IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALPEX PHARMA, S.A., CITIUS PHARMACEUTICALS, LLC and PRENZAMAX, LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 13-1143 (SLR)
ZYDUS PHARMACEUTICALS USA, INC. and CADILA HEALTHCARE LIMITED (d/b/a ZYDUS CADILA),	)	
Defendants.	)	

FIRST AMENDED COMPLAINT

Plaintiffs Alpex Pharma, S.A. ("Alpex"), Citius Pharmaceuticals, LLC ("Citius") and Prenzamax, LLC ("Prenzamax") (collectively, "Plaintiffs") by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

This is an action for patent infringement of U.S. Patent No. 6,149,938 ("the '938 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 an Abbreviated New Drug Application ("ANDA") filed by Zydus Pharmaceuticals USA, Inc. with the U.S. Food and Drug Administration ("FDA") seeking FDA approval to market generic versions of the 15 mg, 30 mg, and 37.5 mg dosages of Plaintiffs' SUPRENZA® drug product.

PARTIES

1. Alpex is a Société Anonyme organized and existing under the laws of Switzerland with its principal place of business at Via Cantonale, 6805 Mezzovico, Switzerland.

2. Citius is a limited liability company organized and existing under the laws of the State of Massachusetts, with its principal place of business at 63 Great Road, Maynard, Massachusetts 01754.

3. Prenzamax is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 11 Commerce Drive, Suite 100, Cranford, New Jersey 07016.

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

5. Zydus USA is a corporation organized and existing under the laws of New Jersey, with its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Upon information and belief, Zydus USA is a wholly-owned subsidiary of Zydus Cadila and is controlled and/or dominated by Zydus Cadila. Upon information and belief, Zydus USA markets and distributes generic drugs for sale and use throughout the United States and in this judicial district at the direction, under the control, and for the benefit of Zydus Cadila.

6. Upon information and belief, Zydus Cadila established Zydus USA, its wholly-owned subsidiary, for the purposes of distributing, marketing, offering for sale and selling its generic drugs throughout the United States. Upon information and belief, Zydus Cadila and Zydus USA (collectively, "Zydus") work in concert with one another, and with other Zydus subsidiaries, to develop, manufacture, and market pharmaceutical products throughout the United

States, including in this judicial district. Upon information and belief, Zydus Cadila directs the operations, management and activities of Zydus USA in the United States.

7. Upon information and belief, Zydus Cadila and Zydus USA acted collaboratively in the preparation and submission of ANDA No. 204663. Upon information and belief, Zydus USA's preparation and submission of ANDA No. 204663 was done at the direction, under the control, and for the direct benefit of Zydus Cadila.

8. Upon information and belief, following any FDA approval of ANDA No. 204663, 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 products that are the subject of ANDA No. 204663 throughout the United States, and/or import such generic products into the United States.

JURISDICTION AND VENUE

9. 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).

10. This Court has personal jurisdiction over Zydus Cadila and Zydus USA because, *inter alia*, they each have committed, or aided, abetted, contributed to, or participated in the commission of, a tortious act of patent infringement in filing ANDA No. 204663 that has led to foreseeable harm and injury to Prenzamax, a Delaware corporation. This Court also has personal jurisdiction over Zydus Cadila and Zydus USA because they have purposely availed themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being haled into court in this district and have had persistent, systematic and continuous contacts with Delaware as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

11. Upon information and belief, Zydus Cadila maintains a website, www.zyduscadila.com, advertising Zydus Cadila's "global operations in four continents spread across USA, Europe, Japan, Brazil, South Africa and 25 other emerging markets."

12. Upon information and belief, Zydus USA distributes for sale hundreds of drug products throughout the United States, including in this judicial district. Upon information and belief, Zydus USA maintains a website, www.zydususa.com, advertising the drug products it markets and/or sells in the United States. According to Zydus USA's website, Zydus USA "has over 50 years of U.S. generic market experience." The Zydus USA website lists seventy-one authorized distributors, including companies with extensive distribution networks in Delaware, such as CVS Pharmacy, Rite-Aid, Wal-Mart, and Walgreens. Walgreens, for example, has twenty-seven locations in Delaware, while Wal-Mart has nineteen.

13. Upon information and belief, Zydus Cadila and Zydus USA regularly do business in Delaware and have engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware. Upon information and belief, Zydus Cadila and Zydus USA have done so with each other's authorization, participation, and assistance, or acting in concert with each other.

14. Upon information and belief, Zydus Cadila has also availed itself of the laws of Delaware and engaged in a course of conduct in Delaware, at least by forming a wholly-owned U.S. subsidiary, Zydus Healthcare USA LLC under Delaware law.

15. Upon information and belief, Zydus Cadila and Zydus USA operate as an integrated, unitary generic pharmaceutical business. For example, Zydus Cadila includes within its Annual Report the activities of its wholly-owned subsidiary Zydus USA, including the revenues earned.

16. Upon information and belief, Zydus Cadila and Zydus USA derive substantial revenue from generic pharmaceutical products that are sold, used, and/or consumed within Delaware.

17. Upon information and belief, Zydus Cadila and Zydus USA have previously availed themselves of the rights and privileges of this forum for the purpose of litigating patent disputes. For example, Zydus Cadila and Zydus USA have submitted to this Court's jurisdiction by asserting counterclaims in other civil actions in this jurisdiction. Specifically, Zydus USA and/or Zydus Cadila admitted jurisdiction for the purpose of the litigation and filed counterclaims in at least the following actions in this Court: *Shire Development Inc. et al. v. Cadila Healthcare Limited et al.*, No. 10-cv-00581-KAJ (D. Del.) (Dkt. Nos. 9, 13); *AbbVie Inc. et al v. Cadila Healthcare Ltd. (d/b/a Zydus Cadila) and Zydus Pharmaceuticals (USA), Inc.*, Civil Action No. 12-065 (D. Del.) (Dkt. No. 7); *Somaxon Pharmaceuticals, Inc. and Procom One, Inc. v. Zydus Pharmaceuticals USA Inc. and Cadila Healthcare Limited (d/b/a Zydus Cadila)*, Civil Action No. 11-537 (D. Del.) (Dkt. No. 8).

BACKGROUND

18. SUPRENZA® is an orally disintegrating tablet formulation (15, 30, 37.5 mg) of phentermine hydrochloride approved by the FDA for the treatment of obesity. SUPRENZA® is sold at dosages of 15 mg, 30 mg, and 37.5 mg in the United States pursuant to New Drug Application (NDA) No. 202088. SUPRENZA® has been approved by the FDA for those dosages. Citius is the current holder of NDA No. 202088.

19. Alpex is the owner of the '938 patent, entitled "Process for the Preparation of a Granulate Suitable to the Preparation of Rapidly Disintegrable Mouth-Soluble Tablets and Compositions Obtained Thereby," which the U.S. Patent and Trademark Office duly and legally issued on November 21, 2000. A true and correct copy of the '938 patent is attached hereto as

Exhibit A. The claims of the '938 patent are valid and enforceable. Citius is an exclusive licensee of the '938 patent with respect to SUPRENZA®, with the right to sue for and obtain equitable relief and damages for infringement of the '938 patent. Prenzamax is an exclusive sub-licensee of the '938 patent with respect to SUPRENZA®, with the right to sue for and obtain equitable relief and damages for infringement of the '938 patent.

20. The dosage form of SUPRENZA® is covered by one or more claims of the '938 patent. The '938 patent has been listed in connection with SUPRENZA® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book."

INFRINGEMENT BY ZYDUS

21. By letter dated May 16, 2013 and received on May 17, 2013, Zydus notified Citius and Alpex that Zydus had submitted ANDA No. 204663 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 15 mg and 30 mg phentermine hydrochloride tablets before the expiration of the '938 patent.

22. By letter dated June 18, 2013 and received on June 19, 2013, Zydus notified Citius and Alpex that Zydus had submitted ANDA No. 204663 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 37.5 mg phentermine hydrochloride tablets before the expiration of the '938 patent.

23. Zydus' ANDA No. 204663 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications") with respect to the '938 patent. Zydus has certified that no valid claim of the '938 patent will be infringed by the manufacture, use, or sale of the generic 15 mg, 30 mg and 37.5 mg phentermine hydrochloride tablets it plans to launch.

24. By filing ANDA No. 204663, Zydus has necessarily represented to the FDA that the components of its generic 15 mg, 30 mg, and 37.5 mg phentermine hydrochloride tablets have the same active ingredients as those of the corresponding components of SUPRENZA®, have the same route of administration, dosage form, and strengths as the corresponding components of SUPRENZA®, and are bioequivalent to the corresponding components of SUPRENZA®.

25. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and relevant law, Plaintiffs are entitled to a 30 month stay of FDA approval with respect to Zydus' proposed generic 15mg and 30mg phentermine hydrochloride tablets based on the notice of Zydus' Paragraph IV Certification received on May 17, 2013, and Plaintiffs are entitled to a separate, overlapping, 30 month stay with respect to Zydus' proposed generic 37.5 mg phentermine hydrochloride tablets based on the notice of Zydus' separate Paragraph IV Certification received on June 19, 2013.

COUNT I (INFRINGEMENT OF THE '938 PATENT)

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

27. Zydus' submission of ANDA No. 204663 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic 15 mg, 30 mg, and 37.5 mg phentermine hydrochloride tablets prior to the expiration of the '938 patent constitutes infringement of one or more of the claims of the '938 patent under 35 U.S.C. § 271(e)(2)(A).

28. Upon information and belief, use of Zydus' generic 15 mg, 30 mg, and 37.5 mg phentermine hydrochloride tablets in accordance with and as directed by Zydus' proposed labeling for that product would infringe one or more claims of the '938 patent.

29. Upon information and belief, Zydus had actual and constructive knowledge of the '938 patent prior to filing ANDA No. 204663 and was aware that the filing of its ANDA with the FDA constituted an act of infringement of the '938 patent.

30. Upon FDA approval of Zydus's ANDA No. 204663, Zydus will further infringe the '938 patent by making, using, offering to sell, and selling generic 15 mg, 30 mg, and 37.5 mg phentermine hydrochloride tablets in the United States and/or importing such tablets into the United States in violation of 35 U.S.C. § 271 unless enjoined by the Court.

31. If Zydus' infringement of the '938 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

a. A judgment that one or more claims of the '938 patent are infringed by Zydus' submission of ANDA No. 204663, and that Zydus' making, using, offering to sell, or selling in the United States, or importing into the United States, of generic 15 mg, 30 mg, and 37.5 mg phentermine hydrochloride tablets will infringe the '938 patent;

b. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Zydus' ANDA No. 204663 shall be a date which is not earlier than the expiration date of the '938 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

c. An order permanently enjoining Zydus, their affiliates, subsidiaries, and each of their 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 generic 15 mg, 30 mg, and 37.5 mg phentermine hydrochloride tablets until after the expiration date of the '938 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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August 1, 2013
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CERTIFICATE OF SERVICE

I hereby certify that on August 1, 2013, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on August 1, 2013, upon the following in the manner indicated:

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VIA ELECTRONIC MAIL
AND FEDERAL EXPRESS

/s/ Maryellen Noreika
Maryellen Noreika (#3208)