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*Attorneys for Plaintiffs AbbVie Inc. and Allergan Pharmaceuticals International Limited,*

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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| ABBVIE INC. and ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED<br><br>Plaintiffs,<br><br>v.<br>QILU PHARMA, INC., QILU ANTIBIOTICS PHARMACEUTICAL CO., LTD., APOTEX INC., FRESENIUS KABI USA, LLC, and FRESENIUS KABI IPSUM SRL<br><br>Defendants. | ) | Civil Action No. _____<br><br>**COMPLAINT FOR PATENT INFRINGEMENT**<br>(Filed Electronically) |

Plaintiffs AbbVie Inc. ("AbbVie") and Allergan Pharmaceuticals International Limited ("Allergan") (together, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants Qilu Pharma, Inc. ("Qilu Pharma") and Qilu Antibiotics Pharmaceutical Co., Ltd. ("Qilu Antibiotics") (together, "Qilu") and Apotex Inc. ("Apotex") (collectively, the "Qilu Defendants"), and Fresenius Kabi USA, LLC ("Fresenius USA") and Fresenius Kabi iPSUM SRL ("Fresenius iPSUM") (together, "Fresenius" or the "Fresenius Defendants") (the Qilu Defendants and Fresenius Defendants, collectively, "Defendants") and allege as follows:

## NATURE OF THE ACTION

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

2. This action is based on 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®.

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.

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.

## 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.

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

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.

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

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.

### *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.

11. Defendant Qilu Pharma holds ANDA No. 219392.

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.

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.

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.

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.

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.

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

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.

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.

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.

***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.

22. Defendant Fresenius USA holds ANDA No. 219325.

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.

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.

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.

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.

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.

## 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.

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

### *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.

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.

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.

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.).

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.).

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.

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.

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.

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.).

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.).

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.

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.

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.

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.

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.

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

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.

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.

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.

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.

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.

***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.

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.

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.).

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.).

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.

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.

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.

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.

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.

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.

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

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.

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.

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.

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.

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.

## 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.

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

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

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

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.

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

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

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

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.

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

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

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

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.

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

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

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

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.

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

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

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

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

**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.

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.

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.

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®."

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

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

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).

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).

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.

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

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

## 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.

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.

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.

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.

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®.

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.

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.

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.

**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.

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.

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.

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.

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®.

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.

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.

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.

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

115. Plaintiffs incorporate each of the preceding paragraphs 1 – 114 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.

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.

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.

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.

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.

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.

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.

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

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.

## COUNT II
## DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,471,025 BY THE QILU DEFENDANTS

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

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

127. Upon information and belief, upon FDA approval of ANDA No. 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.

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.

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.

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

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.

132. The Qilu Defendants' infringement is imminent.

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.

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.

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.

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.

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

137. Plaintiffs incorporate each of the preceding paragraphs 1 – 136 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.

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.

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.

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.

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.

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.

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

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.

## COUNT IV
## DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,835,455 BY THE QILU DEFENDANTS

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

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

148. Upon information and belief, upon FDA approval of ANDA No. 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.

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.

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

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.

152. The Qilu Defendants' infringement is imminent.

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.

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.

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.

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.

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

157. Plaintiffs incorporate each of the preceding paragraphs 1 – 156 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.

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.

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.

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.

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.

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.

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

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.

## COUNT VI
## DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,969,566 BY THE QILU DEFENDANTS

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

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

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.

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.

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

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.

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.

173. The Qilu Defendants' infringement is imminent.

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.

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.

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.

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.

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

178. Plaintiffs incorporate each of the preceding paragraphs 1 – 177 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.

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.

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.

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.

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.

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.

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

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.

## COUNT VIII
## DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,284,314 BY THE QILU DEFENDANTS

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

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

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.

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.

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

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.

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.

194. The Qilu Defendants' infringement is imminent.

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.

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.

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.

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.

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

199. Plaintiffs incorporate each of the preceding paragraphs 1 – 198 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.

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.

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.

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.

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.

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.

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.

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

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.

**COUNT X**
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,695,122 BY THE QILU DEFENDANTS**

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

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

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.

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.

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.

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

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.

216. The Qilu Defendants' infringement is imminent.

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.

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.

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.

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.

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

221. Plaintiffs incorporate each of the preceding paragraphs 1 – 220 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.

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.

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.

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.

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.

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.

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

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.

**COUNT XII**
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,471,025 BY THE FRESENIUS DEFENDANTS**

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

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

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.

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.

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

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.

236. The Fresenius Defendants' infringement is imminent.

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.

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.

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.

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.

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

241. Plaintiffs incorporate each of the preceding paragraphs 1 – 240 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.

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.

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.

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.

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.

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.

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

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.

**COUNT XIV**
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,835,455 BY THE FRESENIUS DEFENDANTS**

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

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

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.

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.

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

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.

256. The Fresenius Defendants' infringement is imminent.

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.

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.

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.

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.

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

261. Plaintiffs incorporate each of the preceding paragraphs 1 –260 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.

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.

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.

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.

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.

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.

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

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.

**COUNT XVI**
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,969,566 BY THE FRESENIUS DEFENDANTS**

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

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

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.

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.

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

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.

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.

277. The Fresenius Defendants' infringement is imminent.

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.

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.

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.

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.

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

282. Plaintiffs incorporate each of the preceding paragraphs 1 – 281 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.

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.

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.

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.

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.

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.

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

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.

**COUNT XVIII**
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,284,314 BY THE FRESENIUS DEFENDANTS**

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

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

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.

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.

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

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.

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.

298. The Fresenius Defendants' infringement is imminent.

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.

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.

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.

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.

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

303. Plaintiffs incorporate each of the preceding paragraphs 1 –302 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.

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.

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.

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.

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.

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.

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

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.

**COUNT XX**
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,695,122 BY THE FRESENIUS DEFENDANTS**

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

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

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.

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.

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

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.

318. The Fresenius Defendants' infringement is imminent.

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.

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.

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.

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.

**PRAYER FOR RELIEF**

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

323. A judgment that one or more of the claims of the Patents-in-Suit are infringed by the Qilu Defendants' submission of ANDA No. 219392 under 35 U.S.C. § 271(e)(2)(A);

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

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

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

327. A declaration under 28 U.S.C. § 2201 that if the Qilu Defendants, the Qilu Defendants' officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities aiding, abetting, acting in concert with it, or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Qilu's proposed generic AVYCAZ® product

prior to the expiration of the Patents-in-Suit, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a), (b), (c), and/or (g);

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

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

330. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 219392 shall not be earlier than the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or becomes entitled;

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

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

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

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

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

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

Dated: June 6, 2024

/s/ *Liza M. Walsh*

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**LOCAL RULE 11.2 CERTIFICATION**

I hereby certify that, to be the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: June 6, 2024

/s/ *Liza M. Walsh*

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**LOCAL RULE 201.1 CERTIFICATION**

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: June 6, 2024

/s/ *Liza M. Walsh*

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