IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEUROCRINE BIOSCIENCES, INC.

Plaintiff,

v.

TEVA PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS DEVELOPMENT, INC., TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Neurocrine Biosciences, Inc. ("Neurocrine"), by way of Complaint against Defendants Teva Pharmaceuticals, Inc. ("Teva Pharmaceuticals"), Teva Pharmaceuticals Development, Inc. ("Teva Development"), Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Industries") (collectively "Teva" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent No. 11,311,532 ("the '532 patent" or "the patent-in-suit"), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Teva's filing of an Abbreviated New Drug Application ("ANDA") No. 215984 under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, import, offer to sell and/or sell Valbenazine Capsules, 40 mg and 80 mg ("Teva's generic products") before the expiration of the patent-in-suit.

2. Neurocrine filed three separate actions involving the same ANDA No. 215984 in

this Court for patent infringement. The first suit alleged infringement of U.S. Patent Nos. 10,065,952 ("the '952 patent"), 10,844,058 ("the '058 patent"), 10,851,103 ("the '103 patent"), 10,851,104 ("the '104 patent"), 10,857,137 ("the '137 patent"), 10,857,148 ("the '148 patent"), 10,874,648 ("the '648 patent"), 10,906,902 ("the '902 patent"), 10,906,903 ("the '903 patent"), 10,912,771 ("the '771 patent"), 10,919,892 ("the '892 patent"), 10,940,141 ("the '141 patent") and 10,952,997 ("the '997 patent") (collectively, "First Suit Patents") in *Neurocrine Biosciences, Inc. v. Teva Pharmaceuticals, Inc. et al.*, No. 1:21-cv-01043-MN (D. Del. filed July 16, 2021) ("the First Suit"). The second suit alleged infringement of U.S. Patent No. 10,993,941 ("the '941 patent" or "Second Suit Patent") in *Neurocrine Biosciences, Inc. v. Teva Pharmaceuticals, Inc. et al.*, No. 1:21-cv-01148-MN (D. Del. filed August 6, 2021) ("the Second Suit"). The third suit alleged infringement of U.S. Patent Nos. 11,026,931 ("the '931 patent"), 11,026,939 ("the '939 patent") and 11,040,029 ("the '029 patent") (collectively, "Third Suit Patents") in *Neurocrine Biosciences, Inc. v. Teva Pharmaceuticals, Inc. et al.*, No. 1:22-cv-00092-MN (D. Del. filed January 21, 2022) ("the Third Suit").

3. The First Suit was filed in response to a letter from Teva dated June 3, 2021 ("Teva's First Notice Letter"), purporting to include a "Notice of ANDA No. 215984 Valbenazine Capsules, 40 mg and 80 mg; With Paragraph IV Certification Concerning [the First Suit Patents]." The First Suit included counts of infringement of the First Suit Patents. Teva's First Notice Letter defined Teva as Teva Development.

4. The Second Suit was filed in response to a second letter from Teva dated June 24, 2021 ("Teva's Second Notice Letter"), purporting to include a "Notice of ANDA No. 215984 Valbenazine Capsules, 40 mg and 80 mg; With Paragraph IV Certification Concerning [the Second Suit Patent]." The Second Suit included a count of infringement of the Second Suit Patent. Teva's Second Notice Letter defined Teva as Teva Development.

5. The Third Suit was filed in response to a third letter from Teva dated December 9, 2021 ("Teva's Third Notice Letter"), purporting to include a "Notice of ANDA No. 215984 Valbenazine Capsules, 40 mg and 80 mg; With Paragraph IV Certification Concerning [the Third Suit Patents]." The Third Suit included counts of infringement of the Third Suit Patents. Teva's Third Notice Letter defined Teva as Teva Development.

6. This complaint is filed in response to a new, fourth letter from Teva dated June 9, 2022 ("Teva's Fourth Notice Letter"), purporting to include a "Notice of ANDA No. 215984 Valbenazine Capsules, 40 mg and 80 mg; With Paragraph IV Certification Concerning [the '532 patent]" pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Teva's Fourth Notice Letter stated that Teva had filed ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products before the expiration of the patent-in-suit. Teva's Fourth Notice Letter defined Teva as Teva Development.

THE PARTIES

7. Neurocrine is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 12780 El Camino Real, San Diego, CA 92130.

8. Neurocrine is engaged in the business of researching, developing and bringing to market innovative pharmaceutical products for the treatment of neurological, endocrine and psychiatric disorders.

9. Upon information and belief, Teva Development was incorporated in Delaware on October 23, 2020, under File Number 3960741.

10. Upon information and belief, Teva Pharmaceuticals was incorporated in Delaware on October 23, 2020, under File Number 3960741.

11. In its January 5, 2022 answers in the First Suit and Second Suit Teva stated that "Teva Development was incorporated on October 23, 2020 and became Teva [Pharmaceuticals,] Inc.

through a name change on June 23, 2021." Defendants Teva Pharmaceuticals, Inc., Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc.'s Answer, Affirmative Defenses, and Counterclaims to Complaint at 4, *Neurocrine Biosciences, Inc. v. Teva Pharmaceuticals, Inc. et al.*, No. 1:21-cv-01148-MN (D. Del. 2021), D.I. 13; Defendants Teva Pharmaceuticals, Inc., Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc.'s Answer, Affirmative Defenses, and Counterclaims to Complaint at 4, *Neurocrine Biosciences, Inc. v. Teva Pharmaceuticals, Inc. et al.*, No. 1:21-cv-01043-MN (D. Del. 2021), D.I. 12. In its May 31, 2022 answer in the Third Suit Teva stated that "Teva Development was incorporated in Delaware on October 23, 2020, under File Number 3960741. Teva further admits that Teva Development became Teva Pharmaceuticals[, Inc.] through a name change on June 23, 2021." Defendants Teva Pharmaceuticals, Inc., Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc.'s Answer, Affirmative Defenses, and Counterclaims to Complaint at 5, *Neurocrine Biosciences, Inc. v. Lupin Ltd. et al.*, No. 1:21-cv-01042-MN (D. Del. 2022) (consolidated), D.I. 44. In Teva's Fourth Notice Letter, however, Teva once again identifies Teva Development as the entity providing notice and further states that FDA has assigned "Teva's ANDA," where "Teva" is defined as "Teva Development," to be ANDA No. 215984.

12. Upon information and belief, Teva Pharmaceuticals is a corporation organized under the laws of Delaware and its principal place of business is located at 400 Interpace Parkway, Suite A1, Parsippany, NJ 07054.

13. Upon information and belief, Teva Development is a corporation organized under the laws of Delaware and its principal place of business is located at 400 Interpace Parkway, Suite A1, Parsippany, NJ 07054.

14. Upon information and belief, Teva USA is a corporation organized under the laws of Delaware and its principal place of business is located at 400 Interpace Parkway, Suite A1,

Parsippany, NJ 07054.

15. Upon information and belief, Teva Industries is a corporation organized under the laws of Israel and its principal place of business is located at 5 Basel Street, Petach Tikva, 49131, Israel.

16. Upon information and belief, Teva Pharmaceuticals is a wholly-owned subsidiary of Teva Industries.

17. Upon information and belief, Teva Development is a wholly-owned subsidiary of Teva Industries.

18. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Industries.

19. Upon information and belief, Teva Pharmaceuticals, Teva Development and Teva USA are generic pharmaceutical companies that, in coordination with each other and Teva Industries or at the direction of Teva Industries, develop, manufacture, market and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

21. This Court has personal jurisdiction over Teva Pharmaceuticals. Upon information and belief, Teva Pharmaceuticals is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva Pharmaceuticals directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Teva Pharmaceuticals purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Teva's generic products.

22. This Court has personal jurisdiction over Teva Development. Upon information

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