IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMICUS THERAPEUTICS US, LLC and AMICUS THERAPEUTICS, INC., Plaintiffs, v. LUPIN LTD. and LUPIN PHARMACEUTICALS, INC., Defendants.	C.A. No. 23-00964-CFC ANDA CASE

LUPIN LIMITED'S AND LUPIN PHARMACEUTICALS, INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT

Defendants Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") (collectively, "Lupin" or "Defendants"), by and through their undersigned counsel, hereby answer and respond to each of the allegations in the Complaint by Amicus Therapeutics US, LLC ("ATUS") and Amicus Therapeutics, Inc. ("AT") (collectively "Amicus" or "Plaintiffs"), and assert their separate defenses, and Lupin Ltd. asserts its separate counterclaims, as follows:

GENERAL DENIAL

Pursuant to Federal Rule of Civil Procedure 8(b)(3), Defendants deny all allegations in Plaintiffs' Complaint except those expressly admitted below.

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 9,000,011 (the "'011 Patent"), 9,987,263 (the "'263 Patent"), 10,383,864 (the "'864 Patent"), 10,406,143 (the "'143 Patent"), 10,925,866 (the "'866 Patent"), 10,813,921 (the "'921 Patent"), and RE48,608 ("RE608") (collectively, "Patents-in-Suit"), arising under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action arises out of Lupin's submission of Abbreviated New Drug Application ("ANDA") No. 217793 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.

ANSWER: The allegations in paragraph 1 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the Complaint purports to state a claim for patent infringement under the patent laws of the United States, Title 35 of the United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. Lupin further admits that Lupin Ltd. submitted Abbreviated New Drug Application ("ANDA") No. 217793 to the U.S. Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j), seeking FDA approval of the migalastat hydrochloride capsules described in ANDA No. 217793 ("Lupin's proposed ANDA product"). Lupin further admits that ANDA No. 217793 was amended to include a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to U.S. Patent Nos. 9,000,011 ("the '011 patent"), 9,987,263 ("the '263 patent"), 10,383,864 ("the '864 patent"), 10,406,143 ("the '143 patent"), 10,925,866 ("the '866 patent"), 10,813,921 ("the '921 patent"),

and RE48,608 ("the '608 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. Lupin denies all other allegations in paragraph 1.

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.

ANSWER: Lupin lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 2 and therefore denies them.

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.

ANSWER: Lupin lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 3 and therefore denies them.

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.

ANSWER: Lupin lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 4 and therefore denies them.

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

ANSWER: Lupin lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 5 and therefore denies them.

6. By a letter dated August 9, 2023 ("Lupin's Notice Letter") and received by Amicus on August 10, 2023, Lupin notified Amicus that Lupin Ltd. had submitted an amendment to ANDA No. 217793 to the United States FDA ("Lupin's ANDA") for "migalastat hydrochloride capsules, eq 123 mg base," a drug product that is a generic version of GALAFOLD ("Lupin's ANDA Product"). Upon information and belief, the purpose of Lupin's submission of Lupin'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 Lupin's ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Lupin admits that in a letter dated August 9, 2023 ("Lupin's 8/9/23 Notice Letter") and, on information and belief received by Plaintiffs on August 10, 2023, Lupin Ltd. notified Plaintiffs that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j) seeking FDA approval of Lupin's proposed ANDA product and that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '011, '263, '864, '143, '866, '921, and '608 patents, and U.S. Patent Nos. 8,592,362 ("the '362 patent"), 9,095,584 ("the '584 patent"), 9,480,682 ("the '682 patent"), 9,999,618 ("the '618 patent"), 10,525,045 ("the '045 patents"), 11,033,538 ("the '538 patent"), and 11,241,422 ("the '422 patent") (collectively, "Notice Letter Patents"). Lupin denies all other allegations in paragraph 6.

7. In Lupin's Notice Letter, Lupin notified Amicus that Lupin Ltd. had filed an amendment to ANDA No. 217793 to include a certification pursuant to Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("¶ IV") with respect to U.S. Patent Nos. 8,592,362, 9,000,011, 9,095,584, 9,480,682, 9,987,263, 9,999,618, 10,383,864, 10,406,143, 10,525,045, 10,813,921, 10,925,866, 11,033,538, 11,241,422, RE48,608 (the "Notice Letter Patents"), which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluation ("Orange Book").

ANSWER: Lupin admits that in Lupin's 8/9/23 Notice Letter, Lupin Ltd. notified Plaintiffs that Lupin Ltd. submitted an amendment to ANDA No. 217793 to include a Paragraph IV Certification that no valid claim of the Notice Letter Patents, which are listed in the FDA's Electronic Orange Book, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for GALAFOLD® migalastat hydrochloride capsules, eq 123 mg base, would be infringed by the manufacture, importation, use, or sale of Lupin's proposed ANDA product. Lupin denies all other allegations in paragraph 7.

8. Lupin's Notice Letter asserts 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 Lupin's ANDA Product (the "¶ IV Certifications"). Lupin's Notice Letter purports to include detailed statements of the factual and legal bases for Lupin's ¶ IV Certifications. Lupin's Notice Letter defines Lupin as Lupin Ltd.

ANSWER: Lupin admits that in Lupin's 8/9/23 Notice Letter, Lupin Ltd. notified Plaintiffs that Lupin Ltd. submitted an amendment to ANDA No. 217793 to include a Paragraph IV Certification that no valid claim of the Notice Letter Patents would be infringed by Lupin's proposed ANDA product. Lupin further admits that

Lupin's 8/9/23 Notice Letter included a detailed statement of the factual and legal bases upon which Lupin Ltd. based its Paragraph IV Certification with respect to the Notice Letter Patents. Lupin denies all other allegations in paragraph 8.

9. Upon information and belief, Lupin Ltd. is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at Kalpataru Inspire, 3rd Floor, Off Western Express Highway, Santacruz (East), Mumbai 40055, India.

ANSWER: Admitted.

10. Upon information and belief, Lupin Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202.

ANSWER: Admitted.

11. Upon information and belief, Lupin Ltd. is a publicly traded company and there is no publicly traded corporation that owns 10% or more of Lupin Ltd.'s stock.

ANSWER: Lupin admits that Lupin Limited is publicly traded on the Bombay Stock Exchange and there is no publicly held corporation that owns 10% or more of Lupin Limited's stock.

12. Upon information and belief, Lupin Pharmaceuticals is an indirect, wholly-owned subsidiary of Lupin Ltd.

ANSWER: Admitted.

13. Upon information and belief, Lupin Ltd. submitted Drug Master File ("DMF") No. 36729 for migalastat hydrochloride to the FDA on March 31, 2022.

ANSWER: Admitted.

14. Upon information and belief, Lupin Ltd. and Lupin Pharmaceuticals are generic pharmaceutical companies that, in coordination with each other, are in the

business of making and selling generic pharmaceutical products, which they distribute throughout the United States including in this judicial district.

ANSWER: The allegations in paragraph 14 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Ltd. manufactures pharmaceutical products, including generic pharmaceutical products. Lupin further admits that Lupin Pharmaceuticals distributes pharmaceutical products, including generic pharmaceutical products manufactured by Lupin Ltd., in the United States. Lupin denies that Lupin Pharmaceuticals is a proper party to this action. Lupin denies all other allegations in paragraph 14.

JURISDICTION AND VENUE

15. 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).

ANSWER: The allegations in paragraph 15 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the Complaint purports to state a claim for patent infringement under 35 U.S.C. § 271. Lupin states that Lupin does not contest subject matter jurisdiction in this Court solely for purposes of Plaintiffs' claims against Lupin in this case and solely as they apply to Lupin's proposed ANDA product. Lupin denies all other allegations in paragraph 15.

16. Upon information and belief, Defendants coordinate, collaborate, and act in concert with respect to the regulatory approval, manufacturing, marketing, sale, and

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

ANSWER: The allegations in paragraph 16 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Ltd. manufactures pharmaceutical products, including generic pharmaceutical products. Lupin further admits that Lupin Pharmaceuticals distributes pharmaceutical products, including generic pharmaceutical products, in the United States. Lupin denies that Lupin Pharmaceuticals is a proper party to this action. Lupin denies all other allegations in paragraph 16.

17. Upon information and belief, Defendants have and will continue to coordinate, collaborate, and act in concert to prepare, submit, and maintain Lupin's ANDA No. 217793 pursuant to Section 505(j) of the FDCA, 21 U.S.C. § 355(j). Defendants are therefore submitters of an ANDA within the jurisdiction of this Court.

ANSWER: The allegations in paragraph 17 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin denies that Lupin Pharmaceuticals is a proper party to this action. Lupin denies all other allegations in paragraph 17.

18. This Court has personal jurisdiction over Lupin Pharmaceuticals 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

and residence in Delaware, are so systematic and continuous as to render Lupin Pharmaceuticals essentially at home in this judicial district.

ANSWER: The allegations in paragraph 18 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Pharmaceuticals is a corporation organized and existing under the laws of Delaware. Lupin states that Lupin does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Lupin in this case and solely as they apply to Lupin's proposed ANDA product. Lupin denies that Lupin Pharmaceuticals is a proper party to this action. Lupin denies all other allegations in paragraph 18.

19. The Court has personal jurisdiction over foreign Defendant Lupin Ltd. because, upon information and belief, Lupin Ltd. controls the actions of its agent and United States subsidiary, Lupin Pharmaceuticals, a Delaware corporation. Therefore, upon information and belief, the activities of Lupin Pharmaceuticals in this jurisdiction are attributed to Lupin Ltd.

ANSWER: The allegations in paragraph 19 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Pharmaceuticals is a corporation organized and existing under the laws of Delaware and Lupin Pharmaceuticals is an indirectly wholly owned subsidiary of Lupin Ltd. Lupin states that Lupin does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Lupin in this case and solely as they apply to Lupin's proposed ANDA product. Lupin denies that Lupin Pharmaceuticals is a proper party to this action. Lupin denies all other allegations in paragraph 19.

20. The Court also has personal jurisdiction over foreign Defendant Lupin Ltd. pursuant to Fed. R. Civ. P. 4(k)(2). This action arises under federal law, out of Lupin's submission of an ANDA filing. To the extent Lupin Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, exercising jurisdiction over Lupin Ltd. is consistent with the Constitution and laws of the United States as Lupin 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 Lupin's ANDA, participating in the preparation and submission of DMF No. 36729, and/or directly or indirectly developing, manufacturing, marketing, and selling Lupin's ANDA Product throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over Lupin Ltd. satisfies due process.

ANSWER: The allegations in paragraph 20 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin admits that Lupin Ltd. submitted Drug Master File ("DMF") No. 36729 for migalastat hydrochloride to the FDA. Lupin further admits that Lupin Ltd. manufactures pharmaceutical products, including generic pharmaceutical products. Lupin states that Lupin Ltd. does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Lupin Ltd. in this case and solely as they apply to Lupin's proposed ANDA product. Lupin denies all other allegations in paragraph 20.

21. This Court also has personal jurisdiction over Lupin because, upon information and belief, Lupin Ltd. and Lupin Pharmaceuticals have frequently availed themselves 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. Upon information and belief, Lupin Ltd. and Lupin Pharmaceuticals have affirmatively availed themselves of the jurisdiction of this Court through the assertion of counterclaims in suits brought in this judicial district, including at least *Amicus Therapeutics US, LLC et al. v. Teva Pharmaceuticals USA, Inc. et al.*, No.

1:22-cv-1461, at Dkt. 50 (D. Del. June 22, 2023), *Neurocrine Biosciences, Inc. v. Lupin Limited et al*, No. 1:22-cv-01061, at Dkt. 6 (D. Del. Sept. 9, 2022), and *ZS Pharma, Inc. et al. v. Lupin Limited et al.*, No. 1:22-cv-01055, at Dkt. 19 (D. Del. Oct. 7, 2022).

ANSWER: The allegations in paragraph 21 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin states that Lupin does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Lupin in this case and solely as they apply to Lupin's proposed ANDA product. Lupin admits that in *Amicus Therapeutics US, LLC et al, v. Teva Pharmaceuticals USA, Inc. et al*, Civil Action No. 1:22-cv-1461, *Neurocrine Biosciences, Inc. v. Lupin Limited et al.*, Civil Action No. 1:22-cv-01061, and *ZS Pharma, Inc. et al v. Lupin Limited et al*, Civil Action No. 1:22-cv-01055, Lupin Ltd. asserted counterclaims. Lupin denies that Lupin Pharmaceuticals is a proper party to this action. Lupin denies all other allegations in paragraph 21.

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

United States and in this judicial district, which will lead to foreseeable harm and injury to Amicus.

ANSWER: The allegations in paragraph 22 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin states that Lupin does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Lupin in this case and solely as they apply to Lupin's proposed ANDA product. Lupin denies that Lupin Pharmaceuticals is a proper party to this action. Lupin denies all other allegations in paragraph 22.

23. Upon information and belief, Defendants have been, and continue to be, joint and prime actors in the preparation, drafting, submission, approval, and maintenance of ANDA No. 217793 for the United States market. Lupin's ANDA No. 217793 relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Lupin's intent to market and sell Lupin's ANDA Product throughout the United States, including in this judicial district.

ANSWER: The allegations in paragraph 23 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin denies that Lupin Pharmaceuticals is a proper party to this action. Lupin denies all other allegations in paragraph 23.

24. Lupin has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of Lupin'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 Defendants will act in concert to market, distribute, and sell Lupin's ANDA Product in this judicial district, among other places, once Lupin receives the requested FDA approval to market Lupin's ANDA Product.

ANSWER: The allegations in paragraph 24 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin admits that Lupin Ltd. manufactures pharmaceutical products, including generic pharmaceutical products. Lupin further admits that Lupin Pharmaceuticals distributes pharmaceutical products, including generic pharmaceutical products, in the United States. Lupin denies that Lupin Pharmaceuticals is a proper party to this action. Lupin denies all other allegations in paragraph 24.

25. 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.

ANSWER: The allegations in paragraph 25 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin states that Lupin does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Lupin in this case and solely as they apply to Lupin's proposed ANDA product. Lupin denies all other allegations in paragraph 25.

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

ANSWER: The allegations in paragraph 26 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin admits that Lupin Ltd. is a company organized and existing under the laws of India. Lupin states that Lupin Ltd. does not contest venue in this Court solely for purposes of Plaintiffs' claims against Lupin Ltd. in this case and solely as they apply to Lupin's proposed ANDA product. Lupin denies all other allegations in paragraph 26.

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

ANSWER: The allegations in paragraph 27 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Pharmaceuticals is a corporation organized and existing under the laws of Delaware. Lupin states that Lupin does not contest venue in this Court solely for purposes of Plaintiffs' claims against Lupin in this case and solely as they apply to Lupin's

proposed ANDA product. Lupin denies that Lupin Pharmaceuticals is a proper party to this action. Lupin denies all other allegations in paragraph 27.

FACTUAL BACKGROUND

The NDA

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

ANSWER: Lupin admits that the FDA's Orange Book lists "AMICUS THERAPEUTICS US LLC" as the Applicant Holder Full Name, "GALAFOLD" as the Proprietary Name, "MIGALASTAT HYDROCHLORIDE" as the Active Ingredient, "CAPSULE; ORAL" as the Dosage Form; Route of Administration, and "EQ 123MG BASE" as the Strength in connection with New Drug Application ("NDA") No. 208623. Lupin lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 28 and therefore denies them.

29. 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.

ANSWER: Lupin admits on information and belief that the prescribing information for GALAFOLD®, revised 06/2023, ("Galafold 06/2023 Prescribing Information") states under the Indications and Usage section 1 that, "GALAFOLD is indicated for the treatment of adults with a confirmed diagnosis of Fabry disease

and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data." Lupin further admits that the Galafold 06/2023 Prescribing Information states under the Dosage and Administration section 2.2 that "[t]he recommended dosage of GALAFOLD is 123 mg orally once every other day." Lupin further admits that the FDA's Orange Book lists "MIGALASTAT HYDROCHLORIDE" as the Active Ingredient in connection with NDA No. 208623. Lupin lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 29 and therefore denies them.

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

ANSWER: Lupin admits that the FDA's Orange Book lists "August 10, 2018" as the Approval Date and "08/10/2023" as the "NCE" Exclusivity Expiration in connection with NDA No. 208623. Lupin lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 30 and therefore denies them.

31. 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.

ANSWER: The allegations in paragraph 31 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the FDA's Orange Book lists "08/10/2025" as the "ODE-205" Exclusivity Expiration,

"MIGALASTAT HYDROCHLORIDE" as the Active Ingredient, "EQ 123MG BASE" as the Strength, and "GALAFOLD" as the Proprietary Name in connection with NDA No. 208623. Lupin lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 31 and therefore denies them.

32. Lupin advertises itself as "one of the fastest-growing pharmaceutical companies in the U.S." *See* https://www.lupin.com/US/generics/ (last accessed August 29, 2023). Lupin further proclaims that it "has a strong and well-established generic presence in the United States." *See* https://www.lupin.com/US/about-us/ (last accessed August 29, 2023).

ANSWER: Lupin admits that https://www.lupin.com/US/generics/ (last accessed September 6, 2023) states, "Lupin entered the U.S. generic pharmaceutical market in 2003 with ANDA approval for Cefuroxime Axetil Tablets. We have since received more than 250 FDA approvals and market a total of 180 generic products. This has solidified us as one of the fastest-growing pharmaceutical companies in the U.S." Lupin admits that https://www.lupin.com/US/about-us/ (last accessed September 6, 2023) states that "Lupin has a strong and well-established generic presence in the United States . . . ." Lupin denies all other allegations in paragraph 32.

33. On February 22, 2022, Springcare USA LLC d/b/a Spring Bio Solution ("SBS"), on behalf of Lupin Ltd., submitted a request pursuant to 21 U.S.C. § 355-2 (the "CREATES Act") to ATUS seeking to purchase eight packs of GALAFOLD for testing purportedly deemed necessary by Lupin to support Lupin's ANDA No. 217793. SBS's request included a letter from Lupin Ltd.'s Vice President, Raghavan Vineeth, stating that Lupin Ltd. "has engaged its distributor and logistics provider

[SBS]" to access GALAFOLD for Lupin Ltd., and instructing ATUS to direct all correspondence to SBS and send the requested GALAFOLD samples to SBS.

ANSWER: Lupin admits that a letter dated February 22, 2022 from Raghavan Vineeth, Vice President at Lupin Limited, to John F. Crowley, Chairman & Chief Executive Officer at Amicus Therapeutics US, LLC, stated that, "Lupin has engaged its distributor and logistics provider, Spring Bio Solution, to assist Lupin in procuring GALAFOLD® (migalastat hydrochloride) 123 mg capsules (NDC 71904-100-01) from Amicus. Please respond to this request by contacting Spring Bio Solution. Lupin requests that Spring Bio Solution handle the transaction, including payment, for Lupin. Lupin further requests the samples be delivered to Spring Bio Solution at 10 Plainfield Avenue, Suite 3, Piscataway, NJ 08854 for Lupin's purposes as stated herein." Lupin lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 33 and therefore denies them.

34. Upon information and belief, Lupin intends to develop a generic version of GALAFOLD.

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin denies all other allegations in paragraph 34.

The Patents-in-Suit

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

ANSWER: The allegations in paragraph 35 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the '011 patent is titled "Methods for Treatment of Fabry Disease" and lists April 7, 2015 as Date of Patent. Lupin further admits that, on information and belief, what purports to be a copy of the '011 patent is attached to Plaintiffs' Complaint filed September 1, 2023 as Exhibit A. Lupin denies all other allegations in paragraph 35.

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

ANSWER: The allegations in paragraph 36 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that according to the United States Patents and Trademark Office's ("PTO") Patent Assignment Search database, Reel No. 046799, Frame No. 0464, dated September 6, 2018, Amicus Therapeutics, Inc. is the assignee of the '011 patent. Lupin lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 36 and therefore denies them.

37. The ’011 Patent currently expires on May 16, 2027.

ANSWER: Lupin admits that the FDA’s Orange Book lists “05/16/2027” as the Patent Expiration for the ’011 patent in connection with NDA No. 208623. Lupin denies all other allegations in paragraph 37.

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

ANSWER: Lupin admits that the ’011 patent is listed in the FDA’s Orange Book in connection with NDA No. 208623 for the product with Proprietary Name “GALAFOLD” and the Dosage Form; Route of Administration “Capsule; Oral.” Lupin denies all other allegations in paragraph 38.

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

ANSWER: The allegations in paragraph 39 are legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: The allegations in paragraph 40 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the ’263 patent is titled “Methods for Treatment of Fabry Disease” and lists June 5, 2018 as the Date of Patent. Lupin further admits that, on information and belief, what purports to be a copy of the ’263 patent is attached to Plaintiffs’ Complaint filed September 1, 2023 as Exhibit B. Lupin denies all other allegations in paragraph 40.

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

ANSWER: The allegations in paragraph 41 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that according to the PTO Patent Assignment Search database Reel No. 046799, Frame No. 0464, dated September 6, 2018, Amicus Therapeutics, Inc. is the assignee of the '263 patent. Lupin lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 41 and therefore denies them.

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

ANSWER: Lupin admits that the FDA's Orange Book lists "05/16/2027" as the Patent Expiration for the '263 patent in connection with NDA No. 208623. Lupin denies all other allegations in paragraph 42.

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

ANSWER: Lupin admits that the '263 patent is listed in the FDA's Orange Book in connection with NDA No. 208623 for the product with Proprietary Name "GALAFOLD" and the Dosage Form; Route of Administration "Capsule; Oral." Lupin denies all other allegations in paragraph 43.

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

ANSWER: The allegations in paragraph 44 are legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: The allegations in paragraph 45 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the '864 patent is titled "Methods for Treatment of Fabry Disease" and lists August 20, 2019 as the Date of Patent. Lupin further admits that, on information and belief, what purports to be a copy of the '864 patent is attached to Plaintiffs' Complaint filed September 1, 2023 as Exhibit C. Lupin denies all other allegations in paragraph 45.

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

ANSWER: The allegations in paragraph 46 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 46 and therefore denies them.

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

ANSWER: Lupin admits that the FDA's Orange Book lists "05/16/2027" as the Patent Expiration for the '864 patent in connection with NDA No. 208623. Lupin denies all other allegations in paragraph 47.

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

ANSWER: Lupin admits that the ’864 patent is listed in the FDA’s Orange Book in connection with NDA No. 208623 for the product with Proprietary Name “GALAFOLD” and the Dosage Form; Route of Administration “Capsule; Oral.” Lupin denies all other allegations in paragraph 48.

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

ANSWER: The allegations in paragraph 49 are legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: The allegations in paragraph 50 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the ’143 patent is titled “Methods for Treatment of Fabry Disease” and lists September 10, 2019 as the Date of Patent. Lupin further admits that, on information and belief, what purports to be a copy of the ’143 patent is attached to Plaintiffs’ Complaint filed September 1, 2023 as Exhibit D. Lupin denies all other allegations in paragraph 50.

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

ANSWER: The allegations in paragraph 51 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 51 and therefore denies them.

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

ANSWER: Lupin admits that the FDA's Orange Book lists "05/16/2027" as the Patent Expiration for the '143 patent in connection with NDA No. 208623. Lupin denies all other allegations in paragraph 52.

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

ANSWER: Lupin admits that the '143 patent is listed in the FDA's Orange Book in connection with NDA No. 208623 for the product with Proprietary Name "GALAFOLD" and the Dosage Form; Route of Administration "Capsule; Oral." Lupin denies all other allegations in paragraph 53.

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

ANSWER: The allegations in paragraph 54 are legal conclusions to which no answer is required. To the extent an answer is required, denied.

55. The PTO duly and legally issued the '866 Patent on February 23, 2021, titled "Dosing Regimens for the Treatment of Lysosomal Storage Diseases Using

Pharmacological Chaperones." A true and correct copy of the '866 Patent is attached as Exhibit E.

ANSWER: The allegations in paragraph 55 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the '866 patent is titled "Dosing Regimens for the Treatment of Lysosomal Storage Diseases Using Pharmacological Chaperones" and lists February 23, 2021 as the Date of Patent. Lupin further admits that, on information and belief, what purports to be a copy of the '866 patent is attached to Plaintiffs' Complaint filed September 1, 2023 as Exhibit E. Lupin denies all other allegations in paragraph 55.

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

ANSWER: The allegations in paragraph 56 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 56 and therefore denies them.

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

ANSWER: Lupin admits that the FDA's Orange Book lists "04/28/2028" as the Patent Expiration for the '866 patent in connection with NDA No. 208623. Lupin denies all other allegations in paragraph 57.

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

ANSWER: Lupin admits that the ’866 patent is listed in the FDA’s Orange Book in connection with NDA No. 208623 for the product with Proprietary Name “GALAFOLD” and the Dosage Form; Route of Administration “Capsule; Oral.” Lupin denies all other allegations in paragraph 58.

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

ANSWER: The allegations in paragraph 59 are legal conclusions to which no answer is required. To the extent an answer is required, denied.

60. The PTO duly and legally issued the ’921 Patent on October 27, 2020, titled “Method to Predict Response to Pharmacological Chaperone Treatment of Diseases.” A true and correct copy of the ’921 Patent is attached as Exhibit F.

ANSWER: The allegations in paragraph 60 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the ’921 patent is titled “Method to Predict Response to Pharmacological Chaperone Treatment of Diseases” and lists October 27, 2020 as the Date of Patent. Lupin further admits that, on information and belief, what purports to be a copy of the ’921 patent is attached to Plaintiffs’ Complaint filed September 1, 2023 as Exhibit F. Lupin denies all other allegations in paragraph 60.

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

ANSWER: The allegations in paragraph 61 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 61 and therefore denies them.

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

ANSWER: Lupin admits that the FDA's Orange Book lists "02/12/2029" as the Patent Expiration for the '921 patent in connection with NDA No. 208623. Lupin denies all other allegations in paragraph 62.

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

ANSWER: Lupin admits that the '921 patent is listed in the FDA's Orange Book in connection with NDA No. 208623 for the product with Proprietary Name "GALAFOLD" and the Dosage Form; Route of Administration "Capsule; Oral." Lupin denies all other allegations in paragraph 63.

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

ANSWER: The allegations in paragraph 64 are legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: The allegations in paragraph 65 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the '608 patent is titled "Method to Predict Response to Pharmacological Chaperone Treatment of Diseases" and lists June 29, 2021 as the Date of Reissued Patent. Lupin further admits that, on information and belief, what purports to be a copy of the '608 patent is attached to Plaintiffs' Complaint filed September 1, 2023 as Exhibit G. Lupin denies all other allegations in paragraph 65.

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

ANSWER: The allegations in paragraph 66 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the face of the '608 patent identifies the patent as a reissue of U.S. Patent No. 8,592,362 and lists November 26, 2013 as the Date of Patent. Lupin denies all other allegations in paragraph 66.

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

ANSWER: The allegations in paragraph 67 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 67 and therefore denies them.

68. RE608 currently expires on February 12, 2029.

ANSWER: Lupin admits that the FDA's Orange Book lists "02/12/2029" as the Patent Expiration for the '608 patent in connection with NDA No. 208623. Lupin denies all other allegations in paragraph 68.

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

ANSWER: Lupin admits that the '608 patent is listed in the FDA's Orange Book in connection with NDA No. 208623 for the product with Proprietary Name "GALAFOLD" and the Dosage Form; Route of Administration "Capsule; Oral." Lupin denies all other allegations in paragraph 69.

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

ANSWER: The allegations in paragraph 70 are legal conclusions to which no answer is required. To the extent an answer is required, denied.

LUPIN'S ANDA

71. Upon information and belief, Defendants submitted ANDA No. 217793 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 "Lupin's ANDA Product"), which are generic versions of Amicus' GALAFOLD Capsules.

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of the migalastat hydrochloride capsules, eq 123 mg base, described in ANDA No. 217793. Lupin further admits that ANDA No. 217793 identifies NDA No. 208623 and

GALAFOLD® (migalastat hydrochloride capsules), eq 123 mg base as the Reference Listed Drug. Lupin denies all other allegations in paragraph 71.

72. Lupin's Notice Letter purports to notify Amicus of Lupin's ANDA No. 217793, including Lupin's "Paragraph IV Certification" with respect to the Notice Letter Patents, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.95.

ANSWER: Lupin admits that in Lupin's 8/9/23 Notice Letter, Lupin Ltd. notified Plaintiffs that Lupin Ltd. submitted an amendment to ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j) seeking FDA approval of Lupin's proposed ANDA product and that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the Notice Letter Patents. Lupin denies all other allegations in paragraph 72.

73. Lupin's Notice Letter states that Lupin had filed ANDA No. 217793 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 Lupin's ANDA Product before the expiration of the Patents-in-Suit.

ANSWER: Lupin admits that in Lupin's 8/9/23 Notice Letter, Lupin Ltd. notified Plaintiffs that Lupin Ltd. submitted an amendment to ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j) seeking FDA approval of Lupin's proposed ANDA product and that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the Notice Letter Patents. Lupin denies all other allegations in paragraph 73.

74. Lupin's Notice Letter further states that ANDA No. 217793 has been amended to include certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV),

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 Lupin's ANDA Product (defined above as Lupin's "¶ IV Certification").

ANSWER: Lupin admits that in Lupin's 8/9/23 Notice Letter, Lupin Ltd. notified Plaintiffs that Lupin Ltd. submitted an amendment to ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j) seeking FDA approval of Lupin's proposed ANDA product and that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the Notice Letter Patents. Lupin further admits that the Paragraph IV Certification in ANDA No. 217793 states that the Notice Letter Patents are "invalid, unenforceable, or will not be infringed by the manufacture, use or sale of" Lupin's proposed ANDA product. Lupin further admits that Lupin's 8/9/23 Notice Letter states that "no valid claim of the '362, '011, '584, '682, '263, '618, '864, '143, '045, '921, '866, '538, '422, and '608 patents will be infringed by the manufacture, importation, use, or sale of Lupin's proposed ANDA product." Lupin further admits that Lupin's 8/9/23 Notice Letter included a detailed statement of the factual and legal bases upon which Lupin Ltd. based its Paragraph IV Certification with respect to the Notice Letter Patents. Lupin denies all other allegations in paragraph 74.

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

ANSWER: Lupin admits that ANDA No. 217793 identifies NDA No. 208623 and GALAFOLD® (migalastat hydrochloride capsules), eq 123 mg base as the Reference Listed Drug. Lupin further admits that the product labeling for the proposed migalastat hydrochloride capsules described in ANDA No. 217793 will comply with applicable law. Lupin denies all other allegations in paragraph 75.

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

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin further admits that the product labeling for the proposed migalastat hydrochloride capsules described in ANDA No. 217793 will comply with applicable law. Lupin denies all other allegations in paragraph 76.

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

ANSWER: Denied.

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

ANSWER: Denied.

79. Upon information and belief, Lupin continues to seek approval of ANDA No. 217793, and upon approval by the FDA, Lupin intends to immediately engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Lupin's ANDA Product.

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin denies all other allegations in paragraph 79.

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

ANSWER: Denied.

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

ANSWER: Denied.

82. Upon information and belief, Lupin will direct or control the treatment of patients using Lupin's ANDA Product if the FDA approves ANDA No. 217793.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

86. 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 Lupin's ANDA Product in accordance with the instructions for use provided in Lupin's Label.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

89. Upon information and belief, Lupin knows or should know that Lupin'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.

ANSWER: Denied.

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

ANSWER: Denied.

COUNT I
(INFRINGEMENT OF THE '011 PATENT)

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

ANSWER: Lupin restates and realleges its answers to each of the preceding paragraphs 1-90 as if fully set forth herein.

92. Lupin filed ANDA No. 217793 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Lupin's ANDA Product before the expiration of the '011 Patent.

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin further admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '011 patent. Lupin denies all other allegations in paragraph 92.

93. Lupin's Notice Letter states that Lupin filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and U.S.C. § 355(j)(2)(B)(iv), a certification alleging that the claims of the '011 Patent are invalid, unenforceable, and/or will not be infringed.

ANSWER: Lupin admits that in Lupin's 8/9/23 Notice Letter, Lupin Ltd. notified Plaintiffs that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '011 patent. Lupin further admits that Lupin's 8/9/23 Notice Letter included a detailed statement of the factual and legal bases upon which Lupin Ltd. based its Paragraph IV Certification with respect to the '011 patent. Lupin denies all other allegations in paragraph 93.

94. By filing ANDA No. 217793, Lupin has represented to the FDA that, upon approval, Lupin'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.

ANSWER: Lupin admits that ANDA No. 217793 identifies NDA No. 208623 and GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base, as the Reference Listed Drug. Lupin further admits that ANDA No. 217793 contains information intended to establish bioequivalence with the Reference Listed Drug. Lupin denies all other allegations in paragraph 94.

95. Lupin has actual knowledge of the '011 Patent, as evidenced by Lupin's Notice Letter.

ANSWER: The allegations in paragraph 95 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '011 patent. Lupin denies all other allegations in paragraph 95.

96. Under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '011 Patent by submitting, or causing to be submitted, to the FDA Lupin's ANDA No. 217793 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Lupin's ANDA Product before the expiration date of the '011 Patent.

ANSWER: Denied.

97. Subject to receiving final approval of ANDA No. 217793, Lupin intends to and will commercially manufacture, use, offer for sale, sell, and/or import Lupin's

ANDA Product within or into the United States before the expiration of the '011 Patent.

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin further admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '011 patent. Lupin denies all other allegations in paragraph 97.

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

ANSWER: Lupin admits that ANDA No. 217793 identifies NDA No. 208623 and GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base as the Reference Listed Drug. Lupin further admits that ANDA No. 217793 contains information intended to establish bioequivalence with the Reference Listed Drug and speaks for itself. Lupin denies all other allegations in paragraph 98.

99. If ANDA No. 217793 is approved, Lupin will infringe one or more claims of the '011 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Lupin'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. 217793 shall be no earlier than the expiration of the '011 Patent.

ANSWER: Denied.

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

ANSWER: Lupin admits that the product labeling for the proposed migalastat hydrochloride capsules described in ANDA No. 217793 will comply with applicable law. Lupin denies all other allegations in paragraph 100.

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

ANSWER: The allegations in paragraph 101 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '011 patent. Lupin denies all other allegations in paragraph 101.

102. Lupin is aware, has knowledge of, and/or specifically intends that Lupin'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 Lupin's ANDA Product according to the instructions for use in Lupin's Label in a way that directly infringes at least one claim of the '011 Patent.

ANSWER: Denied.

103. Lupin's actions relating to Lupin's ANDA No. 217793 complained of herein were done by and for the benefit of Lupin.

ANSWER: Lupin admits Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin denies all other allegations in paragraph 103.

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

ANSWER: Denied.

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

ANSWER: Denied.

COUNT II
(INFRINGEMENT OF THE '263 PATENT)

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

ANSWER: Lupin restates and realleges its answers to each of the preceding paragraphs 1-105 as if fully set forth herein.

107. Lupin filed ANDA No. 217793 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Lupin's ANDA Product before the expiration of the '263 Patent.

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin further admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '263 patent. Lupin denies all other allegations in paragraph 107.

108. Lupin's Notice Letter states that Lupin filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and U.S.C. § 355(j)(2)(B)(iv), a certification alleging that the claims of the '263 Patent are invalid, unenforceable, and/or will not be infringed.

ANSWER: Lupin admits that in Lupin's 8/9/23 Notice Letter, Lupin Ltd. notified Plaintiffs that ANDA No. 217793 was amended to include a Paragraph IV

Certification with respect to the '263 patent. Lupin further admits that Lupin's 8/9/23 Notice Letter included a detailed statement of the factual and legal bases upon which Lupin Ltd. based its Paragraph IV Certification with respect to the '263 patent. Lupin denies all other allegations in paragraph 108.

109. By filing ANDA No. 217793, Lupin has represented to the FDA that, upon approval, Lupin'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.

ANSWER: Lupin admits that ANDA No. 217793 identifies NDA No. 208623 and GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base, as the Reference Listed Drug. Lupin further admits that ANDA No. 217793 contains information intended to establish bioequivalence with the Reference Listed Drug. Lupin denies all other allegations in paragraph 109.

110. Lupin has actual knowledge of the '263 Patent, as evidenced by Lupin's Notice Letter.

ANSWER: The allegations in paragraph 110 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '263 patent. Defendants deny all other allegations in paragraph 110.

111. Under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '263 Patent by submitting, or causing to be submitted, to the FDA Lupin's ANDA No. 217793 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Lupin's ANDA Product before the expiration date of the '263 Patent.

ANSWER: Denied.

112. Subject to receiving final approval of ANDA No. 217793, Lupin intends to and will commercially manufacture, use, offer for sale, sell, and/or import Lupin's ANDA Product within or into the United States before the expiration of the '263 Patent.

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '263 patent. Lupin denies all other allegations in paragraph 112.

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

ANSWER: Lupin admits that ANDA No. 217793 identifies NDA No. 208623 and GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base as the Reference Listed Drug. Lupin further admits that ANDA No. 217793 contains information intended to establish bioequivalence with the Reference Listed Drug and speaks for itself. Lupin denies all other allegations in paragraph 113.

114. If ANDA No. 217793 is approved, Lupin will infringe one or more claims of the '263 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Lupin'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. 217793 shall be no earlier than the expiration of the '263 Patent.

ANSWER: Denied.

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

ANSWER: Lupin admits that the product labeling for the proposed migalastat hydrochloride capsules described in ANDA No. 217793 will comply with applicable law. Lupin denies all other allegations in paragraph 115.

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

ANSWER: The allegations in paragraph 116 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '263 patent. Lupin denies all other allegations in paragraph 116.

117. Lupin is aware, has knowledge of, and specifically intends that Lupin'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 Lupin's ANDA Product according to the instructions for use in Lupin's Label in a way that directly infringes at least one claim of the '263 Patent.

ANSWER: Denied.

118. Lupin's actions relating to Lupin's ANDA No. 217793 complained of herein were done by and for the benefit of Lupin.

ANSWER: Lupin admits Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin denies all other allegations in paragraph 118.

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

ANSWER: Denied.

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

ANSWER: Denied.

COUNT III
(INFRINGEMENT OF THE '864 PATENT)

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

ANSWER: Lupin restates and realleges its answers to each of the preceding paragraphs 1-120 as if fully set forth herein.

122. Lupin filed ANDA No. 217793 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Lupin's ANDA Product before the expiration of the '864 Patent.

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin further admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '864 patent. Lupin denies all other allegations in paragraph 122.

123. Lupin's Notice Letter states that Lupin filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and U.S.C. § 355(j)(2)(B)(iv), a certification alleging that the claims of the '864 Patent are invalid, unenforceable, and/or will not be infringed.

ANSWER: Lupin admits that in Lupin's 8/9/23 Notice Letter, Lupin Ltd. notified Plaintiffs that ANDA No. 217793 was amended to include a Paragraph IV

Certification with respect to the '864 patent. Lupin further admits that Lupin's 8/9/23 Notice Letter included a detailed statement of the factual and legal bases upon which Lupin Ltd. based its Paragraph IV Certification with respect to the '864 patent. Lupin denies all other allegations in paragraph 123.

124. By filing ANDA No. 217793, Lupin has represented to the FDA that, upon approval, Lupin'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.

ANSWER: Lupin admits that ANDA No. 217793 identifies NDA No. 208623 and GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base, as the Reference Listed Drug. Lupin further admits that ANDA No. 217793 contains information intended to establish bioequivalence with the Reference Listed Drug. Lupin denies all other allegations in paragraph 124.

125. Lupin has actual knowledge of the '864 Patent, as evidenced by Lupin's Notice Letter.

ANSWER: The allegations in paragraph 125 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '864 patent. Lupin denies all other allegations in paragraph 125.

126. Under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '864 Patent by submitting, or causing to be submitted, to the FDA Lupin's ANDA No. 217793 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Lupin's ANDA Product before the expiration date of the '864 Patent.

ANSWER: Denied.

127. Subject to receiving final approval of ANDA No. 217793, Lupin intends to and will commercially manufacture, use, offer for sale, sell, and/or import Lupin's ANDA Product within or into the United States before the expiration of the '864 Patent.

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin further admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '864 patent. Lupin denies all other allegations in paragraph 127.

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

ANSWER: Lupin admits that ANDA No. 217793 identifies NDA No. 208623 and GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base as the Reference Listed Drug. Lupin further admits that ANDA No. 217793 contains information intended to establish bioequivalence with the Reference Listed Drug and speaks for itself. Lupin denies all other allegations in paragraph 128.

129. If ANDA No. 217793 is approved, Lupin will infringe one or more claims of the '864 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Lupin'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. 217793 shall be no earlier than the expiration of the '864 Patent.

ANSWER: Denied.

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

ANSWER: Lupin admits that the product labeling for the proposed migalastat hydrochloride capsules described in ANDA No. 217793 will comply with applicable law. Lupin denies all other allegations in paragraph 130.

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

ANSWER: The allegations in paragraph 131 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits only that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '864 patent. Lupin denies all other allegations in paragraph 131.

132. Lupin is aware, has knowledge of, and specifically intends that Lupin'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 Lupin's ANDA Product according to the instructions for use in Lupin's Label in a way that directly infringes at least one claim of the '864 Patent.

ANSWER: Denied.

133. Lupin's actions relating to Lupin's ANDA No. 217793 complained of herein were done by and for the benefit of Lupin.

ANSWER: Lupin admits Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin denies all other allegations in paragraph 133.

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

ANSWER: Denied.

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

ANSWER: Denied.

COUNT IV
(INFRINGEMENT OF THE '143 PATENT)

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

ANSWER: Lupin restates and realleges its answers to each of the preceding paragraphs 1-135, as if fully set forth herein.

137. Lupin filed ANDA No. 217793 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Lupin's ANDA Product before the expiration of the '143 Patent.

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin further admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '143 patent. Lupin denies all other allegations in paragraph 137.

138. Lupin's Notice Letter states that Lupin filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and U.S.C. § 355(j)(2)(B)(iv), a certification alleging that the claims of the '143 Patent are invalid, unenforceable, and/or will not be infringed.

ANSWER: Lupin admits that in Lupin's 8/9/23 Notice Letter, Lupin Ltd. notified Plaintiffs that ANDA No. 217793 was amended to include a Paragraph IV

Certification with respect to the '143 patent. Lupin further admits that Lupin's 8/9/23 Notice Letter included a detailed statement of the factual and legal bases upon which Lupin Ltd. based its Paragraph IV Certification with respect to the '143 patent. Lupin denies all other allegations in paragraph 138.

139. By filing ANDA No. 217793, Lupin has represented to the FDA that, upon approval, Lupin'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.

ANSWER: Lupin admits that ANDA No. 217793 identifies NDA No. 208623 and GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base, as the Reference Listed Drug. Lupin further admits that ANDA No. 217793 contains information intended to establish bioequivalence with the Reference Listed Drug. Lupin denies all other allegations in paragraph 139.

140. Lupin has actual knowledge of the '143 Patent, as evidenced by Lupin's Notice Letter.

ANSWER: The allegations in paragraph 140 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '143 patent. Lupin denies all other allegations in paragraph 140.

141. Under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '143 Patent by submitting, or causing to be submitted, to the FDA Lupin's ANDA No. 217793 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Lupin's ANDA Product before the expiration date of the '143 Patent.

ANSWER: Denied.

142. Subject to receiving final approval of ANDA No. 217793, Lupin intends to and will commercially manufacture, use, offer for sale, sell, and/or import Lupin's ANDA Product within or into the United States before the expiration of the '143 Patent.

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '143 patent. Lupin denies all other allegations in paragraph 142.

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

ANSWER: Lupin admits that ANDA No. 217793 identifies NDA No. 208623 and GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base as the Reference Listed Drug. Lupin further admits that ANDA No. 217793 contains information intended to establish bioequivalence with the Reference Listed Drug and speaks for itself. Lupin denies all other allegations in paragraph 143.

144. If ANDA No. 217793 is approved, Lupin will infringe one or more claims of the '143 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Lupin'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. 217793 shall be no earlier than the expiration of the '143 Patent.

ANSWER: Denied.

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

ANSWER: Lupin admits that the product labeling for the proposed migalastat hydrochloride capsules described in ANDA No. 217793 will comply with applicable law. Lupin denies all other allegations in paragraph 145.

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

ANSWER: The allegations in paragraph 146 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits only that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '143 patent. Lupin denies all other allegations in paragraph 146.

147. Lupin is aware, has knowledge of, and specifically intends that Lupin'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 Lupin's ANDA Product according to the instructions for use in Lupin's Label in a way that directly infringes at least one claim of the '143 Patent.

ANSWER: Denied.

148. Lupin's actions relating to Lupin's ANDA No. 217793 complained of herein were done by and for the benefit of Lupin.

ANSWER: Lupin admits Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin denies all other allegations in paragraph 148.

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

ANSWER: Denied.

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

ANSWER: Denied.

COUNT V
(INFRINGEMENT OF THE '866 PATENT)

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

ANSWER: Lupin restates and realleges its answers to each of the preceding paragraphs 1-150, as if fully set forth herein.

152. Lupin filed ANDA No. 217793 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Lupin's ANDA Product before the expiration of the '866 Patent.

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin further admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '866 patent. Lupin denies all other allegations in paragraph 152.

153. Lupin's Notice Letter states that Lupin filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and U.S.C. § 355(j)(2)(B)(iv), a certification alleging that the claims of the '866 Patent are invalid, unenforceable, and/or will not be infringed.

ANSWER: Lupin admits that in Lupin's 8/9/23 Notice Letter, Lupin Ltd. notified Plaintiffs that ANDA No. 217793 was amended to include a Paragraph IV

Certification with respect to the '866 patent. Lupin further admits that Lupin's 8/9/23 Notice Letter included a detailed statement of the factual and legal bases upon which Lupin Ltd. based its Paragraph IV Certification with respect to the '866 patent. Lupin denies all other allegations in paragraph 153.

154. By filing ANDA No. 217793, Lupin has represented to the FDA that, upon approval, Lupin'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.

ANSWER: Lupin admits that ANDA No. 217793 identifies NDA No. 208623 and GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base, as the Reference Listed Drug. Lupin further admits that ANDA No. 217793 contains information intended to establish bioequivalence with the Reference Listed Drug. Lupin denies all other allegations in paragraph 154.

155. Lupin has actual knowledge of the '866 Patent, as evidenced by Lupin's Notice Letter.

ANSWER: The allegations in paragraph 155 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '866 patent. Lupin denies all other allegations in paragraph 155.

156. Under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '866 Patent by submitting, or causing to be submitted, to the FDA Lupin's ANDA No. 217793 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Lupin's ANDA Product before the expiration of the '866 Patent.

ANSWER: Denied.

157. Subject to receiving final approval of ANDA No. 217793, Lupin intends to and will commercially manufacture, use, offer for sale, sell, and/or import Lupin's ANDA Product within or into the United States before the expiration of the '866 Patent.

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '866 patent. Lupin denies all other allegations in paragraph 157.

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

ANSWER: Lupin admits that ANDA No. 217793 identifies NDA No. 208623 and GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base as the Reference Listed Drug. Lupin further admits that ANDA No. 217793 contains information intended to establish bioequivalence with the Reference Listed Drug and speaks for itself. Lupin denies all other allegations in paragraph 158.

159. If ANDA No. 217793 is approved, Lupin will infringe one or more claims of the '866 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Lupin'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. 217793 shall be no earlier than the expiration of the '866 Patent.

ANSWER: Denied.

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

ANSWER: Lupin admits that the product labeling for the proposed migalastat hydrochloride capsules described in ANDA No. 217793 will comply with applicable law. Lupin denies all other allegations in paragraph 160.

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

ANSWER: The allegations in paragraph 161 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits only that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '866 patent. Lupin denies all other allegations in paragraph 161.

162. Lupin is aware, has knowledge of, and specifically intends that Lupin'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 Lupin's ANDA Product according to the instructions for use in Lupin's Label in a way that directly infringes at least one claim of the '866 Patent.

ANSWER: Denied.

163. Lupin's actions relating to Lupin's ANDA No. 217793 complained of herein were done by and for the benefit of Lupin.

ANSWER: Lupin admits Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin denies all other allegations in paragraph 163.

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

ANSWER: Denied.

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

ANSWER: Denied.

COUNT VI
(INFRINGEMENT OF THE '921 PATENT)

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

ANSWER: Lupin restates and realleges its answers to each of the preceding paragraphs 1-165 as if fully set forth herein.

167. Lupin filed ANDA No. 217793 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Lupin's ANDA Product before the expiration of the '921 Patent.

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin further admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '921 patent. Lupin denies all other allegations in paragraph 167.

168. Lupin's Notice Letter states that Lupin filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and U.S.C. § 355(j)(2)(B)(iv), a certification alleging that the claims of the '921 Patent are invalid, unenforceable, and/or will not be infringed.

ANSWER: Lupin admits that in Lupin's 8/9/23 Notice Letter, Lupin Ltd. notified Plaintiffs that ANDA No. 217793 was amended to include a Paragraph IV

Certification with respect to the '921 patent. Lupin further admits that Lupin's 8/9/23 Notice Letter included a detailed statement of the factual and legal bases upon which Lupin Ltd. based its Paragraph IV Certification with respect to the '921 patent. Lupin denies all other allegations in paragraph 168.

169. By filing ANDA No. 217793, Lupin has represented to the FDA that, upon approval, Lupin'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.

ANSWER: Lupin admits that ANDA No. 217793 identifies NDA No. 208623 and GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base, as the Reference Listed Drug. Lupin further admits that ANDA No. 217793 contains information intended to establish bioequivalence with the Reference Listed Drug. Lupin denies all other allegations in paragraph 169.

170. Lupin has actual knowledge of the '921 Patent, as evidenced by Lupin's Notice Letter.

ANSWER: The allegations in paragraph 170 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '921 patent. Lupin denies all other allegations in paragraph 170.

171. Under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '921 Patent by submitting, or causing to be submitted, to the FDA Lupin's ANDA No. 217793 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Lupin's ANDA Product before the expiration date of the '921 Patent.

ANSWER: Denied.

172. Subject to receiving final approval of ANDA No. 217793, Lupin intends to and will commercially manufacture, use, offer for sale, sell, and/or import Lupin's ANDA Product within or into the United States before the expiration of the '921 Patent.

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin further admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '921 patent. Lupin denies all other allegations in paragraph 172.

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

ANSWER: Lupin admits that ANDA No. 217793 identifies NDA No. 208623 and GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base as the Reference Listed Drug. Lupin further admits that ANDA No. 217793 contains information intended to establish bioequivalence with the Reference Listed Drug and speaks for itself. Lupin denies all other allegations in paragraph 173.

174. If ANDA No. 217793 is approved, Lupin will infringe one or more claims of the '921 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Lupin'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. 217793 shall be no earlier than the expiration of the '921 Patent.

ANSWER: Denied.

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

ANSWER: Lupin admits that the product labeling for the proposed migalastat hydrochloride capsules described in ANDA No. 217793 will comply with applicable law. Lupin denies all other allegations in paragraph 175.

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

ANSWER: The allegations in paragraph 176 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits only that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '921 patent. Lupin denies all other allegations in paragraph 176.

177. Lupin is aware, has knowledge of, and specifically intends that Lupin'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 Lupin's ANDA Product according to the instructions for use in Lupin's Label in a way that directly infringes at least one claim of the '921 Patent.

ANSWER: Denied.

178. Lupin's actions relating to Lupin's ANDA No. 217793 complained of herein were done by and for the benefit of Lupin.

ANSWER: Lupin admits Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin denies all other allegations in paragraph 178.

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

ANSWER: Denied.

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

ANSWER: Denied.

COUNT VII
(INFRINGEMENT OF '608)

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

ANSWER: Lupin restates and realleges its answers to each of the preceding paragraphs 1-180, as if fully set forth herein.

182. Lupin filed ANDA No. 217793 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Lupin's ANDA Product before the expiration of RE608.

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin further admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '608 patent. Lupin denies all other allegations in paragraph 182.

183. Lupin's Notice Letter states that Lupin filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and U.S.C. § 355(j)(2)(B)(iv), a certification alleging that the claims of RE608 are invalid, unenforceable, and/or will not be infringed.

ANSWER: Lupin admits that in Lupin's 8/9/23 Notice Letter, Lupin Ltd. notified Plaintiffs that ANDA No. 217793 was amended to include a Paragraph IV

Certification with respect to the '608 patent. Lupin further admits that Lupin's 8/9/23 Notice Letter included a detailed statement of the factual and legal bases upon which Lupin Ltd. based its Paragraph IV Certification with respect to the '608 patent. Lupin denies all other allegations in paragraph 183.

184. By filing ANDA No. 217793, Lupin has represented to the FDA that, upon approval, Lupin'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.

ANSWER: Lupin admits that ANDA No. 217793 identifies NDA No. 208623 and GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base, as the Reference Listed Drug. Lupin further admits that ANDA No. 217793 contains information intended to establish bioequivalence with the Reference Listed Drug. Lupin denies all other allegations in paragraph 184.

185. Lupin has actual knowledge of RE608 Patent, as evidenced by Lupin's Notice Letter.

ANSWER: The allegations in paragraph 185 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '608 patent. Lupin denies all other allegations in paragraph 185.

186. Under 35 U.S.C. § 271(e)(2)(a), Lupin has infringed at least one claim of RE608 by submitting, or causing to be submitted, to the FDA Lupin's ANDA No. 217793 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Lupin's ANDA Product before the expiration of RE608.

ANSWER: Denied.

187. Subject to receiving final approval of ANDA No. 217793, Lupin intends to and will commercially manufacture, use, offer for sale, sell, and/or import Lupin's ANDA Product within or into the United States before the expiration of RE608.

ANSWER: Lupin admits that Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin further admits that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '608 patent. Lupin denies all other allegations in paragraph 187.

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

ANSWER: Lupin admits that ANDA No. 217793 identifies NDA No. 208623 and GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base as the Reference Listed Drug. Lupin further admits that ANDA No. 217793 contains information intended to establish bioequivalence with the Reference Listed Drug and speaks for itself. Lupin denies all other allegations in paragraph 188.

189. If ANDA No. 217793 is approved, Lupin will infringe one or more claims of RE608 under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Lupin'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. 217793 shall be no earlier than the expiration of RE608.

ANSWER: Denied.

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

ANSWER: Lupin admits that the product labeling for the proposed migalastat hydrochloride capsules described in ANDA No. 217793 will comply with applicable law. Lupin denies all other allegations in paragraph 190.

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

ANSWER: The allegations in paragraph 191 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits only that ANDA No. 217793 was amended to include a Paragraph IV Certification with respect to the '608 patent. Lupin denies all other allegations in paragraph 191.

192. Lupin is aware, has knowledge of, and specifically intends that Lupin'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 Lupin's ANDA Product according to the instructions for use in Lupin's Label in a way that directly infringes at least one claim of RE608.

ANSWER: Denied.

193. Lupin's actions relating to Lupin's ANDA No. 217793 complained of herein were done by and for the benefit of Lupin.

ANSWER: Lupin admits Lupin Ltd. submitted ANDA No. 217793 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval of Lupin's proposed ANDA product. Lupin denies all other allegations in paragraph 193.

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

ANSWER: Denied.

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

ANSWER: Denied.

REQUEST FOR RELIEF

Lupin denies all remaining allegations not specifically admitted herein. Lupin further denies that Plaintiffs are entitled to any judgment or relief requested in the Complaint, or to any relief whatsoever. Lupin respectfully requests that the Court: (a) dismiss the Complaint with prejudice; (b) enter judgment in favor of Lupin; (c) award Lupin the reasonable attorneys' fees and costs of defending this action pursuant to 35 U.S.C. § 285; and (d) award Lupin such further relief as the Court deems just and appropriate.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in their Answer and without admitting any allegations of the Complaint not otherwise admitted, Defendants aver and assert the following Affirmative Defenses to Plaintiffs' Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 9,000,011)

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed migalastat hydrochloride capsules described in ANDA

No. 217793 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid and/or enforceable claim of the ’011 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,000,011)

Upon information and belief, the claims of the ’011 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting.

THIRD AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 9,987,263)

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed migalastat hydrochloride capsules described in ANDA No. 217793 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid and/or enforceable claim of the ’263 patent.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,987,263)

Upon information and belief, the claims of the ’263 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting.

FIFTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,383,864)

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed migalastat hydrochloride capsules described in ANDA No. 217793 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid and/or enforceable claim of the '864 patent.

SIXTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,383,864)

Upon information and belief, the claims of the '864 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting.

SEVENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,406,143)

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed migalastat hydrochloride capsules described in ANDA No. 217793 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid and/or enforceable claim of the '143 patent.

EIGHTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,406,143)

Upon information and belief, the claims of the '143 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting.

NINTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,925,866)

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed migalastat hydrochloride capsules described in ANDA No. 217793 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid and/or enforceable claim of the '866 patent.

TENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,925,866)

Upon information and belief, the claims of the '866 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting.

ELEVENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,813,921)

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United

States of the proposed migalastat hydrochloride capsules described in ANDA No. 217793 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid and/or enforceable claim of the '921 patent.

TWELFTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,813,921)

Upon information and belief, the claims of the '921 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting.

THIRTEENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. RE48,608)

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed migalastat hydrochloride capsules described in ANDA No. 217793 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid and/or enforceable claim of the '608 patent.

FOURTEENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. RE48,608)

Upon information and belief, the claims of the '608 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting.

RESERVATION OF DEFENSES

Lupin expressly reserves the right to supplement and/or amend its Answer to Plaintiffs' Complaint, including, but not limited to, supplementation and/or amendment of their defenses and amplifications of denials, as additional facts and information become known through the course of this case and discovery and hereby reserve any and all defenses.

COUNTERCLAIMS

Lupin Limited ("Counterclaimant" or "Lupin Ltd."), by its attorneys, alleges the following counterclaims against Amicus Therapeutics US, LLC ("ATUS") and Amicus Therapeutics, Inc. ("AT") (collectively, "Amicus" or "Counterclaim Defendants").

THE PARTIES

1. Counterclaimant Lupin Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at Kalpataru Inspire, 3rd Floor, Off Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

2. Upon information and belief, Counterclaim Defendant Amicus Therapeutics US, LLC 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. Upon information and belief, Counterclaim Defendant Amicus Therapeutics, Inc. 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.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, 35 U.S.C. § 1 et seq., and 35 U.S.C. § 271(e)(5).

5. This Court has personal jurisdiction over Counterclaim Defendants because Counterclaim Defendants commenced and continue to maintain this action against Counterclaimant in this district.

6. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), 21 U.S.C. § 355(j)(5)(C)(i)(II), and because Counterclaim Defendants commenced and continue to maintain this action against Counterclaimant in this district.

REGULATORY FRAMEWORK

7. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271), a

pharmaceutical company seeking approval from the U.S. Food and Drug Administration ("FDA") to sell a new drug must file a New Drug Application ("NDA"), which includes specific data concerning the safety and effectiveness of the drug referenced in the NDA, i.e., the reference listed drug ("RLD").

8. The Hatch-Waxman Act provides that NDA holders shall submit to FDA the patent number and expiration date of any patent that the NDA holder believes "claims the drug for which the applicant submitted the [NDA] … and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the [NDA] owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). The FDA lists the patent number(s) and expiration date(s) in its publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book").

9. The Hatch-Waxman Act codified a process for the approval of generic drugs by allowing a generic applicant to seek approval by filing an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j).

10. An ANDA must contain a certification with respect to any patent or patents listed in the Orange Book in connection with the RLD. *See id.* at § 355(j)(2)(A)(vii). ANDA filers may make one of four certifications with respect to each listed patent. Pertinent here is the so-called Paragraph IV Certification, which

asserts that the listed patent is invalid or will not be infringed by the proposed generic drug product. *See id.* at § 355(j)(2)(A)(vii)(IV).

ORANGE BOOK-LISTED PATENTS FOR GALAFOLD®

11. Upon information and belief, Counterclaim Defendant ATUS is the holder of NDA No. 208623 on GALAFOLD® (migalastat hydrochloride) capsules eq 123mg base.

12. Upon information and belief, on April 7, 2015, U.S. Patent No. 9,000,011 ("the '011 patent"), titled "Methods for Treatment of Fabry Disease"—a copy of which Counterclaim Defendants purported to attach to their Complaint filed September 1, 2023 as Exhibit A—was issued to AT as Assignee. The FDA's Orange Book lists the expiration date of the '011 patent as May 16, 2027.

13. Upon information and belief, on June 5, 2018, U.S. Patent No. 9,987,263 ("the '263 patent"), titled "Methods for Treatment of Fabry Disease"—a copy of which Counterclaim Defendants purported to attach to their Complaint filed September 1, 2023 as Exhibit B—was issued to AT as Assignee. The FDA's Orange Book lists the expiration date of the '263 patent as May 16, 2027.

14. Upon information and belief, on August 20, 2019, U.S. Patent No. 10,383,864 ("the '864 patent"), titled "Methods for Treatment of Fabry Disease"—a copy of which Counterclaim Defendants purported to attach to their

Complaint filed September 1, 2023 as Exhibit C—was issued to AT as Assignee. The FDA's Orange Book lists the expiration date of the '864 patent as May 16, 2027.

15. Upon information and belief, on September 10, 2019, U.S. Patent No. 10,406,143 ("the '143 patent"), titled "Methods for Treatment of Fabry Disease"—a copy of which Counterclaim Defendants purported to attach to their Complaint filed September 1, 2023 as Exhibit D—was issued to AT as Assignee. The FDA's Orange Book lists the expiration date of the '143 patent as May 16, 2027.

16. Upon information and belief, on February 23, 2021, U.S. Patent No. 10,925,866 ("the '866 patent"), titled "Dosing Regimens for the Treatment of Lysosomal Storage Diseases Using Pharmacological Chaperones"—a copy of which Counterclaim Defendants purported to attach to their Complaint filed September 1, 2023 as Exhibit E—was issued to AT as Assignee. The FDA's Orange Book lists the expiration date of the '866 patent as April 28, 2028.

17. Upon information and belief, on March 22, 2022, U.S. Patent No. 10,813,921 ("the '921 patent"), titled "Method to Predict Response to Pharmacological Chaperone Treatment of Diseases"—a copy of which Counterclaim Defendants purported to attach to their Complaint filed September 1, 2023 as Exhibit F—was issued to AT as Assignee. The FDA's Orange Book lists the expiration date of the '921 patent as February 12, 2029.

18. Upon information and belief, on June 29, 2021, U.S. Patent No. RE48,608 ("the '608 patent"), titled "Methods to Predict Response to Pharmacological Chaperone Treatment of Diseases"—a copy of which Counterclaim Defendants purported to attach to their Complaint filed September 1, 2023 as Exhibit G—was issued to AT as Assignee. The FDA's Orange Book lists the expiration date of the '608 patent as February 12, 2029.

19. Upon information and belief, Counterclaim Defendant AT submitted the '011 and '263 patents on September 5, 2018, to the FDA for listing in the FDA's Orange Book for GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base.

20. Upon information and belief, Counterclaim Defendant AT submitted the '864 patent on September 4, 2019, to the FDA for listing in the FDA's Orange Book for GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base.

21. Upon information and belief, Counterclaim Defendant AT submitted the '143 patent on September 26, 2019, to the FDA for listing in the FDA's Orange Book for GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base.

22. Upon information and belief, Counterclaim Defendant AT submitted the '866 patent on March 18, 2021, to the FDA for listing in the FDA's Orange Book for GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base.

23. Upon information and belief, Counterclaim Defendant AT submitted the '921 patent on November 18, 2020, to the FDA for listing in the FDA's Orange Book for GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base.

24. Upon information and belief, Counterclaim Defendant AT submitted the '608 patent on July 22, 2021, to the FDA for listing in the FDA's Orange Book for GALAFOLD® (migalastat hydrochloride) capsules, eq 123 mg base.

25. Upon information and belief, the '011, '263, '864, '143, '866, '921, and '608 patents ("Patents-in-Suit") are owned by Counterclaim Defendant AT.

LUPIN'S ANDA

26. On August 10, 2022, Lupin Ltd. filed ANDA No. 217793 with the FDA seeking FDA approval to engage in the commercial manufacture, use or sale of migalastat hydrochloride capsules ("Proposed ANDA Product").

27. Because Lupin Ltd. seeks FDA approval to engage in the commercial manufacture, use or sale of Lupin Ltd.'s Proposed ANDA Product before expiration of the Patents-in-Suit as well as U.S. Patent Nos. 8,592,362 ("the '362 patent"), 9,095,584 ("the '584 patent"), 9,480,682 ("the '682 patent"), 9,999,618 ("the '618 patent"), 10,525,045 ("the '045 patent"), 11,033,538 ("the '538 patent"), and 11,241,422 ("the '422 patent"), Lupin Ltd.'s ANDA No. 217793 was amended to include a Paragraph IV Certification to each of these patents.

28. Lupin Ltd. transmitted a letter dated August 9, 2023 ("Lupin's 8/9/23 Notice Letter") to Counterclaim Defendants, notifying Counterclaim Defendants that an amendment to ANDA No. 217793 had been submitted to the FDA under 21 U.S.C. § 355(j), which included a Paragraph IV Certification that no valid claim of the '362, '011, '584, '682, '263, '618, '864, '143, '045, '921, '866, '538, '422, and '608 patents would be infringed by the proposed migalastat hydrochloride capsules that are the subject of ANDA No. 217793. In Lupin's 8/9/23 Notice Letter, Lupin Ltd. included a detailed statement of the factual and legal bases upon which it based its Paragraph IV Certification and extended to Counterclaim Defendants an Offer of Confidential Access to Lupin Ltd.'s ANDA No. 217793.

29. On September 1, 2023, Counterclaim Defendants filed a patent infringement lawsuit against Lupin Ltd., alleging that Lupin Ltd.'s Proposed ANDA Product would infringe the Patents-in-Suit.

30. As a consequence of Counterclaim Defendants' Complaint against Lupin Ltd., there is now an existing and continuing actual controversy between Counterclaim Defendants and Lupin Ltd. concerning the alleged infringement and validity of the Patents-in-Suit.

31. By listing and maintaining the Patents-in-Suit in the Orange Book, Counterclaim Defendants represent that the Patents-in-Suit "claim[] the drug for which the applicant submitted the application [GALAFOLD®] … and with respect

to which a claim for patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1).

32. Accordingly, by virtue of listing and maintaining the Patents-in-Suit in the Orange Book, Counterclaim Defendants represent that an infringement suit based on the Patents-in-Suit could be asserted against Lupin Ltd. because Lupin Ltd. is seeking approval to market its Proposed ANDA Product before the expiration of the Patents-in-Suit.

33. Unless Lupin Ltd. obtains a court decision of noninfringement and/or invalidity on the Patents-in-Suit, Lupin Ltd. potentially faces infringement liability if it commences marketing before the Patents-in-Suit expire.

34. Accordingly, there is an actual, substantial and continuing justiciable controversy between Lupin Ltd. and Counterclaim Defendants regarding the Patents-in-Suit over which the Court can and should exercise jurisdiction and declare the rights of the parties.

COUNT I
(Declaratory Judgment of Noninfringement of the '011 Patent)

35. Counterclaimant repeats and reasserts the allegations in paragraphs 1 through 34 above as though fully set forth herein.

36. The proposed migalastat hydrochloride capsules that are the subject of ANDA No. 217793 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '011 patent.

COUNT II
(Declaratory Judgment of Invalidity of the '011 Patent)

37. Counterclaimant repeats and reasserts the allegations in paragraphs 1 through 36 above as though fully set forth herein.

38. The claims of the '011 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting.

39. For at least the reasons explained in Lupin's 8/9/23 Notice Letter transmitted to Counterclaim Defendants, which is incorporated fully by reference herein, the claims of the '011 patent are invalid at least under 35 U.S.C. §§ 101, 103, and/or 112 in view of the prior art cited therein.

40. Counterclaimant reserves the right to provide additional and/or modified bases for invalidity of the '011 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

COUNT III
(Declaratory Judgment of Noninfringement of the '263 Patent)

41. Counterclaimant repeats and reasserts the allegations in paragraphs 1 through 40 above as though fully set forth herein.

42. The proposed migalastat hydrochloride capsules that are the subject of ANDA No. 217793 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '263 patent.

COUNT IV
(Declaratory Judgment of Invalidity of the '263 Patent)

43. Counterclaimant repeats and reasserts the allegations in paragraphs 1 through 42 above as though fully set forth herein.

44. The claims of the '263 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting.

45. For at least the reasons explained in Lupin's 8/9/23 Notice Letter transmitted to Counterclaim Defendants, which is incorporated fully by reference herein, the claims of the '263 patent are invalid at least under 35 U.S.C. §§ 101, 103, and/or 112 in view of the prior art cited therein.

46. Counterclaimant reserves the right to provide additional and/or modified bases for invalidity of the '263 patent in its contentions, responses to

discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

COUNT V
(Declaratory Judgment of Noninfringement of the '864 Patent)

47. Counterclaimant repeats and reasserts the allegations in paragraphs 1 through 46 above as though fully set forth herein.

48. The proposed migalastat hydrochloride capsules that are the subject of ANDA No. 217793 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '864 patent.

COUNT VI
(Declaratory Judgment of Invalidity of the '864 Patent)

49. Counterclaimant repeats and reasserts the allegations in paragraphs 1 through 48 above as though fully set forth herein.

50. The claims of the '864 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting.

51. For at least the reasons explained in Lupin's 8/9/23 Notice Letter transmitted to Counterclaim Defendants, which is incorporated fully by reference herein, the claims of the '864 patent are invalid at least under 35 U.S.C. §§ 101, 103, and/or 112 in view of the prior art cited therein.

52. Counterclaimant reserves the right to provide additional and/or modified bases for invalidity of the '864 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

COUNT VII
(Declaratory Judgment of Noninfringement of the '143 Patent)

53. Counterclaimant repeats and reasserts the allegations in paragraphs 1 through 52 above as though fully set forth herein.

54. The proposed migalastat hydrochloride capsules that are the subject of ANDA No. 217793 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '143 patent.

COUNT VIII
(Declaratory Judgment of Invalidity of the '143 Patent)

55. Counterclaimant repeats and reasserts the allegations in paragraphs 1 through 54 above as though fully set forth herein.

56. The claims of the '143 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting.

57. For at least the reasons explained in Lupin's 8/9/23 Notice Letter transmitted to Counterclaim Defendants, which is incorporated fully by reference

herein, the claims of the '143 patent are invalid at least under 35 U.S.C. §§ 101, 103, and/or 112 in view of the prior art cited therein.

58. Counterclaimant reserves the right to provide additional and/or modified bases for invalidity of the '143 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

COUNT IX
(Declaratory Judgment of Noninfringement of the '866 Patent)

59. Counterclaimant repeats and reasserts the allegations in paragraphs 1 through 58 above as though fully set forth herein.

60. The proposed migalastat hydrochloride capsules that are the subject of ANDA No. 217793 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '866 patent.

COUNT X
(Declaratory Judgment of Invalidity of the '866 Patent)

61. Counterclaimant repeats and reasserts the allegations in paragraphs 1 through 60 above as though fully set forth herein.

62. The claims of the '866 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting.

63. For at least the reasons explained in Lupin's 8/9/23 Notice Letter transmitted to Counterclaim Defendants, which is incorporated fully by reference herein, the claims of the '866 patent are invalid at least under 35 U.S.C. §§ 101, 103, and/or 112 in view of the prior art cited therein.

64. Counterclaimant reserves the right to provide additional and/or modified bases for invalidity of the '866 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

COUNT XI
(Declaratory Judgment of Noninfringement of the '921 Patent)

65. Counterclaimant repeats and reasserts the allegations in paragraphs 1 through 64 above as though fully set forth herein.

66. The proposed migalastat hydrochloride capsules that are the subject of ANDA No. 217793 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '921 patent.

COUNT XII
(Declaratory Judgment of Invalidity of the '921 Patent)

67. Counterclaimant repeats and reasserts the allegations in paragraphs 1 through 66 above as though fully set forth herein.

68. The claims of the '921 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not

limited to, §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting.

69. For at least the reasons explained in Lupin's 8/9/23 Notice Letter transmitted to Counterclaim Defendants, which is incorporated fully by reference herein, the claims of the '921 patent are invalid at least under 35 U.S.C. §§ 101, 103, and/or 112 in view of the prior art cited therein.

70. Counterclaimant reserves the right to provide additional and/or modified bases for invalidity of the '921 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

COUNT XIII
(Declaratory Judgment of Noninfringement of the '608 Patent)

71. Counterclaimant repeats and reasserts the allegations in paragraphs 1 through 70 above as though fully set forth herein.

72. The proposed migalastat hydrochloride capsules that are the subject of ANDA No. 217793 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '608 patent.

COUNT XIV
(Declaratory Judgment of Invalidity of the '608 Patent)

73. Counterclaimant repeats and reasserts the allegations in paragraphs 1 through 72 above as though fully set forth herein.

74. The claims of the ’608 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting.

75. For at least the reasons explained in Lupin’s 8/9/23 Notice Letter transmitted to Counterclaim Defendants, which is incorporated fully by reference herein, the claims of the ’608 patent are invalid at least under 35 U.S.C. §§ 101, 103, and/or 112 in view of the prior art cited therein.

76. Counterclaimant reserves the right to provide additional and/or modified bases for invalidity of the ’608 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

PRAYER FOR RELIEF

WHEREFORE, Counterclaimant respectfully requests the Court to enter judgment against Counterclaim Defendants as follows:

A. A declaration that Counterclaimant has not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’011, ’263, ’864, ’143, ’866, ’921, and ’608 patents;

B. A declaration that the claims of the ’011, ’263, ’864, ’143, ’866, ’921, and ’608 patents are invalid for failure to comply with one or more of the

provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103, and/or 112 and/or the judicial doctrine of obviousness-type double patenting;

C. A declaration that Counterclaim Defendants take nothing by their Complaint;

D. A dismissal of Counterclaim Defendants' Complaint with prejudice;

F. An award to Counterclaimant of its reasonable costs and attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285; and

G. An award of any other and further relief that this Court may deem just and proper.

Respectfully submitted,

DATED: September 22, 2023

By: */s/ John C. Phillips, Jr.*

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