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

SUPERNUS PHARMACEUTICALS, INC., *Plaintiff,* v. AJANTA PHARMA LIMITED and AJANTA PHARMA USA INC., *Defendants.*	C.A. No. 3:21-cv-06964-FLW-LHG **DEFENDANTS' ANSWER AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT**

Defendants Ajanta Pharma Limited and Ajanta Pharma USA Inc. ("Ajanta"), by its undersigned attorneys, hereby answers the Complaint (D.I. 1, C.A. No. 3:21-cv-06964) ("Complaint") concerning U.S. Patents Nos. 8,298,576 ("the '576 patent"), 8,298,580 ("the '580 patent"), 8,663,683 ("the '683 patent"), 8,877,248 ("the '248 patent"), 8,889,191 ("the '191 patent"), 8,992,989 ("the '989 patent"), 9,549,940 ("the '940 patent"), 9,555,004 ("the '004 patent"), 9,622,983 ("the '983 patent"), and 10,314,790 ("the '790 patent"), collectively, ("the patents-in-suit").

GENERAL DENIAL

Ajanta denies all allegations in Plaintiff's Complaint except for those specifically

admitted below. With respect to the allegations made in the Complaint, upon knowledge with respect to Ajanta's own acts, and upon information and belief as to other matters, Ajanta responds and alleges as follows:

NATURE OF THE ACTION[1]

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 8,298,576 ("the '576 patent"), 8,298,580 ("the '580 patent"), 8,663,683 ("the '683 patent"), 8,877,248 ("the '248 patent"), 8,889,191 ("the '191 patent"), 8,992,989 ("the '989 patent"), 9,549,940 ("the '940 patent"), 9,555,004 ("the '004 patent"), 9,622,983 ("the '983 patent"), and 10,314,790 ("the '790 patent") attached hereto as Exhibits A–J (collectively, "the patents in suit").

ANSWER: Ajanta admits that the above-captioned action purports to be an action for patent infringement arising under the Patent Laws of the United States, Title 35 of the United States Code. Ajanta further admits that the Complaint purports to relate to the '576 patent, '580 patent, '683 patent, '248 patent, '191 patent, '989 patent, '940 patent, '004 patent, '983 patent, and '790 patent. Ajanta lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations or legal conclusions in paragraph 1, and therefore denies them.

THE PARTIES

2. Plaintiff Supernus is a corporation organized and existing under the laws of Delaware, having its principal place of business at 9715 Key West Avenue, Rockville, Maryland 20850.

ANSWER: Ajanta lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 2, and therefore admits them on information and belief.

3. Upon information and belief, Defendant Ajanta Pharma Limited ("Ajanta Ltd.") is a corporation operating and existing under the laws of India, with its principal place of business at Ajanta House, Charkop, Kandivli West, Mumbai-400 067, Maharashtra, India.

[1] This Answer reproduces the headings of the Complaint for convenience only. This reproduction of the headings should not be construed as an admission of any of the allegations in the Complaint.

ANSWER: Admitted.

4. According to Defendants' website, "Ajanta Pharma is a specialty pharmaceutical company engaged in development, manufacture and marketing of quality finished dosages in domestic and international markets" with over 7,000 employees operating in more than 30 countries across 4 continents. Ajanta Website, http://www.ajantapharma.com/index.aspx (accessed March 26, 2021).

ANSWER: Ajanta admits that the website http://www.ajantapharma.com/index.aspx speaks for itself and denies the allegations of paragraph 4 to the extent they are inconsistent with that website. Ajanta denies the remaining allegation in paragraph 4.

5. Ajanta Ltd.'s Annual Report 2019-2020 states that it experienced "robust growth of 82% in the market" for FY 2020 in the United States. Ajanta Ltd.'s Annual Report 2019-2020 at 3 and 9, http://www.ajantapharma.com/AdminData/AnnualReports/AnnualReportFY2019-20.pdf (accessed March 26, 2021). Ajanta Ltd.'s Annual Report 2019-2020 further states, "[t]his growth was achieved on the back of 7 new product launches and market share gained by [Ajanta Ltd.] existing products. US has played key role in the resilience [Ajanta Ltd.] displayed amidst adversity." Ajanta Ltd.'s Annual Report 2019-2020 at 9, http://www.ajantapharma.com/AdminData/AnnualReports/AnnualReportFY2019-20.pdf (accessed March 26, 2021). Additionally, Ajanta Ltd.'s Annual Report 2019-2020 indicates the company "[r]eceived approvals for 9 ANDAs which lead to a total of 40 approvals (including 1 tentative approval) … [and] 12 New ANDAs filled with USFDA." Ajanta Ltd.'s Annual Report 2019-2020 at 39, http://www.ajantapharma.com/AdminData/AnnualReports/AnnualReportFY2019-20.pdf (accessed March 26, 2021).

ANSWER: Ajanta admits that the website http://www.ajantapharma.com/AdminData/AnnualReports/AnnualReportFY2019-20.pdf speaks for itself and denies the allegations of paragraph 5 to the extent they are inconsistent with that website. Ajanta denies the remaining allegations in paragraph 5.

6. Upon information and belief, Ajanta Ltd. is in the business of, inter alia: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey, and importing generic pharmaceutical products into the United States, including throughout the State of New Jersey; (ii) in concert with and/or through its various subsidiaries, including Defendant Ajanta Pharma USA Inc., the preparation, submission, and filing of Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) in concert with and/or through its various subsidiaries, including

Defendant Ajanta Pharma USA Inc., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

ANSWER: Ajanta admits that Ajanta Pharma Limited ("Ajanta Ltd.") is in the business of manufacturing pharmaceutical drug products, including generic drug products. Ajanta further states that, solely for the limited purpose of this action only, neither Ajanta Ltd. nor Ajanta Pharma USA Inc. ("Ajanta USA") contests personal jurisdiction in this Court, and each reserves the right to contest personal jurisdiction in any other case. Ajanta denies the remaining allegations of paragraph 6.

7. Upon information and belief, Defendant Ajanta Pharma USA Inc. ("Ajanta USA") is a corporation operating and existing under the laws of the State of New Jersey, with its principal place of business at One Grand Commons, 440 US Highway 22 East, Suite 150, Bridgewater, NJ 08807. Upon information and belief, Ajanta USA is a wholly-owned subsidiary of Ajanta Ltd. Upon information and belief, Ajanta USA acts at the direction of, under the control of, and for the direct benefit of Ajanta Ltd. and is controlled and/or dominated by Ajanta Ltd.

ANSWER: Ajanta admits that Ajanta USA is a corporation operating and existing under the laws of the State of New Jersey, with its principal place of business at One Grand Commons, 440 US Highway 22 East, Suite 150, Bridgewater, NJ 08807. Ajanta further admits that Ajanta USA is a wholly-owned subsidiary of Ajanta Ltd. Ajanta further states that, solely for the limited purpose of this action only, neither Ajanta Ltd. nor Ajanta USA contests personal jurisdiction in this Court, and each reserves the right to contest personal jurisdiction in any other case. Ajanta denies the remaining allegations of paragraph 7.

8. Upon information and belief, Ajanta USA is in the business of, inter alia: (i) developing, marketing, distributing, and/or selling generic pharmaceutical products throughout the United States, including throughout the State of New Jersey; (ii) in concert with and/or through its parent, including Defendant Ajanta Ltd. and various subsidiaries, the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) alone or in concert with and/or through its parent, including Defendant Ajanta Ltd. and various subsidiaries, the

distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

ANSWER: Ajanta admits that Ajanta USA is in the business of selling pharmaceutical drug products, including generic drug products, in the United States. Ajanta further states that, solely for the limited purpose of this action only, neither Ajanta Ltd. nor Ajanta USA contests personal jurisdiction in this Court, and each reserves the right to contest personal jurisdiction in any other case. Ajanta denies the remaining allegations of paragraph 8.

9. Upon information and belief, Ajanta Ltd. filed ANDA No. 215663 ("the Ajanta ANDA") with FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of generic topiramate extended-release capsule, containing 25 mg, 50 mg, 100 mg, and 200 mg of topiramate ("the Ajanta Products").

ANSWER: Paragraph 9 states a legal conclusion to which no response is required. To the extent a response is required, Ajanta admits that Ajanta Ltd. filed ANDA No. 215663 ("the Ajanta ANDA") with the FDA to obtain FDA approval for the commercial manufacture and sale in the United States of topiramate extended-release capsule, 25 mg, 50 mg, 100 mg, and 200 mg described in ANDA No. 215663 ("the Ajanta Products"). Ajanta denies the remaining allegations of paragraph 9.

10. Upon information and belief, Ajanta Ltd. and Ajanta USA collaborate to develop, manufacture, import, market, and distribute, and/or sell pharmaceutical products, including generic drug products (e.g., Risperidone Tablet (0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg); Clomipramine Hydrochloride Capsules (25 mg, 50 mg, and 75 mg), and Aripiprazole Tablet (2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg), and Tadalafil Tablet (2.5 mg, 5 mg, 10 mg, 20 mg)) that will be manufactured and sold pursuant to an ANDA, throughout the United States, including throughout the State of New Jersey.

ANSWER: Ajanta admits that Ajanta Ltd. is in the business of manufacturing pharmaceutical drug products, including generic drug products. Ajanta further admits that Ajanta USA is in the business of selling pharmaceutical drug products, including generic drug products,

in the United States. Ajanta is without sufficient knowledge or information to form a belief as to whether Ajanta Ltd. and Ajanta USA will collaborate to develop, manufacture, import, market, and distribute, and/or sell pharmaceutical products, including generic drug products (e.g., Risperidone Tablet (0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg); Clomipramine Hydrochloride Capsules (25 mg, 50 mg, and 75 mg), and Aripiprazole Tablet (2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg), and Tadalafil Tablet (2.5 mg, 5 mg, 10 mg, 20 mg)) that will be manufactured and sold pursuant to an ANDA, throughout the United States, including throughout the State of New Jersey, and therefore denies those allegations of paragraph 10. Ajanta further states that, solely for the limited purpose of this action only, neither Ajanta Ltd. nor Ajanta USA contests personal jurisdiction in this Court, and each reserves the right to contest personal jurisdiction in any other case. Ajanta denies any remaining allegations or legal conclusions of paragraph 10.

11. Upon information and belief, Defendants and/or their affiliates manufacture and/or direct the manufacture of generic pharmaceutical products for which Ajanta Ltd. is the named ANDA applicant. Upon information and belief, Defendants each, directly or indirectly, derive substantial revenue from the sales of such generic pharmaceutical products.

ANSWER: Ajanta admits that Ajanta Ltd. is in the business of manufacturing pharmaceutical drug products, including generic drug products. Ajanta further admits that Ajanta Ltd. is a named ANDA applicant for at least ANDA No. 215663. Ajanta further admits that Ajanta USA is in the business of selling pharmaceutical drug products, including generic drug products, in the United States. Ajanta is without sufficient knowledge or information to form a belief as to whether any revenue derived by Ajanta Ltd. or Ajanta USA from sales of generic pharmaceutical products is or will be substantial, and therefore denies those allegations of paragraph 11. Ajanta further states that, solely for the limited purpose of this action only, neither Ajanta Ltd. nor Ajanta USA contests personal jurisdiction in this Court, and each reserves the

right to contest personal jurisdiction in any other case. Ajanta denies any remaining allegations or legal conclusions of paragraph 11.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 12 states a legal conclusion to which no response is required. To the extent a response is required, Ajanta does not contest the Court's jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. This Court has personal jurisdiction over Defendants under: (i) Fed. R. Civ. P. 4(k)(1) and N.J. Ct. R. 4:4-4; and/or (ii) Fed. R. Civ. P. 4(k)(2).

ANSWER: Paragraph 13 states a legal conclusion to which no response is required. To the extent a response is required, Ajanta states that, solely for the limited purpose of this action only, Ajanta does not contest personal jurisdiction in this Court, and Ajanta Ltd. and Ajanta USA each reserves the right to contest personal jurisdiction in any other case.

14. Upon information and belief, Defendants have purposefully availed themselves of the privilege of doing business in the State of New Jersey by continuously and systematically placing goods in the stream of commerce for distribution and sale throughout the United States, including the State of New Jersey. For example, upon information and belief, Defendants state on their website that they are "gradually building a meaningful presence in the US market with select product portfolio, which include complex technology products to get the competitive advantage in the market place. We expect US market to be our key growth driver in the coming years." Ajanta Website, http://www.ajantapharma.com/overview.html (accessed March 26, 2021). Defendants further state on their website "[o]ur products are already available on the shelf in US through our subsidiary, located in New Jersey, the hub of pharma industry in USA." Ajanta Website, http://www.ajantapharma.com/generics.html (accessed March 26, 2021). In addition, Defendants' website indicates that as of February 2021, Defendants had 42 products approved by FDA with 18 additional products submitted and under approval with FDA. Ajanta Website, http://www.ajantapharma.com/AdminData/InvesterPresentation/InvestorPresentation ofQ3FY2021.pdf (accessed March 26, 2021).

ANSWER: Paragraph 14 states a legal conclusion to which no response is required. To the extent a response is required, Ajanta admits that the website

http://www.ajantapharma.com/overview.html speaks for itself and denies the allegations of paragraph 14 to the extent they are inconsistent with that website. Ajanta further admits that the website http://www.ajantapharma.com/generics.html speaks for itself and denies the allegations of paragraph 14 to the extent they are inconsistent with that website. Ajanta further admits that the website http://www.ajantapharma.com/AdminData/InvesterPresentation/InvestorPresentation ofQ3FY2021.pdf speaks for itself and denies the allegations of paragraph 14 to the extent they are inconsistent with that website. Ajanta further states that, solely for the limited purpose of this action, neither Ajanta Ltd. nor Ajanta USA contests personal jurisdiction in this Court, and each reserves the right to contest personal jurisdiction in any other case. Ajanta denies the remaining allegations of paragraph 14.

15. This Court has personal jurisdiction over Ajanta USA at least because, upon information and belief: (i) Ajanta USA maintains a principal place of business in New Jersey located at One Grand Commons, 440 US Highway 22 East, Suite 150, Bridgewater, NJ 08807; (ii) Ajanta USA is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iii) Ajanta USA, together with its parent Ajanta Ltd., is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (iv) Ajanta USA, together with its parent Ajanta Ltd., has committed, induced, and/or contributed to acts of patent infringement in New Jersey; and (v) Ajanta USA has previously submitted to the jurisdiction of this Court, has availed itself of New Jersey's legal protections in prior litigations, and previously consented to personal jurisdiction and venue in this Judicial District.[2]

ANSWER: Paragraph 15 states a legal conclusion to which no response is required. To the extent a response is required, Ajanta admits that Ajanta USA maintains a principal place

[2] This Court also has personal jurisdiction over Defendants because Ajanta Ltd. and Ajanta USA have previously submitted to the jurisdiction of this Court and have previously availed themselves of this Court by initiating lawsuits, consenting to this Court's jurisdiction, and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Horizon Medicines LLC, et al. v. Ajanta Pharma Ltd., et al.*, Civil Action No. 19-18555 (BRM)(JAD) (D.N.J.) (Ajanta Ltd. and Ajanta USA filed a counterclaim and did not contest jurisdiction) and *Otsuka Pharmaceutical Co., Ltd. v. Ajanta Pharma Ltd., et al.*, Civil Action No. 14-05876 (JBS)(KMW) (D.N.J.) (Ajanta Ltd. and Ajanta USA filed a counterclaim and did not contest jurisdiction).

of business in New Jersey located at One Grand Commons, 440 US Highway 22 East, Suite 150, Bridgewater, NJ 08807. Ajanta further admits that Ajanta Ltd. is in the business of manufacturing pharmaceutical drug products, including generic drug products. Ajanta further admits that Ajanta USA is in the business of selling pharmaceutical drug products, including generic drug products, in the United States. Ajanta admits that it has been named in patent litigations in this District and did not contest this Court's personal jurisdiction over Ajanta solely for the limited purpose of those particular actions only, and reserved the right to contest personal jurisdiction in any other case. Ajanta further states that, solely for the limited purpose of this action only, neither Ajanta Ltd. nor Ajanta USA contests personal jurisdiction in this Court, and each reserves the right to contest personal jurisdiction in any other case. Ajanta denies the remaining allegations of paragraph 15, and specifically denies that it has committed, induced, and/or contributed to acts of patent infringement in New Jersey.

16. Upon information and belief, Ajanta USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0400533904. Upon information and belief, Ajanta USA is registered with the State of New Jersey's Department of Health as a drug & medical device "manufacturer and wholesaler" and "wholesaler" with Registration Number 5004507. Ajanta USA has, therefore, purposefully availed itself of the rights, benefits, and privileges of New Jersey's laws.

ANSWER: Paragraph 16 states a legal conclusion to which no response is required. To the extent a response is required, Ajanta admits that Ajanta USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services with Business Identification Number 0400533904. Ajanta further admits that Ajanta USA is registered with the State of New Jersey's Department of Health as a "manufacturer" with Registration Number 5004507. Ajanta further states that, solely for the limited purpose of this action only, neither Ajanta Ltd. nor Ajanta USA contests personal jurisdiction in this Court, and each reserves the right to contest

personal jurisdiction in any other case. Ajanta denies the remaining allegations of paragraph 16.

17. According to Defendants' website, Ajanta USA is based in Bridgewater, New Jersey, and is a wholly-owned subsidiary of Ajanta Ltd. The website further states "[s]ince making the strategic decision to enter the US market, our Research and Development (R&D) team began developing a product portfolio of [ANDA] filings with a mix of Immediate-Release, Extended-Release, Delayed-Release, Orally Disintegrating Tablets and Powders." http://www.ajantapharmausa.com/overview.html (accessed March 26, 2021).

ANSWER: Ajanta admits that Ajanta USA has a principal place of business at One Grand Commons, 440 US Highway 22 East, Suite 150, Bridgewater, NJ 08807. Ajanta further admits that Ajanta USA is a wholly-owned subsidiary of Ajanta Ltd. Ajanta further admits that the website http://www.ajantapharmausa.com/overview.html speaks for itself and denies the allegations of paragraph 17 to the extent they are inconsistent with that website. Ajanta further states that, solely for the limited purpose of this action only, neither Ajanta Ltd. nor Ajanta USA contests personal jurisdiction in this Court, and each reserves the right to contest personal jurisdiction in any other case. Ajanta denies the remaining allegations of paragraph 17.

18. This Court has personal jurisdiction over Ajanta Ltd. at least because, upon information and belief: (i) Ajanta Ltd. has purposefully directed its activities and the activities of Ajanta USA at residents and corporate entities within the State of New Jersey; (ii) the claims set forth herein against Ajanta Ltd. arise out of or relate to those activities; (iii) Ajanta Ltd.'s contacts with the State of New Jersey (direct and indirect) are continuous and systematic; and (iv) it is reasonable and fair for this Court to exercise personal jurisdiction over Ajanta Ltd.

ANSWER: Paragraph 18 states a legal conclusion to which no response is required. To the extent a response is required, Ajanta states that, solely for the limited purpose of this action only, Ajanta does not contest personal jurisdiction in this Court, and Ajanta Ltd. and Ajanta USA each reserves the right to contest personal jurisdiction in any other case. Ajanta denies the remaining allegations of paragraph 18.

19. Upon information and belief, Ajanta Ltd.'s tortious acts of (i) preparing and filing ANDA No. 215663 with a paragraph IV certification to the patents in suit for the purpose of

obtaining approval to engage in the commercial manufacture, use, offer to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products before the expiration of the patents in suit; and (ii) directing notice of its ANDA submission to Supernus, are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, and/or sale of the Ajanta Products by Defendants before the expiration of the patents in suit throughout the United States, including in this Judicial District. Because defending against an infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, Ajanta Ltd. and Ajanta USA should reasonably anticipate being sued in New Jersey.

ANSWER: Paragraph 19 states a legal conclusion to which no response is required. To the extent a response is required, Ajanta states that, solely for the limited purpose of this action only, neither Ajanta Ltd. nor Ajanta USA contest personal jurisdiction in this Court, and each reserves the right to contest personal jurisdiction in any other case. Ajanta denies the remaining allegations of paragraph 19.

20. This Court has personal jurisdiction over Defendants at least because, upon information and belief, if ANDA No. 215663 is approved, the Ajanta Products will be marketed and distributed by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey. Specifically, upon information and belief, Ajanta USA employs a salesforce that includes personnel who regularly and continuously work in this Judicial District[3] and, if Ajanta Ltd. succeeds in obtaining FDA approval, Ajanta USA will use its salesforce to sell the Ajanta Products in the State of New Jersey.

ANSWER: Paragraph 20 states a legal conclusion to which no response is required. To the extent a response is required, Ajanta admits that the website http://www.ajantapharma.com/business-development.html speaks for itself and denies the allegations of paragraph 20 to the extent they are inconsistent with that website. Ajanta states that, solely for the limited purpose of this action only, neither Ajanta Ltd. nor Ajanta USA contests personal jurisdiction in this Court, and each reserves the right to contest personal

[3] Defendants' website states that its "journey into the US marketplace" includes "a dedicated front end sales and marketing team." Ajanta USA Website, http://www.ajantapharmausa.com/business-development.html (accessed March 26, 2021).

jurisdiction in any other case. Ajanta denies the remaining allegations of paragraph 20.

21. Venue is proper for Ajanta USA under 28 U.S.C. §§ 1391 and/or 1400(b), because, inter alia Ajanta USA is subject to personal jurisdiction in this Judicial District, as set forth above, has committed and/or will commit further acts of infringement in this Judicial District, as set forth above, and/or does business in this Judicial District through a permanent and continuous presence in the State of New Jersey, as set forth above.

ANSWER: Paragraph 21 states a legal conclusion to which no response is required. To the extent a response is required, Ajanta states that, solely for the limited purpose of this action only, Ajanta does not contest that venue is proper in this Court, and Ajanta Ltd. and Ajanta USA each reserves the right to contest venue in any other case. Ajanta further states that, solely for the limited purpose of this action only, neither Ajanta Ltd. nor Ajanta USA contests personal jurisdiction in this Court, and each reserves the right to contest personal jurisdiction in any other case. Ajanta denies the remaining allegations in paragraph 21.

22. Venue is proper for Ajanta Ltd. under 28 U.S.C. §§ 1391 and/or 1400(b) because, inter alia, Ajanta Ltd. is subject to personal jurisdiction in this Judicial District, as set forth above, has committed an act of infringement and will commit further acts of infringement in this Judicial District, as set forth above, and/or continuously transacts business in this Judicial District, as set forth above.

ANSWER: Paragraph 22 states a legal conclusion to which no response is required. To the extent a response is required, Ajanta states that, solely for the limited purpose of this action only, Ajanta does not contest that venue is proper in this Court, and Ajanta Ltd. and Ajanta USA each reserves the right to contest venue in any other case. Ajanta further states that, solely for the limited purpose of this action only, neither Ajanta Ltd. nor Ajanta USA contests personal jurisdiction in this Court, and each reserves the right to contest personal jurisdiction in any other case. Ajanta denies the remaining allegations in paragraph 22.

23. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b), 1391(c), and § 1400(b).

ANSWER: Paragraph 23 states a legal conclusion to which no response is required. To the extent a response is required, Ajanta states that, solely for the limited purpose of this action only, Ajanta does not contest that venue is proper in this Court, and Ajanta Ltd. and Ajanta USA each reserves the right to contest venue in any other case.

FACTS AS TO ALL COUNTS

24. Supernus's Trokendi XR® is sold and marketed under New Drug Application ("NDA") No. 201635, which was approved by FDA for the manufacture and sale of topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg.

ANSWER: Ajanta admits that there is an NDA No. 201635 that was approved by the FDA for topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg, under the trade name TROKENDI XR®. Ajanta is without sufficient knowledge or information to form a belief as to the remaining allegations of paragraph 24, and, therefore, denies those allegations.

25. Trokendi XR® is an antiepileptic drug indicated: (i) as an initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older; (ii) as an adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 6 years of age and older; and (iii) for the preventive treatment of migraine in patients 12 years of age and older.

ANSWER: Ajanta admits that the FDA-approved label for TROKENDI XR® states that it is indicated for: "Epilepsy: initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older; adjunctive therapy for the treatment of partial-onset, primary generalized tonic-clonic seizures, or seizures associated with Lennox- Gastaut syndrome (LGS) in patients 6 years of age and older. Preventive treatment of migraine in patients 12 years of age and older." Ajanta is without sufficient knowledge or information to form a belief as to the allegations of paragraph 25, and, therefore, denies those allegations.

26. Trokendi XR®'s recommended dosage: (i) for monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily, and in patients 6 to 9 years of age is based on weight; (ii) for adjunctive therapy in adults with partial-onset seizures or Lennox-Gastaut Syndrome is 200 mg to 400 mg orally once daily and with primary generalized tonic-clonic seizures is 400 mg orally once daily, and for adjunctive therapy for patients 6 to 16 years of age with partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome is approximately 5 mg/kg to 9 mg/kg orally once daily; and (iii) for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily.

ANSWER: Ajanta admits that the FDA-approved label for TROKENDI XR® states that dosing "for monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily [and] dosing in patients 6 to 9 years of age is based on weight . . . [A]djunctive therapy in adults with partial-onset seizures or Lennox-Gastaut Syndrome is 200 mg to 400 mg orally once daily and with primary generalized tonic-clonic seizures is 400 mg orally once daily . . . [A]djunctive therapy for patients 6 to 16 years of age with partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox- Gastaut syndrome is approximately 5 mg/kg to 9 mg/kg orally once daily . . . [T]reatment for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily." Ajanta is without sufficient knowledge or information to form a belief as to the allegations of paragraph 26, and, therefore, denies those allegations.

27. NDA No. 201635 pertains to Trokendi XR® 25 mg, 50 mg, 100 mg, and 200 mg.

ANSWER: Ajanta admits that there is an NDA No. 201635 for topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg, under the trade name TROKENDI XR®. Ajanta is without sufficient knowledge or information to form a belief as to the allegations of paragraph 27, and, therefore, denies those allegations.

28. FDA's publication titled, "Approved Drug Products with Therapeutic Equivalence Evaluations," (commonly known as the "Orange Book") lists ten (10) patents, specifically the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents, as

covering Supernus's Trokendi XR®. Pursuant to 21 U.S.C. 355(b)(1) and 355(c)(2), these ten (10) patents were submitted to FDA with or after the approval of NDA No. 201635. These ten patents are listed in the Orange Book as covering Trokendi XR®.

ANSWER: Ajanta admits that the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents are, as of this time, listed in the Orange Book in connection with NDA No. 201635. Ajanta is without sufficient knowledge or information to form a belief as to the remaining allegations of paragraph 28, and, therefore, denies those allegations.

29. The '576 patent, entitled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '576 patent.

ANSWER: Ajanta admits that on its face the '576 patent states that it issued on October 30, 2012. Ajanta further admits that on its face the '576 patent is titled "Sustained-Release Formulations of Topiramate." Ajanta further admits that on its face the '576 patent names Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira as alleged inventors of the '576 patent. Ajanta further admits that on its face the '576 patent names Supernus Pharmaceuticals, Inc. as the alleged assignee of the '576 patent. Ajanta denies that the '576 patent was duly and legally issued. Ajanta lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in paragraph 29, and therefore denies them.

30. The '580 patent, entitled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '580 patent.

ANSWER: Ajanta admits that on its face the '580 patent states that it issued on October 30, 2012. Ajanta further admits that on its face the '580 patent is titled "Sustained-Release Formulations of Topiramate." Ajanta further admits that on its face the '580 patent

names Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira as alleged inventors of the '580 patent. Ajanta further admits that on its face the '580 patent names Supernus Pharmaceuticals, Inc. as the alleged assignee of the '580 patent. Ajanta denies that the '580 patent was duly and legally issued. Ajanta lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in paragraph 30, and therefore denies them.

31. The '683 patent, entitled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on March 4, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '683 patent.

ANSWER: Ajanta admits that on its face the '683 patent states that it issued on March 4, 2014. Ajanta further admits that on its face the '683 patent is titled "Sustained-Release Formulations of Topiramate." Ajanta further admits that on its face the '683 patent names Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira as alleged inventors of the '683 patent. Ajanta further admits that on its face the '683 patent names Supernus Pharmaceuticals, Inc. as the alleged assignee of the '683 patent. Ajanta denies that the '683 patent was duly and legally issued. Ajanta lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in paragraph 31, and therefore denies them.

32. The '248 patent, entitled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on November 4, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '248 patent.

ANSWER: Ajanta admits that on its face the '248 patent states that it issued on November 4, 2014. Ajanta further admits that on its face the '248 patent is titled "Sustained-Release Formulations of Topiramate." Ajanta further admits that on its face the '248 patent names Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira as alleged inventors

of the ’248 patent. Ajanta further admits that on its face the ’248 patent names Supernus Pharmaceuticals, Inc. as the alleged assignee of the ’248 patent. Ajanta denies that the ’248 patent was duly and legally issued. Ajanta lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in paragraph 32, and therefore denies them.

33. The ’191 patent, entitled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on November 18, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the ’191 patent.

ANSWER: Ajanta admits that on its face the ’191 patent states that it issued on November 18, 2014. Ajanta further admits that on its face the ’191 patent is titled “Sustained-Release Formulations of Topiramate.” Ajanta further admits that on its face the ’191 patent names Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira as alleged inventors of the ’191 patent. Ajanta further admits that on its face the ’191 patent names Supernus Pharmaceuticals, Inc. as the alleged assignee of the ’191 patent. Ajanta denies that the ’191 patent was duly and legally issued. Ajanta lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in paragraph 33, and therefore denies them.

34. The ’989 patent, entitled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on March 31, 2015, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the ’989 patent.

ANSWER: Ajanta admits that on its face the ’989 patent states that it issued on March 31, 2015. Ajanta further admits that on its face the ’989 patent is titled “Sustained-Release Formulations of Topiramate.” Ajanta further admits that on its face the ’989 patent names Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira as alleged inventors of the ’989

patent. Ajanta further admits that on its face the '989 patent names Supernus Pharmaceuticals, Inc. as the alleged assignee of the '989 patent. Ajanta denies that the '989 patent was duly and legally issued. Ajanta lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in paragraph 34, and therefore denies them.

35. The '940 patent, entitled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on January 24, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '940 patent.

ANSWER: Ajanta admits that on its face the '940 patent states that it issued on January 24, 2017. Ajanta further admits that on its face the '940 patent is titled "Sustained-Release Formulations of Topiramate." Ajanta further admits that on its face the '940 patent names Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira as alleged inventors of the '940 patent. Ajanta further admits that on its face the '940 patent names Supernus Pharmaceuticals, Inc. as the alleged assignee of the '940 patent. Ajanta denies that the '940 patent was duly and legally issued. Ajanta lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in paragraph 35, and therefore denies them.

36. The '004 patent, entitled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on January 31, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '004 patent.

ANSWER: Ajanta admits that on its face the '004 patent states that it issued on January 31, 2017. Ajanta further admits that on its face the '004 patent is titled "Sustained-Release Formulations of Topiramate." Ajanta further admits that on its face the '004 patent names Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira as alleged inventors of the '004 patent. Ajanta further admits that on its face the '004 patent names Supernus

Pharmaceuticals, Inc. as the alleged assignee of the '004 patent. Ajanta denies that the '004 patent was duly and legally issued. Ajanta lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in paragraph 36, and therefore denies them.

37. The '983 patent, entitled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on April 18, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '983 patent.

ANSWER: Ajanta admits that on its face the '983 patent states that it issued on April 18, 2017. Ajanta further admits that on its face the '983 patent is titled "Sustained-Release Formulations of Topiramate." Ajanta further admits that on its face the '983 patent names Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira as alleged inventors of the '983 patent. Ajanta further admits that on its face the '983 patent names Supernus Pharmaceuticals, Inc. as the alleged assignee of the '983 patent. Ajanta denies that the '983 patent was duly and legally issued. Ajanta lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in paragraph 37, and therefore denies them.

38. The '790 patent, entitled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on June 11, 2019, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '790 patent.

ANSWER: Ajanta admits that on its face the '790 patent states that it issued on June 11, 2019. Ajanta further admits that on its face the '790 patent is titled "Sustained-Release Formulations of Topiramate." Ajanta further admits that on its face the '790 patent names Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira as alleged inventors of the '790 patent. Ajanta further admits that on its face the '790 patent names Supernus Pharmaceuticals, Inc. as the alleged assignee of the '790 patent. Ajanta denies that the '790 patent was duly and

legally issued. Ajanta lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in paragraph 38, and therefore denies them.

39. On or about February 10, 2021, Ajanta sent a letter purportedly pursuant to § 505(j)(2)(B)(iv)(II) of the FDCA and 21 C.F.R. §§ 314.94, 314.95 regarding the Ajanta Products and the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents (the "February 10 Notice Letter") to Supernus at 1550 East Gude Drive, Rockville, Maryland 20850.

ANSWER: Ajanta admits that on February 10, 2021, Ajanta Ltd. sent a letter titled "Notice of Paragraph IV Certification Regarding NDA 201635 TROKENDI XR® (Topiramate Extended Release) Capsule, 25 mg, 50 mg, 100 mg and 200 mg With Respect to U.S. Patent No. 8,298,576; 8,298,580; 8,663,683; 8,877,248; 8,889,191; 8,992,989; 9,549,940; 9,555,004; 9,622,983 and 10,314,790, Pursuant to § 505(j)(2)(B)(ii) and § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act" (the "Ajanta Notice Letter"). Ajanta denies the remaining allegations in paragraph 39.

40. The February 10 Notice Letter was signed by Dennies Varughese, Esq., Pharm.D., of Sterne, Kessler, Goldstein & Fox P.L.L.C.—counsel for Ajanta—and authorized such counsel to accept service of process for Ajanta Ltd.

ANSWER: Ajanta admits that the February 10 Notice Letter was signed by Dennies Varughese, Esq., Pharm.D., of Sterne, Kessler, Goldsteing, & Fox P.L.L.C.—and stated "Ajanta designates Sterne, Kessler, Goldstein & Fox P.L.L.C. as an agent in the United States, authorized to accept service of process for Ajanta." Ajanta denies the remaining allegations of paragraph 40.

41. Upon information and belief, ANDA No. 215663 is based upon Trokendi XR® (topiramate extended-release capsule), 25 mg, 50 mg, 100 mg, and 200 mg., as its reference listed drug.

ANSWER: Ajanta admits that both Ajanta Ltd. and Ajanta USA filed ANDA No. 215663 with the FDA to obtain FDA approval for the commercial manufacture and sale in the United States of topiramate extended-release capsule, 25 mg, 50 mg, 100 mg, and 200 mg.

Ajanta denies the remaining allegations in paragraph 41.

42. Upon information and belief, the Ajanta Products are topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg.

ANSWER: Admitted.

43. Upon information and belief, the proposed prescribing information for the Ajanta Products includes a header titled, "Indications and Usage," and states that Ajanta Products are indicated: (i) as an initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older; (ii) as an adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 6 years of age and older; and (iii) for the preventive treatment of migraine in patients 12 years of age and older.

ANSWER: Ajanta admits that the proposed prescribing information for the Ajanta Products speaks for itself and denies the allegations of paragraph 43 to the extent they are inconsistent with that information. Ajanta denies the remaining allegations in paragraph 43.

44. Upon information and belief, the proposed prescribing information for the Ajanta Products includes a header titled, "Dosage and Administration," and states that: (i) the recommended dose for monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily, and dosing in patients 6 to 9 years of age is based on weight; (ii) the recommended total daily dose as adjunctive therapy in adults with partial-onset seizures or Lennox-Gastaut Syndrome is 200 mg to 400 mg orally once daily and with primary generalized tonic-clonic seizures is 400 mg orally once daily, and the recommended total daily dose as adjunctive therapy for patients 6 to 16 years of age with partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome is approximately 5 mg/kg to 9 mg/kg orally once daily; and (iii) the recommended total daily dose as treatment for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily.

ANSWER: Ajanta admits that the proposed prescribing information for the Ajanta Products speaks for itself and denies the allegations of paragraph 44 to the extent they are inconsistent with that information. Ajanta denies the remaining allegations in paragraph 44.

45. Upon information and belief, the proposed prescribing information for the Ajanta Products will also state under the header "Dosage and Administration" that the Ajanta Products

can be taken without regard to meals, to swallow capsule whole and intact, and do not sprinkle on food, chew, or crush.

ANSWER: Ajanta admits that the proposed prescribing information for the Ajanta Products speaks for itself and denies the allegations of paragraph 45 to the extent they are inconsistent with that information. Ajanta denies the remaining allegations in paragraph 45.

46. Upon information and belief, the proposed prescribing information for the Ajanta Products includes a header titled, "Description," and states that the Ajanta Products contain the following inactive ingredients: Sugar Spheres, NF Hypromellose (Type 2910), USP Mannitol, USP Docusate Sodium, USP Sodium Benzoate, NF Ethylcellulose, NF Oleic Acid, NF Medium Chain Triglycerides, NF Polyethylene Glycol, NF Polyvinyl Alcohol, USP Titanium Dioxide, USP Talc, USP Lecithin, NF Xanthan Gum, NF Glycerin, USP-NF.

ANSWER: Ajanta admits that the proposed prescribing information for the Ajanta Products speaks for itself and denies the allegations of paragraph 46 to the extent they are inconsistent with that information. Ajanta denies the remaining allegations in paragraph 46.

47. Upon information and belief, Ajanta Ltd. and Ajanta USA acted in concert to develop the Ajanta Products and to seek approval from FDA to sell the Ajanta Products throughout the United States, including within this Judicial District.

ANSWER: Ajanta admits that Ajanta USA assisted Ajanta Ltd. with submission of the ANDA to the FDA for approval of the Ajanta Products. Ajanta denies the remaining allegations of paragraph 47.

48. Upon information and belief, both Ajanta Ltd. and Ajanta USA participated in the preparation and/or filing of ANDA No. 215663.

ANSWER: Ajanta admits that Ajanta Ltd. and Ajanta USA participated in the filing of ANDA No. 215663. Ajanta denies the remaining allegations of paragraph 48.

49. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such a letter include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid,

unenforceable, or will not be infringed." The detailed statement must include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)-(ii).

ANSWER: Paragraph 49 states a legal conclusion to which no response is required. To the extent a response is required, Ajanta states that 21 U.S.C. §§ 355(j)(2)(B)(iv)(II), 314.95(c)(7), and 314.95(c)(7)(i)-(ii) speak for themselves and denies the allegations of paragraph 49 to the extent they are inconsistent with those sections. Ajanta denies the remaining allegations of paragraph 49.

50. Upon information and belief, as of the date of the February 10 Notice Letter, Ajanta Ltd. and Ajanta USA were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER: Admitted.

51. The February 10 Notice Letter does not include any non-infringement contentions unique to claims 2-18 and 20-30 of the '576 patent, claims 2-16 and 18-31 of the '580 patent, claims 2-24 of the '683 patent, claims 2-13 and 15-20 of the '248 patent, claims 2-24 of the '191 patent, claims 2-13, 16-17, and 19-20 of the '989 patent, claims 2-13, 16-17, and 19-20 of the '940 patent, claims 2-12, 15-16, and 18-30 of the '983 patent, claims 2-11 and 13-15 of the '004 patent, and claims 2-11 and 13-25 of the '790 patent.

ANSWER: Denied.

52. The February 10 Notice Letter does not include any invalidity contentions to any claim of the '576, '580, '683, '191, '004, and '790 patents. Further, the February 10 Notice Letter does not include any invalidity contentions to claims 1-13 and 15-17 of the '248 patent, claims 1-13 and 15-17 of the '989 patent, claims 1-13 and 15-17 of the '940 patent, claims 1-12, 14-16, and 21 of the '983 patent.

ANSWER: Denied.

53. Supernus and Defendants did not reach agreement on mutually acceptable terms for an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95(c)(8). As of the filing of this Complaint, Defendants have not produced the Ajanta ANDA to Supernus.

ANSWER: Ajanta admits that the Ajanta Notice Letter stated that ANDA No. 215663 contained a Paragraph IV Certification regarding the patents-in-suit, accompanied by a detailed statement setting forth the factual and legal basis for Ajanta's assertion that, *inter alia*, the patents-in-suit were invalid and not infringed, and made an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Ajanta further admits that Supernus did not respond to the Offer of Confidential Access nor did Supernus make an attempt to reach an agreement on mutually acceptable terms. Ajanta denies the remaining allegations of paragraph 53.

FIRST COUNT
(Defendants' Infringement of the '576 Patent)

54. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER: No response is required to the general reallegation and incorporation by reference of paragraphs 1 through 53 of the Complaint. To the extent a response is required, Ajanta incorporates by reference paragraphs 1 through 53 as if fully set forth herein.

55. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '576 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the Ajanta Products before the expiration of the '576 patent is an act of infringement of the '576 patent by Ajanta Ltd. of one or more claims of the '576 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Ajanta admits that 35 U.S.C. § 271(e)(2)(A) states that "It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent," and denies the allegations of paragraph 55 to the extent they are inconsistent with that statute. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 55.

56. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

ANSWER: Ajanta admits only that Ajanta Ltd. and Ajanta USA participated in the submission of the Ajanta ANDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Ajanta Products. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 56.

57. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '576 patent under 35 U.S.C. § 271.

ANSWER: Denied.

58. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '576 patent under 35 U.S.C. § 271.

ANSWER: Denied.

59. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '576 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER: Denied.

60. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '576 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

61. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

ANSWER: Denied.

SECOND COUNT
(Defendants' Infringement of the '580 Patent)

62. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER: No response is required to the general reallegation and incorporation by reference of paragraphs 1 through 61 of the Complaint. To the extent a response is required, Ajanta incorporates by reference paragraphs 1 through 61 as if fully set forth herein.

63. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '580 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the Ajanta Products before the expiration of the '580 patent is an act of infringement of the '580 patent by Ajanta Ltd. of one or more claims of the '580 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Ajanta admits that 35 U.S.C. § 271(e)(2)(A) states that "It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent," and denies the allegations of paragraph 63 to the extent they are inconsistent with that statute. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 63.

64. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

ANSWER: Ajanta admits only that Ajanta Ltd. and Ajanta USA participated in the submission of the Ajanta ANDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Ajanta Products. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 64.

65. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '580 patent under 35 U.S.C. § 271.

ANSWER: Denied.

66. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '580 patent under 35 U.S.C. § 271.

ANSWER: Denied.

67. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '580 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER: Denied.

68. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '580 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

69. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

ANSWER: Denied.

THIRD COUNT
(Defendants' Infringement of the '683 Patent)

70. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER: No response is required to the general reallegation and incorporation by reference of paragraphs 1 through 69 of the Complaint. To the extent a response is required, Ajanta incorporates by reference paragraphs 1 through 69 as if fully set forth herein.

71. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '683 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the Ajanta Products before the expiration of the '683 patent is an act of infringement of the '683 patent by Ajanta Ltd. of one or more claims of the '683 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Ajanta admits that 35 U.S.C. § 271(e)(2)(A) states that "It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent," and denies the allegations of paragraph 71 to the extent they are inconsistent with that statute. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 71.

72. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

ANSWER: Ajanta admits only that Ajanta Ltd. and Ajanta USA participated in the submission of the Ajanta ANDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Ajanta Products. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 72.

73. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '683 patent under 35 U.S.C. § 271.

ANSWER: Denied.

74. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '683 patent under 35 U.S.C. § 271.

ANSWER: Denied.

75. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '683 patent do not establish good-faith bases to comply with the statutory

provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER: Denied.

76. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '683 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

77. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

ANSWER: Denied.

FOURTH COUNT
(Defendants' Infringement of the '248 Patent

78. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER: No response is required to the general reallegation and incorporation by reference of paragraphs 1 through 77 of the Complaint. To the extent a response is required, Ajanta incorporates by reference paragraphs 1 through 77 as if fully set forth herein.

79. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '248 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the Ajanta Products before the expiration of the '248 patent is an act of infringement of the '248 patent by Ajanta Ltd. of one or more claims of the '248 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Ajanta admits that 35 U.S.C. § 271(e)(2)(A) states that "It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent," and denies the allegations of paragraph 79 to the extent they are inconsistent with that statute. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 79.

80. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

ANSWER: Ajanta admits only that Ajanta Ltd. and Ajanta USA participated in the submission of the Ajanta ANDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Ajanta Products. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 80.

81. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '248 patent under 35 U.S.C. § 271.

ANSWER: Denied.

82. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '248 patent under 35 U.S.C. § 271.

ANSWER: Denied.

83. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '248 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER: Denied.

84. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '248 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

85. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

ANSWER: Denied.

FIFTH COUNT
(Defendants' Infringement of the '191 Patent)

86. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER: No response is required to the general reallegation and incorporation by reference of paragraphs 1 through 85 of the Complaint. To the extent a response is required, Ajanta incorporates by reference paragraphs 1 through 85 as if fully set forth herein.

87. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '191 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the Ajanta Products before the expiration of the '191 patent is an act of infringement of the '191 patent by Ajanta Ltd. of one or more claims of the '191 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Ajanta admits that 35 U.S.C. § 271(e)(2)(A) states that "It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent," and denies the allegations of paragraph 87 to the extent they are inconsistent with that statute. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 87.

88. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

ANSWER: Ajanta admits only that Ajanta Ltd. and Ajanta USA participated in the submission of the Ajanta ANDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Ajanta Products. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 88.

89. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into

the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '191 patent under 35 U.S.C. § 271.

ANSWER: Denied.

90. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '191 patent under 35 U.S.C. § 271.

ANSWER: Denied.

91. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '191 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER: Denied.

92. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '191 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

93. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

ANSWER: Denied.

SIXTH COUNT
(Defendants' Infringement of the '989 Patent

94. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER: No response is required to the general reallegation and incorporation by reference of paragraphs 1 through 93 of the Complaint. To the extent a response is required, Ajanta incorporates by reference paragraphs 1 through 93 as if fully set forth herein.

95. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '989 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the

Ajanta Products before the expiration of the '989 patent is an act of infringement of the '989 patent by Ajanta Ltd. of one or more claims of the '989 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Ajanta admits that 35 U.S.C. § 271(e)(2)(A) states that "It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent," and denies the allegations of paragraph 95 to the extent they are inconsistent with that statute. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 95.

96. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

ANSWER: Ajanta admits only that Ajanta Ltd. and Ajanta USA participated in the submission of the Ajanta ANDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Ajanta Products. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 96.

97. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '989 patent under 35 U.S.C. § 271.

ANSWER: Denied.

98. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '989 patent under 35 U.S.C. § 271.

ANSWER: Denied.

99. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '989 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER: Denied.

100. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '989 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

101. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

ANSWER: Denied.

SEVENTH COUNT
(Defendants' Infringement of the '940 Patent)

102. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER: No response is required to the general reallegation and incorporation by reference of paragraphs 1 through 101 of the Complaint. To the extent a response is required, Ajanta incorporates by reference paragraphs 1 through 101 as if fully set forth herein.

103. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '940 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the Ajanta Products before the expiration of the '940 patent is an act of infringement of the '940 patent by Ajanta Ltd. of one or more claims of the '940 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Ajanta admits that 35 U.S.C. § 271(e)(2)(A) states that "It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent," and denies the allegations of paragraph 103 to the extent they are inconsistent with that statute. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 103.

104. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

ANSWER: Ajanta admits only that Ajanta Ltd. and Ajanta USA participated in the submission of the Ajanta ANDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Ajanta Products. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 104.

105. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '940 patent under 35 U.S.C. § 271.

ANSWER: Denied.

106. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '940 patent under 35 U.S.C. § 271.

ANSWER: Denied.

107. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '940 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER: Denied.

108. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '940 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

109. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

ANSWER: Denied.

EIGHTH COUNT
(Defendants' Infringement of the '004 Patent)

110. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER: No response is required to the general reallegation and incorporation by reference of paragraphs 1 through 109 of the Complaint. To the extent a response is required, Ajanta incorporates by reference paragraphs 1 through 109 as if fully set forth herein.

111. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '004 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the Ajanta Products before the expiration of the '004 patent is an act of infringement of the '004 patent by Ajanta Ltd. of one or more claims of the '004 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Ajanta admits that 35 U.S.C. § 271(e)(2)(A) states that "It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent," and denies the allegations of paragraph 111 to the extent they are inconsistent with that statute. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 111.

112. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

ANSWER: Ajanta admits only that Ajanta Ltd. and Ajanta USA participated in the submission of the Ajanta ANDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Ajanta Products. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 112.

113. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into

the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '004 patent under 35 U.S.C. § 271.

ANSWER: Denied.

114. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '004 patent under 35 U.S.C. § 271.

ANSWER: Denied.

115. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '004 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER: Denied.

116. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '004 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

117. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

ANSWER: Denied.

NINTH COUNT
(Defendants' Infringement of the '983 Patent)

118. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER: No response is required to the general reallegation and incorporation by reference of paragraphs 1 through 117 of the Complaint. To the extent a response is required, Ajanta incorporates by reference paragraphs 1 through 117 as if fully set forth herein.

119. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '983 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the

Ajanta Products before the expiration of the '983 patent is an act of infringement of the '983 patent by Ajanta Ltd. of one or more claims of the '983 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Ajanta admits that 35 U.S.C. § 271(e)(2)(A) states that "It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent," and denies the allegations of paragraph 119 to the extent they are inconsistent with that statute. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 119.

120. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

ANSWER: Ajanta admits only that Ajanta Ltd. and Ajanta USA participated in the submission of the Ajanta ANDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Ajanta Products. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 120.

121. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '983 patent under 35 U.S.C. § 271.

ANSWER: Denied.

122. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '983 patent under 35 U.S.C. § 271.

ANSWER: Denied.

123. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '983 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER: Denied.

124. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '983 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

125. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

ANSWER: Denied.

TENTH COUNT
(Defendants' Infringement of the '790 Patent)

126. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER: No response is required to the general reallegation and incorporation by reference of paragraphs 1 through 125 of the Complaint. To the extent a response is required, Ajanta incorporates by reference paragraphs 1 through 125 as if fully set forth herein.

127. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '790 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the Ajanta Products before the expiration of the '790 patent is an act of infringement of the '790 patent by Ajanta Ltd. of one or more claims of the '790 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Ajanta admits that 35 U.S.C. § 271(e)(2)(A) states that "It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent," and denies the allegations of paragraph 127 to the extent they are inconsistent with that statute. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 127.

128. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

ANSWER: Ajanta admits only that Ajanta Ltd. and Ajanta USA participated in the submission of the Ajanta ANDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Ajanta Products. Ajanta denies the remaining allegations or legal conclusions contained in paragraph 128.

129. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '790 patent under 35 U.S.C. § 271.

ANSWER: Denied.

130. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '790 patent under 35 U.S.C. § 271.

ANSWER: Denied.

131. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '790 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER: Denied.

132. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '790 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

133. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

ANSWER: Denied.

PRAYER FOR RELIEF

Ajanta denies that Plaintiff is entitled to any judgment or relief against Ajanta and, therefore, specifically denies paragraphs i through ix of the Complaint's Prayer for Relief.

AFFIRMATIVE AND OTHER DEFENSES

Without prejudice to the denials set forth in this Answer, without admitting any averments of Plaintiff's Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiff, Ajanta avers and asserts the following Defenses to the Complaint. Ajanta expressly reserves the right to allege additional defenses as they become known through the course of discovery.

FIRST DEFENSE
(Non-Infringement of the '576 Patent)

Ajanta does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '576 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of the Ajanta Products does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '576 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

SECOND DEFENSE
(Invalidity of the '576 Patent)

Each claim of the '576 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

THIRD DEFENSE
(Non-Infringement of the '580 Patent)

Ajanta does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '580 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of the Ajanta Products does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '580 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

FOURTH DEFENSE
(Invalidity of the '580 Patent)

Each claim of the '580 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

FIFTH DEFENSE
(Non-Infringement of the '683 Patent)

Ajanta does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '683 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of the Ajanta Products does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '683 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

SIXTH DEFENSE
(Invalidity of the '683 Patent)

Each claim of the '683 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

SEVENTH DEFENSE
(Non-Infringement of the '248 Patent)

Ajanta does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '248 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of the Ajanta Products does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '248 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

EIGHTH DEFENSE
(Invalidity of the '248 Patent)

Each claim of the '248 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

NINTH DEFENSE
(Non-Infringement of the '191 Patent)

Ajanta does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '191 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

The manufacture, use, offer for sale, sale, and/or importation of the Ajanta Products does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '191 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

TENTH DEFENSE
(Invalidity of the '191 Patent)

Each claim of the '191 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

ELEVENTH DEFENSE
(Non-Infringement of the '989 Patent)

Ajanta does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '989 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of the Ajanta Products does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '989 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

TWELFTH DEFENSE
(Invalidity of the '989 Patent)

Each claim of the '989 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

THIRTEENTH DEFENSE
(Non-Infringement of the '940 Patent)

Ajanta does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '940 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of the Ajanta Products does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '940 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

FOURTEENTH DEFENSE
(Invalidity of the '940 Patent)

Each claim of the '940 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

FIFTEENTH DEFENSE
(Non-Infringement of the '004 Patent)

Ajanta does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '004 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of the Ajanta Products does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '004 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

SIXTEENTH DEFENSE
(Invalidity of the '004 Patent)

Each claim of the '004 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

SEVENTEENTH DEFENSE
(Non-Infringement of the '983 Patent)

Ajanta does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '983 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of the Ajanta Products does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '983 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

EIGHTEENTH DEFENSE
(Invalidity of the '983 Patent)

Each claim of the '983 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

NINETEENTH DEFENSE
(Non-Infringement of the '790 Patent)

Ajanta does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '790 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

The manufacture, use, offer for sale, sale, and/or importation of the Ajanta Products does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '790 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

TWENTIETH DEFENSE
(Invalidity of the '790 Patent)

Each claim of the '790 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

TWENTY-FIRST DEFENSE
(NO RELIEF AVAILABLE)

Plaintiff is barred from obtaining relief pursuant to one or more provisions of 35 U.S.C. § 1, *et seq.*, including but not limited to §§ 286 and 287.

Plaintiff has not suffered any damages.

Plaintiff is not suffering any irreparable injury.

TWENTY-SECOND DEFENSE
(FAILURE TO STATE A CLAIM)

The Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

TWENTY-THIRD DEFENSE
(NO EXCEPTIONAL CASE)

Ajanta's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

TWENTY-FOURTH DEFENSE
(NO WILLFUL INFRINGEMENT)

Ajanta has not willfully infringed any valid and enforceable claim of the patents-in-suit.

TWENTY-FIFTH DEFENSE
(ESTOPPEL)

Plaintiff is estopped from asserting infringement by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

TWENTY-SIXTH DEFENSE
(WAIVER)

Plaintiff has waived any alleged defect in the way in which Ajanta's Notice Letter was served.

TWENTY-SEVENTH DEFENSE
(DAMAGES)

Plaintiff's damages, if any, are limited pursuant to 35 U.S.C. §§ 286–287.

RESERVATION OF DEFENSES

Ajanta reserves the right to assert additional defenses as may be warranted by discovery or further factual investigation in this action.

COUNTERCLAIMS

Defendants and Counterclaim Plaintiffs Ajanta Pharma Limited and Ajanta Pharma USA Inc. (collectively "Ajanta") assert the following counterclaims against Plaintiff and Counterclaim Defendant Supernus Pharmaceuticals, Inc. ("Supernus").

NATURE OF THE ACTION

1. Ajanta seeks declaratory judgment that one or more claims of U.S. Patents Nos. 8,298,576 ("the '576 patent"), 8,298,580 ("the '580 patent"), 8,663,683 ("the '683 patent"), 8,877,248 ("the '248 patent"), 8,889,191 ("the '191 patent"), 8,992,989 ("the '989 patent"),

9,549,940 ("the '940 patent"), 9,555,004 ("the '004 patent"), 9,622,983 ("the '983 patent"), and 10,314,790 ("the '790 patent") are invalid and/or not infringed.

2. The case arises under the Hatch-Waxman Act, which governs the U.S. Food & Drug Administration's ("FDA") approval of both new and generic drugs. *See* 21 U.S.C. § 355; 35 U.S.C. §§ 156, 271(e).

3. Ajanta participated in the submission of ANDA No. 215663 ("the Ajanta ANDA") to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, or importation of topiramate extended-release capsule, 25 mg, 50 mg, 100 mg, and 200 mg, described therein ("the Ajanta Products").

4. Plaintiff/Counterclaim-Defendant's TROKENDI XR® is the Reference Listed Drug ("RLD") relied upon in Ajanta's ANDA No. 215663.

5. Upon information and belief, Plaintiff/Counterclaim-Defendant caused the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents to be listed in the FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book") as allegedly covering TROKENDI XR® capsule.

6. Under the Hatch-Waxman Act, Ajanta was required to submit patent certifications regarding the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents.

7. Ajanta's ANDA No. 215663 contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certifications") that the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Ajanta Products.

8. On February 10, 2021, in accordance with 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Ajanta sent notice to Supernus Pharmaceuticals, Inc. of Ajanta's Paragraph IV certifications regarding the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents ("the Ajanta Notice Letter").

9. The Ajanta Notice Letter asserted that the claims of the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents are invalid, unenforceable, and/or will not be infringed by the Ajanta ANDA or the products or activities described therein. The Ajanta Notice Letter also expressly reserves the right to raise additional defenses and arguments.

10. The Ajanta Notice Letter included a detailed statement of the legal and factual bases for the Paragraph IV certifications included in the Ajanta ANDA pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c)(7). The detailed statement of the legal and factual bases for the Paragraph IV certifications put Plaintiff/Counterclaim-Defendant on notice that the Ajanta Products do not infringe one or more of the claims of the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents.

11. The Ajanta Notice Letter included an Offer for Confidential Access ("OCA") pursuant to 21 U.S.C. § 355(j)(5)(C)(iii), whereby Plaintiff/Counterclaim-Defendant would be provided access to information contained in the Ajanta ANDA for the purpose of allowing Plaintiff/Counterclaim-Defendant an opportunity to determine whether an infringement action could be brought.

12. Upon information and belief, Plaintiff/Counterclaim-Defendant received Ajanta's Notice Letter shortly after it was sent.

13. On March 26, 2021, Plaintiff/Counterclaim-Defendant filed a Complaint (D.I. 1) against Ajanta in the above-captioned action, alleging infringement of the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 ("Asserted Patents").

14. Plaintiff/Counterclaim-Defendant did not respond to the OCA to request access to the Ajanta ANDA for the purpose of allowing Plaintiff/Counterclaim-defendant an opportunity to determine whether an infringement action could be brought, nor did Plaintiff/Counterclaim-Defendant otherwise contact Ajanta to investigate the reasonableness of the allegations of infringement included in the Complaint (D.I. 1) prior to filing in compliance with Rule 11 of the Federal Rules of Civil Procedure.

15. Ajanta's declaratory judgment action is necessary to remove the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents as a barrier to Ajanta's market entry. The current listing in the Orange Book of the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents delays final approval of the Ajanta ANDA. But for these patents being listed in the Orange Book, the FDA could grant final approval of the Ajanta ANDA.

16. Ajanta therefore seeks a declaration that the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents are invalid and/or not infringed by the Ajanta Products.

THE PARTIES

17. Counterclaimant Ajanta Pharma Limited is a corporation organized and existing under the laws of the Republic of India, with a place of business at Ajanta House, Charkop, Kandivli West, Mumbai-400 067, Maharashtra, India.

18. Counterclaimant Ajanta Pharma USA Inc. is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at One Grand Commons, 440 US Highway 22 East, Suite 150, Bridgewater, NJ 08807.

19. Upon information and belief, Counterclaim Defendant Supernus Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 9715 Key West Avenue, Rockville, Maryland 20850.

JURISDICTION AND VENUE

20. These counterclaims arise at least under the patents laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

21. This Court has subject matter jurisdiction based on 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 21 U.S.C. § 355(j)(5)(C).

22. This Court has personal jurisdiction over Plaintiff/Counterclaim-Defendant because Plaintiff/Counterclaim-Defendant consented to jurisdiction by suing Ajanta in this District.

23. Venue is legally proper in this District under 28 U.S.C. § 1391, § 1400(b), 21 U.S.C. § 355(j)(5)(C)(i)(II), and/or by Plaintiff/Counterclaim-Defendant's choice of forum.

LEGAL FRAMEWORK AND BACKGROUND

24. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. *See* 21 U.S.C. § 355; 35 U.S.C. §§ 156, 271(e).

25. The Hatch-Waxman Act was intended to encourage generic-drug competition while leaving intact incentives for research and development of new drugs by pioneering, *i.e.*, "branded," drug companies. *See* H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984), *reprinted in* U.S.C.C.A.N. 2647, 2648.

26. To accomplish this goal, the Hatch-Waxman Act established a framework with four elements that are pertinent here.

27. First, a company seeking FDA approval of a new drug must submit a New Drug Application ("NDA") to the FDA. *See* 21 U.S.C. § 355. A brand-name drug sponsor must also inform the FDA of every patent that claims the "drug" or "method of using [the] drug" for which a claim of patent infringement could reasonably be asserted against unlicensed manufacture, use, or sale of that drug product. *See* 21 U.S.C. § 355(b)(1) and (c)(2); 21 C.F.R. § 314.53(b) and (c)(2). Upon approval of the NDA, the FDA publishes a listing of patent information for the approved drug in the Orange Book. *See* 21 U.S.C. § 355(b)(1). The new FDA-approved drug is known as the "reference-listed drug" or "RLD."

28. Second, the Hatch-Waxman Act provides a streamlined process for approving generic drugs. Before marketing a generic version of an FDA-approved drug, a generic-drug manufacturer must submit an ANDA to the FDA. An ANDA is "abbreviated" because it is generally not required to include the extensive preclinical and clinical data that must be included in an NDA for a brand-name drug. Instead, the ANDA can rely on the NDA's preclinical and clinical data if the proposed generic product is "bioequivalent" to the corresponding reference-listed drug. *See* 21 U.S.C. § 355(j)(4)(F).

29. An ANDA must also contain one of four certifications for each patent listed in the Orange Book: (i) that there are no patents listed in the Orange Book; (ii) that any listed patent has expired; (iii) that the patent will expire before the generic manufacturer is seeking to market its generic product; or (iv) that the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV); 21 C.F.R. § 314.94(a)(12). The last of these is commonly referred to as a "Paragraph IV certification."

30. An applicant submitting an ANDA containing a Paragraph IV certification must notify both the patent holder and the NDA holder of its Paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i). The Hatch-Waxman Act provides that the ANDA applicant may include an Offer for Confidential Access, a "document providing an offer of confidential access to the application that is in the custody of the applicant . . . for the purpose of determining whether an action . . . should be brought." 21 U.S.C. § 355(j)(5)(C)(iii).

31. Third, the Hatch-Waxman Act encourages prompt resolution of patent disputes by authorizing a patent owner to sue an ANDA applicant for patent infringement if the ANDA applicant makes a Paragraph IV certification. *See* 35 U.S.C. § 271(e)(2). By statute, if the patent owner brings suit within 45 days of receiving notice of the Paragraph IV certification, the suit will trigger an automatic statutory 30-month stay of approval by the FDA of the ANDA to allow the parties time to adjudicate the merits of the infringement action before the generic company launches its product. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

32. Fourth, to encourage prompt generic-market entry, the Hatch-Waxman Act grants the first generic applicant to file a substantially complete ANDA containing a Paragraph IV

certification on an Orange Book-listed patent a 180-day period of marketing exclusivity that begins on the earlier of (1) the date it begins commercial marketing of its generic-drug product, or (2) the date of a court decision finding the listed patent(s) invalid, unenforceable, or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv); *see also* 21 C.F.R. § 314.107(c)(1).

THE PATENTS

33. Upon information and belief, Counterclaim Defendant Supernus Pharmaceuticals, Inc. holds approved NDA No. 201635 for topiramate extended-release capsule under the name TROKENDI XR®.

34. On its face, the ’576 patent issued on October 30, 2012 and is titled “Sustained-Release Formulations of Topiramate.”

35. On its face, the ’580 patent issued on October 30, 2012 and is titled “Sustained-Release Formulations of Topiramate.”

36. On its face, the ’683 patent issued on March 4, 2014 and is titled “Sustained-Release Formulations of Topiramate.”

37. On its face, the ’248 patent issued on November 4, 2014 and is titled “Sustained-Release Formulations of Topiramate.”

38. On its face, the ’191 patent issued on November 18, 2014 and is titled “Sustained-Release Formulations of Topiramate.”

39. On its face, the ’989 patent issued on March 31, 2015 and is titled “Sustained-Release Formulations of Topiramate.”

40. On its face, the ’940 patent issued on January 24, 2017 and is titled “Sustained-Release Formulations of Topiramate.”

41. On its face, the ’004 patent issued on January 31, 2017 and is titled “Sustained-Release Formulations of Topiramate.”

42. On its face, the ’983 patent issued on April 18, 2017 and is titled “Sustained-Release Formulations of Topiramate.”

43. On its face, the ’790 patent issued on June 11, 2019 and is titled “Sustained-Release Formulations of Topiramate.”

44. Under 21 U.S.C. § 355(b)(1), an NDA holder must provide to the FDA the patent number and expiration date of any patent(s) that it believes “claims the drug for which the applicant submitted the application or which claims a method of using such drug.” The FDA publishes these patents in the Orange Book.

45. Upon information and belief, the ’576, ’580, ’683, ’248, ’191, ’989, ’940, ’004, ’983, and ’790 patents remain listed in the Orange Book for NDA No. 201635 for TROKENDI XR® topiramate extended-release capsule, 25 mg, 50 mg, 100 mg, and 200 mg.

FIRST COUNTERCLAIM
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’576, ’580, ’683, ’248, ’191, ’989, ’940, ’004, ’983, AND ’790 PATENTS

46. Counterclaimant Ajanta incorporates by reference, as though fully set forth herein, paragraphs 1 through 45 of the Counterclaims.

47. Plaintiff/Counterclaim-Defendant has alleged in this action that Ajanta has infringed the ’576, ’580, ’683, ’248, ’191, ’989, ’940, ’004, ’983, and ’790 patents under 35

U.S.C. § 271(e)(2) by filing ANDA No. 215663 and that the manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of Ajanta's ANDA Products would directly infringe, induce others' direct infringement of, and contribute to infringement of the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents in violation of 35 U.S.C. § 271(a), (b), and/or (c).

48. Ajanta denies that the filing of ANDA No. 215663 was an act of infringement and denies that Ajanta's manufacture, use, offer for sale, sale, or importation of Ajanta's ANDA Products would constitute direct, induced, or contributory infringement of any valid and enforceable claim of the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents.

49. Plaintiff/Counterclaim-Defendant's suit has restrained the free exploitation of Ajanta's non-infringing goods by excluding Ajanta from entering the market for the proposed generic product described in ANDA No. 215663.

50. There is an actual, immediate, and justiciable controversy between the parties regarding whether the filing of Ajanta's ANDA No. 215663 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Ajanta's ANDA Products infringes, has infringed, and/or will infringe any valid and enforceable claim of the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents.

51. Ajanta is entitled to a declaration by this Court that Ajanta has not infringed, does not infringe, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid and enforceable claim of the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents, either directly, contributorily, or by inducement and is not liable for any such alleged infringement.

52. Ajanta is entitled to further necessary or proper relief based on this Court's declaratory judgment or decree.

SECOND COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '576, '580, '683, '248, '191, '989, '940, '004, '983, AND '790 PATENTS

53. Counterclaimant Ajanta incorporates by reference, as though fully set forth herein, paragraphs 1 through 52 of the Counterclaims.

54. The '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents are invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

55. There is an actual, immediate, and justiciable controversy between the parties.

56. Ajanta is entitled to a declaration by this Court that one or more of the claims of the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents are invalid.

57. Ajanta is entitled to further necessary or proper relief based on this Court's declaratory judgment or decree.

PRAYER FOR RELIEF

WHEREFORE, Ajanta requests that the Court enter judgment in its favor against Plaintiff/Counterclaim-Defendant as follows:

(a) Declaring that the filing of Ajanta's ANDA No. 215663 has not infringed, does not infringe, and will not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '576 patent;

(b) Declaring that the filing of Ajanta's ANDA No. 215663 has not infringed, does not infringe, and will not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '580 patent;

(c) Declaring that the filing of Ajanta's ANDA No. 215663 has not infringed, does not infringe, and will not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '683 patent;

(d) Declaring that the filing of Ajanta's ANDA No. 215663 has not infringed, does not infringe, and will not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '248 patent;

(e) Declaring that the filing of Ajanta's ANDA No. 215663 has not infringed, does not infringe, and will not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '191 patent;

(f) Declaring that the filing of Ajanta's ANDA No. 215663 has not infringed, does not infringe, and will not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '989 patent;

(g) Declaring that the filing of Ajanta's ANDA No. 215663 has not infringed, does not infringe, and will not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '940 patent;

(h) Declaring that the filing of Ajanta's ANDA No. 215663 has not infringed, does not infringe, and will not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '004 patent;

(i) Declaring that the filing of Ajanta's ANDA No. 215663 has not infringed, does not infringe, and will not infringe, either directly, contributorily, or by inducement, any valid and

enforceable claim of the ’983 patent;

(j) Declaring that the filing of Ajanta’s ANDA No. 215663 has not infringed, does not infringe, and will not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the ’790 patent;

(k) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Ajanta’s ANDA Products does not, and will not, infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the ’576 patent;

(l) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Ajanta’s ANDA Products does not, and will not, infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the ’580 patent;

(m) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Ajanta’s ANDA Products does not, and will not, infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the ’683 patent;

(n) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Ajanta’s ANDA Products does not, and will not, infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the ’248 patent;

(o) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Ajanta’s ANDA Products does not, and will not, infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the ’191 patent;

(p) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Ajanta’s ANDA Products does not, and will not, infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the ’989 patent;

(q) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the

United States of Ajanta's ANDA Products does not, and will not, infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '940 patent;

(r) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Ajanta's ANDA Products does not, and will not, infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '004 patent;

(s) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Ajanta's ANDA Products does not, and will not, infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '983 patent;

(t) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Ajanta's ANDA Products does not, and will not, infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '790 patent;

(u) Declaring that the claims of the '576 patent are invalid and/or unenforceable;

(v) Declaring that the claims of the '580 patent are invalid and/or unenforceable;

(w) Declaring that the claims of the '683 patent are invalid and/or unenforceable;

(x) Declaring that the claims of the '248 patent are invalid and/or unenforceable;

(y) Declaring that the claims of the '191 patent are invalid and/or unenforceable;

(z) Declaring that the claims of the '989 patent are invalid and/or unenforceable;

(aa) Declaring that the claims of the '940 patent are invalid and/or unenforceable;

(ab) Declaring that the claims of the '004 patent are invalid and/or unenforceable;

(ac) Declaring that the claims of the '983 patent are invalid and/or unenforceable;

(ad) Declaring that the claims of the '790 patent are invalid and/or unenforceable;

(ae) Declaring that the case is exceptional within the meaning of 35 U.S.C. § 285, at least because Plaintiff/Counterclaim-Defendant failed to review Ajanta's ANDA pursuant to

Ajanta's Offer of Confidential Access to confirm the allegations of infringement Plaintiff/Counterclaim-Defendant alleged in its Complaint, and awarding Ajanta its reasonable attorney fees and costs reasonably incurred in prosecuting this action;

(af) Granting Ajanta such other and further relief as this Court deems just and appropriate; and

(ag) Ordering that Plaintiff/Counterclaim-Defendant's Complaint be dismissed with prejudice and judgment be entered in favor of Ajanta.

Dated: June 7, 2021

By: /s/ *Dennies Varughese*

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Attorneys for Defendants Ajanta Pharma Limited and Ajanta Pharma USA Inc.

CERTIFICATE OF SERVICE

I certify that on this 7th day of June, 2021, a true and correct copy of the foregoing was electronically filed with the Clerk of Court using the CM/ECF system, which sends notification of such filing to all counsel of record.

/s/ Dennies Varughese
Dennies Varughese