IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG and LTS LOHMANN THERAPIE-SYSTEME AG Plaintiffs, v. ZYDUS NOVELTECH INC., ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LTD. (d/b/a ZYDUS CADILA) Defendants.	:	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG and LTS Lohmann Therapie-Systeme AG, for their Complaint against defendants Zydus Noveltech Inc., Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd. allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Plaintiff Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

4. Plaintiff Novartis Pharma AG ("Pharma AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

5. Plaintiff LTS Lohmann Therapie-Systeme AG ("LTS") is a corporation organized and existing under the laws of Germany, having an office and place of business at Lohmannstraße 2, D-56626 Andernach, Germany.

6. On information and belief, defendant Zydus Noveltech Inc. ("Zydus Noveltech") is a corporation organized and existing under the laws of the State of New Jersey with a principal place of business at 1775 Williston Road, Suite 210, So. Burlington, VT, 05403.

7. On information and belief, defendant Zydus Pharmaceuticals (USA) Inc. ("Zydus Pharmaceuticals") is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business located at 73 Route 31 N., Pennington, NJ 08534.

8. On information and belief, defendant Cadila Healthcare Ltd. (d/b/a Zydus Cadila) ("Cadila") is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015 Gujarat, India. On information and belief, Zydus International Private Ltd., a wholly-owned subsidiary of Cadila, owns 85% of Zydus Noveltech. On information and belief, Zydus Pharmaceuticals is a wholly-owned subsidiary of Zydus International Private Ltd.

9. On information and belief, the acts of Zydus Noveltech complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of Zydus Pharmaceuticals and Cadila.

10. Defendants Zydus Noveltech, Zydus Pharmaceuticals, and Cadila are referred to collectively herein as "Zydus."

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

12. On information and belief, Zydus Noveltech is involved in the development, manufacture, marketing, sale, and distribution of generic pharmaceuticals. On information and belief, Zydus Noveltech, Zydus Pharmaceuticals, and Cadila each act as agents of each other and/or work in concert with each other to further the aims of Cadila. On information and belief, Zydus Noveltech, which is responsible for, *inter alia*, developing and submitting abbreviated new drug applications ("ANDAs") to the U.S. Food and Drug Administration ("FDA"), relies on contributions from Zydus Pharmaceuticals and Cadila.

13. On information and belief, Zydus Pharmaceuticals is the United States division of Cadila. On information and belief, Zydus Noveltech acts on behalf of Cadila in the United States to develop and market drug products.

14. On information and belief, Zydus Noveltech, Zydus Pharmaceuticals, and Cadila are in the business of manufacturing, marketing, importing into the United States and/or selling pharmaceutical drug products, including generic drug products. On information and belief, Cadila and Zydus Noveltech directly or through their affiliates and agents, including Zydus Pharmaceuticals, market and sell drug products throughout the United States and in this judicial district, and have purposely availed themselves of the rights and benefits of Delaware law and this Court.

15. On information and belief, Zydus Noveltech, Zydus Pharmaceuticals, and Cadila share common directors.

16. This Court has personal jurisdiction over Zydus Pharmaceuticals and Cadila because they have affirmatively availed themselves of the jurisdiction of this Court by filing counterclaims in this district, and have previously been sued in this district and have not challenged personal jurisdiction. *See, e.g.*, *Forest Labs., Inc. et al. v. Apotex Corp. et al.*, 1:14-cv-00200 (D. Del.) (defendants and counterclaimants); *UCB, Inc. et al. v. Zydus Pharms. (USA) Inc. et al.*, 1:13-cv-01220 (D. Del.) (defendants and counterclaimants); *Pfizer Inc. et al. v. Zydus Pharms. (USA) Inc. et al.*, 1:12-cv-00808 (D. Del.) (defendants and counterclaimants); *Abbott Labs. et al. v. Cadila Healthcare Ltd. et al.*, 1:12-cv-00065 (D. Del.) (defendants and counterclaimants); *Warner Chilcott Co. v. Zydus Pharms. (USA) Inc.*, 1:11-cv-01105 (D. Del.) (defendants and counterclaimants); *Somaxon Pharms., Inc. et al. v. Zydus Pharms. USA, Inc. et al.*, 1:11-cv-00537 (D. Del.) (defendants and counterclaimants); *Shire Dev. Inc. et al. v. Cadila Healthcare Ltd. et al.*, 1:10-cv-00581 (D. Del.) (defendants and counterclaimants); *Wyeth v. Cadila Healthcare Ltd. et al.*, 1:09-cv-00239 (D. Del.) (defendants and counterclaimants); *Teijin Ltd. et al. v. Zydus Pharms. (USA), Inc. et al*, 1:13-cv-02086 (D. Del.) (defendants); *Alpex Pharma, S.A. et al. v. Zydus Pharms. (USA) Inc. et al.*, 1:13-cv-01143 (D. Del.) (defendants).

17. 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.

18. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF – PATENT INFRINGEMENT

19. Plaintiff NPC holds an approved new drug application ("NDA") No. 22-083 for Exelon® Patch (rivastigmine transdermal system or extended release film) (4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths), which patch contains the active ingredient

rivastigmine. Exelon® Patch (4.6 mg/24 hr and 9.5 mg/24 hr dosage strengths) was approved by the FDA on July 6, 2007, and Exelon® Patch (13.3 mg/24 hr dosage strength) was approved by the FDA on August 31, 2012. Exelon® Patch is indicated for the treatment of mild to moderate dementia of the Alzheimer's type and mild to moderate dementia associated with Parkinson's disease. Exelon® Patch (4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths) is sold in the United States by Plaintiff NPC.

20. Rivastigmine is known chemically as (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate.

21. Plaintiffs Novartis AG and LTS are the owners of United States Letters Patent No. 6,316,023 ("the '023 patent"). The '023 patent was duly and legally issued on November 13, 2001.

22. The '023 patent claims pharmaceutical compositions, *inter alia*, comprising 1 to 40 weight percent of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in the form of a free base or acid addition salt, 0.01 to 0.5 weight percent of an antioxidant, and a diluent or carrier, wherein the weight percents are based on the total weight of the pharmaceutical composition, as well as transdermal devices. A true copy of the '023 patent is attached hereto as Exhibit A.

23. Plaintiffs Novartis AG and LTS are the owners of United States Letters Patent No. 6,335,031 ("the '031 patent"). The '031 patent was duly and legally issued on January 1, 2002.

24. The '031 patent claims pharmaceutical compositions, *inter alia*, comprising: (a) a therapeutically effective amount of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in free base or acid addition salt form; (b) about 0.01 to about 0.5

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