IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMICUS THERAPEUTICS US, LLC and AMICUS THERAPEUTICS, INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC.; TEVA PHARMACEUTICALS, INC.; and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Amicus Therapeutics US, LLC ("ATUS") and Amicus Therapeutics, Inc. ("AT") (collectively "Amicus" or "Plaintiffs"), by way of Complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA"), Teva Pharmaceuticals, Inc. ("Teva Pharmaceuticals"), and Teva Pharmaceutical Industries Ltd. ("Teva Industries") (collectively "Teva" or "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 9,000,011 (the "'011 Patent"), 9,987,263 (the "'263 Patent"), 10,383,864 (the "'864 Patent"), 10,406,143 (the "'143 Patent"), 9,999,618 (the "'618 Patent"), 10,925,866 (the "'866 Patent"), 10,813,921 (the "'921 Patent"), and RE48,608 ("RE608") (collectively, "Patents-in-Suit"), arising under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action arises out of Teva's submission of Abbreviated New Drug Application ("ANDA") No. 217586 under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21

U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market a generic version of GALAFOLD migalastat 123 mg free base capsules before the expiration of the Patents-in-Suit.

THE PARTIES

2. Amicus Therapeutics US, LLC (*i.e.*, ATUS) is a limited liability company organized and existing under the laws of the state of Delaware with its corporate headquarters at 3675 Market Street, Philadelphia, PA 19104.

3. Amicus Therapeutics, Inc. (*i.e.*, AT) is a corporation organized and existing under the laws of the state of Delaware with its corporate headquarters at 3675 Market Street, Philadelphia, PA 19104.

4. Amicus is a global, patient-dedicated biotechnology company focused on discovering, developing, and delivering novel and high-quality medicines for people living with rare diseases. The cornerstone of Amicus's portfolio is GALAFOLD, the first approved oral precision medicine for people living with Fabry disease who have amenable genetic variants. Fabry disease is a genetic disorder known as a lysosomal storage disorder. Fabry disease is caused by a mutation or variant to the GLA gene, which encodes the enzyme α-galactosidase A (α-Gal A). The variant causes the substrate globotriaosylceramide (GL-3) to accumulate in various tissues and organs.

5. Amicus sells GALAFOLD migalastat 123 mg free base capsules throughout the United States, including in this judicial district.

6. By a letter dated October 5, 2022 ("October 5 Notice Letter"), and received by Amicus on October 6, 2022, Teva notified Amicus that Teva Pharmaceuticals had submitted an ANDA to the United States FDA ("Teva's ANDA") for "Migalastat HCl capsules, Eq. 123 mg

Base," a drug product that is a generic version of GALAFOLD ("Teva's ANDA Product"). By a letter dated October 26, 2022 ("October 26 Notice Letter"), and received by Amicus on October 27, 2022, Teva notified Amicus that Teva Pharmaceuticals had amended Teva's ANDA. Upon information and belief, the purpose of Teva's submission of Teva's ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product prior to the expiration of the Patents-in-Suit.

7. In its October 5 Notice Letter, Teva notified Amicus that, as part of Teva's ANDA, Teva had filed a certification pursuant to Section 505(j)(2)(B)(iv)(II) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(iv)(II) ("¶ IV"), with respect to U.S. Patent Nos. 8,592,362; 9,000,011; 9,095,584; 9,480,682; 9,987,263; 9,999,618; 10,076,514; 10,251,873; 10,383,864; 10,406,143; 10,471,053; 10,525,045; 10,792,278; 10,792,279; 10,799,491; 10,806,727; 10,813,921; 10,849,889; 10,849,890; 10,857,141; 10,857,142; 10,874,655; 10,874,656; 10,874,657; 10,925,866; 11,033,538; 11,234,972; 11,241,422; 11,278,536; 11,278,537; 11,278,538; 11,278,539; 11,278,540; 11,304,940; 11,357,761; 11,357,762; 11,357,763; 11,357,764; 11,357,765; 11,357,784; 11,376,244; 11,389,436; 11,389,437; and RE48,608 (collectively, the "October 5 Patents"), which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluation ("Orange Book"). In its October 26 Notice Letter, Teva notified Amicus that, as part of Teva's ANDA, Teva had filed a certification pursuant to ¶ IV with respect to U.S. Patent Nos. 11,426,396 and 11,458,128 (collectively, the "October 26 Patents"; together with the October 5 Patents, the "Notice Letter Patents"). Teva's October 5 Notice Letter and October 26 Notice Letter (collectively, "Teva's Notice Letters") asserted that the Notice Letter Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and offer for sale,

sale, and/or importation within or into the United States of Teva's ANDA Product (the "¶ IV Certifications"). Teva's Notice Letters purported to include detailed statements of the factual and legal bases for Teva's ¶ IV Certifications. Teva's Notice Letters defined Teva as Teva Pharmaceuticals.

8. Upon information and belief, Teva USA is a corporation organized and existing under the laws of the state of Delaware with its principal place of business at 400 Interpace Parkway #3, Parsippany, NJ 07054.

9. Upon information and belief, Teva Pharmaceuticals is a corporation organized and existing under the laws of the state of Delaware with its principal place of business at 400 Interpace Parkway #3, Parsippany, NJ 07054.

10. Upon information and belief, Teva Industries is a corporation organized under the laws of Israel with its principal place of business located at 124 Dvora HaNevi'a St., Tel Aviv, Israel, 6944020.

11. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Industries.

12. Upon information and belief, Teva Pharmaceuticals is a wholly-owned subsidiary of Teva Industries.

13. Upon information and belief, Teva Industries is a publicly traded company and is the only publicly-traded company that owns 10% or more of stock of Teva USA and Teva Pharmaceuticals.

14. Upon information and belief, Teva USA and Teva Pharmaceuticals are United States agents acting at the direction of, and for the benefit of, Teva Industries regarding Teva's ANDA No. 217586.

15. Upon information and belief, Teva Industries submitted Drug Master File ("DMF") No. 36618 for migalastat hydrochloride to the FDA on February 28, 2022.

16. Upon information and belief, Teva USA and Teva Pharmaceuticals are generic pharmaceutical companies that, in coordination with each other and Teva Industries and at the direction of Teva Industries, are in the business of making and selling generic pharmaceutical products, which they distribute throughout the United States including in this judicial district.

JURISDICTION AND VENUE

17. This is an action for patent infringement arising under 35 U.S.C. § 271. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

18. Upon information and belief, Defendants hold themselves out as a unitary entity and operate as a single integrated business directed and/or controlled by Teva Industries with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

19. Upon information and belief, Defendants have and will continue to coordinate, collaborate, and act in concert to prepare, submit, and maintain Teva's ANDA No. 217586 pursuant to Section 505(j) of the FDCA, 21 U.S.C. § 355(j). Defendants are therefore submitters of an ANDA within the jurisdiction of this Court.

20. This Court has personal jurisdiction over Teva USA and Teva Pharmaceuticals because, upon information and belief, their affiliations with and business activities within the State of Delaware and this judicial district, including by virtue of their incorporation in Delaware, are so systematic and continuous as to render Teva USA and Teva Pharmaceuticals essentially at home in this judicial district.

21. This Court has personal jurisdiction over foreign Defendant Teva Industries because, upon information and belief, Teva Industries controls the actions of its agents and United States subsidiaries Teva USA and Teva Pharmaceuticals, Delaware corporations. Therefore, upon information and belief, the activities of Teva USA and Teva Pharmaceuticals in this jurisdiction are attributable to Teva Industries.

22. The Court also has personal jurisdiction over foreign Defendant Teva Industries pursuant to Fed. R. Civ. P. 4(k)(2). This action arises under federal law, out of Teva's submission of an ANDA filing. To the extent Teva Industries is not subject to jurisdiction in any state's courts of general jurisdiction, exercising jurisdiction over Teva Industries is consistent with the Constitution and laws of the United States as Teva Industries has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation, submission, and maintenance of Teva's ANDA, participating in the preparation and submission of DMF No. 36618 to the FDA, and/or directly or indirectly developing, manufacturing, marketing, and selling Teva's ANDA Product throughout the United States, including in this judicial district, such that this Court's exercise of personal jurisdiction over Teva Industries satisfies due process.

23. This Court also has personal jurisdiction over each Defendant because, upon information and belief, each has frequently availed itself of the legal protections of the State of Delaware by, among other things, selecting the State of Delaware as the place of incorporation for itself and/or its subsidiaries and asserting claims and counterclaims in lawsuits filed in the United States District Court for the District of Delaware, including at least *Otsuka Pharmaceutical Co., Ltd. v. Teva Pharmaceuticals, Inc.*, No. 1:22-cv-00513-RGA, at Dkt. 12 (D. Del. July 12, 2022) and *Journey Medical Corp. et al v. Teva Pharmaceuticals, Inc.*, No. 1:22-cv-00288-CFC, at Dkt. 15 (D. Del. Apr. 25, 2022).

24. This Court also has personal jurisdiction over each Defendant because, upon information and belief, each is a submitter of Teva's ANDA. This Court also has personal jurisdiction over each Defendant because, upon information and belief, each has committed or aided, abetted, contributed to, or participated in tortious acts of patent infringement in submitting Teva's ANDA that has led to foreseeable harm and injury to Amicus, which manufactures GALAFOLD for sale and use throughout the United States, including within this judicial district. Upon information and belief, each Defendant will imminently commit, or aid, abet, contribute to, or participate in tortious acts of patent infringement by directly or indirectly developing, manufacturing, marketing, and selling Teva's ANDA Product throughout the United States and in this judicial district, which will lead to foreseeable harm and injury to Amicus.

25. Upon information and belief, Defendants have been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of ANDA No. 217586 for the United States market. Teva's ANDA No. 217586 relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Teva's intent to market and sell Teva's ANDA Product throughout the United States, including in this judicial district.

26. Teva has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of Teva's ANDA Product—which, upon information and belief, will be purposefully directed at this judicial district and elsewhere throughout the United States. Upon information and belief, Defendants will act in concert to market, distribute, and sell Teva's ANDA Product in this judicial district, among other places, once Teva receives the requested FDA approval to market Teva's ANDA Product.

27. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, each Defendant is subject to personal jurisdiction in this judicial district.

28. Venue is proper for Teva USA in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Teva USA is incorporated and therefore resides in the state of Delaware and has committed acts of infringement giving rise to the claims against it in this judicial district. Venue is also proper for Teva USA in this judicial district because Teva USA is a submitter of Teva's ANDA.

29. Venue is proper for Teva Pharmaceuticals in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Teva Pharmaceuticals is incorporated and therefore resides in the state of Delaware and has committed acts of infringement giving rise to the claims against it in this judicial district. Venue is also proper for Teva Pharmaceuticals in this judicial district because Teva Pharmaceuticals is a submitter of Teva's ANDA.

30. Venue is proper for Teva Industries in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) and/or Fed. R. Civ. P. 4(k)(2) because Teva Industries is incorporated in Israel and may be sued in any judicial district in the United States. Venue is also proper for Teva Industries in this judicial district because Teva Industries is a submitter of Teva's ANDA.

FACTUAL BACKGROUND

The NDA

31. ATUS is the holder of New Drug Application ("NDA") No. 208623 for GALAFOLD capsules comprising 123 mg free base migalastat ("GALAFOLD Capsules").

32. GALAFOLD is an oral medication administered every other day approved for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable α-galactosidase

A (GLA) gene variant. Migalastat, which is an iminosugar, is the active ingredient in GALAFOLD Capsules.

33. The FDA approved NDA No. 208623 on August 10, 2018. GALAFOLD enjoys New Chemical Entity ("NCE") exclusivity until August 10, 2023.

34. GALAFOLD is designated as an orphan drug under the Orphan Drug Act, 21 U.S.C. § 360aa *et seq.* and enjoys Orphan Drug Exclusivity ("ODE") until August 10, 2025. Amicus markets capsules comprising 123 mg free base migalastat in the United States under the trademark GALAFOLD.

35. Teva advertises itself as the "leading generic drug company in the United States." https://www.tevausa.com/about-teva/ (last accessed November 7, 2022).

36. On August 5, 2020, Defendant Teva USA submitted a request pursuant to 21 U.S.C. § 355-2 (the "CREATES Act") to ATUS seeking to purchase GALAFOLD for testing purportedly deemed necessary by Teva to support Teva's ANDA No. 217586. On March 29, 2021, Teva Pharmaceuticals Development, Inc. ("TPDI")—which subsequently changed its name to Teva Pharmaceuticals, Inc. (*i.e.*, Defendant Teva Pharmaceuticals)—sent a request to ATUS seeking to purchase an additional twenty-five (25) packs of GALAFOLD to purportedly complete testing required for approval of a generic version of GALAFOLD (*i.e.*, Teva's ANDA Product) pursuant to Teva's ANDA No. 217586. In July 2021, TPDI initiated Civil Action No. 2:21-cv-03105 against ATUS in the Eastern District of Pennsylvania citing the CREATES Act and its second request for GALAFOLD. In September 2021, TPDI (as Defendant Teva Pharmaceuticals) dismissed with prejudice Civil Action No. 2:21-cv-03105.

37. Upon information and belief, Teva intends to develop a generic version of GALAFOLD.

The Patents-in-Suit

38. The United States Patent and Trademark Office (the "PTO") duly and legally issued the '011 Patent on April 7, 2015, titled "Methods for Treatment of Fabry Disease." A true and correct copy of the '011 Patent is attached as Exhibit A.

39. AT is the owner of all right, title, and interest in the '011 Patent by assignment recorded with the PTO on September 6, 2018.

40. The '011 Patent currently expires on May 16, 2027.

41. The '011 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

42. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '011 Patent.

43. The PTO duly and legally issued the '263 Patent on June 5, 2018, titled "Methods for Treatment of Fabry Disease." A true and correct copy of the '263 Patent is attached as Exhibit B.

44. AT is the owner of all right, title, and interest in the '263 Patent by assignment recorded with the PTO on September 6, 2018.

45. The '263 Patent currently expires on May 16, 2027.

46. The '263 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

47. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '263 Patent.

48. The PTO duly and legally issued the '864 Patent on August 20, 2019, titled "Methods for Treatment of Fabry Disease." A true and correct copy of the '864 Patent is attached as Exhibit C.

49. AT is the owner of all right, title, and interest in the '864 Patent by assignment recorded with the PTO on September 6, 2018.

50. The '864 Patent currently expires on May 16, 2027.

51. The '864 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

52. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '864 Patent.

53. The PTO duly and legally issued the '143 Patent on September 10, 2019, titled "Methods for Treatment of Fabry Disease." A true and correct copy of the '143 Patent is attached as Exhibit D.

54. AT is the owner of all right, title, and interest in the '143 Patent by assignment recorded with the PTO on September 6, 2018.

55. The '143 Patent currently expires on May 16, 2027.

56. The '143 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

57. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '143 Patent.

58. The PTO duly and legally issued the '618 Patent on June 19, 2018, titled "Dosing Regimens for the Treatment of Lysosomal Storage Diseases Using Pharmacological Chaperones." A true and correct copy of the '618 Patent is attached as Exhibit E.

59. AT is the owner of all right, title, and interest in the '618 Patent by assignment recorded with the PTO on December 15, 2017.

60. The '618 Patent currently expires on April 28, 2028.

61. The '618 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

62. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '618 Patent.

63. The PTO duly and legally issued the '866 Patent on February 23, 2021, titled "Dosing Regimens for the Treatment of Lysosomal Storage Diseases Using Pharmacological Chaperones." A true and correct copy of the '866 Patent is attached as Exhibit F.

64. AT is the owner of all right, title, and interest in the '866 Patent by assignment recorded with the PTO on December 15, 2017.

65. The '866 Patent currently expires on April 28, 2028.

66. The '866 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

67. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '866 Patent.

68. The PTO duly and legally issued the '921 Patent on October 27, 2020, titled "Method to Predict Response to Pharmacological Chaperone Treatment of Diseases." A true and correct copy of the '921 Patent is attached as Exhibit G.

69. AT is the owner of all right, title, and interest in the '921 Patent by assignment recorded with the PTO on October 15, 2013.

70. The '921 Patent currently expires on February 12, 2029.

71. The ’921 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

72. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the ’921 Patent.

73. The PTO duly and legally issued RE608 on June 29, 2021, titled “Method to Predict Response to Pharmacological Chaperone Treatment of Diseases.” A true and correct copy of RE608 is attached as Exhibit H.

74. RE608 is a re-issue of U.S. Patent No. 8,592,362, which was originally issued by the PTO on November 26, 2013.

75. AT is the owner of all right, title, and interest in RE608 by assignment recorded with the PTO on May 19, 2011.

76. RE608 currently expires on February 12, 2029.

77. RE608 is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

78. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of RE608.

TEVA’S ANDA

79. Upon information and belief, Teva submitted ANDA No. 217586 with the FDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of 123 mg free base migalastat capsules (defined above as “Teva’s ANDA Product”), which are generic versions of Amicus’ GALAFOLD Capsules.

80. Teva's Notice Letters purport to include a "Notice of ANDA No. 217586 Migalastat HCl Capsules, Eq 123 mg Base; With Paragraph IV Certification Concerning the [Notice Letter Patents]" pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95. Teva's October 5 Notice Letter stated that Teva had filed ANDA No. 217586 with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product before the expiration of the October 5 Patents. Teva's October 26 Notice Letter stated that Teva had amended ANDA No. 217586 seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product before the expiration of the October 26 Patents. Together, Teva's Notice Letters state that Teva's ANDA seeks FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product before the expiration of the Patents-in-Suit.

81. Teva's Notice Letters state that ANDA No. 217586 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), alleging that the claims of the Patents-in-Suit are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product (defined above as Teva's "¶ IV Certifications").

82. Amicus commenced this action within 45 days of receiving Teva's Notice Letters, which triggers a stay of FDA approval of Teva's ANDA No. 217586, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

83. Upon information and belief, Teva will knowingly provide Teva's ANDA Product with a label ("Teva's Label") including instructions for use that substantially copy the instructions in the label for GALAFOLD Capsules.

84. Teva's Notice Letters state that Teva's Label "is identical in all relevant respects to the labeling of GALAFOLD."

85. Upon information and belief, Teva has made and will continue to make substantial and meaningful preparations to engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product that will be administered to patients according to the instructions for use on Teva's Label.

86. Upon information and belief, Teva's ANDA Product will be administered to patients according to the instructions for use on Teva's Label, which will result in formation of the compositions claimed by the Patents-in-Suit prior to their expiration.

87. Upon information and belief, Teva's ANDA Product will be administered to patients using the methods claimed by the Patents-in-Suit prior to their expiration.

88. Upon information and belief, Teva continues to seek approval of ANDA No. 217586, and upon approval by the FDA, Teva intends to immediately engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product.

89. Upon information and belief, upon approval by the FDA, and upon commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States, Teva's ANDA Product will be administered to patients according to the instructions for use on Teva's Label, which will practice the compositions and methods claimed by the Patents-in-Suit prior to their expiration.

90. Upon information and belief, the compositions and methods covered by the claims of the Patents-in-Suit are an essential component of administering Teva's ANDA Product to patients.

91. Upon information and belief, Teva will direct or control the treatment of patients using Teva's ANDA Product if the FDA approves ANDA No. 217586.

92. Upon information and belief, the treatment of patients using Teva's ANDA Product will occur at Teva's active behest and with its intent, knowledge, and encouragement.

93. Upon information and belief, Teva will actively encourage, aid, and abet the treatment of patients using Teva's ANDA Product with knowledge that such treatment is in contravention of Amicus' rights under the Patents-in-Suit.

94. Upon information and belief, Teva knows the instructions for use in Teva's Label will induce and/or contribute to others using Teva's ANDA Product in the manner set forth in the instructions.

95. Upon information and belief, physicians, health care providers, and/or patients will directly infringe one or more claims of the Patents-in-Suit by using Teva's ANDA Product in accordance with the instructions for use provided in Teva's Label.

96. Upon information and belief, Teva specifically intends that physicians, health care providers, and/or patients will use Teva's ANDA Product in accordance with the instructions for use provided in Teva's Label to directly infringe one or more claims of the Patents-in-Suit.

97. Upon information and belief, Teva knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using Teva's ANDA Product in a manner that directly infringes at least one claim of the Patents-in-Suit.

98. Upon information and belief, Teva knows or should know that Teva's ANDA Product will be especially made or especially adapted for use in infringement of at least one claim of the Patents-in-Suit, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

99. Upon information and belief, Teva will actively induce and/or contribute to infringement of the Patents-in-Suit.

COUNT I

(INFRINGEMENT OF THE '011 PATENT)

100. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

101. Teva filed ANDA No. 217586 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '011 Patent.

102. Teva's October 5 Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7), a certification alleging that the claims of the '011 Patent are invalid, unenforceable, and/or will not be infringed.

103. By filing ANDA No. 217586, Teva has represented to the FDA that, upon approval, Teva's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

104. Teva has actual knowledge of the '011 Patent, as evidenced by Teva's October 5 Notice Letter.

105. Under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '011 Patent by submitting, or causing to be submitted, to the FDA Teva's ANDA No. 217586 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration date of the '011 Patent.

106. Subject to receiving final approval of ANDA No. 217586, Teva intends to and will commercially manufacture, use, offer for sale, sell, and/or import Teva's ANDA Product within or into the United States before the expiration of the '011 Patent.

107. Upon information and belief, Teva has represented to the FDA that Teva's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

108. If ANDA No. 217586 is approved, Teva will infringe one or more claims of the '011 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Teva's ANDA Product within or into the United States and/or 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. 217586 shall be no earlier than the expiration of the '011 Patent.

109. Teva knows, should know, and intends that physicians will prescribe and patients will take Teva's ANDA Product according to the instructions for use in Teva's Label.

110. Teva has knowledge of the '011 Patent and, by virtue of Teva's Label for Teva's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '011 Patent, either literally or under the doctrine of equivalents.

111. Teva is aware, has knowledge of, and/or specifically intends that Teva's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because

healthcare professionals and/or patients will use Teva's ANDA Product according to the instructions for use in Teva's Label in a way that directly infringes at least one claim of the '011 Patent.

112. Teva's actions relating to Teva's ANDA No. 217586 complained of herein were done by and for the benefit of Teva.

113. Amicus will be substantially and irreparably harmed by Teva's infringement of the '011 Patent unless enjoined by the Court.

114. Amicus does not have any adequate remedy at law.

COUNT II

(INFRINGEMENT OF THE '263 PATENT)

115. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

116. Teva filed ANDA No. 217586 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '263 Patent.

117. Teva's October 5 Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R.§ 314.95(c)(7), a certification alleging that the claims of the '263 Patent are invalid, unenforceable, and/or will not be infringed.

118. By filing ANDA No. 217586, Teva has represented to the FDA that, upon approval, Teva's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

119. Teva has actual knowledge of the '263 Patent, as evidenced by Teva's October 5 Notice Letter.

120. Under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '263 Patent by submitting, or causing to be submitted, to the FDA Teva's ANDA No. 217586 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration date of the '263 Patent.

121. Subject to receiving final approval of ANDA No. 217586, Teva intends to and will commercially manufacture, use, offer for sale, sell, and/or import Teva's ANDA Product within or into the United States before the expiration of the '263 Patent.

122. Upon information and belief, Teva has represented to the FDA that Teva's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

123. If ANDA No. 217586 is approved, Teva will infringe one or more claims of the '263 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Teva's ANDA Product within or into the United States and/or 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. 217586 shall be no earlier than the expiration of the '263 Patent.

124. Teva knows, should know, and intends that physicians will prescribe and patients will take Teva's ANDA Product according to the instructions for use in Teva's Label.

125. Teva has knowledge of the '263 Patent and, by virtue of Teva's Label for Teva's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '263 Patent, either literally or under the doctrine of equivalents.

126. Teva is aware, has knowledge of, and specifically intends that Teva's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's ANDA Product according to the instructions for use in Teva's Label in a way that directly infringes at least one claim of the '263 Patent.

127. Teva's actions relating to Teva's ANDA No. 217586 complained of herein were done by and for the benefit of Teva.

128. Amicus will be substantially and irreparably harmed by Teva's infringement of the '263 Patent unless enjoined by the Court.

129. Amicus does not have any adequate remedy at law.

COUNT III

(INFRINGEMENT OF THE '864 PATENT)

130. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

131. Teva filed ANDA No. 217586 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '864 Patent.

132. Teva's October 5 Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R.§ 314.95(c)(7), a certification alleging that the claims of the '864 Patent are invalid, unenforceable, and/or will not be infringed.

133. By filing ANDA No. 217586, Teva has represented to the FDA that, upon approval, Teva's ANDA Product will have the same active ingredient, method of administration, dosage

form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

134. Teva has actual knowledge of the '864 Patent, as evidenced by Teva's October 5 Notice Letter.

135. Under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '864 Patent by submitting, or causing to be submitted, to the FDA Teva's ANDA No. 217586 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration date of the '864 Patent.

136. Subject to receiving final approval of ANDA No. 217586, Teva intends to and will commercially manufacture, use, offer for sale, sell, and/or import Teva's ANDA Product within or into the United States before the expiration of the '864 Patent.

137. Upon information and belief, Teva has represented to the FDA that Teva's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

138. If ANDA No. 217586 is approved, Teva will infringe one or more claims of the '864 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Teva's ANDA Product within or into the United States and/or 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. 217586 shall be no earlier than the expiration of the '864 Patent.

139. Teva knows, should know, and intends that physicians will prescribe and patients will take Teva's ANDA Product according to the instructions for use in Teva's Label.

140. Teva has knowledge of the '864 Patent and, by virtue of Teva's Label for Teva's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '864 Patent, either literally or under the doctrine of equivalents.

141. Teva is aware, has knowledge of, and specifically intends that Teva's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's ANDA Product according to the instructions for use in Teva's Label in a way that directly infringes at least one claim of the '864 Patent.

142. Teva's actions relating to Teva's ANDA No. 217586 complained of herein were done by and for the benefit of Teva.

143. Amicus will be substantially and irreparably harmed by Teva's infringement of the '864 Patent unless enjoined by the Court.

144. Amicus does not have any adequate remedy at law.

COUNT IV

(INFRINGEMENT OF THE '143 PATENT)

145. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

146. Teva filed ANDA No. 217586 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '143 Patent.

147. Teva's October 5 Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R.§ 314.95(c)(7), a certification alleging that the claims of the '143 Patent are invalid, unenforceable, and/or will not be infringed.

148. By filing ANDA No. 217586, Teva has represented to the FDA that, upon approval, Teva's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

149. Teva has actual knowledge of the '143 Patent, as evidenced by Teva's October 5 Notice Letter.

150. Under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '143 Patent by submitting, or causing to be submitted, to the FDA Teva's ANDA No. 217586 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration date of the '143 Patent.

151. Subject to receiving final approval of ANDA No. 217586, Teva intends to and will commercially manufacture, use, offer for sale, sell, and/or import Teva's ANDA Product within or into the United States before the expiration of the '143 Patent.

152. Upon information and belief, Teva has represented to the FDA that Teva's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

153. If ANDA No. 217586 is approved, Teva will infringe one or more claims of the '143 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Teva's ANDA Product within or into the United States and/or 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. 217586 shall be no earlier than the expiration of the '143 Patent.

154. Teva knows, should know, and intends that physicians will prescribe and patients will take Teva's ANDA Product according to the instructions for use in Teva's Label.

155. Teva has knowledge of the '143 Patent and, by virtue of Teva's Label for Teva's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '143 Patent, either literally or under the doctrine of equivalents.

156. Teva is aware, has knowledge of, and specifically intends that Teva's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's ANDA Product according to the instructions for use in Teva's Label in a way that directly infringes at least one claim of the '143 Patent.

157. Teva's actions relating to Teva's ANDA No. 217586 complained of herein were done by and for the benefit of Teva.

158. Amicus will be substantially and irreparably harmed by Teva's infringement of the '143 Patent unless enjoined by the Court.

159. Amicus does not have any adequate remedy at law.

COUNT V

(INFRINGEMENT OF THE '618 PATENT)

160. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

161. Teva filed ANDA No. 217586 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '618 Patent.

162. Teva's October 5 Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R.§ 314.95(c)(7), a certification alleging that the claims of the '618 Patent are invalid, unenforceable, and/or will not be infringed.

163. By filing ANDA No. 217586, Teva has represented to the FDA that, upon approval, Teva's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

164. Teva has actual knowledge of the '618 Patent, as evidenced by Teva's October 5 Notice Letter.

165. Under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '618 Patent by submitting, or causing to be submitted, to the FDA Teva's ANDA No. 217586 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration date of the '864 Patent.

166. Subject to receiving final approval of ANDA No. 217586, Teva intends to and will commercially manufacture, use, offer for sale, sell, and/or import Teva's ANDA Product within or into the United States before the expiration of the '618 Patent.

167. Upon information and belief, Teva has represented to the FDA that Teva's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

168. If ANDA No. 217586 is approved, Teva will infringe one or more claims of the '618 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Teva's ANDA Product within or into the United States and/or 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. 217586 shall be no earlier than the expiration of the '618 Patent.

169. Teva knows, should know, and intends that physicians will prescribe and patients will take Teva's ANDA Product according to the instructions for use in Teva's Label.

170. Teva has knowledge of the '618 Patent and, by virtue of Teva's Label for Teva's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '618 Patent, either literally or under the doctrine of equivalents.

171. Teva is aware, has knowledge of, and specifically intends that Teva's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's ANDA Product according to the instructions for use in Teva's Label in a way that directly infringes at least one claim of the '618 Patent.

172. Teva's actions relating to Teva's ANDA No. 217586 complained of herein were done by and for the benefit of Teva.

173. Amicus will be substantially and irreparably harmed by Teva's infringement of the '618 Patent unless enjoined by the Court.

174. Amicus does not have any adequate remedy at law.

COUNT VI

(INFRINGEMENT OF THE '866 PATENT)

175. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

176. Teva filed ANDA No. 217586 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '866 Patent.

177. Teva's October 5 Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R.§ 314.95(c)(7), a certification alleging that the claims of the '866 Patent are invalid, unenforceable, and/or will not be infringed.

178. By filing ANDA No. 217586, Teva has represented to the FDA that, upon approval, Teva's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

179. Teva has actual knowledge of the '866 Patent, as evidenced by Teva's October 5 Notice Letter.

180. Under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '866 Patent by submitting, or causing to be submitted, to the FDA Teva's ANDA No. 217586 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '866 Patent.

181. Subject to receiving final approval of ANDA No. 217586, Teva intends to and will commercially manufacture, use, offer for sale, sell, and/or import Teva's ANDA Product within or into the United States before the expiration of the '866 Patent.

182. Upon information and belief, Teva has represented to the FDA that Teva's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

183. If ANDA No. 217586 is approved, Teva will infringe one or more claims of the '866 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Teva's ANDA Product within or into the United States and/or 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. 217586 shall be no earlier than the expiration of the '866 Patent.

184. Teva knows, should know, and intends that physicians will prescribe and patients will take Teva's ANDA Product according to the instructions for use in Teva's Label.

185. Teva has knowledge of the '866 Patent and, by virtue of Teva's Label for Teva's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '866 Patent, either literally or under the doctrine of equivalents.

186. Teva is aware, has knowledge of, and specifically intends that Teva's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's ANDA Product according to the instructions for use in Teva's Label in a way that directly infringes at least one claim of the '866 Patent.

187. Teva's actions relating to Teva's ANDA No. 217586 complained of herein were done by and for the benefit of Teva.

188. Amicus will be substantially and irreparably harmed by Teva's infringement of the '866 Patent unless enjoined by the Court.

189. Amicus does not have any adequate remedy at law.

COUNT VII

(INFRINGEMENT OF THE '921 PATENT)

190. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

191. Teva filed ANDA No. 217586 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '921 Patent.

192. Teva's October 5 Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R.§ 314.95(c)(7), a certification alleging that the claims of the '921 Patent are invalid, unenforceable, and/or will not be infringed.

193. By filing ANDA No. 217586, Teva has represented to the FDA that, upon approval, Teva's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

194. Teva has actual knowledge of the '921 Patent, as evidenced by Teva's October 5 Notice Letter.

195. Under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '921 Patent by submitting, or causing to be submitted, to the FDA Teva's ANDA No. 217586 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration date of the '921 Patent.

196. Subject to receiving final approval of ANDA No. 217586, Teva intends to and will commercially manufacture, use, offer for sale, sell, and/or import Teva's ANDA Product within or into the United States before the expiration of the '921 Patent.

197. Upon information and belief, Teva has represented to the FDA that Teva's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

198. If ANDA No. 217586 is approved, Teva will infringe one or more claims of the '921 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Teva's ANDA Product within or into the United States and/or 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. 217586 shall be no earlier than the expiration of the '921 Patent.

199. Teva knows, should know, and intends that physicians will prescribe and patients will take Teva's ANDA Product according to the instructions for use in Teva's Label.

200. Teva has knowledge of the '921 Patent and, by virtue of Teva's Label for Teva's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '921 Patent, either literally or under the doctrine of equivalents.

201. Teva is aware, has knowledge of, and specifically intends that Teva's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's ANDA Product according to the instructions for use in Teva's Label in a way that directly infringes at least one claim of the '921 Patent.

202. Teva's actions relating to Teva's ANDA No. 217586 complained of herein were done by and for the benefit of Teva.

203. Amicus will be substantially and irreparably harmed by Teva's infringement of the '921 Patent unless enjoined by the Court.

204. Amicus does not have any adequate remedy at law.

COUNT VIII

(INFRINGEMENT OF RE608)

205. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

206. Teva filed ANDA No. 217586 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of RE608.

207. Teva's October 5 Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R.§ 314.95(c)(7), a certification alleging that the claims of RE608 are invalid, unenforceable, and/or will not be infringed.

208. By filing ANDA No. 217586, Teva has represented to the FDA that, upon approval, Teva's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

209. Teva has actual knowledge of RE608 Patent, as evidenced by Teva's October 5 Notice Letter.

210. Under 35 U.S.C. § 271(e)(2)(a), Teva has infringed at least one claim of RE608 by submitting, or causing to be submitted, to the FDA Teva's ANDA No. 217586 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of RE608.

211. Subject to receiving final approval of ANDA No. 217586, Teva intends to and will commercially manufacture, use, offer for sale, sell, and/or import Teva's ANDA Product within or into the United States before the expiration of RE608.

212. Upon information and belief, Teva has represented to the FDA that Teva's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

213. If ANDA No. 217586 is approved, Teva will infringe one or more claims of RE608 under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Teva's ANDA Product within or into the United States and/or 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. 217586 shall be no earlier than the expiration of RE608.

214. Teva knows, should know, and intends that physicians will prescribe and patients will take Teva's ANDA Product according to the instructions for use in Teva's Label.

215. Teva has knowledge of RE608 and, by virtue of Teva's Label for Teva's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of RE608, either literally or under the doctrine of equivalents.

216. Teva is aware, has knowledge of, and specifically intends that Teva's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's ANDA Product according to the instructions for use in Teva's Label in a way that directly infringes at least one claim of RE608.

217. Teva's actions relating to Teva's ANDA No. 217586 complained of herein were done by and for the benefit of Teva.

218. Amicus will be substantially and irreparably harmed by Teva's infringement of RE608 unless enjoined by the Court.

219. Amicus does not have any adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '011 Patent through Teva's submission of ANDA No. 217586 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '011 Patent;

B. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Teva's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product before the expiration of the '011 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '011 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

C. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '263 Patent through Teva's submission of ANDA No. 217586 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '263 Patent;

D. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Teva's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product before the expiration of the '263 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '263 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

E. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '864 Patent through Teva's submission of ANDA No. 217586 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '864 Patent;

F. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Teva's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product before the expiration of the '864 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '864 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

G. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '143 Patent through Teva's submission of ANDA No. 217586 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '143 Patent;

H. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Teva's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product before the expiration of the '143 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '143 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

I. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '618 Patent through Teva's submission of ANDA No. 217586 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '618 Patent;

J. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Teva's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product before the expiration of the '618 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '618 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

K. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '866 Patent through Teva's submission of ANDA No. 217586 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '866 Patent;

L. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Teva's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product before the expiration of the '866 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '866 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

M. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '921 Patent through Teva's submission of ANDA No. 217586 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '921 Patent;

N. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Teva's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product before the expiration of the '921 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '921 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

O. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of RE608 through Teva's submission of ANDA No. 217586 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of RE608;

P. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Teva's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product before the expiration of RE608 will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of RE608 under 35 U.S.C. §§ 271(a), (b), and/or (c);

Q. The issuance of an order providing that the effective date of any FDA approval of Teva's ANDA Product shall be no earlier than the expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Amicus and/or the Patents-in-Suit become entitled, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

R. The entry of a permanent and/or preliminary injunction enjoining Teva and all persons acting in concert with Teva from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product, until the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Amicus and/or the Patents-in-Suit are or become entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

S. The entry of a permanent and/or preliminary injunction enjoining Teva and all persons acting in concert with Teva from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the Patents-in-Suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

T. Damages, including under 35 U.S.C. §§ 271(e)(4)(C) and/or 285, or other monetary relief awarded to Amicus if Teva engages in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product prior to the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Amicus is or becomes entitled;

U. A declaration that this is an exceptional case and an award to Amicus of its costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

V. An award to Amicus of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

W. An award to Amicus of any further and additional relief that this Court deems just and proper.

Dated: November 7, 2022

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** *Pro Hac Vice* application forthcoming

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