA-approved Prescribing Information for AVYCAZ® states in part as follows:

> **----------DOSAGE FORMS AND STRENGTHS----------**
> AVYCAZ 2.5g (ceftazidime and avibactam) for injection is supplied as a sterile powder for constitution in single-dose vials containing ceftazidime 2 grams (equivalent to 2.635 grams of ceftazidime pentahydrate/sodium carbonate powder) and avibactam 0.5 grams (equivalent to 0.551 grams of avibactam sodium). (*3*)

(AVYCAZ® Prescribing Information (Revised: 1/2024) (available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/206494s012lbl.pdf (last accessed February 13, 2025))). Fresenius denies any and all remaining allegations contained in Paragraph 94.

95. 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).

ANSWER: Paragraph 95 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that the current FDA-approved Prescribing Information for AVYCAZ® states in part as follows:

> **----------INDICATIONS AND USAGE----------**
> AVYCAZ is a combination of ceftazidime, a cephalosporin, and avibactam, a beta-lactamase inhibitor, indicated for the treatment of the following infections caused by designated susceptible Gram-negative microorganisms in adult and pediatric patients (at least 31 weeks gestational age):
> - Complicated Intra-abdominal Infections (cIAI), used in combination with metronidazole (*1.1*)
> - Complicated Urinary Tract Infections (cUTI), including Pyelonephritis (*1.2*)
> - Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP) (*1.3*)

(AVYCAZ® Prescribing Information (Revised: 1/2024) (available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/206494s012lbl.pdf (last accessed

February 13, 2025))). Fresenius denies any and all remaining allegations contained in Paragraph 95.

96. 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.

ANSWER: Paragraph 96 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that FDA's Orange Book identifies the following in connection with NDA No. 206494 for AVYCAZ®:

Product No	Patent No
001	7112592
001	7612087
001	8471025
001	8835455
001	8969566
001	9284314
001	9695122

(https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=206494&Appl_type=N (last accessed February 13, 2025)). Fresenius denies any and all remaining allegations contained in Paragraph 96.

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

ANSWER: Paragraph 97 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 97 and therefore denies those allegations.

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

ANSWER: Paragraph 98 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that FDA's Orange Book identifies, *inter alia*, the Patents-in-Suit in connection with NDA No. 206494 for AVYCAZ®. Fresenius denies any and all remaining allegations contained in Paragraph 98.

QILU'S PROPOSED GENERIC AVYCAZ® PRODUCT

99. Qilu's Notice Letter states that the FDA received ANDA No. 219392 from Defendant Qilu Pharma 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 avibactam sodium (0.5 g base/vial); ceftazidime (2 g/vial) powder for intravenous injection, which is a generic version of AbbVie's AVYCAZ®, before the expiration of the Patents-in-Suit.

ANSWER: Paragraph 99 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 99 and therefore denies those allegations.

100. Qilu's Notice Letter represents that ANDA No. 219392 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 Qilu's proposed generic AVYCAZ® product.

ANSWER: Paragraph 100 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 100 and therefore denies those allegations.

101. Qilu's Notice Letter does not state or otherwise indicate that the Qilu 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, the Qilu 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.

ANSWER: Paragraph 101 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 101 and therefore denies those allegations.

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

ANSWER: Paragraph 102 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 102 and therefore denies those allegations.

103. By submitting ANDA No. 219392, and as stated in Qilu's Notice Letter, the Qilu Defendants have represented to the FDA that Qilu's proposed generic AVYCAZ® product has the same active ingredient, dosage form, route of administration, and strength as AVYCAZ®, and is bioequivalent to AVYCAZ®.

ANSWER: Paragraph 103 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 103 and therefore denies those allegations.

104. The Qilu Defendants have knowledge of the Patents-in-Suit and had knowledge of the Patents-in-Suit when ANDA No. 219392 was submitted to the FDA.

ANSWER: Paragraph 104 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 104 and therefore denies those allegations.

105. Qilu's Notice Letter contained an Offer of Confidential Access to certain confidential information within ANDA No. 219392 regarding Qilu's proposed generic AVYCAZ® product. Outside counsel for Plaintiffs negotiated in good faith with outside counsel for the Qilu Defendants in an attempt to reach an agreement on reasonable terms of confidential access to ANDA No. 219392. Despite multiple email exchanges, as of June 5, 2024, the parties were unable to reach an agreement. As of June 5, 2024, Plaintiffs have not received access to ANDA No. 219392.

ANSWER: Paragraph 105 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 105 and therefore denies those allegations.

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

ANSWER: Paragraph 106 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 106 and therefore denies those allegations.

FRESENIUS'S PROPOSED GENERIC AVYCAZ® PRODUCT

107. 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.

ANSWER: Paragraph 107 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA sent a Notification of Certification of Invalidity, Unenforceability and/or Non-Infringement relevant to certain patents listed in the Orange Book in connection with NDA No. 206494 to AbbVie, Inc. and Allergan Sales, LLC ("Fresenius USA's Notice Letter"). In further answering, Fresenius admits that Fresenius USA's Notice Letter provided notice that FDA had received Fresenius USA's

ANDA No. 219325 and further admits that the contents of Fresenius USA's Notice Letter speak for themselves. Fresenius denies any and all remaining allegations contained in Paragraph 107.

108. 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.

ANSWER: Paragraph 108 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA served Fresenius USA's Notice Letter, the contents of which speak for themselves. Fresenius denies any and all remaining allegations contained in Paragraph 108.

109. Fresenius's Notice Letter does not state or otherwise indicate that the Fresenius 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, the Fresenius 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.

ANSWER: Paragraph 109 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA served Fresenius USA's Notice Letter, the contents of which speak for themselves. Fresenius denies any and all remaining allegations contained in Paragraph 109.

110. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

111. By submitting ANDA No. 219325, and as stated in Fresenius's Notice Letter, the Fresenius 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®.

ANSWER: Paragraph 111 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA submitted ANDA No. 219325 to FDA seeking approval to market Fresenius USA's ANDA Product. Answering further, Fresenius USA's Notice Letter states that "[t]he ANDA contains the required bioavailability and/or bioequivalence data and/or bioequivalence waiver." Fresenius denies any and all remaining allegations contained in Paragraph 111.

112. The Fresenius 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.

ANSWER: Paragraph 112 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that, in accordance with Section 505(j) of the Federal Food, Drug, and Cosmetic Act, as amended, and 21 C.F.R. § 314.94, Fresenius was required to address any patent and exclusivity data from the Orange Book relevant to NDA No. 206494 for AVYCAZ® with its patent certification statement; as such, Fresenius had knowledge of the Patents-in-Suit when Fresenius USA submitted ANDA No. 219325 to FDA. Fresenius denies any and all remaining allegations contained in Paragraph 112.

113. 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 the Fresenius Defendants in an attempt to reach an agreement on reasonable terms of confidential access to ANDA No. 219325. Despite multiple email exchanges, as of June 5, 2024, the parties were unable to reach an agreement. As of June 5, 2024, Plaintiffs have not received access to ANDA No. 219325.

ANSWER: Paragraph 113 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that, pursuant to 21 C.F.R. § 314.95(c)(8), Fresenius USA's Notice Letter contained an Offer of Confidential Access ("OCA") to portions of Fresenius USA's ANDA that would allow Plaintiffs to determine whether an action

under 21 U.S.C. § 355 should be filed. Answering further, Fresenius USA's OCA included reasonable terms, which Plaintiffs did not accept; Plaintiffs subsequently filed suit on June 6, 2024. Fresenius denies any and all remaining allegations contained in Paragraph 113.

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

ANSWER: Paragraph 114 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Plaintiffs filed the Complaint on June 6, 2024. Fresenius denies any and all remaining allegations contained in Paragraph 114.

COUNT I
U.S. PATENT NO. 8,471,025: 35 U.S.C. § 271(e)(2)
(QILU)

115. Plaintiffs incorporate each of the preceding paragraphs 1 – 114 as if fully set forth herein.

ANSWER: No response is required from Fresenius to the extent that the allegations in Paragraph 115 are directed to an entity other than Fresenius. To the extent that Fresenius is required to answer, Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 114 of the Complaint as if fully set forth herein.

116. The Qilu Defendants' submission of ANDA No. 219392, 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 Qilu'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.

ANSWER: Paragraph 116 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 116 and therefore denies those allegations.

117. Upon information and belief, Qilu Antibiotics and Apotex 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. 219392 to the FDA.

ANSWER: Paragraph 117 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 117 and therefore denies those allegations.

118. After FDA approval of ANDA No. 219392, the Qilu 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 Qilu'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. 219392 shall be no earlier than the expiration of the '025 Patent and any additional periods of exclusivity.

ANSWER: Paragraph 118 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 118 and therefore denies those allegations.

119. Qilu's Notice Letter does not contest infringement of claims 1-16 and 27-30 of the '025 Patent. If the Qilu Defendants had a factual or legal basis to contest infringement of those claims of the '025 Patent, they were required by applicable regulations to state such a basis in Qilu's Notice Letter. See 21 C.F.R. § 314.95(c)(7); see also 21 C.F.R. § 314.52.

ANSWER: Paragraph 119 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 119 and therefore denies those allegations.

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

ANSWER: Paragraph 120 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or

information to form a belief as to the allegations of Paragraph 120 and therefore denies those allegations.

121. The Qilu 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.

ANSWER: Paragraph 121 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 121 and therefore denies those allegations.

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

ANSWER: Paragraph 122 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 122 and therefore denies those allegations.

123. The Qilu Defendants have knowledge and are aware of the '025 Patent, as evidenced by Qilu's Notice Letter.

ANSWER: Paragraph 123 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 123 and therefore denies those allegations.

124. Unless the Qilu 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.

ANSWER: Paragraph 124 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or

information to form a belief as to the allegations of Paragraph 124 and therefore denies those allegations.

COUNT II
DECLARATORY JUDGMENT: U.S. PATENT NO. 8,471,025
(QILU)

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

ANSWER: No response is required from Fresenius to the extent that the allegations in Paragraph 125 are directed to an entity other than Fresenius. To the extent that Fresenius is required to answer, Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 124 of the Complaint as if fully set forth herein.

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

ANSWER: Paragraph 126 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 126 and therefore denies those allegations.

127. Upon information and belief, upon FDA approval of ANDA No. 219392, the Qilu 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 Qilu's proposed generic AVYCAZ® product, unless enjoined by the Court.

ANSWER: Paragraph 127 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 127 and therefore denies those allegations.

128. Upon information and belief, the Qilu 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. 219392 is approved by marketing Qilu's proposed generic AVYCAZ® product and encouraging doctors and patients to infringe the '025 Patent, unless enjoined by the Court.

ANSWER: Paragraph 128 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 128 and therefore denies those allegations.

129. Qilu's Notice Letter does not contest infringement of claims 1-16 and 27-30 of the '025 Patent. If the Qilu Defendants had a factual or legal basis to contest infringement of those claims of the '025 Patent, they were required by applicable regulations to state such a basis in Qilu's Notice Letter. *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

ANSWER: Paragraph 129 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 129 and therefore denies those allegations.

130. The Qilu Defendants have knowledge and are aware of the '025 Patent, as evidenced by Qilu's Notice Letter.

ANSWER: Paragraph 130 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 130 and therefore denies those allegations.

131. Upon information and belief, the Qilu Defendants will contribute to infringement of one or more claims of the '025 Patent under 35 U.S.C. § 271(c) when ANDA No. 219392 is approved, unless enjoined by the Court, because the Qilu Defendants know or should know that Qilu's proposed generic AVYCAZ® product is especially made or adapted for use in infringing the '025 Patent, and Qilu's proposed generic AVYCAZ® product is not suitable for substantial noninfringing use.

ANSWER: Paragraph 131 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or

information to form a belief as to the allegations of Paragraph 131 and therefore denies those allegations.

132. The Qilu Defendants' infringement is imminent.

ANSWER: Paragraph 132 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 132 and therefore denies those allegations.

133. The Qilu Defendants have notified AbbVie of the submission of ANDA No. 219392 seeking approval to engage in the manufacture, use, sale, or importation of Qilu's proposed generic AVYCAZ® product before the expiration of the '025 Patent.

ANSWER: Paragraph 133 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 133 and therefore denies those allegations.

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

ANSWER: Paragraph 134 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 134 and therefore denies those allegations.

135. 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.

ANSWER: Paragraph 135 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or

information to form a belief as to the allegations of Paragraph 135 and therefore denies those allegations.

136. Unless the Qilu 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.

ANSWER: Paragraph 136 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 136 and therefore denies those allegations.

COUNT III
U.S. PATENT NO. 8,835,455: 35 U.S.C. § 271(e)(2)
(QILU)

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

ANSWER: No response is required from Fresenius to the extent that the allegations in Paragraph 137 are directed to an entity other than Fresenius. To the extent that Fresenius is required to answer, Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 136 of the Complaint as if fully set forth herein.

138. The Qilu Defendants' submission of ANDA No. 219392, 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 Qilu'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.

ANSWER: Paragraph 138 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 138 and therefore denies those allegations.

139. Upon information and belief, Qilu Antibiotics and Apotex 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. 219392 to the FDA.

ANSWER: Paragraph 139 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 139 and therefore denies those allegations.

140. After FDA approval of ANDA No. 219392, the Qilu 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 Qilu'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. 219392 shall be no earlier than the expiration of the '455 Patent and any additional periods of exclusivity.

ANSWER: Paragraph 140 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 140 and therefore denies those allegations.

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

ANSWER: Paragraph 141 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 141 and therefore denies those allegations.

142. The Qilu 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.

ANSWER: Paragraph 142 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or

information to form a belief as to the allegations of Paragraph 142 and therefore denies those allegations.

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

ANSWER: Paragraph 143 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 143 and therefore denies those allegations.

144. The Qilu Defendants have knowledge and are aware of the '455 Patent, as evidenced by Qilu's Notice Letter.

ANSWER: Paragraph 144 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 144 and therefore denies those allegations.

145. Unless the Qilu 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.

ANSWER: Paragraph 145 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 145 and therefore denies those allegations.

COUNT IV
DECLARATORY JUDGMENT: U.S. PATENT NO. 8,835,455
(QILU)

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

ANSWER: No response is required from Fresenius to the extent that the allegations in Paragraph 146 are directed to an entity other than Fresenius. To the extent that Fresenius is required to answer, Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 145 of the Complaint as if fully set forth herein.

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

ANSWER: Paragraph 147 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 147 and therefore denies those allegations.

148. Upon information and belief, upon FDA approval of ANDA No. 219392, the Qilu 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 Qilu's proposed generic AVYCAZ® product, unless enjoined by the Court.

ANSWER: Paragraph 148 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 148 and therefore denies those allegations.

149. Upon information and belief, the Qilu 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. 219392 is approved by marketing Qilu's proposed generic AVYCAZ® product and encouraging doctors and patients to infringe the '455 Patent, unless enjoined by the Court.

ANSWER: Paragraph 149 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or

information to form a belief as to the allegations of Paragraph 149 and therefore denies those allegations.

150. The Qilu Defendants have knowledge and are aware of the '455 Patent, as evidenced by Qilu's Notice Letter.

ANSWER: Paragraph 150 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 150 and therefore denies those allegations.

151. Upon information and belief, the Qilu Defendants will contribute to infringement of one or more claims of the '455 Patent under 35 U.S.C. § 271(c) when ANDA No. 219392 is approved, unless enjoined by the Court, because the Qilu Defendants know or should know that Qilu's proposed generic AVYCAZ® product is especially made or adapted for use in infringing the '455 Patent, and Qilu's proposed generic AVYCAZ® product is not suitable for substantial noninfringing use.

ANSWER: Paragraph 151 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 151 and therefore denies those allegations.

152. The Qilu Defendants' infringement is imminent.

ANSWER: Paragraph 152 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 152 and therefore denies those allegations.

153. The Qilu Defendants have notified AbbVie of the submission of ANDA No. 219392 seeking approval to engage in the manufacture, use, sale, or importation of Qilu's proposed generic AVYCAZ® product before the expiration of the '455 Patent.

ANSWER: Paragraph 153 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or

information to form a belief as to the allegations of Paragraph 153 and therefore denies those allegations.

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

ANSWER: Paragraph 154 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 154 and therefore denies those allegations.

155. 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.

ANSWER: Paragraph 155 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 155 and therefore denies those allegations.

156. Unless the Qilu 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.

ANSWER: Paragraph 156 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 156 and therefore denies those allegations.

COUNT V
U.S. PATENT NO. 8,969,566: 35 U.S.C. § 271(e)(2)
(QILU)

157. Plaintiffs incorporate each of the preceding paragraphs 1 – 156 as if fully set forth herein.

ANSWER: No response is required from Fresenius to the extent that the allegations in Paragraph 157 are directed to an entity other than Fresenius. To the extent that Fresenius is required to answer, Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 156 of the Complaint as if fully set forth herein.

158. The Qilu Defendants' submission of ANDA No. 219392, 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 Qilu'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.

ANSWER: Paragraph 158 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 158 and therefore denies those allegations.

159. Upon information and belief, Qilu Antibiotics and Apotex 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. 219392 to the FDA.

ANSWER: Paragraph 159 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 159 and therefore denies those allegations.

160. After FDA approval of ANDA No. 219392, the Qilu 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 Qilu'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. 219392 shall be no earlier than the expiration of the '566 Patent and any additional periods of exclusivity.

ANSWER: Paragraph 160 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 160 and therefore denies those allegations.

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

ANSWER: Paragraph 161 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 161 and therefore denies those allegations.

162. The Qilu 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.

ANSWER: Paragraph 162 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 162 and therefore denies those allegations.

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

ANSWER: Paragraph 163 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 163 and therefore denies those allegations.

164. The Qilu Defendants have knowledge and are aware of the '566 Patent, as evidenced by Qilu's Notice Letter.

ANSWER: Paragraph 164 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 164 and therefore denies those allegations.

165. Unless the Qilu 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.

ANSWER: Paragraph 165 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 165 and therefore denies those allegations.

COUNT VI
DECLARATORY JUDGMENT: U.S. PATENT NO. 8,969,566
(QILU)

166. Plaintiffs incorporate each of the preceding paragraphs 1 – 165 as if fully set forth herein.

ANSWER: No response is required from Fresenius to the extent that the allegations in Paragraph 166 are directed to an entity other than Fresenius. To the extent that Fresenius is required to answer, Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 165 of the Complaint as if fully set forth herein.

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

ANSWER: Paragraph 167 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or

information to form a belief as to the allegations of Paragraph 167 and therefore denies those allegations.

168. Upon information and belief, upon FDA approval of ANDA No. 219392, the Qilu 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 Qilu's proposed generic AVYCAZ® product, unless enjoined by the Court.

ANSWER: Paragraph 168 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 168 and therefore denies those allegations.

169. Upon information and belief, the Qilu 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. 219392 is approved by marketing Qilu's proposed generic AVYCAZ® product and encouraging doctors and patients to infringe the '566 Patent, unless enjoined by the Court.

ANSWER: Paragraph 169 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 169 and therefore denies those allegations.

170. The Qilu Defendants have knowledge and are aware of the '566 Patent, as evidenced by Qilu's Notice Letter.

ANSWER: Paragraph 170 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 170 and therefore denies those allegations.

171. Upon information and belief, the Qilu Defendants will contribute to infringement of one or more claims of the '566 Patent under 35 U.S.C. § 271(c) when ANDA No. 219392 is approved, unless enjoined by the Court, because the Qilu Defendants know or should know that Qilu's proposed generic AVYCAZ® product is especially made or adapted for use in infringing

the ’566 Patent, and Qilu’s proposed generic AVYCAZ® product is not suitable for substantial noninfringing use.

ANSWER: Paragraph 171 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 171 and therefore denies those allegations.

172. Upon information and belief, the Qilu Defendants will infringe one or more claims of the ’566 Patent under 35 U.S.C. § 271(g) when ANDA No. 219392 is approved, unless enjoined by the Court, because Qilu’s proposed generic AVYCAZ® product will be made by a process that infringes the ’566 Patent and then imported into the United States.

ANSWER: Paragraph 172 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 172 and therefore denies those allegations.

173. The Qilu Defendants’ infringement is imminent.

ANSWER: Paragraph 173 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 173 and therefore denies those allegations.

174. The Qilu Defendants have notified AbbVie of the submission of ANDA No. 219392 seeking approval to engage in the manufacture, use, sale, or importation of Qilu’s proposed generic AVYCAZ® product before the expiration of the ’566 Patent.

ANSWER: Paragraph 174 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 174 and therefore denies those allegations.

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

ANSWER: Paragraph 175 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 175 and therefore denies those allegations.

176. 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.

ANSWER: Paragraph 176 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 176 and therefore denies those allegations.

177. Unless the Qilu 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.

ANSWER: Paragraph 177 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 177 and therefore denies those allegations.

COUNT VII
U.S. PATENT NO. 9,284,314: 35 U.S.C. § 271(e)(2)
(QILU)

178. Plaintiffs incorporate each of the preceding paragraphs 1 – 177 as if fully set forth herein.

ANSWER: No response is required from Fresenius to the extent that the allegations in Paragraph 178 are directed to an entity other than Fresenius. To the extent that Fresenius is

required to answer, Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 177 of the Complaint as if fully set forth herein.

179. The Qilu Defendants' submission of ANDA No. 219392, 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 Qilu'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.

ANSWER: Paragraph 179 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 179 and therefore denies those allegations.

180. Upon information and belief, Qilu Antibiotics and Apotex 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. 219392 to the FDA.

ANSWER: Paragraph 180 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 180 and therefore denies those allegations.

181. After FDA approval of ANDA No. 219392, the Qilu 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 Qilu'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. 219392 shall be no earlier than the expiration of the '314 Patent and any additional periods of exclusivity.

ANSWER: Paragraph 181 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 181 and therefore denies those allegations.

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

ANSWER: Paragraph 182 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 182 and therefore denies those allegations.

183. The Qilu 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.

ANSWER: Paragraph 183 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 183 and therefore denies those allegations.

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

ANSWER: Paragraph 184 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 184 and therefore denies those allegations.

185. The Qilu Defendants have knowledge and are aware of the '314 Patent, as evidenced by Qilu's Notice Letter.

ANSWER: Paragraph 185 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 185 and therefore denies those allegations.

186. Unless the Qilu 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.

ANSWER: Paragraph 186 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 186 and therefore denies those allegations.

COUNT VIII
DECLARATORY JUDGMENT: U.S. PATENT NO. 9,284,314
(QILU)

187. Plaintiffs incorporate each of the preceding paragraphs 1 – 186 as if fully set forth herein.

ANSWER: No response is required from Fresenius to the extent that the allegations in Paragraph 187 are directed to an entity other than Fresenius. To the extent that Fresenius is required to answer, Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 186 of the Complaint as if fully set forth herein.

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

ANSWER: Paragraph 188 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 188 and therefore denies those allegations.

189. Upon information and belief, upon FDA approval of ANDA No. 219392, the Qilu 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 Qilu's proposed generic AVYCAZ® product, unless enjoined by the Court.

ANSWER: Paragraph 189 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or

information to form a belief as to the allegations of Paragraph 189 and therefore denies those allegations.

190. Upon information and belief, the Qilu 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. 219392 is approved by marketing Qilu's proposed generic AVYCAZ® product and encouraging doctors and patients to infringe the '314 Patent, unless enjoined by the Court.

ANSWER: Paragraph 190 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 190 and therefore denies those allegations.

191. The Qilu Defendants have knowledge and are aware of the '314 Patent, as evidenced by Qilu's Notice Letter.

ANSWER: Paragraph 191 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 191 and therefore denies those allegations.

192. Upon information and belief, the Qilu Defendants will contribute to infringement of one or more claims of the '314 Patent under 35 U.S.C. § 271(c) when ANDA No. 219392 is approved, unless enjoined by the Court, because the Qilu Defendants know or should know that Qilu's proposed generic AVYCAZ® product is especially made or adapted for use in infringing the '314 Patent, and Qilu's proposed generic AVYCAZ® product is not suitable for substantial noninfringing use.

ANSWER: Paragraph 192 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 192 and therefore denies those allegations.

193. Upon information and belief, the Qilu 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. 219392 is approved, unless enjoined by the Court, because Qilu's proposed generic AVYCAZ®

product will be made by a process that infringes the '314 Patent and then imported into the United States.

ANSWER: Paragraph 193 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 193 and therefore denies those allegations.

194. The Qilu Defendants' infringement is imminent.

ANSWER: Paragraph 194 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 194 and therefore denies those allegations.

195. The Qilu Defendants have notified AbbVie of the submission of ANDA No. 219392 seeking approval to engage in the manufacture, use, sale, or importation of Qilu's proposed generic AVYCAZ® product before the expiration of the '314 Patent.

ANSWER: Paragraph 195 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 195 and therefore denies those allegations.

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

ANSWER: Paragraph 196 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 196 and therefore denies those allegations.

197. 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.

ANSWER: Paragraph 197 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 197 and therefore denies those allegations.

198. Unless the Qilu 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.

ANSWER: Paragraph 198 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 198 and therefore denies those allegations.

COUNT IX
U.S. PATENT NO. 9,695,122: 35 U.S.C. § 271(e)(2)
(QILU)

199. Plaintiffs incorporate each of the preceding paragraphs 1 – 198 as if fully set forth herein.

ANSWER: No response is required from Fresenius to the extent that the allegations in Paragraph 199 are directed to an entity other than Fresenius. To the extent that Fresenius is required to answer, Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 198 of the Complaint as if fully set forth herein.

200. The Qilu Defendants' submission of ANDA No. 219392, 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 Qilu'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.

ANSWER: Paragraph 200 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 200 and therefore denies those allegations.

201. Upon information and belief, Qilu Antibiotics and Apotex 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. 219392 to the FDA.

ANSWER: Paragraph 201 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 201 and therefore denies those allegations.

202. After FDA approval of ANDA No. 219392, the Qilu 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 Qilu'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. 219392 shall be no earlier than the expiration of the '122 Patent and any additional periods of exclusivity.

ANSWER: Paragraph 202 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 202 and therefore denies those allegations.

203. Qilu's Notice Letter does not contest infringement of claims 1, 7-8, and 13-14 of the '122 Patent. If the Qilu Defendants had a factual or legal basis to contest infringement of those

claims of the '122 Patent, they were required by applicable regulations to state such a basis in Qilu's Notice Letter. See 21 C.F.R. § 314.95(c)(7); see also 21 C.F.R. § 314.52.

ANSWER: Paragraph 203 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 203 and therefore denies those allegations.

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

ANSWER: Paragraph 204 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 204 and therefore denies those allegations.

205. The Qilu 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.

ANSWER: Paragraph 205 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 205 and therefore denies those allegations.

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

ANSWER: Paragraph 206 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 206 and therefore denies those allegations.

207. The Qilu Defendants have knowledge and are aware of the '122 Patent, as evidenced by Qilu's Notice Letter.

ANSWER: Paragraph 207 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 207 and therefore denies those allegations.

208. Unless the Qilu 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.

ANSWER: Paragraph 208 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 208 and therefore denies those allegations.

COUNT X
DECLARATORY JUDGMENT: U.S. PATENT NO. 9,695,122
(QILU)

209. Plaintiffs incorporate each of the preceding paragraphs 1 – 208 as if fully set forth herein.

ANSWER: No response is required from Fresenius to the extent that the allegations in Paragraph 209 are directed to an entity other than Fresenius. To the extent that Fresenius is required to answer, Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 208 of the Complaint as if fully set forth herein.

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

ANSWER: Paragraph 210 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or

information to form a belief as to the allegations of Paragraph 210 and therefore denies those allegations.

211. Upon information and belief, upon FDA approval of ANDA No. 219392, the Qilu 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 Qilu's proposed generic AVYCAZ® product, unless enjoined by the Court.

ANSWER: Paragraph 211 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 211 and therefore denies those allegations.

212. Upon information and belief, the Qilu 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. 219392 is approved by marketing Qilu's proposed generic AVYCAZ® product and encouraging doctors and patients to infringe the '122 Patent, unless enjoined by the Court.

ANSWER: Paragraph 212 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 212 and therefore denies those allegations.

213. Qilu's Notice Letter does not contest infringement of claims 1, 7-8, and 13-14 of the '122 Patent. If the Qilu Defendants had a factual or legal basis to contest infringement of those claims of the '122 Patent, they were required by applicable regulations to state such a basis in Qilu's Notice Letter. *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

ANSWER: Paragraph 213 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 213 and therefore denies those allegations.

214. The Qilu Defendants have knowledge and are aware of the '122 Patent, as evidenced by Qilu's Notice Letter.

ANSWER: Paragraph 214 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 214 and therefore denies those allegations.

215. Upon information and belief, the Qilu Defendants will contribute to infringement of one or more claims of the '122 Patent under 35 U.S.C. § 271(c) when ANDA No. 219392 is approved, unless enjoined by the Court, because the Qilu Defendants know or should know that Qilu's proposed generic AVYCAZ® product is especially made or adapted for use in infringing the '122 Patent, and Qilu's proposed generic AVYCAZ® product is not suitable for substantial noninfringing use.

ANSWER: Paragraph 215 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 215 and therefore denies those allegations.

216. The Qilu Defendants' infringement is imminent.

ANSWER: Paragraph 216 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 216 and therefore denies those allegations.

217. The Qilu Defendants have notified AbbVie of the submission of ANDA No. 219392 seeking approval to engage in the manufacture, use, sale, or importation of Qilu's proposed generic AVYCAZ® product before the expiration of the '122 Patent.

ANSWER: Paragraph 217 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 217 and therefore denies those allegations.

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

ANSWER: Paragraph 218 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 218 and therefore denies those allegations.

219. 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.

ANSWER: Paragraph 219 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 219 and therefore denies those allegations.

220. Unless the Qilu 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.

ANSWER: Paragraph 220 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 220 and therefore denies those allegations.

COUNT XI
U.S. PATENT NO. 8,471,025: 35 U.S.C. § 271(e)(2)
(FRESENIUS)

221. Plaintiffs incorporate each of the preceding paragraphs 1 – 220 as if fully set forth herein.

ANSWER: Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 220 of the Complaint as if fully set forth herein.

222. The Fresenius 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.

ANSWER: Denied.

223. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

224. After FDA approval of ANDA No. 219325, the Fresenius 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.

ANSWER: Denied.

225. The Fresenius 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.

ANSWER: Denied.

226. The Fresenius 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.

ANSWER: Denied.

227. The Fresenius 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.

ANSWER: Denied.

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

ANSWER: Paragraph 228 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA's Notice Letter discloses that Fresenius USA submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '025 patent to FDA. Fresenius denies any and all remaining allegations contained in Paragraph 228.

229. Unless the Fresenius 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.

ANSWER: Denied.

COUNT XII
DECLARATORY JUDGMENT: U.S. PATENT NO. 8,471,025
(FRESENIUS)

230. Plaintiffs incorporate each of the preceding paragraphs 1 – 229 as if fully set forth herein.

ANSWER: Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 229 of the Complaint as if fully set forth herein.

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

ANSWER: Paragraph 231 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, denied.

232. Upon information and belief, upon FDA approval of ANDA No. 219325, the Fresenius 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.

ANSWER: Denied.

233. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

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

ANSWER: Paragraph 234 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA's Notice Letter discloses that Fresenius USA submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '025 patent to FDA. Fresenius denies any and all remaining allegations contained in Paragraph 234.

235. Upon information and belief, the Fresenius 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 the Fresenius 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.

ANSWER: Denied.

236. The Fresenius Defendants' infringement is imminent.

ANSWER: Denied.

237. The Fresenius 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.

ANSWER: Paragraph 237 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA's Notice Letter states that Fresenius USA submitted ANDA No. 219325 to FDA seeking approval to market Fresenius USA's ANDA Product before the expiration of the '025 patent. Fresenius denies any and all remaining allegations contained in Paragraph 237.

238. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

239. 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.

ANSWER: Denied.

240. Unless the Fresenius 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.

ANSWER: Denied.

COUNT XIII
U.S. PATENT NO. 8,835,455: 35 U.S.C. § 271(e)(2)
(FRESENIUS)

241. Plaintiffs incorporate each of the preceding paragraphs 1 – 240 as if fully set forth herein.

ANSWER: Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 240 of the Complaint as if fully set forth herein.

242. The Fresenius 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.

ANSWER: Denied.

243. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

244. After FDA approval of ANDA No. 219325, the Fresenius 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.

ANSWER: Denied.

245. The Fresenius 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.

ANSWER: Denied.

246. The Fresenius 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.

ANSWER: Denied.

247. The Fresenius 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.

ANSWER: Denied.

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

ANSWER: Paragraph 248 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA's Notice Letter discloses that Fresenius USA submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '455 patent to FDA. Fresenius denies any and all remaining allegations contained in Paragraph 248.

249. Unless the Fresenius 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.

ANSWER: Denied.

COUNT XIV
DECLARATORY JUDGMENT: U.S. PATENT NO. 8,835,455
(FRESENIUS)

250. Plaintiffs incorporate each of the preceding paragraphs 1 – 249 as if fully set forth herein.

ANSWER: Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 249 of the Complaint as if fully set forth herein.

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

ANSWER: Paragraph 251 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, denied.

252. Upon information and belief, upon FDA approval of ANDA No. 219325, the Fresenius 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.

ANSWER: Denied.

253. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

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

ANSWER: Paragraph 254 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA's Notice Letter discloses that Fresenius USA submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '455 patent to FDA. Fresenius denies any and all remaining allegations contained in Paragraph 254.

255. Upon information and belief, the Fresenius 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 the Fresenius 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.

ANSWER: Denied.

256. The Fresenius Defendants' infringement is imminent.

ANSWER: Denied.

257. The Fresenius 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.

ANSWER: Paragraph 257 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA's Notice Letter states that Fresenius USA submitted ANDA No. 219325 to FDA seeking approval to market Fresenius USA's ANDA Product before the expiration of the '455 patent. Fresenius denies any and all remaining allegations contained in Paragraph 257.

258. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

259. 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.

ANSWER: Denied.

260. Unless the Fresenius 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.

ANSWER: Denied.

COUNT XV
U.S. PATENT NO. 8,969,566: 35 U.S.C. § 271(e)(2)
(FRESENIUS)

261. Plaintiffs incorporate each of the preceding paragraphs 1 –260 as if fully set forth herein.

ANSWER: Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 260 of the Complaint as if fully set forth herein.

262. The Fresenius 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.

ANSWER: Denied.

263. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

264. After FDA approval of ANDA No. 219325, the Fresenius 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.

ANSWER: Denied.

265. The Fresenius 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.

ANSWER: Denied.

266. The Fresenius 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.

ANSWER: Denied.

267. The Fresenius 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.

ANSWER: Denied.

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

ANSWER: Paragraph 268 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA's Notice Letter discloses that Fresenius USA submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '566 patent to FDA. Fresenius denies any and all remaining allegations contained in Paragraph 268.

269. Unless the Fresenius 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.

ANSWER: Denied.

COUNT XVI
DECLARATORY JUDGMENT: U.S. PATENT NO. 8,969,566
(FRESENIUS)

270. Plaintiffs incorporate each of the preceding paragraphs 1 – 269 as if fully set forth herein.

ANSWER: Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 269 of the Complaint as if fully set forth herein.

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

ANSWER: Denied.

272. Upon information and belief, upon FDA approval of ANDA No. 219325, the Fresenius 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.

ANSWER: Denied.

273. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

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

ANSWER: Paragraph 274 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA's Notice Letter discloses that Fresenius USA submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '566 patent to FDA. Fresenius denies any and all remaining allegations contained in Paragraph 274.

275. Upon information and belief, the Fresenius 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 the Fresenius 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.

ANSWER: Denied.

276. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

277. The Fresenius Defendants' infringement is imminent.

ANSWER: Denied.

278. The Fresenius 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.

ANSWER: Paragraph 278 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA's Notice Letter states that Fresenius USA submitted ANDA No. 219325 to FDA seeking approval to market Fresenius USA's ANDA Product before the expiration of the '566 patent. Fresenius denies any and all remaining allegations contained in Paragraph 278.

279. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

280. 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.

ANSWER: Denied.

281. Unless the Fresenius 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.

ANSWER: Denied.

COUNT XVII
U.S. PATENT NO. 9,284,314: 35 U.S.C. § 271(e)(2)
(FRESENIUS)

282. Plaintiffs incorporate each of the preceding paragraphs 1 – 281 as if fully set forth herein.

ANSWER: Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 281 of the Complaint as if fully set forth herein.

283. The Fresenius 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.

ANSWER: Denied.

284. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

285. After FDA approval of ANDA No. 219325, the Fresenius 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.

ANSWER: Denied.

286. The Fresenius 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.

ANSWER: Denied.

287. The Fresenius 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.

ANSWER: Denied.

288. The Fresenius 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.

ANSWER: Denied.

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

ANSWER: Paragraph 289 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA's Notice

Letter discloses that Fresenius USA submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '314 patent to FDA. Fresenius denies any and all remaining allegations contained in Paragraph 289.

290. Unless the Fresenius 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.

ANSWER: Denied.

COUNT XVIII
DECLARATORY JUDGMENT: U.S. PATENT NO. 9,284,314
(FRESENIUS)

291. Plaintiffs incorporate each of the preceding paragraphs 1 – 290 as if fully set forth herein.

ANSWER: Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 290 of the Complaint as if fully set forth herein.

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

ANSWER: Denied.

293. Upon information and belief, upon FDA approval of ANDA No. 219325, the Fresenius 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.

ANSWER: Denied.

294. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

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

ANSWER: Paragraph 295 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA's Notice Letter discloses that Fresenius USA submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '314 patent to FDA. Fresenius denies any and all remaining allegations contained in Paragraph 295.

296. Upon information and belief, the Fresenius 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 the Fresenius 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.

ANSWER: Denied.

297. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

298. The Fresenius Defendants' infringement is imminent.

ANSWER: Denied.

299. The Fresenius 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.

ANSWER: Paragraph 299 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA's Notice Letter states that Fresenius USA submitted ANDA No. 219325 to FDA seeking approval to market Fresenius USA's ANDA Product before the expiration of the '314 patent. Fresenius denies any and all remaining allegations contained in Paragraph 299.

300. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

301. 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.

ANSWER: Denied.

302. Unless the Fresenius 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.

ANSWER: Denied.

COUNT XIX
U.S. PATENT NO. 9,695,122: 35 U.S.C. § 271(e)(2)
(FRESENIUS)

303. Plaintiffs incorporate each of the preceding paragraphs 1 –302 as if fully set forth herein.

ANSWER: Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 302 of the Complaint as if fully set forth herein.

304. The Fresenius 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.

ANSWER: Denied.

305. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

306. After FDA approval of ANDA No. 219325, the Fresenius 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.

ANSWER: Denied.

307. The Fresenius 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.

ANSWER: Denied.

308. The Fresenius 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.

ANSWER: Denied.

309. The Fresenius 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.

ANSWER: Denied.

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

ANSWER: Paragraph 310 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA's Notice Letter discloses that Fresenius USA submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '122 patent to FDA. Fresenius denies any and all remaining allegations contained in Paragraph 310.

311. Unless the Fresenius 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.

ANSWER: Denied.

COUNT XX
DECLARATORY JUDGMENT: U.S. PATENT NO. 9,695,122
(FRESENIUS)

312. Plaintiffs incorporate each of the preceding paragraphs 1 – 311 as if fully set forth herein.

ANSWER: Fresenius incorporates by reference its responses to the preceding Paragraphs 1 through 311 of the Complaint as if fully set forth herein.

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

ANSWER: Denied.

314. Upon information and belief, upon FDA approval of ANDA No. 219325, the Fresenius 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.

ANSWER: Denied.

315. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

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

ANSWER: Paragraph 316 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA's Notice Letter discloses that Fresenius USA submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '122 patent to FDA. Fresenius denies any and all remaining allegations contained in Paragraph 316.

317. Upon information and belief, the Fresenius 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 the Fresenius 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.

ANSWER: Denied.

318. The Fresenius Defendants' infringement is imminent.

ANSWER: Denied.

319. The Fresenius 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.

ANSWER: Paragraph 319 contains legal conclusions to which no answer is required. To the extent that Fresenius is required to answer, Fresenius admits that Fresenius USA's Notice Letter states that Fresenius USA submitted ANDA No. 219325 to FDA seeking approval to market Fresenius USA's ANDA Product before the expiration of the '122 patent. Fresenius denies any and all remaining allegations contained in Paragraph 319.

320. Upon information and belief, the Fresenius 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.

ANSWER: Denied.

321. 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.

ANSWER: Denied.

322. Unless the Fresenius 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.

ANSWER: Denied.

PRAYER FOR RELIEF

Fresenius denies that Plaintiffs are entitled to any of the relief prayed for in Paragraphs 323 through 336 of the Complaint ("Request For Relief") or to any relief whatsoever, and further

requests that the Court: (a) dismiss this action with prejudice; (b) enter judgment in favor of Fresenius; (c) award reasonable attorneys' fees and costs incurred in defending this action pursuant to, *inter alia*, 35 U.S.C. § 285; and, (d) award Fresenius such further relief as the Court deems just and appropriate.

DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting any allegations in the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs, Fresenius asserts the following defenses:

FIRST DEFENSE
(Invalidity)

The claims of U.S. Patent No. 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, "Asserted Patents") are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including without limitation §§ 101, 102, 103 and/or 112, and/or any judicially-created basis for invalidation or unenforceability.

SECOND DEFENSE
(Non-Infringement)

The manufacture, use, sale, offer for sale or importation of the product described in Fresenius USA's ANDA No. 219325, has not infringed, does not infringe, and would not infringe, either directly or indirectly, any valid and/or enforceable claim of the Asserted Patents, either literally or under the doctrine of equivalents.

THIRD DEFENSE
(No Inducement)

Fresenius has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the Asserted Patents.

FOURTH DEFENSE
(No Contributory Infringement)

Fresenius has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the Asserted Patents.

FIFTH DEFENSE
(No Subject Matter Jurisdiction)

The Court lacks subject matter jurisdiction over this action for any claims against Fresenius iPSUM, and for any and all claims asserted under 35 U.S.C. § 271 (a), (b), (c) or (g).

SIXTH DEFENSE
(No Personal Jurisdiction)

The Court lacks personal jurisdiction over Fresenius USA.

SEVENTH DEFENSE
(Lack of Venue)

Venue is not proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

EIGHTH DEFENSE
(Safe Harbor)

Fresenius is exempt from liability under the safe harbor provision of 35 U.S.C. § 271(e)(1).

NINTH DEFENSE
(No Exceptional Case)

The Complaint fails to state a claim for exceptional case.

TENTH DEFENSE
(Failure to State a Claim)

The Complaint fails to state a claim upon which relief can be granted.

ELEVENTH DEFENSE
(Additional Defenses)

Any additional defenses or counterclaims that discovery may reveal, including unenforceability.

* * *

COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff Fresenius Kabi USA, LLC ("Fresenius USA" or "Defendant/Counterclaim-Plaintiff"), for its Counterclaims against Plaintiff/Counterclaim-Defendants Plaintiffs AbbVie Inc. ("AbbVie") and Allergan Pharmaceuticals International Limited ("Allergan") (collectively "Plaintiffs/Counterclaim-Defendants"), alleges as follows:

The Parties

1. 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.

2. On information and belief and according to the Complaint (Dkt. 1 ¶ 6), AbbVie claims and purports to be 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.

3. On information and belief and according to the Complaint (Dkt. 1 ¶ 10), Allergan claims and purports to be 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.

Jurisdiction and Venue

4. These Counterclaims arise 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.

5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a) and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because they have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction, of this forum by suing Fresenius USA in this District, and, on information and belief, because Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular systemic contact with, this District.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

Background

8. On or about June 25, 2013, the U.S. Patent and Trademark Office (the "USPTO") issued U.S. Patent No. 8,471,025 ("the '025 patent").

9. On or about September 16, 2014, the USPTO issued U.S. Patent No. 8,835,455 ("the '455 patent").

10. On or about March 3, 2015, the USPTO issued U.S. Patent No. 8,969,566 ("the '566 patent").

11. On or about March 15, 2016, the USPTO issued U.S. Patent No. 9,284,314 ("the '314 patent").

12. On or about July 4, 2017, the USPTO issued U.S. Patent No. 9,695,122 ("the '122 patent").

13. Plaintiffs/Counterclaim-Defendants purport and claim to own the '025 patent, the '455 patent, the '566 patent, the '314 patent, and the '122 patent (collectively, "Asserted Patents") (Dkt. 1 ¶¶ 39, 43, 47, 51, 55).

14. On or about June 6, 2024, Plaintiffs/Counterclaim-Defendants sued Fresenius USA in this District alleging that the proposed Ceftazidime and Avibactam for Injection, 2 g/0.5 g per

vial, Sterile Powder that is the subject of Fresenius USA's ANDA No. 219325 ("Fresenius USA's ANDA Product"), will infringe the Asserted Patents under 35 U.S.C. § 271(e)(2).

COUNT I
(Declaratory Judgment of Non-Infringement of the '025 Patent)

15. Fresenius USA incorporates each of the preceding paragraphs as if fully set forth herein.

16. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of Fresenius USA's ANDA Product would infringe any valid and/or enforceable claim of the '025 patent.

17. Fresenius USA's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '025 patent.

18. Fresenius USA is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Fresenius USA's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '025 patent.

COUNT II
(Declaratory Judgment of Invalidity of the '025 Patent)

19. Fresenius USA incorporates each of the preceding paragraphs as if fully set forth herein.

20. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '025 patent.

21. One or more claims of the '025 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability, for at least the reasons stated in Fresenius USA's Notice Letter.

22. As a sufficient example, as described in Fresenius USA's Notice Letter, all claims of the '025 patent are at least invalid as obvious under § 103 in light of at least the following prior art: U.S. Patent No. 7,112,592 (the "'592 patent"); INT'L CONF. ON HARMONISATION OF TECH. REQUIREMENTS FOR REGISTRATION OF PHARMS. FOR HUMAN USE, ICH HARMONISED TRIPARTITE GUIDELINE: SPECIFICATIONS: TEST PROCEDURES AND ACCEPTANCE CRITERIA FOR NEW DRUG SUBSTANCES AND NEW DRUG PRODUCTS: CHEMICAL SUBSTANCES, Q6A (1999) ("ICH Guidelines"); and U.S. Patent Application Publication No. 2005/0020572 A1 (the "'572 publication"). Additionally, at least claims 1-16 are invalid as anticipated under § 102 in light of at least the following prior art: '592 patent and '572 publication. Furthermore, at least claims 1 and 10-34 are invalid as not enabled with respect to mixtures of enantiomers of trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide as well as the XRPD characteristic peaks and d-spacing values for such mixtures, especially as that mixture approaches a racemic mixture. Additional contentions will be provided consistent with this District's Local Patent Rules.

23. Fresenius USA is entitled to a judicial declaration that the claims of the '025 patent are invalid.

COUNT III
(Declaratory Judgment of Non-Infringement of the '455 Patent)

24. Fresenius USA incorporates each of the preceding paragraphs as if fully set forth herein.

25. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of Fresenius USA's ANDA Product would infringe any valid and/or enforceable claim of the '455 patent.

26. Fresenius USA's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '455 patent.

27. Fresenius USA is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Fresenius USA's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '455 patent

COUNT IV
(Declaratory Judgment of Invalidity of the '455 Patent)

28. Fresenius USA incorporates each of the preceding paragraphs as if fully set forth herein.

29. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '455 patent.

30. One or more claims of the '455 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability, for at least the reasons stated in Fresenius USA's Notice Letter.

31. As a sufficient example, as described in Fresenius USA's Notice Letter, claims 1-6 and 9-10 of the '455 patent are at least invalid as obvious under § 103 in light of at least the following prior art: '592 patent; ICH Guidelines; and '572 publication. Additionally, at least claims 1-6 and 9-10 of the '455 patent are invalid as anticipated under § 102 in light of at least the following prior art: '592 patent and '572 publication. Furthermore, at least claims 1-10 are invalid for lack of written description as to a composition containing any possible form including, e.g., a non-crystalline form of the sodium salt of "(1R,2S,5R)-7-oxo-6-sulphooxy-1,6-diazabicyclo[3.2.1]octane-2-carboxamide." Additional contentions will be provided consistent with this District's Local Patent Rules.

32. Fresenius USA is entitled to a judicial declaration that the claims of the '455 patent are invalid.

COUNT V
(Declaratory Judgment of Non-Infringement of the '566 Patent)

33. Fresenius USA incorporates each of the preceding paragraphs as if fully set forth herein.

34. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of Fresenius USA's ANDA Product would infringe any valid and/or enforceable claim of the '566 patent.

35. Fresenius USA's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '566 patent.

36. Fresenius USA is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Fresenius USA's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '566 patent.

COUNT VI
(Declaratory Judgment of Invalidity of the '566 Patent)

37. Fresenius USA incorporates each of the preceding paragraphs as if fully set forth herein.

38. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '566 patent.

39. One or more claims of the '566 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability, for at least the reasons stated in Fresenius USA's Notice Letter.

40. As a sufficient example, as described in Fresenius USA's Notice Letter, all claims of the '566 patent are at least invalid as obvious under § 103 in light of at least the following prior art: '592 patent; David M. Livermore et al., *NXL104 Combinations Versus Enterobacteriaceae*

with CTX-M Extended-Spectrum β-lactamases and Carbapenemases, 62 J. ANTIMICROBIAL CHEMOTHERAPY 1053 (2008) ("Livermore"); and U.S. Patent No. 7,612,087 B2 (the "'087 patent"). Additionally, at least claim 9 of the '566 patent is invalid as anticipated under § 102 in light of at least the following prior art: '592 patent; '087 patent; and Livermore. Furthermore, at least claim 9 of the '566 patent is invalid as indefinite with respect to the term "({[(2S,5R)-2-carbamoyl-7-oxo-1,6-diazabicyclo[3.2.1]oct-6-yl]oxy}sulphonyl)oxidanide prepared according to the process of claim 1." Additional contentions will be provided consistent with this District's Local Patent Rules.

41. Fresenius USA is entitled to a judicial declaration that the claims of the '566 patent are invalid.

COUNT VII
(Declaratory Judgment of Non-Infringement of the '314 Patent)

42. Fresenius USA incorporates each of the preceding paragraphs as if fully set forth herein.

43. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of Fresenius USA's ANDA Product would infringe any valid and/or enforceable claim of the '314 patent.

44. Fresenius USA's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '314 patent.

45. Fresenius USA is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Fresenius USA's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '314 patent.

COUNT VIII
(Declaratory Judgment of Invalidity of the '314 Patent)

46. Fresenius USA incorporates each of the preceding paragraphs as if fully set forth herein.

47. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '314 patent.

48. One or more claims of the '314 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability, for at least the reasons stated in Fresenius USA's Notice Letter.

49. As a sufficient example, as described in Fresenius USA's Notice Letter, all claims of the '314 patent are at least invalid as obvious under § 103 in light of at least the following prior art: '592 patent; '087 patent; and Livermore. Additionally, at least claim 15 is invalid as anticipated under § 102 in light of at least the following prior art: '592 patent; '087 patent; and Livermore. Furthermore, all claims of the '314 patent are invalid as indefinite at least with respect to selection and definitions of R1-R7 substituents as related to the compounds of Formula (I)-(III), and claim 15 is further invalid as indefinite at least with respect to the term "({[(2S,5R)-2-carbamoyl-7-oxo-1,6-diazabicyclo[3.2.1]oct-6-yl]oxy}sulphonyl)oxidanide prepared according to the process of claim 1." Additionally, all claims of the '314 patent are invalid as lacking written description and/or not enabled at least with respect to preparing a compound of Formula (I) by treating any compound of Formula (II) with a source of nitrogen or an amine to prepare any compound of Formula (III), and/or at least with respect to compounds in which R1 and R2 form a heterocycle. Additional contentions will be provided consistent with this District's Local Patent Rules.

50. Fresenius USA is entitled to a judicial declaration that the claims of the ’314 patent are invalid.

COUNT IX
(Declaratory Judgment of Non-Infringement of the ’122 Patent)

51. Fresenius USA incorporates each of the preceding paragraphs as if fully set forth herein.

52. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of Fresenius USA’s ANDA Product would infringe any valid and/or enforceable claim of the ’122 patent.

53. Fresenius USA’s ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’122 patent.

54. Fresenius USA is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Fresenius USA’s ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’122 patent.

COUNT X
(Declaratory Judgment of Invalidity of the ’122 Patent)

55. Fresenius USA incorporates each of the preceding paragraphs as if fully set forth herein.

56. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the ’122 patent.

57. One or more claims of the ’122 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability, for at least the reasons stated in Fresenius USA’s Notice Letter.

58. As a sufficient example, as described in Fresenius USA's Notice Letter, at least claims 1, 7-8, and 12-14 of the '122 patent are at least invalid as obvious under § 103 in light of at least the following prior art: '592 patent; '572 publication; and International Application Publication No. WO 2011/042560 A1 ("WO 560"). Additionally, at least claims 1, 7-8 and 12-14 of the '122 patent are invalid as anticipated under § 102 in light of at least the following prior art: '592 patent; '572 publication; and WO 560. Moreover, at least claims 1, 7-8, and 12-14 are invalid for obviousness-type double patenting in view of at least claim 1 of the '455 patent. Furthermore, at least claims 1-2, 4-5, 7-8, and 11 are invalid as indefinite at least with respect to selection and definitions of R1, R2, and R5-R7 substituents. Additionally, at least claims 1-14 are invalid as lacking written description and/or not enabled at least with respect to a pharmaceutical composition, a decarbonyl impurity, and/or the claimed compounds of Formula (III). Additional contentions will be provided consistent with this District's Local Patent Rules.

59. Fresenius USA is entitled to a judicial declaration that the claims of the '122 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Fresenius USA respectfully prays for judgment in its favor and against Plaintiffs/Counterclaim-Defendants:

(a) Declaring that the manufacture, use, sale, offer for sale or importation of Fresenius USA's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any and/or enforceable claim of the Asserted Patents;

(b) Declaring that the claims of the Asserted Patents are invalid;

(c) Ordering that Plaintiffs/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Defendant/Counterclaim-Plaintiff Fresenius USA;

(d) Declaring this case exceptional and awarding Fresenius USA its reasonable attorneys' fees and costs of these Counterclaims under 35 U.S.C. § 285; and

(e) Awarding Fresenius USA such other and further relief as the Court may deem just and proper.

Dated: February 13, 2025

Respectfully submitted,

s/ *Eric I. Abraham*
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Attorneys for Defendants Fresenius Kabi USA, LLC and Fresenius Kabi iPSUM S.r.l.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, Defendants Fresenius Kabi USA, LLC and Fresenius Kabi iPSUM S.r.l., by their undersigned counsel, hereby certify that the matter in controversy is not subject to any other action pending in any court, or any pending arbitration or administrative proceeding, except that the same plaintiffs have asserted the patents in this case in the following pending matter in the Northern District of Illinois:

AbbVie Inc. et al v. Fresenius Kabi USA, LLC et al., C.A. No. 1:24-cv-4914 (N.D. Ill.).

By: *s/ Eric I. Abraham*
Eric I. Abraham

Dated: February 13, 2025

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Fresenius Kabi USA, LLC and Fresenius Kabi iPSUM S.r.l., by their undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

By: *s/ Eric I. Abraham*
Eric I. Abraham

Dated: February 13, 2025

CERTIFICATION OF SERVICE

The undersigned attorney certifies that a copy of the foregoing Answer, Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on February 13, 2025.

By: *s/ Eric I. Abraham*
Eric I. Abraham

Dated: February 13, 2025