

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEUROCRINE BIOSCIENCES, INC.

Plaintiff,

v.

SANDOZ INTERNATIONAL GMBH,
SANDOZ INC., SANDOZ AG, CRYSTAL
PHARMACEUTICAL (SUZHOU) CO., LTD.
and CRYSTAL PHARMATECH CO., LTD.

Defendants.

Civil Action No. _____

**COMPLAINT FOR PATENT
INFRINGEMENT**

Neurocrine Biosciences, Inc. (“Neurocrine”), by way of Complaint against Defendants Sandoz Inc., Sandoz AG and Sandoz International GmbH (“Sandoz Int’l”) (collectively, “Sandoz”), and Crystal Pharmaceutical (Suzhou) Co., Ltd. (“Crystal Suzhou”) and Crystal Pharmatech Co., Ltd. (“Crystal Pharmatech”) (collectively “Crystal”) (all of the foregoing collectively, “Defendants”) allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 8,039,627, (“the ’627 patent”), 8,357,697 (“the ’697 patent”) and 11,311,532 (“the ’532 patent”) (collectively, “the patents-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 Defendants’ filing of

an Abbreviated New Drug Application (“ANDA”) No. 215962 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 tosylate capsules, equivalent to 40 mg and 80 mg of valbenazine base (“Defendants’ generic products”) before the expiration of the patents-in-suit.

2. Neurocrine filed a separate action involving the same ANDA No. 215962 in this Court for patent 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. Crystal Pharmaceutical (Suzhou) Co., Ltd. et al.*, No. 1:21-cv-01067-MN (D. Del. filed July 23, 2021) (“the First Suit”), which on April 19, 2022 was consolidated in this Court in *Neurocrine Biosciences, Inc. v. Lupin Limited et al.*, No. 1:21-cv-01042-MN (consolidated).

3. The First Suit was filed in response to two letters from Crystal dated June 9, 2021 (“the First Notice Letter”) and June 11, 2011 (“the Second Notice Letter”), which stated that ANDA No. 215962 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the First Suit patents are invalid, unenforceable or will not be infringed by the manufacture, use, sale, offer for sale and/or importation of Defendants’ generic products. The First Suit included counts of infringement of the First Suit Patents.

4. Neurocrine also filed a separate action involving the same ANDA No. 215962 in this Court for patent infringement of U.S. Patent Nos. 10,993,941 (“the ’941 patent”),

11,026,931 (“the ’931 patent”), 11,026,939 (“the ’939 patent”) and 11,040,029 (“the ’029 patent”) (collectively, “Second Suit Patents”) in *Neurocrine Biosciences, Inc. v. Crystal Pharmaceutical (Suzhou) Co., Ltd. et al.*, No. 1:21-cv-01464-MN (D. Del. filed Oct. 18, 2021) (“the Second Suit”), which on April 19, 2022 was consolidated in this Court in *Neurocrine Biosciences, Inc. v. Lupin Limited et al.*, No. 1:21-cv-01042-MN (consolidated).

5. The Second Suit was filed in response to a third letter from Crystal dated September 3, 2021 (“the Third Notice Letter”), which stated that ANDA No. 215962 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the Second Suit Patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, import, offer to sell and/or sale of Defendants’ generic products. The Second Suit included counts of infringement of the Second Suit Patents.

6. This complaint is filed in response to a new, fourth letter regarding ANDA No. 215962 purportedly from Sandoz dated July 14, 2022 (“the Fourth Notice Letter”), purporting to include a “Paragraph IV Patent Certification Notice U.S. Patent Nos. [patents-in-suit] Sandoz Inc. ANDA 215962 Ingrezza® (Valbenazine) Capsules 40 mg and 80 mg” pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95. The Fourth Notice Letter states that ANDA No. 215962 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the patents-in-suit are invalid, unenforceable and/or will not be infringed by the manufacture, use, import, offer to sell and/or sale of Defendants’ generic products.

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, Sandoz Int'l is a corporation organized under the laws of Germany and its principal place of business is located at Industriestrasse 25, 83607 Holzkirchen, Germany.

10. Upon information and belief, Sandoz Inc. is a corporation organized under the laws of Delaware (file number 7944830) and its principal place of business is located at 100 College Rd. West, Princeton, NJ 08540. Upon information and belief, Sandoz Inc. is a wholly-owned subsidiary of Sandoz Int'l.

11. Upon information and belief, Sandoz AG is a corporation organized under the laws of Switzerland and its principal place of business is located at Lichtstr. 35, CH-4056 Basel, Switzerland. Upon information and belief, Sandoz AG is a wholly-owned subsidiary of Sandoz Int'l.

12. Upon information and belief, Sandoz Inc. and Sandoz AG are generic pharmaceutical companies that, in coordination with each other and Sandoz Int'l or at the direction of Sandoz Int'l, develop, manufacture, market and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

13. Upon information and belief, Crystal Suzhou is a corporation organized under the laws of China and its principal place of business is located at B4-301, Biobay, 218 Xinghu Street, Suzhou Industrial Park, China, 215123.

14. Upon information and belief, Crystal Pharmatech is a corporation organized under the laws of China and its principal place of business is located at B4-101, Biobay 218 Xinghu Street, Suzhou Industrial Park, Suzhou, Jiangsu Province, China, 215123.

15. Upon information and belief, Crystal Suzhou is a wholly-owned subsidiary of Crystal Pharmatech.

16. Upon information and belief, Crystal Suzhou and Crystal Pharmatech are generic pharmaceutical companies that, in coordination with each other or at the direction of Crystal Pharmatech, develop, manufacture, market and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

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

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

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

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