IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMICUS THERAPEUTICS US, LLC and AMICUS THERAPEUTICS, INC., Plaintiffs, v. AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC., 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 Aurobindo Pharma Ltd. ("Aurobindo Pharma Ltd."), and Aurobindo Pharma USA, Inc. ("Aurobindo Pharma USA") (collectively "Aurobindo" or "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 12,042,489 (the "'489 Patent"), 12,042,490 (the "'490 Patent"), and 12,109,205 (the "'205 Patent") (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 Aurobindo's submission of Abbreviated New Drug Application ("ANDA") No. 217786 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 notice letters dated October 6, 2022, November 11, 2022, May 9, 2023, June 16, 2023, July 27, 2023, December 13, 2023, February 15, 2024, May 3, 2024, July 9, 2024, and December 3, 2024 (collectively, "Aurobindo's Notice Letters") Aurobindo notified Amicus that Aurobindo Pharma Ltd. had submitted an ANDA to the United States FDA ("Aurobindo's ANDA") for Aurobindo's ANDA Product. Aurobindo's Notice Letters notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to ¶ IV with respect to

certain patents listed in the Orange Book for GALAFOLD, asserting that the 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 Aurobindo's ANDA Product (the "¶ IV Certifications"). Aurobindo's Notice Letters purported to include detailed statements of the factual and legal basis for Aurobindo's ¶ IV Certifications. Upon information and belief, the purpose of Aurobindo's submission of Aurobindo'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 Aurobindo's ANDA Product prior to the expiration of patents listed in the Orange Book for GALAFOLD.

7. In Aurobindo's October 2022 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo 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") and 21 C.F.R. § 314.95(c)(7), with respect to U.S. Patent Nos. 10,076,514; 10,251,873; 10,471,053; 10,792,278; 10,792,279; 10,799,491; 10,806,727; 10,849,889; 10,849,890; 10,857,141; 10,857,142; 10,874,655; 10,874,656; 10,874,657; 11,234,972; 11,278,536; 11,278,537; 11,278,538; 11,278,539; 11,278,540; 11,304,940; 11,357,762; 11,357,763; 11,357,764; 11,357,765; 11,357,784; 11,376,244; 11,389,436; and 11,389,437 (collectively, the "October 2022 Patents"), which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluation ("Orange Book").

8. In Aurobindo's November 2022 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to ¶ IV and 21 C.F.R. § 314.95(c)(7), with respect to U.S. Patent Nos. 11,357,761, 11,426,396, and 11,458,128 (collectively, the "November 2022 Patents"), which are listed in the Orange Book.

9. In Aurobindo's May 2023 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to ¶ IV and 21 C.F.R. § 314.95(c)(7), with respect to U.S. Patent Nos. 11,612,593; 11,612,594; and 11,622,962 (collectively, the "May 2023 Patents"), which are listed in the Orange Book.

10. In Aurobindo's June 2023 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to ¶ IV and 21 C.F.R. § 314.95(c)(7), with respect to U.S. Patent Nos. 11,633,387; 11,633,388; and 11,642,334 (collectively, the "June 2023 Patents"), which are listed in the Orange Book.

11. In Aurobindo's July 2023 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to ¶ IV and 21 C.F.R. § 314.95(c)(7), with respect to U.S. Patent No. 11,666,564 (the "July 2023 Patent"), which is listed in the Orange Book.

12. In Aurobindo's December 2023 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to ¶ IV and 21 C.F.R. § 314.95(c)(7), with respect to U.S. Patent No. 11,786,516 (the "December 2023 Patent"), which is listed in the Orange Book.

13. In Aurobindo's February 2024 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to ¶ IV and 21 C.F.R. § 314.95(c)(7), with respect to U.S. Patent Nos. 11,813,255; 11,826,360; and 11,833,164 (collectively, the "February 2024 Patents"), which are listed in the Orange Book.

14. In Aurobindo's May 2024 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to ¶ IV and 21 C.F.R.

§ 314.95(c)(7), with respect to U.S. Patent No. 11,903,938 (the "May 2024 Patent"), which is listed in the Orange Book.

15. In Aurobindo's July 9, 2024 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to ¶ IV and 21 C.F.R. § 314.95(c)(7), with respect to U.S. Patent No. RE 48,608 (the "July 2024 Patent"), which is listed in the Orange Book.

16. In Aurobindo's December 3, 2024 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to ¶ IV and 21 C.F.R. § 314.95(c)(7), with respect to U.S. Patent Nos. 12,042,488; 12,042,489; 12,042,490; and 12,109,205 (together with the October 2022 Patents, November 2022 Patents, May 2023 Patents, June 2023 Patents, July 2023 Patent, December 2023 Patent, February 2024 Patents, May 2024 Patent, and July 2024 Patent, the "Notice Letter Patents"), which are listed in the Orange Book.

17. Aurobindo's Notice Letters assert that the Notice Letter Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product (the "¶ IV Certifications"). Aurobindo's Notice Letters purport to include detailed statements of the factual and legal bases for Aurobindo's ¶ IV Certifications. Aurobindo's Notice Letters defined Aurobindo as Aurobindo Pharma Ltd.

18. Aurobindo Pharma Ltd. is a company organized under the laws of India having a principal place of business at Maitrivihar, Plot No. 2, Ameerpet, Hyderabad, Telangana 500038, India and Galaxy, Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Hyderabad, Telangana 500032, India.

19. Aurobindo Pharma USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520.

20. Aurobindo Pharma Ltd. is a non-governmental, publicly held corporation and has no parent company. No publicly held company owns 10% or more of the stock of Aurobindo Pharma Ltd.

21. Aurobindo Pharma USA is a wholly-owned subsidiary of Aurobindo Pharma Ltd.

22. Aurobindo Pharma USA has acted as Aurobindo Pharma Ltd.'s agent with respect to Aurobindo's ANDA No. 217786.

23. Upon information and belief, Aurobindo Pharma USA has acted at the direction of, and for the benefit of, Aurobindo Pharma Ltd. regarding Aurobindo's ANDA No. 217786.

24. Aurobindo Pharma Ltd. submitted Drug Master File ("DMF") No. 36827 for migalastat hydrochloride to the FDA on February 25, 2022.

25. Upon information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA are generic pharmaceutical companies that, in coordination with each other and at the direction of Aurobindo Pharma Ltd., 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

26. 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).

27. The Court also has jurisdiction over this action pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and justiciable controversy exists between Amicus and Defendants of sufficient immediacy and reality to warrant the issuance

of a declaratory judgment regarding the parties' adverse legal interests with respect to the Patents-in-Suit.

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

29. This Court has personal jurisdiction over Aurobindo Pharma USA 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 Aurobindo Pharma USA essentially at home in this judicial district.

30. This Court has personal jurisdiction over foreign Defendant Aurobindo Pharma Ltd. because, upon information and belief, Aurobindo Pharma Ltd. controls the actions of its agent and United States subsidiary, Aurobindo Pharma USA, a Delaware corporation. Therefore, upon information and belief, the activities of Aurobindo Pharma USA in this jurisdiction are attributable to Aurobindo Pharma Ltd.

31. The Court also has personal jurisdiction over foreign Defendant Aurobindo Pharma Ltd. pursuant to Fed. R. Civ. P. 4(k)(2). This action arises under federal law, out of Aurobindo's submission of an ANDA filing. To the extent Aurobindo Pharma Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, exercising jurisdiction over Aurobindo Pharma Ltd. is consistent with the Constitution and laws of the United States as Aurobindo Pharma Ltd. has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation, submission, and maintenance of Aurobindo's ANDA, participating in the

preparation and submission of DMF No. 36827 to the FDA, and/or directly or indirectly developing, manufacturing, marketing, and selling Aurobindo's ANDA Product throughout the United States, including in this judicial district, such that this Court's exercise of personal jurisdiction over Aurobindo Pharma Ltd. satisfies due process.

32. 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.

33. This Court also has personal jurisdiction over each Defendant because, upon information and belief, each is a submitter of Aurobindo'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 Aurobindo's ANDA No. 217786 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 and as indicated in Aurobindo's Notice Letters, ANDA No. 217786 was prepared and filed with the intention of seeking to market Aurobindo's ANDA Product nationwide, 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 Aurobindo's ANDA Product throughout the United States and in this judicial district, which will lead to foreseeable harm and injury to Amicus.

34. 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. 217786 for the

United States market. Aurobindo's ANDA No. 217786 relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Aurobindo's intent to import, market, distribute, offer to sell, and sell Aurobindo's ANDA Product throughout the United States, including in this judicial district.

35. Aurobindo has taken the significant step of applying to the FDA for approval to engage in future activities—including the manufacture, importation, offer for sale, and sale of Aurobindo'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, the Aurobindo Defendants will act in concert to manufacture, import, market, distribute, offer to sell, and sell Aurobindo's ANDA Product in this judicial district, among other places, once Aurobindo's ANDA No. 217786 is approved by the FDA.

36. 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.

37. Venue is proper for Aurobindo Pharma USA in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Aurobindo Pharma 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 Aurobindo Pharma USA in this judicial district because Aurobindo Pharma USA is a submitter of Aurobindo's ANDA.

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

FACTUAL BACKGROUND

The NDA

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

40. 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.

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

42. 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.

43. Aurobindo advertises that its vision is to "become a consistent top 10 generic pharmaceutical supplier." *Mission & Values*, Aurobindo USA, https://www.aurobindousa.com/company/our-story/mission-values/ (last accessed December 6, 2024).

44. In April 2020, Defendant Aurobindo Pharma 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 Aurobindo to support Aurobindo's ANDA No. 217786. On March 28, 2022, Aurobindo sent a request to ATUS seeking to purchase seven packs of

GALAFOLD to purportedly complete testing required for approval of a generic version of GALAFOLD (i.e., Aurobindo's ANDA Product) pursuant to Aurobindo's ANDA No. 217786.

45. Upon information and belief, Aurobindo intends to develop a generic version of GALAFOLD.

The Patents-in-Suit

46. Amicus previously filed patent infringement actions under the Hatch-Waxman Act against Aurobindo and other generic defendants on patents that were listed in the Orange Book and for which Aurobindo had provided its February 2024 Notice Letter and June 2023 Notice Letter prior to the date the Complaints in the earlier actions were filed. *See Amicus Therapeutics US, LLC v. Teva Pharmaceuticals USA, Inc.*, Case No. 22-1461 (consolidated), D.I. 145 (D. Del. June 13, 2024) (Amicus' Third Amended Consolidated Complaint for Patent Infringement asserting, *inter alia*, U.S. Patent No. 11,633,388 against Aurobindo); *Amicus Therapeutics US, LLC v. Aurobindo Pharma Ltd.*, Case No. 24-cv-00698, D.I. 1 (D. Del. June 13, 2024) (Amicus' Complaint for Patent Infringement asserting U.S. Patent No. 11,833,164 against Aurobindo) (case now consolidated with Case No. 22-1461).

47. After the Complaints were filed in Case Nos. 22-1461 and 24-cv-00698, the U.S. Patent and Trademark Office issued additional patents to Amicus covering GALAFOLD and the use of GALAFOLD. In anticipation of the issuance of those additional patents, the parties agreed that Amicus would assert those patents after issuance in additional actions that would be consolidated with the original action. For example, Amicus served an August 22, 2024 Final Election of Asserted Claims which provided notice to Aurobindo and the other defendants that Amicus would assert the following claims once issued:

- Claim 59 of U.S. Patent No. 12,109,205 (allowed Claim 79 of U.S. Patent Appl. No. 17/078,840)

- Claim 73 of U.S. Patent No. 12,109,205 (allowed Claim 93 of U.S. Patent Appl. No. 17/078,840)
- Claim 86 of U.S. Patent No. 12,109,205 (allowed Claim 106 of U.S. Patent Appl. No. 17/078,840)
- Claim 89 of U.S. Patent No. 12,109,205 (allowed Claim 109 of U.S. Patent Appl. No. 17/078,840)
- Claim 17 of U.S. Patent No. 12,042,489 (allowed Claim 29 of U.S. Patent Appl. No. 18/326,279)
- Claim 23 of U.S. Patent No. 12,042,489 (allowed Claim 36 of U.S. Patent Appl. No. 18/326,279)
- Claim 9 of U.S. Patent No. 12,042,490 (allowed Claim 21 of U.S. Patent Appl. No. 18/326,281)

48. The United States Patent and Trademark Office (the "PTO") duly and legally issued the '489 Patent on July 23, 2024, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '489 Patent is attached as Exhibit A.

49. AT is the owner of all right, title, and interest in the '489 Patent by assignment recorded with the PTO on August 5, 2022, available at reel/frame 061099/0803.

50. The '489 Patent currently expires on May 30, 2038.

51. The '489 Patent is listed in the Orange Book as of July 30, 2024 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 '489 Patent.

53. The PTO duly and legally issued the '490 Patent on July 23, 2024, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '490 Patent is attached as Exhibit B.

54. AT is the owner of all right, title, and interest in the '490 Patent by assignment recorded with the PTO on August 5, 2022, available at reel/frame 061099/0803.

55. The '490 Patent currently expires on May 30, 2038.

56. The ’490 Patent is listed in the Orange Book as of July 30, 2024 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 ’490 Patent.

58. The PTO duly and legally issued the ’205 Patent on October 8, 2024, titled “Methods of Treating Fabry Patients Having Renal Impairment.” A true and correct copy of the ’205 Patent is attached as Exhibit C.

59. AT is the owner of all right, title, and interest in the ’205 Patent by assignment recorded with the PTO on August 5, 2022, available at reel/frame 061099/0803.

60. The ’205 Patent currently expires on May 30, 2038.

61. The ’205 Patent is listed in the Orange Book as of October 15, 2024 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 ’205 Patent.

Aurobindo’s ANDA

63. Upon information and belief, Aurobindo submitted ANDA No. 217786 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 “Aurobindo’s ANDA Product”), which are generic versions of Amicus’ GALAFOLD Capsules, prior to the expiration of the Patents-in-Suit.

64. Aurobindo’s Notice Letters purport to include a “Notice of Paragraph IV Certification Regarding the [patents listed in the Orange Book for GALAFOLD]” pursuant to § 505(j)(2)(B)(i)-(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. Aurobindo's Notice Letters state that Aurobindo had filed ANDA No. 217786 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 Aurobindo's ANDA Product before the expiration of patents listed in the Orange Book for GALAFOLD.

65. Upon information and belief, Aurobindo's Notice Letters indicate that Aurobindo seeks FDA approval of Aurobindo's ANDA Product before the expiration of the Patents-in-Suit.

66. Aurobindo's Notice Letters state that ANDA No. 217786 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), alleging that the claims of patents listed in the Orange Book for GALAFOLD 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 Aurobindo's ANDA Product (defined above as Aurobindo's "¶ IV Certifications").

67. Upon information and belief, Aurobindo's ANDA No. 217786 contains a certification 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 Aurobindo's ANDA Product.

68. Upon information and belief, Aurobindo will knowingly provide Aurobindo's ANDA Product with a label ("Aurobindo's Label") including instructions for use that substantially copy the instructions in the label for GALAFOLD Capsules. Aurobindo's Notice Letters state that Aurobindo's Label "is identical in all relevant respects to the labeling of GALAFOLD."

69. Upon information and belief, Aurobindo 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 Aurobindo's ANDA Product that will be administered to patients according to the instructions for use on Aurobindo's Label.

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

71. Upon information and belief, Aurobindo continues to seek approval of ANDA No. 217786, and upon approval by the FDA, Aurobindo intends to immediately engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product.

72. 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, Aurobindo's ANDA Product will be administered to patients according to the instructions for use on Aurobindo's Label, which will practice the methods and/or compositions claimed by the Patents-in-Suit prior to their expiration.

73. Upon information and belief, the methods and/or compositions claimed by the Patents-in-Suit are an essential component of administering Aurobindo's ANDA Product to patients.

74. Upon information and belief, Aurobindo will direct or control the treatment of patients using Aurobindo's ANDA Product if the FDA approves ANDA No. 217786.

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

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

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

78. 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 Aurobindo's ANDA Product in accordance with the instructions for use provided in Aurobindo's Label.

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

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

81. Upon information and belief, Aurobindo knows or should know that Aurobindo'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.

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

COUNT I

(INFRINGEMENT OF THE '489 PATENT)

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

84. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules, which includes the '489 Patent.

85. Aurobindo's Notice Letters state that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of certain patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules are invalid, unenforceable, and/or will not be infringed.

86. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo'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.

87. Aurobindo has actual and/or constructive notice of the '489 Patent prior to this suit as evidenced by the '489 Patent's listing in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

88. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least claims 17 and 23 of the '489 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use,

offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '489 Patent.

89. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '489 Patent.

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

91. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '489 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo'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. 217786 shall be no earlier than the expiration of the '489 Patent.

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

93. Aurobindo has actual and/or constructive knowledge of the '489 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce and/or contribute to direct infringement of at least claims 17 and 23 of the '489 Patent, either literally or under the doctrine of equivalents.

94. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo'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 Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least claims 17 and 23 of the '489 Patent.

95. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

96. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '489 Patent unless enjoined by the Court.

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

COUNT II

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '489 PATENT)

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

99. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

100. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Amicus and Aurobindo regarding infringement of the '489 Patent such that the Court may entertain Amicus's request for declaratory relief consistent with Article III of the U.S. Constitution.

101. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules, which includes the '489 Patent.

102. Aurobindo's Notice Letters state that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of certain patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules are invalid, unenforceable, and/or will not be infringed.

103. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo'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. Aurobindo has actual and/or constructive notice of the '489 Patent prior to this suit as evidenced by the '489 Patent's listing in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

105. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '489 Patent.

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

107. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '489 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo'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. 217786 shall be no earlier than the expiration of the '489 Patent.

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

109. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions and methods claimed in the '489 Patent, and therefore such physicians and patients will directly infringe at least claims 17 and 23 of the '489 Patent, either literally or under the doctrine of equivalents.

110. Aurobindo has actual and/or constructive knowledge of the '489 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce and/or contribute to direct infringement of at least claims 17 and 23 of the '489 Patent, either literally or under the doctrine of equivalents.

111. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo'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 Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least claims 17 and 23 of the '489 Patent.

112. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

113. Aurobindo's conduct including, but not limited to, Aurobindo's filing of ANDA No. 217786 attempting to meet the regulatory requirements for approval of Aurobindo's ANDA Product, demonstrates that Aurobindo has made and will continue to make substantial and meaningful preparations to infringe the '489 Patent and that Aurobindo intends to engage in the

commercial manufacture, use, offer for sale, marketing, distribution, and or/importation of Aurobindo's ANDA Product immediately and imminently upon final approval of Aurobindo's ANDA and prior to the expiration of the '489 Patent.

114. Aurobindo's actions indicate that it does not intend to change its course of action to avoid infringing the '489 Patent.

115. Amicus is entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to expiration of the '489 Patent will constitute infringement of the '489 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

116. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '489 Patent unless enjoined by the Court.

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

COUNT III

(INFRINGEMENT OF THE '490 PATENT)

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

119. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules, which includes the '490 Patent.

120. Aurobindo's Notice Letters state that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of

certain patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules are invalid, unenforceable, and/or will not be infringed.

121. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo'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.

122. Aurobindo has actual and/or constructive notice of the '490 Patent prior to this suit as evidenced by the '490 Patent's listing in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

123. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least claim 9 of the '490 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '490 Patent.

124. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '490 Patent.

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

126. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '490 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo'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. 217786 shall be no earlier than the expiration of the '490 Patent.

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

128. Aurobindo has actual and/or constructive knowledge of the '490 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce and/or contribute to direct infringement of at least claim 9 of the '490 Patent, either literally or under the doctrine of equivalents.

129. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo'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 Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least claim 9 of the '490 Patent.

130. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

131. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '490 Patent unless enjoined by the Court.

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

COUNT IV

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '490 PATENT)

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

134. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

135. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Amicus and Aurobindo regarding infringement of the '490 Patent such that the Court may entertain Amicus's request for declaratory relief consistent with Article III of the U.S. Constitution.

136. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules, which includes the '490 Patent.

137. Aurobindo's Notice Letters state that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of certain patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules are invalid, unenforceable, and/or will not be infringed.

138. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo'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.

139. Aurobindo has actual and/or constructive notice of the '490 Patent prior to this suit as evidenced by the '490 Patent's listing in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

140. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '490 Patent.

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

142. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '490 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo'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. 217786 shall be no earlier than the expiration of the '490 Patent.

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

144. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will use the methods claimed in the '490 Patent, and therefore such physicians and patients will directly infringe at least claim 9 of the '490 Patent, either literally or under the doctrine of equivalents.

145. Aurobindo has actual and/or constructive knowledge of the '490 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce and/or contribute to direct infringement of at least claim 9 of the '490 Patent, either literally or under the doctrine of equivalents.

146. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo'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 Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least claim 9 of the '490 Patent.

147. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

148. Aurobindo's conduct including, but not limited to, Aurobindo's filing of ANDA No. 217786 attempting to meet the regulatory requirements for approval of Aurobindo's ANDA Product, demonstrates that Aurobindo has made and will continue to make substantial and meaningful preparations to infringe the '490 Patent and that Aurobindo intends to engage in the commercial manufacture, use, offer for sale, marketing, distribution, and or/importation of Aurobindo's ANDA Product immediately and imminently upon final approval of Aurobindo's ANDA and prior to the expiration of the '490 Patent.

149. Aurobindo's actions indicate that it does not intend to change its course of action to avoid infringing the '490 Patent.

150. Amicus is entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to expiration of the

'490 Patent will constitute infringement of the '490 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

151. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '490 Patent unless enjoined by the Court.

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

COUNT V

(INFRINGEMENT OF THE '205 PATENT)

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

154. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

155. Aurobindo's Notice Letters state that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of certain patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules are invalid, unenforceable, and/or will not be infringed.

156. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo'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.

157. Aurobindo has actual and/or constructive notice of the '205 Patent prior to this suit as evidenced by the '205 Patent's issuance by the PTO from U.S. Patent Application No. 17/078,840.

158. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least claims 59, 73, 86, and 89 of the '205 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '205 Patent.

159. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '205 Patent.

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

161. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '205 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo'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. 217786 shall be no earlier than the expiration of the '205 Patent.

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

163. Aurobindo has actual and/or constructive knowledge of the '205 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce and/or contribute to direct infringement of at least claims 59, 73, 86, and 89 of the '205 Patent, either literally or under the doctrine of equivalents.

164. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo'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 Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least claims 59, 73, 86, and 89 of the '205 Patent.

165. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

166. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '205 Patent unless enjoined by the Court.

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

COUNT VI

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '205 PATENT)

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

169. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

170. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Amicus and Aurobindo regarding infringement of the '205

Patent such that the Court may entertain Amicus's request for declaratory relief consistent with Article III of the U.S. Constitution.

171. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

172. Aurobindo's Notice Letters state that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of certain patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules are invalid, unenforceable, and/or will not be infringed.

173. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo'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.

174. Aurobindo has actual and/or constructive notice of the '205 Patent prior to this suit as evidenced by the '205 Patent's issuance by the PTO from U.S. Patent Application No. 17/078,840.

175. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '205 Patent.

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

177. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '205 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo'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. 217786 shall be no earlier than the expiration of the '205 Patent.

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

179. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions and methods claimed in the '205 Patent, and therefore such physicians and patients will directly infringe at least claims 59, 73, 86, and 89 of the '205 Patent, either literally or under the doctrine of equivalents.

180. Aurobindo has actual and/or constructive knowledge of the '205 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce and/or contribute to direct infringement of at least claims 59, 73, 86, and 89 of the '205 Patent, either literally or under the doctrine of equivalents.

181. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo'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 Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least claims 59, 73, 86, and 89 of the '205 Patent.

182. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

183. Aurobindo's conduct including, but not limited to, Aurobindo's filing of ANDA No. 217786 attempting to meet the regulatory requirements for approval of Aurobindo's ANDA Product, demonstrates that Aurobindo has made and will continue to make substantial and meaningful preparations to infringe the '205 Patent and that Aurobindo intends to engage in the commercial manufacture, use, offer for sale, marketing, distribution, and or/importation of Aurobindo's ANDA Product immediately and imminently upon final approval of Aurobindo's ANDA and prior to the expiration of the '205 Patent.

184. Aurobindo's actions indicate that it does not intend to change its course of action to avoid infringing the '205 Patent.

185. Amicus is entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to expiration of the '205 Patent will constitute infringement of the '205 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

186. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '205 Patent unless enjoined by the Court.

187. 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 Aurobindo has infringed at least one claim of the '489 Patent through Aurobindo's submission of ANDA No. 217786 to the

FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '489 Patent;

B. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '489 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '489 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

C. A judicial declaration that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '489 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '489 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

D. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '490 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '490 Patent;

E. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '490 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '490 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

F. A judicial declaration that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product

before the expiration of the '490 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '490 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 Aurobindo has infringed at least one claim of the '205 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '205 Patent;

H. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '205 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '205 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

I. A judicial declaration that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '205 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '205 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

J. The issuance of an order providing that the effective date of any FDA approval of Aurobindo'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);

K. The entry of a permanent and/or preliminary injunction enjoining Aurobindo and all persons acting in concert with Aurobindo from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo'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;

L. The entry of a permanent and/or preliminary injunction enjoining Aurobindo and all persons acting in concert with Aurobindo 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;

M. Damages, including under 35 U.S.C. §§ 271(e)(4)(C) and/or 285, or other monetary relief awarded to Amicus if Aurobindo engages in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo'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;

N. 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);

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

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

Dated: December 6, 2024

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*To Be Admitted *pro hac vice*

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