IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES and ABBOTT RESPIRATORY LLC,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
CADILA HEALTHCARE LTD. d/b/a ZYDUS CADILA and ZYDUS PHARMACEUTICALS USA INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Abbott Laboratories and Abbott Respiratory LLC (collectively, "Abbott"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

This is an action for patent infringement of U.S. Patent No. 6,080,428 ("the '428 patent") arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 and 281. This action relates to Abbreviated New Drug Application ("ANDA") No. 203285 filed by Zydus Pharmaceuticals USA Inc. ("Zydus USA") with the U.S. Food and Drug Administration ("FDA") for approval to market 500 mg, 750 mg, and 1000 mg niacin extended release tablets, which are generic versions of the 500 mg, 750 mg, and 1000 mg forms of Abbott's NIASPAN® drug product.

PARTIES

1. Abbott Laboratories is a corporation organized and existing under the laws of the State of Illinois, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

2. Abbott Respiratory LLC ("Abbott Respiratory") is a limited liability corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

3. Upon information and belief, Cadila Healthcare Ltd., doing business as Zydus Cadila ("Zydus Cadila"), is a company organized and existing under the laws of India, having its principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015 Gujarat, India.

4. Upon information and belief, Zydus Cadila is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market through various directly or indirectly owned operating subsidiaries, including its wholly-owned subsidiary, Zydus USA.

5. Zydus USA is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 73 Route 31 N., Pennington, NJ 08534.

6. Upon information and belief, Zydus USA manufactures and/or distributes numerous generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district. For example, Zydus USA maintains a website, www.zydususa.com, identifying seventy-one authorized distributors for its generic drug products, including companies with extensive distribution networks in Delaware, such as CVS Pharmacy, Rite-Aid, Wal-Mart, and Walgreens.

7. Upon information and belief, Zydus USA is a wholly-owned subsidiary of Zydus Cadila and is controlled and/or dominated by Zydus Cadila.

8. Upon information and belief, Zydus USA manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Zydus Cadila.

9. Upon information and belief, Zydus Cadila established Zydus USA for the purposes of distributing, marketing, offering for sale and/or selling its generic drug products throughout the United States. Upon information and belief, Zydus Cadila and Zydus USA work in concert with one another and hold themselves out as an integrated "group" for purposes of developing, manufacturing, marketing, and selling generic drug products throughout the United States, including in this judicial district. For example, Zydus Cadila includes within its Annual Report the activities of its wholly-owned subsidiary Zydus USA, including the revenues earned. In addition, Zydus Cadila maintains a website, www.zyduscadila.com, advertising Zydus Cadila's "global operations," including in the "USA." In an October 7, 2010 press release, Zydus Cadila announced:

> Zydus Cadila has received an approval from the USFDA to market Losartan Potassium tablets (25mg, 50mg and 100mg) and Losartan Potassium + Hydrocholorothiazide tablets (50/12.5mg and 100/25mg) in the US market. . . . Zydus Pharmaceuticals (USA) Inc., launched both products on the very same day after receiving approvals from the USFDA. . . . The group has 56 approvals and has so far filed 113 ANDAs since the commencement of filing process in FY 2003-04.

Press Release, Zydus Cadila, *Zydus Cadila Receives USFDA Approval for Losartan Potassium tablets and Losartan Potassium + Hydrocholorothiazide Tablets*, (Oct. 7, 2010), available at http://www.zyduscadila.com/press/PressNote07-10-10.pdf (last accessed Jan. 19, 2012). According to Zydus Cadila's 2010-2011 Annual Report, the group "ranks amongst the top three players in the market for nine out of the top ten products marketed by it in the US and has also recently been ranked 12th amongst the top US generic companies based on scripts."

10. Upon information and belief, and consistent with their past practices, Zydus Cadila and Zydus USA acted collaboratively in the preparation and submission of ANDA No. 203285.

11. Upon information and belief, and consistent with its past practices, Zydus USA's preparation and submission of ANDA No. 203285 was done at the direction, under the control, and for the direct benefit of Zydus Cadila.

12. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 203285, Zydus USA and Zydus Cadila will work in concert with one another, and with other Zydus subsidiaries, to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 203285 throughout the United States, and/or import such generic drug products into the United States.

13. Zydus Cadila and Zydus USA are collectively referred to hereafter as "Zydus."

JURISDICTION AND VENUE

14. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

15. This Court has personal jurisdiction over Zydus because, *inter alia*, it has committed, or aided, abetted, contributed to, or participated in the commission of, a tortious act of patent infringement in filing ANDA No. 203285 that has led to foreseeable harm and injury to Abbott Respiratory, a Delaware corporation, and Abbott Laboratories, a corporation actively engaged in business in Delaware.

16. This Court also has personal jurisdiction over Zydus because, as described above, it manufactures, distributes, markets, and sells generic drug products throughout the United States and within Delaware and therefore purposefully avails itself of the privilege of conducting activities within Delaware.

17. This Court also has personal jurisdiction over Zydus because it has availed itself of the legal protections of the State of Delaware by, *inter alia*, creating wholly-owned subsidiaries in Delaware (*e.g.*, Zydus Healthcare USA LLC) and admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware (*e.g.*, *Wyeth. v. Cadila Healthcare Ltd. and Zydus Pharmaceuticals (USA) Inc.*, Civil Action No. 1:09-cv-00239-JJF (D. Del.); *Shire Development, Inc. et al. v. Cadila Healthcare Limited (d/b/a Zydus Cadila) and Zydus Pharmaceuticals (USA) Inc.*, Civil Action No. 1:10-cv-00581-JJF (D. Del.); *Somaxon Pharmaceuticals, Inc. and Procom One, Inc. v. Zydus Pharmaceuticals USA Inc. and Cadila Healthcare Limited (d/b/a Zydus Cadila)*, Civil Action No. 1:11-cv-00537-SLR).

18. 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.

PATENT IN SUIT

19. Abbott Respiratory is the owner by assignment of the ’428 patent, entitled “Nicotinic Acid Compositions for Treating Hyperlipidemia and Related Methods Thereof,” which the U.S. Patent and Trademark Office duly and legally issued on June 27, 2000. A true and correct copy of the ’428 patent is attached hereto as Exhibit A. The claims of the ’428 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the ’428 patent with

respect to NIASPAN®, with the right to sue for and obtain equitable relief and damages for infringement of the '428 patent.

20. Abbott Laboratories is the holder of New Drug Application ("NDA") No. 20-0381 by which the FDA granted approval for the marketing and sale of 500 mg, 750 mg and 1000 mg strength niacin extended-release tablets, which Abbott markets in the United States under the trade name "NIASPAN®". The formulation and dosing of NIASPAN® is covered by certain claims of the '428 patent. The FDA's official publication of approved drugs (the "Orange Book") includes NIASPAN® together with the '428 patent.

INFRINGEMENT BY ZYDUS

21. By letter dated December 8, 2011, ("the Notice Letter"), Zydus notified Abbott that Zydus had submitted ANDA No. 203285 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of its 500 mg, 750 mg, and 1000 mg generic niacin extended-release tablets before the expiration of the '428 patent. Upon information and belief, Zydus intends to engage in the commercial manufacture, use, and sale of its 500 mg, 750 mg, and 1000 mg generic niacin extended-release tablets promptly upon receiving FDA approval to do so.

22. By filing ANDA No. 203285, Zydus has necessarily represented to the FDA that its generic niacin extended-release tablets have the same active ingredient as NIASPAN®, have the same route of administration, dosage form, and strengths as NIASPAN®, and are bioequivalent to NIASPAN®.

23. The Notice Letter does not identify that Zydus's commercial manufacture, use, and/or sale of its proposed 500 mg, 750 mg, and 1000 mg generic niacin extended-release tablets would not infringe the '428 patent.

24. This Complaint is being filed before the expiration of the forty-five days from the date Abbott received the Notice Letter.

COUNT I (INFRINGEMENT OF THE '428 PATENT)

25. Each of the preceding paragraphs 1 to 24 is incorporated as if fully set forth.

26. Zydus's submission of ANDA No. 203285 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of its 500 mg, 750 mg, and 1000 mg generic niacin extended-release tablets prior to the expiration of the '428 patent constitutes infringement of one or more of the claims of the '428 patent under 35 U.S.C. § 271(e)(2)(A).

27. Upon FDA approval of Zydus's ANDA No. 203285, Zydus will further infringe the '428 patent by making, using, offering to sell, and selling its 500 mg, 750 mg, and 1000 mg generic niacin extended-release tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

28. Upon information and belief, Zydus had actual and constructive knowledge of the '428 patent prior to filing ANDA No. 203285 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '428 patent.

29. If Zydus's infringement of the '428 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Abbott prays that this Court grant the following relief:

1. A judgment that one or more claims of the '428 patent are infringed by Zydus's submission of ANDA No. 203285, and that Zydus's making, using, offering to sell, or selling in the United States, or importing into the United States Zydus's 500 mg, 750 mg, and 1000 mg generic niacin extended-release tablets will infringe the '428 patent.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 203285 shall be a date which is not earlier than the latest expiration date of the '428 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled.

3. An order permanently enjoining Zydus, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Zydus's 500 mg, 750 mg, and 1000 mg generic niacin extended-release tablets until after the latest expiration date of the '428 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled.

4. Damages or other monetary relief to Abbott if Zydus engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Zydus's 500 mg, 750 mg, and 1000 mg generic niacin extended-release tablets prior to the latest expiration date of the '428 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled.

Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

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