

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AMICUS THERAPEUTICS US, LLC	:	
and AMICUS THERAPEUTICS, INC.,	:	
	:	C.A. No. 1:22-cv-01461-CJB
<i>Plaintiffs,</i>	:	
	:	(Consolidated)
v.	:	
	:	ANDA Case
TEVA PHARMACEUTICALS USA, INC.,	:	
and TEVA PHARMACEUITCALS, INC.,	:	
	:	
<i>Defendants.</i>	:	
	:	

**AUROBINDO PHARMA LTD. AND AUROBINDO PHARMA USA, INC.'S
AMENDED ANSWER TO PLAINTIFFS' COMPLAINT**

Defendants Aurobindo Pharma Ltd. (“APL”) and Aurobindo Pharma USA, Inc. (“APUI”) (collectively “Aurobindo or “Defendants”), by and through their undersigned counsel, respectfully submit their Amended Answer to Plaintiffs’ Complaint (“Complaint”), stating as follows:

RESPONSE TO ALLEGATIONS CONCERNING THE 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.

RESPONSE: Aurobindo admits Plaintiffs purport to bring a civil action to assert alleged 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”) patents under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.* Aurobindo admits APL submitted ANDA No. 217786 (“APL

ANDA") seeking FDA approval of the product described therein. Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

RESPONSE TO ALLEGATIONS PERTAINING TO 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.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo admits it notified Amicus of the filing of APL’s ANDA, which APL submitted to obtain regulatory approval by the U.S. Food and Drug Administration (“FDA”), by letters dated October 7, 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 admits Aurobindo’s Notice Letters notified Amicus that, as part of Aurobindo’s ANDA, APL had submitted paragraph IV certifications 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. Aurobindo admits its Notice Letters included detailed statements of the legal and factual basis for Aurobindo’s paragraph IV certifications. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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 Notice Letter Patents”), which are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluation (“Orange Book”).

RESPONSE: Aurobindo admits APL served the October 2022 Notice Letter identifying the October 2022 Notice Letter Patents as the subject of APL’s certification pursuant to 21 U.S.C. § 355(j)(A)(vii)(IV) that APL’s ANDA would not infringe any valid or enforceable claim of the patents identified therein. Aurobindo admits the October Notice Letter Patents are listed in the Orange Book. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo admits APL served the November 2022 Notice Letter identifying the November 2022 Patents as the subject of APL’s further certification pursuant to 21 U.S.C. § 355(j)(A)(vii)(IV) that APL’s ANDA would not infringe any valid or enforceable claim of the patents identified therein. Aurobindo admits the November 2022 Patents are listed in the Orange Book. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo admits APL served the May 2023 Notice Letter identifying the May 2023 Patents as the subject of APL’s further certification pursuant to 21 U.S.C. § 355(j)(A)(vii)(IV) that APL’s ANDA would not infringe any valid or enforceable claim of the patents identified therein.

Aurobindo admits the May 2023 Patents are listed in the Orange Book. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo admits APL served the June 2023 Notice Letter identifying the June 2023 Patents as the subject of APL's further certification pursuant to 21 U.S.C. § 355(j)(A)(vii)(IV) that APL's ANDA would not infringe any valid or enforceable claim of the patents identified therein. Aurobindo admits the June 2023 Patents are listed in the Orange Book. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo admits APL served the July 2023 Notice Letter identifying the July 2023 Patent as the subject of APL's further certification pursuant to 21 U.S.C. § 355(j)(A)(vii)(IV) that APL's ANDA would not infringe any valid or enforceable claim of the patent identified therein. Aurobindo admits the July 2023 Patent is listed in the Orange Book. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo admits APL served the December 2023 Notice Letter identifying the December 2023 Patent as the subject of APL's further certification pursuant to 21 U.S.C. § 355(j)(A)(vii)(IV) that APL's ANDA would not infringe any valid or enforceable claim of the patent

identified therein. Aurobindo admits the December 2023 Patent is listed in the Orange Book. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo admits APL served the February 2024 Notice Letter identifying the February 2024 Patents as the subject of APL's further certification pursuant to 21 U.S.C. § 355(j)(A)(vii)(IV) that APL's ANDA would not infringe any valid or enforceable claim of the patents identified therein. Aurobindo admits the February 2024 Patents are listed in the Orange Book. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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 Nos. 11,903,938 (the "May 2024 Patent"), which is listed in the Orange Book.

RESPONSE: Aurobindo admits APL served the May 2024 Letter identifying the May 2024 Patent as the subject of APL's further certification pursuant to 21 U.S.C. § 355(j)(A)(vii)(IV) that APL's ANDA would not infringe any valid or enforceable claim of the patent identified therein. Aurobindo admits the May 2024 Patent is listed in the Orange Book. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo admits APL served the July 2024 Letter identifying the July 2024 Patent as the subject of APL's further certification pursuant to 21 U.S.C. § 355(j)(A)(vii)(IV) that

APL's ANDA would not infringe any valid or enforceable claim of the patent identified therein. Aurobindo admits the July 2024 Patent is listed in the Orange Book. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo admits APL served the December 2024 Letter identifying the December 2024 Patents as the subject of APL's further certification pursuant to 21 U.S.C. § 355(j)(A)(vii)(IV) that APL's ANDA would not infringe any valid or enforceable claim of the patent identified therein. Aurobindo admits the December 2024 Patents are listed in the Orange Book. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo admits APL'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. Aurobindo admits APL's Notice Letters included detailed statements of the factual and legal bases for APL's ¶ IV Certifications. Aurobindo avers APL's Notice Letters identified Aurobindo Pharma Limited as the ANDA and Notice Letter owner. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

18. Aurobindo Pharma Ltd. is a company organized under the laws of India having a principal place of business at Maitrivihaar, 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.

RESPONSE: Aurobindo admits APL is a company organized under the laws of India with a places of business located at, *inter alia*, Plot no. 2, Maitrivihaar, Ameerpet, Hyderabad—500038, Telangana, India, and Galaxy, Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Ranga Reddy District, Hyderabad—500032, Telangana, India. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo admits APU is a corporation organized under the laws of the State of Delaware with a place of business located at 279 Princeton Hightstown Road, East Windsor, NJ 08520. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Admitted.

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

RESPONSE: Admitted.

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

RESPONSE: Aurobindo admits APU has acted as APL's agent with respect to ANDA No. 217786. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo avers APL's agent with respect to ANDA No. 217786. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

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

RESPONSE: Admitted.

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.

RESPONSE: Denied.

**RESPONSE TO ALLEGATIONS PERTAINING TO
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).

RESPONSE: Aurobindo admits Plaintiffs purport to bring a civil action for alleged patent infringement under 35 U.S.C. § 271. Aurobindo admits the Court has subject matter jurisdiction over this action. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Denied.

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, and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

RESPONSE: Denied.

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

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not contest personal jurisdiction in this Court. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not contest personal jurisdiction in this Court. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not contest personal jurisdiction in this Court. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not contest personal jurisdiction in this Court. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not contest personal jurisdiction in this Court. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not contest personal jurisdiction in this Court. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not contest venue in this District. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not contest venue in this District. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

RESPONSES TO PLAINTIFF'S ALLEGED FACTUAL BACKGROUND

Responses to Allegations Pertaining to "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").

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

43. Aurobindo advertises that its vision is to “become a consistent top 10 generic pharmaceutical supplier.” <https://www.aurobindousa.com/company/our-story/mission-values/> (last accessed June 13, 2024).

RESPONSE: Aurobindo denies that the quoted statement reflects APUI’s complete statement regarding its vision as stated on its Web site located at <https://www.aurobindousa.com/company/our-story/mission-values/> (last accessed July 3, 2024). Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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 an 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.

RESPONSE: Aurobindo admits APUI requested to purchase samples of the Galafold product from ATUS in connection with APL's ANDA No. 217786 in April 2020 and on or about March 28, 2022. Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Aurobindo admits that APL has developed the product that is the subject of APL's ANDA No. 217786. Aurobindo is without information sufficient to form a conclusion regarding the intended meaning of "generic version of GALAFOLD" and, therefore, denies any intention "to develop a generic version of GALAFOLD" as alleged. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

Responses to Allegations Pertaining to "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).

RESPONSE: Admitted.

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)

RESPONSE: Admitted

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.

RESPONSE: Aurobindo admits Exhibit A appears to be a copy of the ’489 patent, which is titled “Methods of Treating Fabry Patients Having Renal Impairment.” Aurobindo admits the face of the ’489 Patent identifies July 23, 2024 as the date of issuance. Aurobindo denies all further allegations. Allegations not expressly admitted are denied.

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 061009/0803.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

51. The '489 Patent is listed in the Orange Book as of July 30, 2024 in connection with NDA No. 208623 for GALAFOLD Capsules.

RESPONSE: Upon information and belief, admitted.

52. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '489 Patent.

RESPONSE: Denied.

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.

RESPONSE: Aurobindo admits Exhibit B to the Complaint appears to be a copy of the '490 patent, which Aurobindo admits is titled "Methods of Treating Fabry Patients Having Renal Impairment." Aurobindo admits the face of the '490 patent states the '490 patent issued July 23, 2024. Aurobindo denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Upon information and belief, admitted.

56. The '490 Patent is listed in the Orange Book as of July 30, 2024 in connection with NDA No. 208623 for GALAFOLD Capsules.

RESPONSE: Upon information and belief, admitted.

57. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '490 Patent.

RESPONSE: Denied.

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.

RESPONSE: Aurobindo admits Exhibit C appears to be a copy of the '205 patent, which is titled "Methods of Treating Fabry Patients Having Renal Impairment." Aurobindo admits the face of the '205 Patent identifies October 8, 2024 as the date of issuance. Aurobindo denies all further allegations. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Upon information and belief, admitted.

61. The '205 Patent is listed in the Orange Book as of October 15, 2024 in connection with NDA No. 208623 for GALAFOLD Capsules.

RESPONSE: Upon information and belief, admitted.

62. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '205 Patent.'

RESPONSE: Denied.

Responses to Allegations Pertaining to "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.

RESPONSE: Aurobindo admits APL submitted ANDA No. 217786 with the FDA under 21 U.S.C. § 355(j) to obtain regulatory approval of the product described therein. Aurobindo denies all

remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo admits APL's Notice Letters each notified Plaintiffs of the submission of APL's ANDA seeking FDA approval of APL's ANDA product prior to the expiration of certain Orange Book-listed patents identified therein. Aurobindo denies all further allegations in this paragraph of the complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo admits APL's Notice Letters each notified Plaintiffs of the submission of APL's ANDA seeking FDA approval of APL's ANDA product prior to the expiration of certain Orange Book-listed patents identified therein. Aurobindo denies all further allegations in this paragraph of the complaint. Allegations not expressly admitted are denied.

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").

RESPONSE: Aurobindo admits APL's Notice Letters notified Plaintiffs that APL had submitted paragraph IV certifications on the basis that the patents identified in APL's Notice Letters 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 APL's ANDA Product. Aurobindo denies all further allegations in this paragraph of the complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Aurobindo admits APL's ANDA, as amended and supplemented, contains a paragraph IV certification on the basis 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 APL's ANDA Product. Aurobindo denies all further allegations in this paragraph of the complaint. Allegations not expressly admitted are denied.

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."

RESPONSE: Denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Aurobindo admits it continues to seek approval of ANDA No. 217786. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations, which are purely speculative and hypothetical, in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Denied.

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

RESPONSE: Denied.

**RESPONSES TO ALLEGATIONS PERTAINING TO COUNT I
(ALLEGED INFRINGEMENT OF THE '489 PATENT)**

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

RESPONSE: Aurobindo restates and incorporates by reference each response to each preceding paragraph of the Complaint as though fully restated 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.

RESPONSE: Aurobindo admits APL filed ANDA No. 217786 seeking regulatory approval for APL's ANDA Product. Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Admitted.

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.

RESPONSE: Denied.

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.

RESPONSE: Aurobindo admits having knowledge of the '489 patent at least as early as the date of Aurobindo's submission of its Paragraph IV certification for the '489 patent. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Pursuant to the case-narrowing stipulation entered into by the Parties in the related litigations (*see* D.I.191), Aurobindo has stipulated to infringement of claims 17 and 23 of the '489 patent to the extent those claims are not found invalid or unenforceable. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Aurobindo admits representing to FDA that it's ANDA product is bioequivalent to GALAFOLD. Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Pursuant to the case-narrowing stipulation entered into by the Parties in the related litigations (*see* D.I.191), Aurobindo has stipulated to infringement of claims 17 and 23 of the '489 patent to the extent those claims are not found invalid or unenforceable. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Aurobindo admits having knowledge of the '489 patent. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT II
(DECLARATORY JUDGMENT OF
ALLEGED INFRINGEMENT OF THE '489 PATENT)

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

RESPONSE: Aurobindo restates and incorporates by reference each response to each preceding paragraph of the Complaint as though fully restated herein.

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

RESPONSE: Aurobindo admits Plaintiffs purport to bring this claim pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Aurobindo admits APL filed ANDA No. 217786 seeking regulatory approval for APL's ANDA Product. Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Admitted.

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.

RESPONSE: Denied.

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.

RESPONSE: Aurobindo admits that it had knowledge of the '489 patent prior to this suit. Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Aurobindo admits representing to FDA that it's ANDA product is bioequivalent to GALAFOLD. Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Pursuant to the case-narrowing stipulation entered into by the Parties in the related litigations (*see* D.I.191), Aurobindo has stipulated to infringement of claims 17 and 23 of the '489 patent to the extent those claims are not found invalid or unenforceable. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Admitted.

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.

RESPONSE: Denied.

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.

RESPONSE: Aurobindo admits having knowledge of the '489 patent. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Denied.

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

RESPONSE: Denied.

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.

RESPONSE: Denied.

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

RESPONSE: Denied.

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).

RESPONSE: Pursuant to the case-narrowing stipulation entered into by the Parties in the related litigations (*see* D.I.191), Aurobindo has stipulated to infringement of claims 17 and 23 of the '489 patent to the extent those claims are not found invalid or unenforceable. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT III
(ALLEGED INFRINGEMENT OF THE '490 PATENT)

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

RESPONSE: Aurobindo restates and incorporates by reference each response to each preceding paragraph of the Complaint as though fully restated 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.

RESPONSE: Aurobindo admits APL filed ANDA No. 217786 seeking regulatory approval for APL's ANDA Product. Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Admitted.

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.

RESPONSE: Denied.

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.

RESPONSE: Aurobindo admits that it had knowledge of the '490 patent prior to this suit. Aurobindo denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Pursuant to the case-narrowing stipulation entered into by the Parties in the related litigations (*see* D.I.191), Aurobindo has stipulated to infringement of claim 9 of the '490 patent to the extent the claim is not found invalid or unenforceable. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Aurobindo admits representing to FDA that it's ANDA product is bioequivalent to GALAFOLD. Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Pursuant to the case-narrowing stipulation entered into by the Parties in the related litigations (*see* D.I.191), Aurobindo has stipulated to infringement of claim 9 of the '490 patent to the extent those claims are not found invalid or unenforceable. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Aurobindo admits having knowledge of the '490 patent. Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO COUNT IV
(DECLARATORY JUDGMENT OF
ALLEGED INFRINGEMENT OF THE '490 PATENT)

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

RESPONSE: Aurobindo restates and incorporates by reference each response to each preceding paragraph of the Complaint as though fully restated herein.

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

RESPONSE: Aurobindo admits Plaintiffs purport to bring this claim pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Aurobindo admits APL filed ANDA No. 217786 seeking regulatory approval for APL's ANDA Product. Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Admitted.

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.

RESPONSE: Denied.

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.

RESPONSE: Aurobindo admits having knowledge of the '490 patent prior to this suit. Aurobindo denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Aurobindo admits representing to FDA that it's ANDA product is bioequivalent to GALAFOLD. Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Pursuant to the case-narrowing stipulation entered into by the Parties in the related litigations (*see* D.I.191), Aurobindo has stipulated to infringement of claim 9 of the '490 patent to the extent those claims are not found invalid or unenforceable. Aurobindo denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Denied.

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.

RESPONSE: Denied.

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

RESPONSE: Denied.

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.

RESPONSE: Denied.

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

RESPONSE: Denied.

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).

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

**RESPONSES TO ALLEGATIONS PERTAINING TO COUNTS V AND VI
(ALLEGED INFRINGEMENT OF THE '205 PATENT)**

153 - 187 *See Complaint*

RESPONSE TO ¶¶153-187: Aurobindo denies all material allegations pertaining to Plaintiffs' allegations of infringement of the '205 patent, which is the subject of a Covenant Not to Sue issued by Plaintiffs in accordance with the case-narrowing stipulation entered into by the Parties in the related litigations (*see D.I.191*).

GENERAL DENIAL AND RESPONSE TO PLAINTIFFS' REQUEST FOR RELIEF

All allegations in Plaintiff's Complaint not expressly admitted by Aurobindo are hereby denied. Having answered Plaintiff's Complaint, Aurobindo denies Plaintiff is entitled to any of the relief requested in the Complaint or any relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not expressly admitted, Aurobindo asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest on Plaintiff.

FIRST SEPARATE DEFENSE

But for the case-narrowing stipulation entered into by the Parties in the related litigations (*see D.I.191*), the manufacture, use, or sale, offer for sale, or importation of the products that are the subject of APL's ANDA has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '489 and '490 patents for the reasons set forth in Aurobindo's Noninfringement Contentions served in the related litigations.

SECOND SEPARATE DEFENSE

Each of the claim of the '489 and '490 patents is invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code or for satisfying other bases (including judicially-created bases) for invalidation or unenforceability, for example, for at least the reasons set forth in APL's Notice Letters and the Invalidity Contentions served in the related litigations.

THIRD SEPARATE DEFENSE

Each of claim of the '489 and '490 patents is invalid as anticipated or obvious, pursuant to 35 U.S.C. §§ 102 or 103, for example, for at least the reasons set forth in APL's Notice Letters and the Invalidity Contentions served in related litigations.

FOURTH SEPARATE DEFENSE

Each of claim of the '489 and '490 patents is invalid, pursuant to 35 U.S.C. § 112, as, for example, indefinite, not enabled and/or failing to provide adequate written description for the reasons set forth in APL's Notice Letters and the Invalidity Contentions served in related litigations.

FIFTH SEPARATE DEFENSE

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the Asserted Patents, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the Asserted Patents is infringed by the product that is the subject of APL's ANDA.

SIXTH SEPARATE DEFENSE

Plaintiffs have failed to state a claim upon which relief can be granted.

SEVENTH SEPARATE DEFENSE

Any and all additional defenses and counterclaims that discovery may reveal.

WHEREFORE, Aurobindo hereby demands judgment in its favor based on a finding of non-infringement and/or invalidity and/or unenforceability of the Asserted Patents, an award of all costs and fees incurred in defense of this Action and for such other relief as the Court may deem just and proper.

Dated: February 10, 2025

KRATZ & BARRY LLP

/s/ R Touhey Myer

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