Theodora McCormick
Lauren B. Cooper
Robert Lufrano
EPSTEIN BECKER & GREEN, P.C.
150 College Road West, Suite 301
Princeton, New Jersey 08540
(609) 455-1540

Attorneys For Defendants
Zydus Pharmaceuticals (USA) Inc.
and Cadila Healthcare Limited

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUPERNUS PHAMACEUTICALS, INC., Plaintiff, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED, Defendants.	Civil Action No. 3:21-17104 (FLW) (LHG) *Document Electronically Filed* **ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S COMPLAINT**

Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Cadila Healthcare Limited ("Cadila") (collectively, "Defendants") for their Answer and Affirmative Defenses to the Complaint of Supernus Pharmaceuticals, Inc. ("Plaintiff") state as follows:

All averments not expressly admitted are denied.

NATURE OF THE ACTION

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: The allegations in paragraph 1 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiff's Complaint purports to be a civil action alleging infringement of United States Patent Nos. 8,298,576 ("the '576 patent"), 8,298,580 ("the '580 patent), 8,663,683 ('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") pursuant to Title 35 of the United States Code but deny that Defendants have infringed any claim of the '576 patent, the '580 patent, the '683 patent, the '248 patent, the '191 patent, the '989 patent, the '940 patent, the '004 patent, the '983 patent, or the '790 patent. Defendants further admit that what purports to be copies of the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents are attached to Plaintiff's Complaint as Exhibits, A, B, C, D, E, F, G, H, I, and J, respectively. Defendants deny all other allegations in paragraph 1.

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, MD 20850.

ANSWER: Upon information and belief, Defendants admit that Supernus Pharmaceuticals, Inc. is a Delaware corporation having its principal place of business at 9715 Key West Avenue, Rockville, MD 20850. Defendants lack knowledge or information sufficient to form a belief regarding all other allegations in paragraph 2 and, therefore, deny them.

3. Upon information and belief, Defendant Zydus USA is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 73 Route 31 North, Pennington, NJ 08534. Upon information and belief, Zydus USA is a wholly-owned subsidiary, directly or indirectly, of Defendant Zydus Cadila. Upon information and belief, Zydus USA acts at the direction of, under the control of, and for the direct benefit of Zydus Cadila and is controlled and/or dominated by Zydus Cadila.

ANSWER: Defendants admit that Zydus USA is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Defendants further admit that Zydus USA is a wholly owned subsidiary of Cadila. Defendants deny all other allegations in paragraph 3.

4. Upon information and belief, Defendant Zydus Cadila is a corporation operating and existing under the laws of India, with its principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad, Gujarat, 382481, India.

ANSWER: Defendants admit that Cadila is an Indian company having its principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad, Gujarat, 382481, India. Defendants deny all other allegations in paragraph 4.

5. Upon information and belief, Zydus filed Abbreviated New Drug Application ("ANDA") No. 216167 ("the Zydus ANDA") with the 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 capsules containing 200 mg of topiramate ("the Zydus ANDA Product").

ANSWER: Defendants admit that Zydus USA filed Abbreviated New Drug Application ("ANDA") No. 216167 with the FDA seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the 200 mg topiramate extended-release capsule product described in ANDA No. 216167 ("Zydus's Proposed ANDA Product"). Defendants deny all other allegations in paragraph 5.

6. Upon information and belief, Zydus Cadila and Zydus USA are acting cooperatively with respect to the Zydus ANDA.

ANSWER: The allegations in paragraph 6 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 216167 to FDA, seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of Zydus's Proposed

ANDA Product. Defendants further admit that ANDA No. 216167 identifies Cadila as the manufacturer of Zydus's Proposed ANDA Product. Defendants further admit that Zydus USA is a wholly owned subsidiary of Cadila. Defendants deny all other allegations in paragraph 6.

7. Upon information and belief, Zydus Cadila and Zydus USA collaborate to develop, manufacture, import, market, and distribute, and/or sell pharmaceutical products, including generic drug products (e.g., Donepezil Hydrochloride Tablets (5 mg and 10 mg), Divalproex Sodium Capsules (125 mg), and Gabapentin Tablets (600 mg and 800 mg)), that will be manufactured and sold pursuant to an ANDA throughout the United States, including throughout the State of New Jersey.

ANSWER: Defendants admit that Zydus USA is the holder of ANDA No. 090100 for donepezil hydrochloride oral tablets, 5 mg and 10 mg; ANDA No. 077100 for divalproex sodium delayed-release oral tablets, 125 mg, 250 mg, and 500 mg; and ANDA No. 078926 for gabapentin oral tablets, 600 mg and 800 mg. Defendants further admit that Cadila manufacturers pharmaceutical products, including general pharmaceutical products. Defendants further admit that Zydus USA sells pharmaceutical products, including pharmaceutical products manufactured by Cadila, in the United States, including in the State of New Jersey. Defendants deny all other allegations in paragraph 7.

8. Upon information and belief, Defendants and/or their affiliates manufacture and/or direct the manufacture of generic pharmaceutical products for which Zydus 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: Defendants admit that Zydus USA is the named ANDA applicant for certain products for which Cadila is the manufacturer. Defendants further admit that Zydus USA sells pharmaceutical products, including pharmaceutical products manufactured by Cadila. Defendants deny all other allegations in paragraph 8.

9. Upon information and belief, Zydus will market the Zydus ANDA Product throughout the United States, including in New Jersey, upon approval of the Zydus ANDA.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 216167 to FDA, seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of Zydus's Proposed ANDA Product. Defendants deny all other allegations in paragraph 9.

JURISDICTION AND VENUE

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

ANSWER: The allegations in paragraph 10 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest subject matter jurisdiction in this Court for the limited purpose of Plaintiff's claims against Defendants in this case and solely with respect to the proposed product described in ANDA No. 216167. Defendants deny all other allegations in paragraph 10.

11. 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: The allegations in paragraph 11 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court for the limited purpose of Plaintiff's claims against Defendants in this case and solely with respect to the proposed product described in ANDA No. 216167. Defendants deny all other allegations in paragraph 11.

12. 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, in Zydus's Annual Report 2020-21, Zydus states that the "Company launched 30 new products in the US generics market" during the year, filed "22 additional ANDAs [] with the USFDA during the year, taking the cumulative number of ANDA filings to 412," and received "approval for 35 ANDAs during the year," taking the "[c]umulative number of ANDA approvals at the end of the year [to] 317." Zydus Annual Report 2020-21 at 31, https://www.zyduscadila.com/public/pdf/financial/annual/Annual-Report-2020-2021.pdf (accessed September 17, 2021). The Annual Report further states that "[t]he Company is now ranked fifth amongst US generic companies based on prescriptions." Zydus Annual

Report 2020-21 at 30, https://www.zyduscadila.com/public/pdf/financial/annual/Annual-Report-2020-2021.pdf (accessed September 17, 2021). Zydus's Annual Report also states that "the Company's formulations business in the US posted a sales of Rs. 65,445 Mio. during the year, up 3%." Zydus Annual Report 2020-21 at 31, https://www.zyduscadila.com/public/pdf/financial/annual/Annual-Report-2020-2021.pdf (accessed September 17, 2021).

ANSWER: The allegations in paragraph 12 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit the Cadila Annual Report 2020-21 at 31, available at https://www.zyduscadila.com/public/pdf/financial/annual/Annual-Report-2020-2021.pdf, states "[d]uring the year gone by, the Company launched 30 new products in the US generics market," "[t]he Company received approval for 35 ANDAs during the year (incl. 11 tentative approvals)," and the "[c]umulative number of ANDA approvals at the end of the year stood at 317." Defendants further admit the Cadila Annual Report 2020-21 at 30 states "[t]he Company is now ranked fifth amongst US generic companies based on prescriptions." Defendants also admit the Cadila Annual Report 2020-21 at 31 states, "[o]verall the Company's formulations business in the US posted a sales of Rs. 64,445 Mio. during the year, up 3%." Defendants deny all other allegations in paragraph 12.

13. This Court has personal jurisdiction over Zydus USA at least because, upon information and belief: (i) Zydus USA maintains a principal place of business in New Jersey located at 73 Route 31 North, Pennington, New Jersey 08534; (ii) Zydus USA is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iii) Zydus USA, together with its parent Zydus Cadila, is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (iv) Zydus USA, together with its parent Zydus Cadila, has committed, induced, and/or contributed to acts of patent infringement in New Jersey; and (v) Zydus 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.[1]

[1] This Court also has personal jurisdiction over Defendants because Zydus Cadila and Zydus USA have previously submitted to the jurisdiction of this Judicial District and have previously availed themselves of this Judicial District by initiating lawsuits, consenting to this Judicial District's jurisdiction, and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., Merck Sharp & Dohme B. V. v. Zydus Pharm. (USA) Inc.,* No. 20-3068 (CCC)(MF) (D.N.J.), ECF No. 23 (showing that Zydus Cadila and Zydus USA did not contest

ANSWER: The allegations in paragraph 13 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court for the limited purpose of Plaintiff's claims against Defendants in this case and solely with respect to the proposed products described in ANDA No. 216167. Defendants admit that Zydus USA has a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534; that Zydus USA sells pharmaceutical products, including pharmaceutical products manufactured by Cadila, in the United States, including in the State of New Jersey; and that Zydus USA is a wholly owned subsidiary of Cadila. In response to footnote 1, Defendants admit that in *Merck Sharp & Dohme B. V. v. Zydus Pharms. (USA) Inc.*, No. 20-03068-CCC-MF (D.N.J), ECF No. 23, Defendants stated: "To the extent an answer is required, Zydus USA does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Zydus USA in this case and solely as they apply to the proposed products described in ANDA No. 214290," and that "[t]o the extent an answer is required, Zydus USA does not contest venue in this Court solely for purposes of Plaintiffs' claims against Zydus USA in this case and solely as they apply to the proposed products described in ANDA No. 214290." Defendants admit that Zydus USA filed suit in the District of New Jersey in *Zydus Pharms. (USA) Inc. v. Novartis Pharms. Corp.*, 19-21259-SRC-CLW (D.N.J.), ECF No. 1. Defendants admit that in *Takeda Pharms. Co. v. Zydus Pharms. (USA) Inc.*, No. 18-01994-FLW-TJB (D.N.J.), ECF No. 22,

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jurisdiction or venue); *Zydus Pharm. (USA) Inc. v. Novartis Pharm. Corp.,* 19-21259 (SRC)(CLW) (D.N.J.), ECF No. 1 (showing that Zydus USA availed itself of the rights, benefits, and privileges of this Court by filing a complaint in the District of New Jersey and admitted to jurisdiction and proper venue); *Takeda Pharm. Co. v. Zydus Pharm. (USA) Inc.,* No. 18-1944 (FLW)(TJB) (D.N.J.), ECF No. 22 (showing that Zydus Cadila and Zydus USA did not oppose jurisdiction or venue, and that Zydus Cadila and Zydus USA filed counterclaims); *Supernus Pharm., Inc. v. Zydus Pharm. (USA) Inc.,* No. 14-7272 (SDW)(SCM) (D.N.J.), ECF No. 29 (showing that Zydus Cadila and Zydus USA did not contest jurisdiction or venue, and that Zydus Cadila and Zydus USA filed counterclaims).

Defendants stated: "To the extent a response is required, Defendants do not contest subject matter jurisdiction, personal jurisdiction or venue in this District." Defendants admit that in *Supernus Pharms., Inc. v. Zydus Pharms. (USA) Inc.*, No. 14-7272-SDW-SCM (D.N.J.), ECF No. 29, Defendants stated: "To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court solely for purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the proposed products described in ANDA No. 207382" and "[t]o the extent an answer is required, Defendants do not contest venue in this Court solely for purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the proposed products described in ANDA No. 207382." Defendants deny all other allegations in paragraph 13.

14. According to Defendants' website and Annual Report 2020-21, Zydus USA is based in Pennington, New Jersey, and is a wholly owned subsidiary of Zydus Cadila. Zydus Website, https://zydususa.com/overview/ (accessed September 17, 2021); Zydus Annual Report 2020-21 at 83, https://www.zyduscadila.com/public/pdf/financial/annual/Annual-Report-2020-2021.pdf (accessed September 17, 2021).

ANSWER: Defendants admit that Zydus USA has a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534 and is a wholly owned subsidiary of Cadila. Defendants deny all other allegations in paragraph 14.

15. Upon information and belief, Zydus 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(s), including Zydus Cadila, and/or its 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(s), including Zydus Cadila, and/or its subsidiaries, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

ANSWER: The allegations in paragraph 15 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA is a wholly owned subsidiary of Cadila; that Cadila manufactures pharmaceutical products, including

generic pharmaceutical products; that Zydus USA has filed ANDAs seeking FDA approval to market pharmaceutical products in the United States, including products manufactured by Cadila; and that Zydus USA sells pharmaceutical products, including pharmaceutical products manufactured by Cadila, in the United States, including in the State of New Jersey. Defendants deny all other allegations in paragraph 15.

16. Upon information and belief, Zydus USA derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) throughout the United States, including in this Judicial District.

ANSWER: Defendants admit that Zydus USA sells pharmaceutical products in the United States, including in the State of New Jersey. Defendants deny all other allegations in paragraph 16.

17. Upon information and belief, Zydus 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 0100915422. New Jersey's Division of Revenue and Enterprise Services Website, https://www.njportal.com/DOR/BusinessNameSearch/Search/ BusinessName (accessed September 17, 2021). Upon information and belief, Zydus USA is registered with the State of New Jersey's Department of Health as a drug and medical device wholesaler with Registration Number 5003171. New Jersey Department of Health Website, https://healthapps. state.nj.us/fooddrug/fdList.aspx (accessed September 17, 2021). Zydus USA has, therefore, purposefully availed itself of the rights, benefits, and privileges of New Jersey's laws.

ANSWER: Defendants admit that Zydus 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 0100915422. Defendants further admit that Zydus USA is registered with the State of New Jersey's Department of Health as a drug and medical device wholesaler with Registration Number 5003171. Defendants deny all other allegations in paragraph 17.

18. This Court has personal jurisdiction over Zydus Cadila at least because, upon information and belief: (i) Zydus Cadila has purposefully directed its activities and the activities of Zydus USA at residents and corporate entities within the State of New Jersey; (ii) the claims set forth herein against Zydus Cadila arise out of or relate to those activities; (iii) Zydus Cadila'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 Zydus Cadila.

ANSWER: The allegations in paragraph 18 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court for the limited purpose of Plaintiff's claims against Defendants in this case and solely with respect to the proposed products described in ANDA No. 216167. Defendants deny all other allegations in paragraph 18.

19. Upon information and belief, Zydus Cadila derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) throughout the United States, including in this Judicial District.

ANSWER: Defendants admit that Cadila develops and manufactures pharmaceutical products, including generic pharmaceutical products, and that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Cadila, in the United States including in the State of New Jersey. Defendants deny all other allegations in paragraph 19.

20. Upon information and belief, Zydus Cadila 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 subsidiaries, including Defendant Zydus USA, 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) in concert with and/or through its subsidiaries, including Defendant Zydus USA, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

ANSWER: The allegations in paragraph 20 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Cadila manufactures pharmaceutical products, including generic pharmaceutical products; that Zydus USA has filed ANDAs seeking approval from the FDA to market pharmaceutical products in the United States, including products manufactured by Cadila; and that Zydus USA sells pharmaceutical products,

including pharmaceutical products manufactured by Cadila, in the United States, including in the State of New Jersey. Defendants deny all other allegations in paragraph 20.

21. According to Defendants' website, "Zydus Pharmaceuticals (USA) Inc. is the US generic drug division of a much larger company known as Zydus Cadila Healthcare," which is a "global, fully integrated pharmaceutical company with a presence in 50 countries and is committed to growing its presence around the world and in the United States." Zydus USA Website, https://zydususa.com/ (accessed September 17, 2021). Defendants' website states that "[w]ith the strength and worldwide reputation of Zydus Cadila supporting the US division, Zydus is looking forward to continuing its growth in the US marketplace." Zydus USA Website, https://zydususa.com/overview/ (accessed September 17, 2021). Defendants' website also states that "Zydus has filed over 120 drug master files (DMFs), received final USFDA approval on 283 Abbreviated New Drug Applications (ANDAs), received tentative USFDA approval on 28 ANDAs, and has 133 ANDAs pending approval with the USFDA." Zydus USA Website, https://zydususa.com/overview/ (accessed September 17, 2021). According to Defendants' Annual Report 2020-21, the "US was the second largest contributor to the consolidated revenues of [Zydus Cadila] with 43% share." Zydus Annual Report 2020-21 at 30, https://www.zyduscadila.com/public/pdf/financial/ annual/Annual-Report-2020-2021.pdf (accessed September 17, 2021).

ANSWER: Defendants admit the website, https://zydususa.com/, states "Zydus Pharmaceuticals (USA) Inc. is the US generic drug division of a much larger company known as Zydus Cadila Healthcare"; "Zydus Cadila is a global, fully integrated pharmaceutical company with a presence in 50 countries and is committed to growing its presence around the world and in the United States"; "[w]ith the strength and worldwide reputation of Zydus Cadila supporting the US division, Zydus is looking forward to continuing its growth in the US marketplace"; "Zydus has filed over 120 drug master files (DMFs), received final USFDA approval on 291 Abbreviated New Drug Applications (ANDAs), received tentative USFDA approval on 30 ANDAs, and has 106 ANDAs pending approval with the USFDA." Defendants further admit the Cadila Annual Report 2020-21, available at https://www.zyduscadila.com/public/pdf/financial/annual/Annual-Report-2020-2021.pdf, states "[t]he US was the second largest contributor to the consolidated revenues of the Company with 43% share." Defendants deny all other allegations in paragraph 21.

22. Upon information and belief, Zydus's tortious acts of (i) preparing and filing the Zydus ANDA 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 Zydus ANDA Product 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, offer to sell, and/or sale of the Zydus ANDA Product 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, Zydus should reasonably anticipate being sued in New Jersey.

ANSWER: Denied.

23. This Court has personal jurisdiction over Zydus at least because, upon information and belief, if the Zydus ANDA is approved, the Zydus ANDA Product will be marketed and distributed by Zydus USA at the direction and control of Zydus Cadila, 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, if Zydus succeeds in obtaining FDA approval, Zydus will sell the Zydus ANDA Product in the State of New Jersey. Zydus has previously admitted to marketing and selling drug products in the State of New Jersey and throughout the United States, or to seeking to do the same, directly and through its affiliates.[2]

ANSWER: The allegations in paragraph 23 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court for the limited purpose of Plaintiff's claims against Defendants in this case and solely with respect to the proposed products described in ANDA No. 216167. In response to Footnote 2, Defendants admit that in *Merck Sharp & Dohme B. V. v. Zydus Pharms. (USA) Inc.*, No. 20-3068-CCC-MF (D.N.J.), ECF No. 23, Defendants stated "Zydus admits that Zydus USA submitted ANDA No. 214290 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of sugammadex . . . Zydus

[2] *See, e.g., Merck Sharp & Dohme B. V. v. Zydus Pharm. (USA) Inc.,* No. 20-3068 (CCC)(MF) (D.N.J.), ECF No. 23 at 3, 5 (showing Zydus admitted to marketing and selling drug products through the United States, including the State of New Jersey, or to seeking to the do the same); *Takeda Pharm. Co. v. Zydus Pharm. (USA) Inc.,* No. 18-1944 (FLW)(TJB) (D.N.J.), ECF No. 22 at 5-6 (showing Zydus admitted to marketing and selling drug products through the United States, including the State of New Jersey, or to seeking to the do the same).

further admits that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Cadila, in the United States." Defendants admit that in *Takeda Pharms. Co. v. Zydus Pharms. (USA) Inc.*, No. 18-01994-FLW-TJB (D.N.J.), ECF No. 22, Defendants stated "Defendants admit that its ANDA Product is intended to be distributed and sold in New Jersey upon FDA approval." Defendants deny all other allegations in paragraph 23.

24. Upon information and belief, Zydus Cadila intends to benefit directly if the Zydus ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of the Zydus ANDA.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 216167 to FDA, seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of Zydus's Proposed ANDA Product. Defendants further admit that ANDA No. 216167 identifies Cadila as the manufacturer of Zydus's Proposed ANDA Product. Defendants deny all other allegations in paragraph 24.

25. Upon information and belief, Zydus USA intends to benefit directly if the Zydus ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of the Zydus ANDA.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 216167 to FDA, seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of Zydus's Proposed ANDA Product. Defendants deny all other allegations in paragraph 25.

26. Upon information and belief, Zydus USA acts at the direction, and for the benefit, of Zydus Cadila and is controlled and/or dominated by Zydus Cadila.

ANSWER: The allegations in paragraph 26 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA is a wholly owned subsidiary of Cadila. Defendants deny all other allegations in paragraph 26.

27. Upon information and belief, Zydus USA and Zydus Cadila act, operate, and/or hold themselves out to the public as a single, fully integrated business.

ANSWER: The allegations in paragraph 27 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA is a wholly owned subsidiary of Cadila. Defendants deny all other allegations in paragraph 27.

28. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because, upon information and belief, Zydus USA has a principal place of business in New Jersey and has and will continue to engage in infringing activities in New Jersey.

ANSWER: The allegations in paragraph 28 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this Court for the limited purpose of Plaintiff's claims against Defendants in this case and solely with respect to the proposed products described in ANDA No. 216167. Defendants admit that Zydus USA has a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Defendants deny all other allegations in paragraph 28.

29. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because, upon information and belief, Zydus Cadila is incorporated in India and may be sued in any judicial district in the United States in which the Defendant is subject to the court's personal jurisdiction.

ANSWER: The allegations in paragraph 29 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this Court for the limited purpose of Plaintiff's claims against Defendants in this case and solely with respect to the proposed products described in ANDA No. 216167. Defendants admit that Cadila is an Indian company. Defendants deny all other allegations in paragraph 29.

30. Venue is proper under 28 U.S.C. §§ 1391(b) and (c), and/or § 1400(b). Zydus has previously consented to venue in this Judicial District.[3]

[3] *See, e.g., Merck Sharp & Dohme B. V. v. Zydus Pharm. (USA) Inc.,* No. 20-3068 (CCC)(MF) (D.N.J.), ECF No. 23 (showing that Zydus Cadila and Zydus USA did not contest venue); *Zydus Pharm. (USA) Inc. v. Novartis Pharm. Corp.,* 19-21259 (SRC)(CLW) (D.N.J.), ECF No. 1 (showing that Zydus USA availed itself of the rights, benefits, and privileges of this Court by filing a complaint in the District of New Jersey and admitted to proper venue); *Takeda Pharm. Co. v. Zydus Pharm. (USA) Inc.,* No. 18-1944 (FLW)(TJB) (D.N.J.), ECF No. 22 (showing that

ANSWER: The allegations in paragraph 30 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this Court for the limited purpose of Plaintiff's claims against Defendants in this case and solely with respect to the proposed products described in ANDA No. 216167. In response to footnote 3, Defendants admit that in *Merck Sharp & Dohme B. V. v. Zydus Pharms. (USA) Inc.*, No. 20-03068-CCC-MF (D.N.J), ECF No. 23, Defendants stated "[t]o the extent an answer is required, Zydus USA does not contest venue in this Court solely for purposes of Plaintiffs' claims against Zydus USA in this case and solely as they apply to the proposed products described in ANDA No. 214290." Defendants admit that Zydus USA filed suit in the District of New Jersey in *Zydus Pharms. (USA) Inc. v. Novartis Pharms. Corp.*, 19-21259-SRC-CLW (D.N.J.), ECF No. 1. Defendants admit that in *Takeda Pharms. Co. v. Zydus Pharms. (USA) Inc.*, No. 18-01994-FLW-TJB (D.N.J.), ECF No. 22, Defendants stated "[t]o the extent a response is required, Defendants do not contest subject matter jurisdiction, personal jurisdiction or venue in this District." Defendants admit that in *Supernus Pharms., Inc. v. Zydus Pharms. (USA) Inc.*, No. 14-7272-SDW-SCM (D.N.J.), ECF No. 29, Defendants stated "[t]o the extent an answer is required, Defendants do not contest venue in this Court solely for purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the proposed products described in ANDA No. 207382." Defendants deny all other allegations in paragraph 30.

FACTS AS TO ALL COUNTS

31. 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.

Zydus Cadila and Zydus USA did not oppose venue); *Supernus Pharm., Inc. v. Zydus Pharm. (USA) Inc.,* No. 14-7272 (SDW)(SCM) (D.N.J.), ECF No. 29 (showing that Zydus Cadila and Zydus USA did not contest venue).

ANSWER: Defendants admit that FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") lists Supernus Pharmaceuticals Inc. as the Applicant Holder; the Proprietary Name as Trokendi XR; the Active Ingredient as Topiramate; the Dosage Form; Route of Administration as Capsule; Extended Release; Oral; and Strengths as 25 mg, 50 mg, 100 mg, and 200 mg in connection with New Drug Application ("NDA") No. 201635. Defendants deny all other allegations in paragraph 31.

32. 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: Defendants admit on information and belief that the November 2020 product insert for Trokendi XR®, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/201635s025lbl.pdf, includes the statement:

> ----------**INDICATIONS AND USAGE**----------
> TROKENDI XR® 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 (1.1); 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 (1.2)
> - Preventive treatment of migraine in patients 12 years of age and older (1.3)

Defendants deny all other allegations in paragraph 32.

33. 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: Defendants admit on information and belief that the November 2020 product insert for Trokendi XR®, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/201635s025lbl.pdf states that "[t]he recommended dose for TROKENDI XR monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily;" that "[d]osing in patient 6 to 9 years of age is based on weight;" that "[t]he recommended total daily dose of TROKENDI XR® as adjunctive therapy in adults with partial-onset seizures or Lennox-Gastaut Syndrome is 200 mg to 400 mg orally once daily and with primarily generalized tonic-clonic seizure is 400 mg orally once daily;" that "[t]he recommended total daily dose of TROKENDI XR® as adjunctive therapy for patients 6 to 16 years of age with partial-onset seizures, primarily generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome is approximately 5 mg/kg to 9 mg/kg orally once daily;" and that "[t]he recommended total daily dose of TROKENDI XR® as treatment for the preventative treatment of migraine in patients 12 years of age and older is 100 mg once daily." Defendants deny all other allegations in paragraph 33.

34. 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.

ANSWER: The allegations in paragraph 34 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Orange Book lists Supernus Pharmaceuticals Inc. as the Applicant Holder and the Proprietary Name as Trokendi XR in connection with NDA No. 201635. Defendants further admit that the Orange Book lists the '576 patent, the '580 patent, the '683 patent, the '248 patent, the '191 patent, the '989 patent,

the ’940 patent, the ’004 patent, the ’983 patent, and the ’790 patent in connection with NDA No. 201635, Topiramate (Trokendi XR) Capsule, Extended Release 200 mg. Defendants deny all other allegations in paragraph 34.

35. The ’576 patent, titled “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: The allegations in paragraph 35 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit on information and belief that what purports to be a copy of U.S. Patent No. 8,298,576 is attached to the Complaint as Exhibit A. Defendants further admit that Exhibit A is entitled “Sustained-release Formulations of Topiramate” and lists October 30, 2012 as the Date of Patent. Defendants further admit that Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed as Inventors on the face of the patent and that Supernus Pharmaceuticals, Inc. is listed as Assignee on the face of the patent. Defendants deny all other allegations of paragraph 35.

36. The ’580 patent, titled “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: The allegations in paragraph 36 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit on information and belief that what purports to be a copy of U.S. Patent No. 8,298,580 is attached to the Complaint as Exhibit B. Defendants further admit that Exhibit B is entitled “Sustained-release Formulations of Topiramate” and lists October 30, 2012 as the Date of Patent. Defendants further admit that Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed as Inventors on the face of the patent and that Supernus Pharmaceuticals, Inc. is listed as Assignee on the face of the patent. Defendants deny all other allegations of paragraph 36.

37. The '683 patent, titled "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: The allegations in paragraph 37 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit on information and belief that what purports to be a copy of U.S. Patent No. 8,663,683 is attached to the Complaint as Exhibit C. Defendants further admit that Exhibit C is entitled "Sustained-release Formulations of Topiramate" and lists March 4, 2014 as the Date of Patent. Defendants further admit that Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed as Inventors on the face of the patent and that Supernus Pharmaceuticals, Inc. is listed as Assignee on the face of the patent. Defendants deny all other allegations of paragraph 37.

38. The '248 patent, titled "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: The allegations in paragraph 38 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit on information and belief that what purports to be a copy of U.S. Patent No. 8,877,248 is attached to the Complaint as Exhibit D. Defendants further admit that Exhibit D is entitled "Sustained-release Formulations of Topiramate" and lists November 4, 2014 as the Date of Patent. Defendants further admit that Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed as Inventors on the face of the patent and that Supernus Pharmaceuticals, Inc. is listed as Assignee on the face of the patent. Defendants deny all other allegations of paragraph 38.

39. The '191 patent, titled "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: The allegations in paragraph 39 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit on information and belief that what purports to be a copy of U.S. Patent No. 8,889,191 is attached to the Complaint as Exhibit E. Defendants further admit that Exhibit E is entitled "Sustained-release Formulations of Topiramate" and lists November 18, 2014 as the Date of Patent. Defendants further admit that Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed as Inventors on the face of the patent and that Supernus Pharmaceuticals, Inc. is listed as Assignee on the face of the patent. Defendants deny all other allegations of paragraph 39.

40. The '989 patent, titled "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: The allegations in paragraph 40 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit on information and belief that what purports to be a copy of U.S. Patent No. 8,992,989 is attached to the Complaint as Exhibit F. Defendants further admit that Exhibit F is entitled "Sustained-release Formulations of Topiramate" and lists November 18, 2014 as the Date of Patent. Defendants further admit that Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed as Inventors on the face of the patent and that Supernus Pharmaceuticals, Inc. is listed as Assignee on the face of the patent. Defendants deny all other allegations of paragraph 40.

41. The '940 patent, titled "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: The allegations in paragraph 41 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit on information and belief that what purports to be a copy of U.S. Patent No. 9,549,940 is attached to the Complaint as Exhibit

G. Defendants further admit that Exhibit G is entitled "Sustained-release Formulations of Topiramate" and lists January 24, 2017 as the Date of Patent. Defendants further admit that Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed as Inventors on the face of the patent and that Supernus Pharmaceuticals, Inc. is listed as Assignee on the face of the patent. Defendants deny all other allegations of paragraph 41.

42. The '004 patent, titled "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: The allegations in paragraph 42 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit on information and belief that what purports to be a copy of U.S. Patent No. 9,555,004 is attached to the Complaint as Exhibit H. Defendants further admit that Exhibit H is entitled "Sustained-release Formulations of Topiramate" and lists January 31, 2017 as the Date of Patent. Defendants further admit that Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed as Inventors on the face of the patent and that Supernus Pharmaceuticals, Inc. is listed as Assignee on the face of the patent. Defendants deny all other allegations of paragraph 42.

43. The '983 patent, titled "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: The allegations in paragraph 43 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit on information and belief that what purports to be a copy of U.S. Patent No. 9,622,983 is attached to the Complaint as Exhibit I. Defendants further admit that Exhibit I is entitled "Sustained-release Formulations of Topiramate" and lists April 18, 2017 as the Date of Patent. Defendants further admit that Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed as Inventors on the face

of the patent and that Supernus Pharmaceuticals, Inc. is listed as Assignee on the face of the patent. Defendants deny all other allegations of paragraph 43.

44. The '790 patent, titled "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: The allegations in paragraph 44 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit on information and belief that what purports to be a copy of U.S. Patent No. 10,314,790 is attached to the Complaint as Exhibit J. Defendants further admit that Exhibit J is entitled "Sustained-release Formulations of Topiramate" and lists January 11, 2019 as the Date of Patent. Defendants further admit that Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are listed as Inventors on the face of the patent and that Supernus Pharmaceuticals, Inc. is listed as Assignee on the face of the patent. Defendants deny all other allegations of paragraph 44.

45. In 2014, Zydus submitted ANDA No. 207382 seeking approval from the FDA to engage in the commercial use, manufacture, sale, offer for sale, or importation of generic 25 mg, 50 mg, and 100 mg topiramate extended-release capsules ("Zydus Products")—a generic version of Trokendi XR®. *See Supernus Pharm., Inc. v. Zydus Pharm. (USA) Inc.,* No. 14-7272 (SDW)(SCM) (D.N.J.) ("Prior Lawsuit"), ECF No. 1. Supernus sued Zydus in the District of New Jersey asserting that the Zydus Products, if sold and marketed, would infringe certain patents. *See* Prior Lawsuit, ECF No. 1. The Prior Lawsuit against Zydus was settled, and the parties entered into settlement and license agreements (referred herein separately as "Settlement Agreement" and "License Agreement") that permitted Zydus to launch the Zydus Products on January 1, 2023, or earlier under certain circumstances. *See* https://ir.supernus.com/news-releases/news-release-details/supernus-announces-settlement-zydus-trokendi-xrr-patent (accessed September 17, 2021); https://www.sec.gov/Archives/edgar/data/1356576/000110465917031191/a17-10293_1exl0dl.htm (accessed September 17, 2021) (attached hereto as Exhibit K).

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 207382 to FDA to obtain FDA approval to engage in the commercial manufacture, use or sale of topiramate extended release capsules, 25 mg, 50 mg, and 100 mg. Defendants further admit that Plaintiff and Defendants previously engaged in litigation regarding those products, captioned as *Supernus*

Pharm., Inc. v. Zydus Pharm. (USA) Inc., No. 14-7272 (SDW)(SCM) (D.N.J.). Defendants further admit that Supernus sued Zydus USA in the District of New Jersey for alleged "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'), and 8,663,683 ('the '683 patent')." *Id.* at ECF No. 1. Defendants further admit that Supernus and Zydus entered into a Settlement Agreement and License Agreement on March 6, 2017. Defendants further admit that the March 6, 2017 License Agreement states, "Supernus hereby grants to Zydus a non-exclusive license, under the Licensed Patents to: (i) Manufacture, have Manufactured, import, use and Market the Zydus Product in, into or for the Territory, on and after the applicable Zydus License Date . . ." and contains an "Anticipated License Date" of "January 1, 2023." Defendants deny all other allegations in paragraph 45.

46. On or about August 5, 2021, Zydus sent a letter purportedly pursuant to 21 U.S.C. § 355(j)(2)(B) and Section 505(j)(2)(B) of the Food, Drug, and Cosmetic Act ("FDCA") regarding the Zydus ANDA Product and the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents (the "August 5 Notice Letter") to Supernus at 9715 Key West Ave., Rockville, MD 20850.

ANSWER: Defendants admit that Zydus USA transmitted a letter dated August 5, 2021 addressed to Supernus Pharmaceuticals, Inc. at 9715 Key West Ave., Rockville, MD 20850 notifying Supernus that Zydus USA submitted to FDA ANDA No. 216167 under 21 U.S.C. § 355(j), which included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '576 patent, the '580 patent, the '683 patent, the '248 patent, the '191 patent, the '989 patent, the '940 patent, the '004 patent, the '983 patent, and the '790 patent ("Zydus USA's August 5, 2021 Letter"). Defendants deny all other allegations in paragraph 46.

47. The August 5 Notice Letter was signed by Brij Khera, Ph.D., Executive Vice President and Chief Legal Officer of Zydus USA.

ANSWER: Admitted.

48. Upon information and belief, the Zydus ANDA identifies Trokendi XR® (topiramate extended-release capsules), 200 mg as the reference listed drug.

ANSWER: Admitted.

49. Upon information and belief, the Zydus ANDA Product is topiramate extended-release capsules, 200 mg.

ANSWER: Admitted.

50. Upon information and belief, the proposed prescribing information for the Zydus ANDA Product includes a header titled "Indications and Usage" and states that the Zydus ANDA Product is 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: Defendants deny that the allegations in paragraph 50 accurately recited the complete terms of the proposed prescribing information for ANDA No. 216167 and, therefore, deny the allegations in paragraph 50.

51. Upon information and belief, the proposed prescribing information for the Zydus ANDA Product 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: Defendants deny that the allegations in paragraph 51 accurately recited the complete terms of the proposed prescribing information for ANDA No. 216167 and, therefore, deny the allegations in paragraph 51.

52. Upon information and belief, the proposed prescribing information for the Zydus ANDA Product will also state under the header "Dosage and Administration" that the Zydus ANDA Product can be taken without regard to meals, should be swallowed whole and intact, and should not be sprinkled on food, chewed, or crushed.

ANSWER: Defendants deny that the allegations in paragraph 52 accurately recited the complete terms of the proposed prescribing information for ANDA No. 216167 and, therefore, deny the allegations in paragraph 52.

53. Upon information and belief, Zydus Cadila and Zydus USA acted in concert to develop the Zydus ANDA Product and/or seek approval from the FDA to sell the Zydus ANDA Product throughout the United States, including within this Judicial District.

ANSWER: The allegations in paragraph 53 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 216167 to FDA, seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of Zydus's Proposed ANDA Product. Defendants further admit that ANDA No. 216167 identifies Cadila as the manufacturer of Zydus's Proposed ANDA Product. Defendants further admit that Zydus USA is a wholly owned subsidiary of Cadila. Defendants deny all other allegations in paragraph 53.

54. Upon information and belief, both Zydus Cadila and Zydus USA participated in the preparation and/or filing of the Zydus ANDA.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 216167 to FDA, seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of Zydus's Proposed ANDA Product. Defendants further admit that ANDA No. 216167 identifies Cadila as the manufacturer of Zydus's Proposed ANDA Product. Defendants deny all other allegations in paragraph 54.

55. Upon information and belief, Zydus manufactured the Zydus ANDA Product for development and use in preparing and filing the Zydus ANDA.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 216167 to FDA, seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of Zydus's Proposed ANDA Product. Defendants

further admit that ANDA No. 216167 identifies Cadila as the manufacturer of Zydus's Proposed ANDA Product. Defendants deny all other allegations in paragraph 55.

56. 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: The allegations in paragraph 56 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that Zydus USA's August 5, 2021 Letter complied with applicable law. Defendants deny all other allegations in paragraph 56.

57. Upon information and belief, as of the date of the August 5 Notice Letter, Zydus was 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.

58. Contrary to Defendants' contentions in the August 5 Notice Letter, the License Agreement does not authorize or under any circumstances grant Zydus permission to manufacture, have manufactured, import, use, or market in, into, or for the United States the Zydus ANDA Product. *See* Exhibit K.

ANSWER: The allegations in paragraph 58 state legal conclusions to which no answer is required. To the extent that an answer is required, Defendants deny that the allegations in paragraph 58 accurately and completely recite the terms of Zydus USA's August 5, 2021 Letter and the License Agreement and, therefore, deny the allegations in paragraph 58.

59. The August 5 Notice Letter alleges that all of the patents in suit are invalid. The Settlement Agreement and License Agreement specifically prohibit Defendants from challenging the validity or enforceability of most of the patents in suit. *See* Exhibit K.

ANSWER: The allegations in paragraph 59 state legal conclusions to which no answer is required. To the extent that an answer is required, Defendants deny that the allegations in paragraph 59 accurately and completely recite the terms of Zydus USA's August 5, 2021 Letter, the Settlement Agreement, and the License Agreement. Defendants have not challenged the validity or enforceability of the '576 Patent, the '580 Patent, the '683 Patent, the '248 Patent, the '191 Patent, and the '989 Patent in this litigation. Defendants deny all other allegations in paragraph 59.

60. Supernus and Zydus 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, Zydus has not produced the Zydus ANDA to Supernus.

ANSWER: Defendants admit that Zydus USA's August 5, 2021 Letter contained an Offer of Confidential Access to ANDA No. 216167, pursuant to 21 U.S.C. § 355(j)(5)(C), which included a confidential disclosure agreement; that Plaintiff request that Zydus provide materials beyond the requirements of applicable law; and that Plaintiff and Zydus USA did not reach agreement to the terms for confidential access to ANDA No. 216167 before the filing of the Complaint. Defendants deny all other allegations in paragraph 60.

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

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

ANSWER: Defendants repeat and re-allege their answers to each of the foregoing paragraphs, as if fully set forth herein.

62. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '576 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '576 patent is an act of infringement of the '576 patent by Zydus of one or more claims of the '576 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

63. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 216167 to FDA, seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of Zydus's Proposed ANDA Product. Defendants deny all other allegations in paragraph 63.

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

ANSWER: Denied.

65. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus 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.

66. Upon information and belief, the factual and legal bases in the August 5 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.

67. Zydus acted without a reasonable basis for believing that it 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.

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

ANSWER: Denied.

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

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

ANSWER: Defendants repeat and re-allege their answers to each of the foregoing paragraphs, as if fully set forth herein.

70. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '580 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '580 patent is an act of infringement of the '580 patent by Zydus of one or more claims of the '580 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

71. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 216167 to FDA, seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of Zydus's Proposed ANDA Product. Defendants deny all other allegations in paragraph 71.

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

ANSWER: Denied.

73. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus 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.

74. Upon information and belief, the factual and legal bases in the August 5 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.

75. Zydus acted without a reasonable basis for believing that it 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.

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

ANSWER: Denied.

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

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

ANSWER: Defendants repeat and re-allege their answers to each of the foregoing paragraphs, as if fully set forth herein.

78. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '683 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '683 patent is an act of infringement of the '683 patent by Zydus of one or more claims of the '683 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

79. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 216167 to FDA, seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of Zydus's Proposed ANDA Product. Defendants deny all other allegations in paragraph 79.

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

ANSWER: Denied.

81. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus 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.

82. Upon information and belief, the factual and legal bases in the August 5 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.

83. Zydus acted without a reasonable basis for believing that it 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.

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

ANSWER: Denied.

FOURTH COUNT
(Defendants' Infringement of the '248 Patent)

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

ANSWER: Defendants repeat and re-allege their answers to each of the foregoing paragraphs, as if fully set forth herein.

86. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '248 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '248 patent is an act of

infringement of the '248 patent by Zydus of one or more claims of the '248 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

87. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of ANDA No. 216167.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 216167 to FDA, seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of Zydus's Proposed ANDA Product. Defendants deny all other allegations in paragraph 87.

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

ANSWER: Denied.

89. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus 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.

90. Upon information and belief, the factual and legal bases in the August 5 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.

91. Zydus acted without a reasonable basis for believing that it 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.

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

ANSWER: Denied.

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

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

ANSWER: Defendants repeat and re-allege their answers to each of the foregoing paragraphs, as if fully set forth herein.

94. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '191 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '191 patent is an act of infringement of the '191 patent by Zydus of one or more claims of the '191 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

95. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 216167 to FDA, seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of Zydus's Proposed ANDA Product. Defendants deny all other allegations in paragraph 95.

96. Upon information and belief, Zydus's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Zydus ANDA Product will infringe, directly and/or indirectly, one or more claims of the '191 patent under 35 U.S.C. § 271.

ANSWER: Denied.

97. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus 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.

98. Upon information and belief, the factual and legal bases in the August 5 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.

99. Zydus acted without a reasonable basis for believing that it 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.

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

ANSWER: Denied.

SIXTH COUNT
(Defendants' Infringement of the '989 Patent)

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

ANSWER: Defendants repeat and re-allege their answers to each of the foregoing paragraphs, as if fully set forth herein.

102. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '989 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '989 patent is an act of infringement of the '989 patent by Zydus of one or more claims of the '989 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

103. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 216167 to FDA, seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of Zydus's Proposed ANDA Product. Defendants deny all other allegations in paragraph 103.

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

ANSWER: Denied.

105. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus 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.

106. Upon information and belief, the factual and legal bases in the August 5 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.

107. Zydus acted without a reasonable basis for believing that it 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.

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

ANSWER: Denied.

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

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

ANSWER: Defendants repeat and re-allege their answers to each of the foregoing paragraphs, as if fully set forth herein.

110. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '940 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '940 patent is an act of

infringement of the '940 patent by Zydus of one or more claims of the '940 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

111. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 216167 to FDA, seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of Zydus's Proposed ANDA Product. Defendants deny all other allegations in paragraph 111.

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

ANSWER: Denied.

113. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus 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.

114. Upon information and belief, the factual and legal bases in the August 5 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.

115. Zydus acted without a reasonable basis for believing that it 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.

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

ANSWER: Denied.

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

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

ANSWER: Defendants repeat and re-allege their answers to each of the foregoing paragraphs, as if fully set forth herein.

118. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '004 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '004 patent is an act of infringement of the '004 patent by Zydus of one or more claims of the '004 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

119. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 216167 to FDA, seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of Zydus's Proposed ANDA Product. Defendants deny all other allegations in paragraph 119.

120. Upon information and belief, Zydus's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Zydus ANDA Product will infringe, directly and/or indirectly, one or more claims of the '004 patent under 35 U.S.C. § 271.

ANSWER: Denied.

121. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus 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.

122. Upon information and belief, the factual and legal bases in the August 5 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.

123. Zydus acted without a reasonable basis for believing that it 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.

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

ANSWER: Denied.

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

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

ANSWER: Defendants repeat and re-allege their answers to each of the foregoing paragraphs, as if fully set forth herein.

126. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '983 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '983 patent is an act of infringement of the '983 patent by Zydus of one or more claims of the '983 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

127. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 216167 to FDA, seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in,

and/or importation into, the United States of Zydus's Proposed ANDA Product. Defendants deny all other allegations in paragraph 127.

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

ANSWER: Denied.

129. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus 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.

130. Upon information and belief, the factual and legal bases in the August 5 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.

131. Zydus acted without a reasonable basis for believing that it 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.

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

ANSWER: Denied.

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

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

ANSWER: Defendants repeat and re-allege their answers to each of the foregoing paragraphs, as if fully set forth herein.

134. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '790 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '790 patent is an act of infringement of the '790 patent by Zydus of one or more claims of the '790 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

135. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 216167 to FDA, seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of Zydus's Proposed ANDA Product. Defendants deny all other allegations in paragraph 135.

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

ANSWER: Denied.

137. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus 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.

138. Upon information and belief, the factual and legal bases in the August 5 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.

139. Zydus acted without a reasonable basis for believing that it 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.

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

ANSWER: Denied.

PRAYER FOR RELIEF

Defendants specifically deny that Plaintiff is entitled to the general or specific relief requested against Defendants, or to any relief whatsoever, and pray for judgment in favor of Defendants dismissing this action with prejudice, and awarding Defendants their reasonable attorney's fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in their Answer and without admitting any allegations of the Complaint not otherwise admitted, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (collectively, "Defendants") aver and assert the following Affirmative Defenses to Supernus Pharmaceuticals, Inc.'s Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,298,576)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell in the United States, or importation into the United States of the proposed 200 mg topiramate extended-release capsules that are the subject of ANDA No. 216167 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any claim of the '576 patent.

SECOND AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,298,580)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell in the United States, or importation into the United States

of the proposed 200 mg topiramate extended-release capsules that are the subject of ANDA No. 216167 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any claim of the '580 patent.

THIRD AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,663,683)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell in the United States, or importation into the United States of the proposed 200 mg topiramate extended-release capsules that are the subject of ANDA No. 216167 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any claim of the '683 patent.

FOURTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,877,248)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell in the United States, or importation into the United States of the proposed 200 mg topiramate extended-release capsules that are the subject of ANDA No. 216167 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any claim of the '248 patent.

FIFTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,889,191)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell in the United States, or importation into the United States of the proposed 200 mg topiramate extended-release capsules that are the subject of ANDA No. 216167 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any claim of the '191 patent.

SIXTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,992,989)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell in the United States, or importation into the United States of the proposed 200 mg topiramate extended-release capsules that are the subject of ANDA No. 216167 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any claim of the '989 patent.

SEVENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 9,549,940)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell in the United States, or importation into the United States of the proposed 200 mg topiramate extended-release capsules that are the subject of ANDA No. 216167 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any claim of the '940 patent.

EIGHTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,549,940)

Upon information and belief, the claims of the '940 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

NINTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 9,555,004)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell in the United States, or importation into the United States of the proposed 200 mg topiramate extended-release capsules that are the subject of ANDA No. 216167 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any claim of the '004 patent.

TENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,555,004)

Upon information and belief, the claims of the '004 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

ELEVENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 9,622,983)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell in the United States, or importation into the United States of the proposed 200 mg topiramate extended-release capsules that are the subject of ANDA No. 216167 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any claim of the '983 patent.

TWELFTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,622,983)

Upon information and belief, the claims of the '983 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

THIRTEENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,314,790)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell in the United States, or importation into the United States of the proposed 200 mg topiramate extended-release capsules that are the subject of ANDA No. 216167 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any claim of the '790 patent.

FOURTEENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,314,790)

Upon information and belief, the claims of the '790 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

RESERVATION OF DEFENSES

Defendants hereby reserve any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

Dated: December 28, 2021

Respectfully submitted,

By: */s/Theodora McCormick*

Theodora McCormick
Lauren B. Cooper
Robert Lufrano
EPSTEIN BECKER & GREEN, P.C.
150 College Road West, Suite 301
Princeton, New Jersey 08540
(609) 455-1540

Of Counsel:

Michael J. Gaertner (admitted *pro hac vice*)
James T. Peterka (admitted *pro hac vice*)
Timothy F. Peterson (admitted *pro hac vice*)
LOCKE LORD LLP
111 South Wacker Drive
Chicago, IL 60606
(312) 443-0700

Counsel for Defendants
Zydus Pharmaceuticals (USA) Inc.
and Cadila Healthcare Limited

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Rule 11.2, I hereby certify that the within action is not the subject of any other action pending in any other court, or of any pending arbitration or administrative proceeding.

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: December 28, 2021

/s/Theodora McCormick
Theodora McCormick

CERTIFICATE OF SERVICE

I hereby certify that on December 28, 2021, I electronically filed the foregoing with the Clerk of the Court by using the Court's CM/ECF system, and accordingly served all parties who receive notice of the filing via the Court's CM/ECF system.

/s/Theodora McCormick
Theodora McCormick