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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

GRÜNENTHAL GMBH,

Plaintiff,

v.

TEVA PHARMACEUTICALS, INC. and
TEVA PHARMACEUTICAL INDUSTRIES
LIMITED,

Defendants.

Civil Action No. 24-6104

Document Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

In this patent infringement action, Plaintiff Grünenthal GmbH (“Grünenthal” or “Plaintiff”), for its complaint against Defendants Teva Pharmaceuticals, Inc. (“Teva Inc.”) and Teva Pharmaceutical Industries Limited (“Teva Ltd.”) (collectively, “Teva” or “Defendants”), hereby alleges 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 U.S. Patent No. 11,344,512 (“the ’512 patent”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 204972,

submitted upon information and belief in the name of Teva to the U.S. Food and Drug Administration (“FDA”).

2. Plaintiff seeks judgment that Teva has infringed and/or will infringe at least one claim of the ’512 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. Teva has infringed at least one claim of the ’512 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 204972, which seeks approval to engage in the commercial manufacture, use, and sale of generic versions of NUCYNTA[®] ER in 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg dosage strengths before the expiration of the ’512 patent.

THE PARTIES

3. Plaintiff Grünenthal is a corporation organized and existing under the laws of Germany, having a principal place of business at Zieglerstrasse 6, Aachen, Germany D-52078. Grünenthal is the owner of the ’512 patent.

4. On information and belief, Teva Ltd. is a company organized and existing under the laws of Israel, having a principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva, 4951033 Israel.

5. On information and belief, Teva Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

6. On information and belief, Teva Inc. is a wholly-owned subsidiary of Teva Ltd.

7. On information and belief, Teva maintains a physical place of business in this District, in at least Parsippany, New Jersey. Teva Inc.’s website states that its “US Headquarters”

is located in Parsippany, New Jersey. See <https://www.tevausea.com/contact-us/> (last accessed May 13, 2024).

8. On information and belief, Teva is a pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of New Jersey and throughout the United States.

9. On information and belief, Teva developed the proposed generic products that are the subject of ANDA No. 204972 and seeks regulatory approval from FDA to manufacture, market, and sell the proposed products that are the subject of ANDA No. 204972 throughout the United States, including within New Jersey.

10. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 204972, Teva will distribute and sell the generic products that are the subject of ANDA No. 204972 throughout the United States and within New Jersey.

JURISDICTION AND VENUE

11. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

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

13. This Court has personal jurisdiction over Teva Inc. because, *inter alia*, Teva Inc., on information and belief, (1) has substantial, continuous, and systematic contacts with this State; (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 that are the subject of

ANDA No. 204972 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 Teva Inc. because it has previously been sued in this District and has not challenged personal jurisdiction and/or has affirmatively availed itself of the jurisdiction of this Court by filing claims and counterclaims in this District. *See, e.g., Theravance Biopharma R&D IP, LLC, et al. v. Eugia Pharma Specialties Ltd., et al.*, Civil Action No. 23-6667 (D.N.J.); *GW Research Ltd. v. Teva Pharms., Inc., et al.*, Civil Action No. 23-3914 (D.N.J.); *Axsome Therapeutics, Inc., et al. v. Teva Pharms., Inc.*, Civil Action No. 23-1695 (D.N.J.); *Jazz Pharms. Ireland Ltd. v. Teva Pharms., Inc.*, Civil Action No. 23-1617 (D.N.J.); *Catalyst Pharms., Inc., et al. v. Teva Pharms., Inc., et al.*, Civil Action No. 23-1190 (D.N.J.); *Theravance Biopharma R&D IP, LLC, et al. v. Eugia Pharma Specialties Ltd., et al.*, Civil Action No. 23-0926 (D.N.J.); *GW Research Ltd. v. Teva Pharms., Inc., et al.*, Civil Action No. 23-0018 (D.N.J.); *Evoke Pharma, Inc. v. Teva Pharms., Inc., et al.*, Civil Action No. 22-2019 (D.N.J.); *Horizon Orphan LLC, et al. v. Teva Pharms., Inc.*, Civil Action No. 22-1382 (D.N.J.).

15. This Court has personal jurisdiction over Teva Ltd. because, *inter alia*, Teva Ltd., on information and belief, (1) has substantial, continuous, and systematic contacts with this State; (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 that are the subject of ANDA No. 204972 to residents of this State; and (4) enjoys substantial income from sales of its generic pharmaceutical products in this State.

16. On information and belief, Teva Ltd. has substantial contacts with and within New Jersey and has purposefully conducted and continues to conduct business in this judicial district, including that this judicial district is the likely destination of Teva's generic products. On

information and belief, Teva has “establish[ed] its North America headquarters in Parsippany-Troy Hills, including more than 1,000 high-wage jobs.” <https://www.tevapharm.com/news-and-media/latest-news/teva-and-new-jersey-governor-murphy-formalize-north-america-headquarters-move-with-ceremony-in-israel/> (last accessed May 13, 2024).

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

18. This Court has personal jurisdiction over Teva by virtue of, *inter alia*, the fact that it 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 Plaintiff.

19. On information and belief, and consistent with its practice with respect to other generic pharmaceutical products, following FDA approval of ANDA No. 204972, Teva will market, distribute, and sell the proposed generic products that are the subject of ANDA No. 204972 throughout the United States, including in New Jersey.

20. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Teva.

21. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b), at least because Teva Inc. resides in the State of New Jersey.

22. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b), at least because Teva Ltd. is incorporated in Israel and may be sued in any judicial district in the United States.

THE PATENT-IN-SUIT

23. On May 31, 2022, the U.S. Patent and Trademark Office duly and legally issued the '512 patent, entitled “Titration of Tapentadol,” naming Claudia Lange and Ferdinand

Rombout as the inventors. A true and correct copy of the '512 patent is attached hereto as Exhibit A. The claims of the '512 patent are valid and enforceable.

24. Plaintiff Grünenthal lawfully owns all right, title, and interest in the '512 patent, including the right to sue and to recover for past infringement thereof.

25. Collegium Pharmaceutical, Inc. is the holder of NDA No. 200533 for NUCYNTA[®] ER, which is indicated for the management of (1) severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate, and (2) severe and persistent neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate. In accordance with 21 U.S.C. § 355(b)(1), the '512 patent is listed in the Orange Book in connection with NDA No. 200533 as a “patent for 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. 204972

26. On information and belief, Teva submitted ANDA No. 204972 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 strengths 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.

27. On information and belief, ANDA No. 204972 contains a “Paragraph IV” certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging, *inter alia*, that the '512 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 that are the subject of ANDA No. 204972.

28. Teva sent a letter dated March 28, 2024, with the heading “Re: Notice of Amended ANDA No. 204972 Tapentadol Extended-Release Tablets with Paragraph IV Certification Concerning U.S. Patent No. 11,344,512” (“Notice Letter”) to Grünenthal.

29. The Notice Letter indicated that an amendment to ANDA No. 204972 had recently been filed with the FDA seeking approval to engage in the commercial manufacture, use, or sale of the proposed generic products that are the subject of ANDA No. 204972 before the expiration of, *inter alia*, the ’512 patent.

30. Plaintiff commenced this action within the 45-day period after receiving the March 28, 2024 Notice Letter as described in 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I (INFRINGEMENT OF THE ’512 PATENT)

31. Plaintiff incorporates and realleges paragraphs 1 through 30 above as though fully restated herein.

32. On information and belief, Teva filed ANDA No. 204972 seeking approval to manufacture, use, import, offer to sell, and/or sell the proposed generic products that are the subject of ANDA No. 204972 in the United States before the expiration of the ’512 patent.

33. On information and belief, Teva 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 ’512 patent are purportedly invalid, unenforceable, and/or not infringed.

34. On information and belief, in ANDA No. 204972, Teva has represented to the FDA that the proposed generic products that are the subject of ANDA No. 204972 are pharmaceutically and therapeutically equivalent to NUCYNTA[®] ER tablets.

35. Teva had actual knowledge of the '512 patent when the above-described amendment to ANDA No. 204972 and Paragraph IV certification concerning the '512 patent were submitted to the FDA, as evidenced by the March 28, 2024 Notice Letter.

36. Pursuant to 35 U.S.C. § 271(e)(2)(a), Teva has infringed one or more claims of the '512 patent by submitting, or causing to be submitted, ANDA No. 204972 and the accompanying Paragraph IV certification regarding the '512 patent to the FDA, seeking approval for the commercial manufacture, use, import, offer to sell or sale of the proposed generic products that are the subject of ANDA No. 204972 before the expiration of the '512 patent. This infringement entitles Plaintiff 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. 204972 be a date that is not earlier than the expiration date of the '512 patent, including any extensions of that date.

37. The proposed generic products that are the subject of ANDA No. 204972, or the use or manufacture thereof, are covered by one or more claims of the '512 patent, including but not limited to independent claim 1, which recites, *inter alia*, a method of treating pain with a lower incidence of somnolence in a subject in need thereof, said method comprising orally administering to said subject: (i) a first dose of tapentadol of 50 mg±5% or 100 mg±5% twice daily (bid) during a first administration interval of at least 1-3 days; (ii) a second dose of tapentadol calculated by increasing said first dose by 50 mg to 100 mg±5% or 150 mg±5% twice daily (bid), respectively, during a second administration interval of at least 3-11 days following said first administration interval; and (iii) a third dose of tapentadol calculated by increasing said second dose by 50 mg to 150 mg±5% or 200 mg±5% twice daily (bid), respectively, during a third administration interval of at least 3-14 days following said second administration interval, and various claims dependent therefrom.

38. On information and belief, if ANDA No. 204972 is approved by the FDA before the expiration of the '512 patent, Teva will begin manufacturing, using, importing, offering for sale, and/or selling the proposed generic products that are the subject of ANDA No. 204972, despite the '512 patent.

39. On information and belief, if ANDA No. 204972 is approved by the FDA, Teva will begin marketing the proposed generic products that are the subject of ANDA No. 204972 for the management of (1) severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate, and (2) severe and persistent neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate, and doctors and patients will use each of the dosage strengths of the proposed generic products that are the subject of ANDA No. 204972 for the indication(s) marketed by Teva.

40. On information and belief, if ANDA No. 204972 is approved by the FDA, Teva's commercial importation, manufacture, use, sale, and/or offer for sale of the proposed generic products that are the subject of ANDA No. 204972 before the expiration of the '512 patent will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '512 patent under 35 U.S.C. § 271(a)-(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 204972 shall be no earlier than the expiration of the '512 patent and any additional periods of exclusivity.

41. On information and belief, the proposed generic products that are the subject of ANDA No. 204972 and their use according to Teva's proposed package insert constitute a material part of the inventions covered by the claims of the '512 patent.

42. On information and belief, Teva knows that the proposed generic products that are the subject of ANDA No. 204972 and their use according to Teva's proposed package insert are especially made or especially adapted for use in the infringement of one or more claims of the '512 patent.

43. On information and belief, Teva has had and continues to have knowledge that there is no substantial non-infringing use for the proposed generic products that are the subject of ANDA No. 204972.

44. On information and belief, the administration of the proposed generic products that are the subject of ANDA No. 204972 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 '512 patent.

45. On information and belief, the proposed label for the proposed generic products that are the subject of ANDA No. 204972 will explicitly instruct Healthcare Providers and patients to use the proposed generic products that are the subject of ANDA No. 204972 in a manner that will directly infringe one or more claims of the '512 patent, including but not limited to claim 1, which recites a method of treating pain in a subject. NUCYNTA[®] ER is indicated for, *inter alia*, the management of (1) severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate, and (2) severe and persistent neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

46. On information and belief, if the proposed generic products that are the subject of ANDA No. 204972 are approved by the FDA, Teva will actively induce others including, *e.g.*,

Healthcare Providers and patients, to directly infringe one or more claims of the '512 patent. Since at least the date of the Notice Letter, Teva has acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '512 patent.

47. On information and belief, Teva's actions relating to ANDA No. 204972 complained of herein were done by and for the benefit of Teva.

48. Unless Teva is enjoined by the Court, Plaintiff will be substantially and irreparably harmed by Teva's infringement of the '512 patent. Plaintiff does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. Adjudging, pursuant to 35 U.S.C. § 271(e)(2)(A), that Teva has infringed, literally or by the doctrine of equivalents, one or more claims of the '512 patent through the submission of ANDA No. 204972 to the FDA seeking approval to manufacture, use, import, offer to sell, and/or sell the proposed generic products that are the subject of ANDA No. 204972 in the United States before the expiration of the '512 patent.

B. Adjudging, pursuant to 35 U.S.C. § 271(a), (b), and/or (c) that Teva's making, using, offering to sell, selling, or importing of the proposed generic products that are the subject of ANDA No. 204972 before the expiration of the '512 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 '512 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. 204972 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 '512 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 Federal Rule of Civil Procedure 65, Teva and all 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 Teva, and Teva's 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. 204972, including the proposed generic products that are the subject of ANDA No. 204972 or any other drug product that infringes the '512 patent;

E. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B), 283, and Federal Rule of Civil Procedure 65, Teva and all 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 Teva, and Teva's successors and assigns, from seeking, obtaining, or maintaining approval of ANDA No. 204972 until the expiration of the '512 patent;

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

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

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

Dated: May 13, 2024
Newark, New Jersey

Respectfully submitted,

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