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Neurocrine Biosciences, Inc.*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

NEUROCRINE BIOSCIENCES, INC.

Plaintiff,

v.

ZYDUS PHARMACEUTICALS (USA) INC.,  
ZYDUS WORLDWIDE DMCC, ZYDUS  
HEALTHCARE (USA) LLC and CADILA  
HEALTHCARE LIMITED

Defendants.

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR PATENT INFRINGEMENT**

Neurocrine Biosciences, Inc. (“Neurocrine”), by way of Complaint against Defendants Zydus Pharmaceuticals (USA) Inc. (“Zydus Pharmaceuticals”), Zydus Worldwide DMCC (“Zydus Worldwide”), Zydus Healthcare (USA) LLC (“Zydus Healthcare”) and Cadila Healthcare Limited d/b/a Zydus Cadila (“Zydus Cadila”) (collectively “Zydus” or “Defendants”), alleges as follows:

### **NATURE OF THE ACTION**

1. This is a civil action 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, “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 Zydus’ filing of an Abbreviated New Drug Application (“ANDA”) No. 216137 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 (“Zydus’ generic products”) before the expiration of the patents-in-suit.

### **THE PARTIES**

2. 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.

3. 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.

4. Upon information and belief, Zydus Pharmaceuticals is a corporation organized under the laws of New Jersey and its principal place of business is located at 73 Route 31 N., Pennington, New Jersey 08534.

5. Upon information and belief, Zydus Worldwide is a corporation organized under the laws of the United Arab Emirates and its principal place of business is located at Armada Tower 2, P2, Cluster P, 9 Floor, Office 908, Al Thanyah 5, Hadaeq Mohammed Bin Rashid, Dubai, United Arab Emirates.

6. Upon information and belief, Zydus Healthcare is a company organized under the laws of the state of Delaware and its principal place of business is located at 73 Route 31 N., Pennington, NJ, 08534-3601.

7. Upon information and belief, Zydus Cadila is a corporation organized under the laws of the Republic of India and its principal place of business is located at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad, Gandinagar GJ 382481 IN.

8. Upon information and belief, Zydus Pharmaceuticals is a subsidiary of Zydus Cadila.

9. Upon information and belief, Zydus Worldwide is a subsidiary of Zydus Cadila.

10. Upon information and belief, Zydus Healthcare is a subsidiary of Zydus Cadila.

### **JURISDICTION AND VENUE**

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

12. Plaintiff believes this case belongs in Delaware but is concurrently filing a case in this district out of an abundance of caution.

13. This Court has personal jurisdiction over Zydus Pharmaceuticals because, upon information and belief, Zydus Pharmaceuticals directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district.

14. This Court has personal jurisdiction over Zydus Worldwide because, upon information and belief, Zydus Worldwide directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district.

15. Upon information and belief, Zydus Worldwide is the holder of ANDA No. 216137.

16. This Court has personal jurisdiction over Zydus Healthcare because, upon information and belief, Zydus Healthcare directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district.

17. This Court has personal jurisdiction over Zydus Cadila because, upon information and belief, Zydus Cadila directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district.

18. Upon information and belief, Zydus Pharmaceuticals, Zydus Worldwide, Zydus Healthcare and Zydus Cadila hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

19. Upon information and belief, Zydus Pharmaceuticals, Zydus Worldwide, Zydus Healthcare and Zydus Cadila have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 216137.

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

21. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Zydus Worldwide is incorporated in the United Arab Emirates and may be sued in any judicial district in the United States.

22. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Zydus Pharmaceuticals is incorporated in the state of New Jersey.

23. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because, upon information and belief, Zydus Healthcare's principal place of business is located in New Jersey.

24. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Zydus Cadila is incorporated in the Republic of India and may be sued in any judicial district in the United States.

### **FACTUAL BACKGROUND**

#### **The NDA**

25. Neurocrine is the holder of New Drug Application ("NDA") No. 209241 for INGREZZA<sup>®</sup> (valbenazine) Capsules in 40, 60, and 80 mg dosage forms ("INGREZZA<sup>®</sup> Capsules").

26. The FDA approved NDA No. 209241 on April 11, 2017.

27. INGREZZA<sup>®</sup> Capsules are prescription drugs approved for the treatment of tardive dyskinesia. Valbenazine, which is present as the tosylate salt, is the active ingredient in INGREZZA<sup>®</sup> Capsules.

28. Valbenazine Capsules are marketed in the United States under the trademark INGREZZA<sup>®</sup>.

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