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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASSERTIO THERAPEUTICS INC.; DEPO NF SUB, LLC; and GRÜNENTHAL GMBH, Plaintiffs, v. ALKEM LABORATORIES LIMITED and ASCEND LABORATORIES, LLC, Defendants.	Civil Action No. 19-17170 *Document Electronically Filed*

COMPLAINT

In this patent infringement action, Plaintiffs Assertio Therapeutics Inc. ("Assertio"), Depo NF Sub, LLC ("Depo NF Sub"), and Grünenthal GmbH ("Grünenthal") (collectively, "Plaintiffs"), for their complaint against Defendants Alkem Laboratories Limited ("Alkem Labs") and Ascend Laboratories, LLC ("Ascend Labs") (collectively, "Alkem" or "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, for infringement of United States Patent No. 8,309,060 ("the '060 patent"). This action relates to the Abbreviated New Drug Application ("ANDA") No. 205016, submitted upon information and belief in the name of Alkem Labs to the U.S. Food and Drug Administration ("FDA").

2. Plaintiffs seek judgment that Defendants have infringed and/or will infringe the '060 patent, which is listed in the FDA *Approved Drug Products With Therapeutic Equivalence Evaluations* ("Orange Book") as covering NUCYNTA® ER (tapentadol hydrochloride) an extended-release pain medication that is the subject of FDA-approved New Drug Application ("NDA") No. 200533. Alkem Labs has infringed the '060 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 205016, which seeks approval to manufacture and sell generic versions of NUCYNTA® ER in 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg dosage strengths before the expiration of the '060 patent.

THE PARTIES

3. Plaintiff Assertio is a corporation organized and existing under the laws of Delaware, having a principal place of business at 100 S. Saunders Road, Suite 300, Lake Forest, Illinois 60045. Assertio is an exclusive licensee of the '060 patent and holds the commercial rights with respect to NUCYNTA® ER. Under NDA No. 200533, NUCYNTA® ER is sold in the United States in 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg tablets.

4. Plaintiff Depo NF Sub is a corporation organized and existing under the laws of Delaware, having a principal place of business at 100 S. Saunders Road, Suite 300, Lake Forest, Illinois 60045. Depo NF Sub is an exclusive licensee of the '060 patent. Depo NF Sub is also the holder of NDA No. 200533 for NUCYNTA® ER, which is indicated for the management of (1)

pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate, and (2) neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

5. Plaintiff Grünenthal is a corporation organized and existing under the laws of Germany, having an address at 52078 Aachen, Zieglerstrasse 6, Germany. Grünenthal is the owner of the '060 patent.

6. On information and belief, Defendant Alkem Labs is an Indian company having its principal place of business at Alkem House, Devashish Building, Senapati Bapat Marg, Lower Parel (West), Mumbai 400013, India. On information and belief, Alkem Labs is in the business of manufacturing and selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States.

7. On information and belief, Defendant Ascend Labs is a limited liability company organized and existing under the laws of New Jersey, having a principal place of business at 339 Jefferson Road, Suite 101, Parsippany, New Jersey 07054, and is registered to do business in New Jersey under Business I.D. No. 0600158194.

8. On information and belief, Defendant Ascend Labs is a wholly owned subsidiary of The Pharma Network, LLC ("The Pharma Network"). On information and belief, The Pharma Network is a limited liability company organized and existing under the laws of New Jersey, having a principal place of business at 339 Jefferson Road, Suite 101, Parsippany, New Jersey 07054, and is registered to do business in New Jersey under Business I.D. No. 0600087295. On information and belief, The Pharma Network is wholly owned by Alkem Labs. Thus, on information and belief, Alkem Labs wholly owns Ascend Labs through its ownership of The

Pharma Network.

9. On information and belief, Defendant Ascend Labs, itself and through its parents and any subsidiaries and agents, develops, manufactures, markets, sells, and/or imports generic pharmaceutical versions of branded products in the State of New Jersey and throughout the United States.

JURISDICTION AND VENUE

10. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. This Court has personal jurisdiction over Alkem Labs with respect to this action because Alkem Labs has represented that Alkem Labs will not object to jurisdiction in this judicial district for the limited scope of matters involving, *inter alia*, ANDA No. 205016. *See, e.g.*, *Grünenthal GmbH, et al. v. Alkem Labs. Ltd., et al.*, No. 2:13-cv-4507 (CCC) (MF) (D.N.J. July 25, 2013), ECF No. 64, dated Sept. 26, 2013, at ¶ 1.

13. This Court has personal jurisdiction over Alkem Labs for the additional reasons that, *inter alia*, Alkem Labs, on information and belief, (1) has substantial, continuous, and systematic contacts with this State, including by virtue of organizing, forming, and/or maintaining at least two subsidiary companies in this State, Ascend Labs and The Pharma Network; (2) markets, sells, and/or distributes generic pharmaceutical drug products to residents of this State; (3) intends to market, sell, and/or distribute the proposed generic products described in ANDA No. 205016 to residents of this State; and (4) enjoys substantial income from sales of its

generic pharmaceutical products in this State.

14. This Court also has personal jurisdiction over Alkem Labs because it has previously been sued in this District and has not challenged personal jurisdiction and has affirmatively availed itself of the jurisdiction of this Court by filing claims and counterclaims in this District. *See, e.g.*, *AstraZeneca Pharms LP, et al. v. Alkem Labs. Ltd.*, No. 3:18-cv-16399 (D.N.J. Nov. 21, 2018); *Janssen Pharms, Inc, et al.. v. Alkem Labs. Ltd.*, No. 2:13-cv-07803 (D.N.J. Dec. 23, 2013).

15. This Court has personal jurisdiction over Ascend Labs because, *inter alia*, Ascend Labs, on information and belief, (1) is organized and existing under the laws of the State of New Jersey; (2) maintains its principal place of business in New Jersey; (3) has purposely availed itself of the privilege of doing business in New Jersey; (4) markets, sells, and/or distributes generic pharmaceutical drug products to residents of this State; and (5) intends to market, sell, and/or distribute the proposed generic products described in ANDA No. 205016 to residents of this State.

16. This Court also has personal jurisdiction over Ascend Labs because it has been sued previously in this District and has not challenged personal jurisdiction, and has affirmatively availed itself of the jurisdiction of this Court by litigating in this District. *See, e.g., Otuska Pharm. Co. v. Alkem Labs. Ltd., et al.*, No. 1:16-cv-06067 (D.N.J. Sept. 26, 2016); *AstraZeneca AB, et al. v. Alkem Labs. Ltd., et al.*, No. 3:15-cv-06609 (D.N.J. Nov. 9, 2015).

17. On information and belief, Alkem Labs makes generic pharmaceutical products in the United States and India. On information and belief, Alkem Labs directs Ascend Labs to sell these generic pharmaceutical products throughout the United States and in New Jersey specifically. On information and belief, these products include at least the following, all of which are generic versions of branded products: Amlodipine Besylate (a generic version of Norvasc®, in 2.5, 5, and 10 mg tablets); Cephalexin (a generic version of Keflex®, in 250, 500, and 750 mg capsules);

Gabapentin (a generic version of Neurontin®, in 100, 300, and 400 mg capsules); Metformin HCL (a generic version of Glucophage®, in 500, 850, and 1000 mg tablets); and Mycophenolate Mofetil (a generic version of Cellcept®, in 500 mg tablets).

18. This Court also has personal jurisdiction over Defendants because, *inter alia*, this action arises from activities of Defendants directed toward New Jersey.

19. This Court has personal jurisdiction over Alkem Labs and Ascend Labs by virtue of, *inter alia*, the fact that each has committed, aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement, and intends a future course of conduct that includes acts of patent infringement in New Jersey, that has led and/or will lead to foreseeable harm and injury to Plaintiffs.

20. On information and belief, and consistent with their practice with respect to other generic pharmaceutical products, following FDA approval of ANDA No. 205016, Defendants will market, distribute, and sell the proposed generic products described in ANDA No. 205016 throughout the United States, including in New Jersey.

21. This Court may also exercise jurisdiction over Alkem Labs pursuant to Fed. R. Civ. P. 4(k)(2) because (a) Plaintiffs' claim arise under federal law; (b) Alkem Labs is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Alkem Labs has sufficient contacts with the United States as a whole, including but not limited to preparing and submitting various ANDAs such as ANDA No. 205016 to the FDA, and manufacturing and selling pharmaceutical products and active pharmaceutical ingredients that are used in pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Alkem Labs satisfies due process.

22. For these reasons and other reasons that will be presented to the Court if jurisdiction

is challenged, the Court has personal jurisdiction over Defendants.

23. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b), because Ascend Labs is organized and resides in the State of New Jersey, and Alkem Labs is incorporated in India and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction.

THE PATENT-IN-SUIT

The '060 Patent

24. The '060 patent, entitled "ABUSE-PROOFED DOSAGE FORM," was duly and legally issued on November 13, 2012, naming Johannes Bartholomäus, Heinrich Kugelmann, and Elisabeth Arkenau-Marić as the inventors. A copy of the '060 patent is attached hereto as Exhibit 1.

25. Plaintiff Grünenthal lawfully owns all right, title, and interest in the '060 patent, including the right to sue and to recover for past infringement thereof.

26. Plaintiffs Assertio and Depo NF Sub are exclusive licensees of the '060 patent.

27. In accordance with 21 U.S.C. § 355(b)(1), the '060 patent is listed in the Orange Book in connection with NDA No. 200533 as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" NUCYNTA® ER.

ANDA NO. 205016

28. On information and belief, Alkem Labs submitted ANDA No. 205016 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale in the United States of generic tapentadol hydrochloride extended release tablets in dosage forms of

50 mg, 100 mg, 150 mg, 200 mg, and 250 mg based on the Reference Listed Drug NUCYNTA® ER, which is the subject of approved NDA No. 200533.

29. On information and belief, ANDA No. 205016 contains a "Paragraph IV" certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging, *inter alia*, that the '060 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, importation, offer for sale, or sale of the proposed generic products described in ANDA No. 205016.

30. On July 11, 2019, Grünenthal received a letter sent by Alkem Labs, dated July 10, 2019, purporting to be a "Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95)" for ANDA No. 205016 ("Notice Letter"). The Notice Letter was each received by Assertio and Depo NF Subs on or about July 11, 2019.

31. The Notice Letter indicated that an amendment to ANDA No. 205016 had recently been filed with the FDA. The Notice Letter further indicated that the amendment included "a recertification" pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '060 patent, seeking approval to engage in the commercial manufacture, use, or sale of the proposed generic products described in ANDA No. 205016 before the expiration of, *inter alia*, the '060 patent.

32. Plaintiffs commenced this action within the 45-day period after receiving the July 10, 2019 Notice Letter as described in 21 U.S.C. § 355(j)(5)(B)(iii).

33. On information and belief, the acts of Alkem Labs complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, Ascend Labs.

34. On information and belief, the acts of Ascend Labs complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, Alkem Labs.

COUNT I: INFRINGEMENT OF THE '060 PATENT

35. Plaintiffs incorporate and reallege paragraphs 1 through 34 above as though fully restated herein.

36. On information and belief, Alkem Labs filed ANDA No. 205016 seeking approval to manufacture, use, import, offer to sell and/or sell the proposed generic products described in ANDA No. 205016 in the United States before the expiration of the '060 patent.

37. On information and belief, Alkem Labs filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '060 patent are purportedly invalid, unenforceable, and/or not infringed.

38. On information and belief, in ANDA No. 205016, Alkem Labs has represented to the FDA that the proposed generic products described in ANDA No. 205016 are pharmaceutically and therapeutically equivalent to NUCYNTA® ER tablets.

39. Alkem Labs had actual knowledge of the '060 patent when the above-described amendment to ANDA No. 205016 and Paragraph IV certification concerning the '060 patent were submitted to the FDA, as evidenced by the July 10, 2019 Notice Letter.

40. Pursuant to 35 U.S.C. § 271(e)(2)(a), Alkem Labs has infringed one or more claims of the '060 patent by submitting, or causing to be submitted, ANDA No. 205016 and the accompanying Paragraph IV certification regarding the '060 patent to the FDA, seeking approval for the commercial manufacture, use, import, offer to sell or sale of the proposed generic products described in ANDA No. 205016 before the expiration of the '060 patent. This infringement entitles Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of

this Court that the effective date of approval for ANDA No. 205016 be a date which is not earlier than the expiration date of the '060 patent, including any extensions of that date.

41. The proposed generic products described in ANDA No. 205016, or the use or manufacture thereof, are covered by one or more claims of the '060 patent, including but not limited to independent claim 1, which recites, *inter alia*, an abuse-proofed, thermoformed dosage form comprising an active ingredient with abuse potential, and at least one polymer having a molecular weight of at least 0.5 million, wherein the dosage form has a breaking strength of at least 500 N, and various claims dependent therefrom.

42. On information and belief, if ANDA No. 205016 is approved by the FDA before the expiration of the '060 patent, Defendants will begin manufacturing, using, importing, offering for sale, and/or selling the proposed generic products described in ANDA No. 205016, despite the '060 patent.

43. On information and belief, if ANDA No. 205016 is approved by the FDA, Defendants will begin marketing the proposed generic products described in ANDA No. 205016 for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate and/or for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate, and doctors and patients will use each of the dosage strengths of the proposed generic products described in ANDA No. 205016 for the indication(s) marketed by Defendants.

44. On information and belief, if ANDA No. 205016 is approved by the FDA, Defendants' commercial importation, manufacture, use, sale, and/or offer for sale of the proposed

generic products described in ANDA No. 205016 before the expiration of the '060 patent will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '060 patent under 35 U.S.C. § 271(a)-(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 205016 shall be no earlier than the expiration of the '060 patent and any additional periods of exclusivity.

45. The proposed generic products described in ANDA No. 205016 constitute a material part of the inventions covered by the claims of the '060 patent.

46. On information and belief, Defendants know that the proposed generic products described in ANDA No. 205016 are especially made or especially adapted for use in the infringement of one or more claims of the '060 patent.

47. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for the proposed generic products described in ANDA No. 205016.

48. The administration of the proposed generic products described in ANDA No. 205016 by any healthcare providers, including, but not limited to doctors, physicians, and nurse practitioners ("Healthcare Providers"), and patients, will directly infringe one or more claims of the '060 patent.

49. The proposed label for the proposed generic products described in ANDA No. 205016 will explicitly instruct Healthcare Providers and patients to use the proposed generic products described in ANDA No. 205016 in a manner that will directly infringe one or more claims of the '060 patent, including but not limited to claim 28, which recites a method of treating a therapeutic condition in a patient comprising administering a dosage form according to claim 1, and dependent claim 29, which recites that the therapeutic condition is pain. NUCYNTA®

ER is indicated for, *inter alia*, the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

50. If the proposed generic products described in ANDA No. 205016 are approved by the FDA, Defendants will actively induce others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '060 patent. Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '060 patent.

51. On information and belief, Defendants' actions relating to ANDA No. 205016 complained of herein were done by and for the benefit of Defendants.

52. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '060 patent. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Adjudging, pursuant to 35 U.S.C. § 271(e)(2)(A), that Alkem Labs has infringed, literally or by the doctrine of equivalents, one or more claims of the '060 patent through the submission of ANDA No. 205016 to the FDA seeking approval to manufacture, use, import, offer to sell, and/or sell the proposed generic products described in ANDA No. 205016 in the United States before the expiration of the '060 patent.

B. Adjudging, pursuant to 35 U.S.C. § 271(a), (b), and/or (c) that Defendants' making, using, offering to sell, selling, or importing of the proposed generic products described in ANDA No. 205016 before the expiration of the '060 patent would infringe, literally or by the doctrine of equivalents, induce infringement of, and/or contribute to the infringement of one or

more claims of the ’060 patent under 35 U.S.C. § 271(a), (b), and/or (c);

C. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 205016 and the proposed generic products described therein, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the date of expiration of the ’060 patent, plus any additional periods of extension or exclusivity attached thereto;

D. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B), 283 and Fed. R. Civ. P. 65, Defendants, their officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that is the subject of ANDA No. 205016, including the proposed generic products described in ANDA No. 205016 or any other drug product that infringes the ’060 patent;

E. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B), 283 and Fed. R. Civ. P. 65, Defendants, their officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from seeking, obtaining or maintaining approval of ANDA No. 205016 until the expiration of the ’060 patent;

F. Declaring this an exceptional case and awarding Plaintiffs their attorneys’ fees and costs, as provided by 35 U.S.C. §§ 271(e)(4) and 285;

G. Awarding Plaintiffs any further appropriate relief under 35 U.S.C. § 271(e)(4); and

H. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

Dated: August 23, 2019
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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