IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

APTALIS PHARMATECH, INC. and IVAX INTERNATIONAL GMBH, Plaintiffs, v. APOTEX INC. and APOTEX CORP., Defendants.	C.A. No. _____

COMPLAINT

Plaintiffs Aptalis Pharmatech, Inc. ("Aptalis") and Ivax International GmbH ("Ivax") (collectively, "Plaintiffs") for their complaint against Apotex Inc. and Apotex Corp. (collectively, "Apotex" or "Defendants"), to the best of their knowledge, information and belief, allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the Food and Drug and Patent Laws of the United States, Titles 21 and 35, respectively, arising from the Defendants filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA"), seeking approval to commercially market generic versions of AMRIX® drug products (cyclobenzaprine HCl extended release capsules) prior to the expiration of United States Patent Nos. 7,790,199 ("the '199 patent") and 7,829,121 ("the '121 patent") (collectively, the "patents-in-suit"), which cover the AMRIX® drug products.

THE PARTIES

2. Plaintiff Aptalis Pharmatech, Inc. ("Aptalis"), formerly known as Eurand, Inc., is a corporation, organized, existing and doing business under and by virtue of the laws of the State of Nevada, with its office and principal place of business located at 845 Center Drive, Vandalia, Ohio 45377.

3. Plaintiff Ivax International GmbH ("Ivax") is a Swiss corporation having a principal place of business at Alpenstrasse 2, 8640 Rapperswil, Switzerland.

4. On information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, with its principal place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada.

5. On information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

6. On information and belief, Defendant Apotex Corp. is a wholly-owned subsidiary of Apotex Inc.

7. On information and belief, Defendant Apotex Corp. serves as Apotex Inc.'s United States sales agent and distributor for generic pharmaceuticals, which it distributes in the State of Delaware and throughout the United States. On information and belief, Defendant Apotex Inc. conducts its North American operations, in part, through Apotex Corp. On information and belief, together, Apotex Inc. and Apotex Corp. collaborate in the manufacture, marketing, and sale of pharmaceutical products (including generic drug products manufactured and sold pursuant to approved Abbreviated New Drug Applications) within the United States generally, and the State of Delaware specifically.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and 35 U.S.C. § 271.

9. Based on the facts and causes alleged herein, this Court has personal jurisdiction over Defendants Apotex Inc. and Apotex Corp.

10. Apotex Corp. is incorporated in Delaware and therefore subject to the jurisdiction of this Court. As a domestic corporation, Apotex Corp. is registered to do business with the Delaware Department of State Division of Corporations. Furthermore, Apotex Corp. markets and sells generic drugs within the State of Delaware and throughout the United States.

11. Upon information and belief, Apotex Corp. avails itself of the benefits and protections of the laws of the State of Delaware. For example, upon information and belief, Apotex Corp. is registered with the Delaware Board of Pharmacy pursuant to 24 *Del. C.* § 2540.

12. This Court also has personal jurisdiction over Defendants by virtue of their systematic and continuous contacts with the State of Delaware.

13. On information and belief, Defendants have at all relevant times maintained continuous and systematic contacts with the State of Delaware, including but not limited to, their aforementioned business of preparing generic pharmaceuticals that they distribute in the State of Delaware; and Defendants plan to continue to maintain such contacts.

14. On information and belief, Defendants are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including in Delaware, and including the 15 mg and 30 mg cyclobenzaprine HCl extended-release capsules described in

Defendants' ANDA No. 206703 (the "Apotex Generic Products"), which are accused of infringing the patents-in-suit.

15. If ANDA No. 206703 is approved, the Apotex Generic Products would, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware.

16. Defendants know and intend that the Apotex Generic Products will be distributed and sold in the United States, including in Delaware. On information and belief, if ANDA No. 206703 is approved Defendant Apotex Inc. will manufacture the Apotex Generic Products for distribution throughout the United States, including Delaware. On information and belief, Defendant Apotex Corp. will distribute the Apotex Generic Products for sale and/or use in Delaware.

17. In addition, Defendants have previously availed themselves of this Court by, for example, filing suit in this jurisdiction, consenting to jurisdiction, and/or asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Bristol-Myers Squibb Co. v. Apotex Inc. & Apotex Corp.*, C.A. No. 14-351-RGA, D.I. 6 (D. Del. June 16, 2014); *Forest Labs., Inc. et al. v. Apotex Corp. & Watson Labs., Inc. – Florida*, C.A. No. 14-200-LPS, D.I. 32 (D. Del. May 6, 2014); *Apotex Inc. & Apotex Corp. v. Senju Pharm. Co. Ltd. et al.*, C.A. No. 12-196-SLR, D.I. 1 (D. Del. Feb. 16, 2012).

18. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

19. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq*., as amended by the Hatch-Waxman Amendments, sets forth the rules FDA follows when considering whether to approve the marketing of pharmaceutical drugs.

20. With the passage of the Hatch-Waxman Act in 1984, the FFDCA provisions with respect to the generic drug approval process were amended in several aspects. One provision requires innovator drug companies to submit patent information to FDA "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). FDA publishes the submitted patent information in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book").

21. The Hatch-Waxman Act further amended the FFDCA to permit generic drug companies to gain approval of generic copies of innovator drugs (also called "reference drugs") by referencing studies performed by the innovator, without having to expend the same considerable investment in time and resources. Thus, generic drug companies are permitted to file what is referred to as an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 255(j). When filing an ANDA, generic drug companies are required to review the patent information that FDA lists in the Orange Book for the reference drug and make a statutory certification (commonly called "patent certification") with respect to the same.

22. The generic drug company may state that it does not seek FDA approval to market its generic drug products prior to patent expiration (commonly called a "Paragraph III Certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(III). Alternatively, the generic drug company may seek FDA approval to market its generic drug products prior to patent expiration by stating in its

ANDA that the Orange Book listed patents are "invalid or will not be infringed …" (commonly called a "Paragraph IV Certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

THE PATENTS-IN-SUIT AND NDA NO. 21-777

23. On September 7, 2010, the PTO duly and legally issued the '199 patent titled "Modified Release Dosage Forms of Skeletal Muscle Relaxants" to Eurand. Eurand subsequently changed its name to Aptalis. Aptalis is the lawful owner of all right, title and interest in and to the '199 patent. A true and correct copy of the '199 patent is attached hereto as **Exhibit A**.

24. On November 9, 2010, the PTO duly and legally issued the '121 patent titled "Modified Release Dosage Forms of Skeletal Muscle Relaxants" to Eurand. Eurand subsequently changed its name to Aptalis. Aptalis is the lawful owner of all right, title and interest in and to the '121 patent. A true and correct copy of the '121 patent is attached hereto as **Exhibit B**.

25. Plaintiff Ivax is the holder of New Drug Application ("NDA") No. 21-777 for AMRIX® brand cyclobenzaprine HCl extended-release capsules, in 15 mg and 30 mg doses. FDA approved AMRIX® for marketing in the United States under NDA No. 21-777, pursuant to section 505(b) of the FFDCA, 21 U.S.C. § 355(b).

26. Ivax is an exclusive licensee to the '199 and '121 patents in the United States.

27. In conjunction with NDA No. 21-777, the '199 and '121 patents are listed in the Orange Book for AMRIX® brand cyclobenzaprine HCl extended-release capsules, in 15 mg and 30 mg doses.

ACTS GIVING RISE TO THIS ACTION FOR INFRINGEMENT OF THE PATENTS-IN-SUIT

28. On information and belief, the Defendants are engaged in the practice of reviewing pharmaceutical patents and challenging those patents.

29. This action arises because of the Defendants' efforts to gain approval from FDA to market generic versions of AMRIX® prior to the expiration of the patents-in-suit.

30. On information and belief, Defendants submitted ANDA No. 206703 to FDA under § 505(j) of the FFDCA (21 U.S.C. § 355(j)). That ANDA seeks, *inter alia*, FDA approval to commercially manufacture, use, and sell generic cyclobenzaprine HCl extended-release capsules, 15 mg and 30 mg, throughout the United States including Delaware. ANDA No. 206703 specifically seeks FDA approval to market the Apotex Generic Products prior to the expiration of the patents-in-suit.

31. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Apotex Inc. alleged in ANDA No. 206703 that the clams of the '199 and '121 patents are invalid and/or will not be infringed by the commercial manufacture, use or sale throughout the United States of the Apotex Generic Products. Aptalis and Ivax received written notification of ANDA No. 206703 and Apotex Inc.'s § 505(j)(2)(A)(vii)(IV) allegations from Apotex Inc. on or about June 30, 2014 ("Paragraph IV letter").

32. The stated purpose of the Paragraph IV letter was to notify Aptalis and Ivax that Apotex Inc. had filed a certification with FDA in conjunction with ANDA No. 206703 for approval, *inter alia*, to commercially manufacture and sell a generic version of Plaintiffs' AMRIX® brand cyclobenzaprine HCl extended release capsules, 15 mg and 30 mg. The Paragraph IV letter alleges that the claims of the '199 and '121 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale throughout the United States of the Apotex Generic Products.

33. In the Paragraph IV letter, Apotex initially offered confidential access to portions of ANDA No. 206703 on terms and conditions set forth in an attached "Offer of Confidential

Access" ("the Initial Apotex Offer"). The Initial Apotex Offer contained various restrictions, above and beyond those that would apply under a protective order, on who could view the ANDA. For example, the Initial Apotex Offer barred any access to in-house counsel and outside experts.

34. Under 21 U.S.C. § 355(j)(5)(C)(i)(III), an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

35. After receiving the Paragraph IV letter and the accompanying Initial Apotex Offer, Plaintiffs negotiated with Apotex to procure a copy of ANDA No. 206703 under restrictions "as would apply had a protective order been issued." On July 29, 2014, Plaintiff Ivax entered into a Confidential Disclosure Agreement with Defendants whereby Defendants agreed to provide certain sections of ANDA No. 206703 to allow Plaintiffs to determine whether to bring an infringement action.

36. On August 1, 2014, Ivax received certain sections of ANDA No. 206703 pursuant to the Confidential Disclosure Agreement.

37. After reviewing the sections of ANDA No. 206703 that were provided, on August 8, 2014, Plaintiffs' counsel requested samples of the products described in ANDA No. 206703 from Defendants' counsel in order to further substantiate Plaintiffs' infringement allegations. On August 11, 2014, Plaintiffs reiterated their request for product samples and requested that Defendants produce the entire ANDA No. 206703. As of the filing of this Complaint, Defendants' counsel has not responded to Plaintiffs' requests.

38. In light of the limited information Plaintiffs have received regarding the Apotex Generic Products, and given the 45-day statutory deadline to file suit set forth in 21 U.S.C. §

355(j)(5)(B)(iii), Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to further confirm their allegations of infringement and to present to the Court evidence that the Apotex Generic Products fall within the scope of one or more claims of the '199 and '121 patents.

39. Defendants have made, and continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import the Apotex Generic Products prior to patent expiry.

40. Defendants' actions, including, but not limited to, the development of the Apotex Generic Products and the filing of ANDA No. 206703 with a Paragraph IV certification, indicate a refusal to change the course of their action in the face of acts by Plaintiffs.

41. On information and belief, Defendants continue to seek approval of ANDA No. 206703 from FDA and intend to commercially manufacture, market, and sell generic cyclobenzaprine HCl extended-release capsules. Accordingly, Plaintiffs make the following allegations on information and belief and subject to Fed. R. Civ. P. 11(b)(3):

COUNT I

(Infringement of the '199 Patent Under 35 U.S.C. § 271(e)(2))

42. Paragraphs 1 to 41 are incorporated herein as set forth above.

43. Upon information and belief, on or before June 27, 2014, Defendants submitted ANDA No. 206703 to FDA to obtain approval under the FFDCA to engage in the commercial manufacture, use or sale throughout the United States, including Delaware, of the Apotex Generic Products. By submitting ANDA No. 206703, Defendants, individually and collectively, have committed an act of infringement with respect to the '199 patent under 35 U.S.C. § 271(e)(2)(A).

44. Any commercial manufacture, use, offer for sale, sale and/or importation of the Apotex Generic Products prior to patent expiry will constitute direct and/or contributory infringement and/or active inducement of infringement of the '199 patent.

45. The commercial manufacture, use, offer for sale, sale and/or importation of the Apotex Generic Products prior to patent expiry will infringe at least one claim of the '199 patent, literally or under the doctrine of equivalents.

COUNT II

(Declaratory Judgment of Infringement of the '199 Patent Under 35 U.S.C. § 271(a)-(c))

46. Paragraphs 1 to 45 are incorporated herein as set forth above.

47. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

48. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

49. Defendants have made, and will continue to make, substantial preparation in the United States, including Delaware, to manufacture, sell, offer to sell and/or import the Apotex Generic Products.

50. Defendants' actions indicate a refusal to change the course of their action in the face of acts by Plaintiffs.

51. Any commercial manufacture, use, offer for sale, sale and/or importation of the Apotex Generic Products prior to patent expiry will constitute direct and/or contributory infringement and/or active inducement of the '199 patent.

52. The commercial manufacture, use, offer for sale, sale and/or importation of the Apotex Generic Products prior to patent expiry will infringe at least one claim of the '199 patent, literally or under the doctrine of equivalents.

53. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of the Apotex Generic Products by Defendants prior to patent expiry will constitute direct and/or contributory infringement and/or active inducement of infringement of the '199 patent.

COUNT III

(Infringement of the '121 Patent Under 35 U.S.C. § 271(e)(2))

54. Paragraphs 1 to 53 are incorporated herein as set forth above.

55. Upon information and belief, on or before June 27, 2014, Defendants submitted ANDA No. 206703 to FDA to obtain approval under the FFDCA to engage in the commercial manufacture, use or sale throughout the United States, including Delaware, of the Apotex Generic Products. By submitting ANDA No. 206703, Defendants, individually and collectively, have committed an act of infringement with respect to the '121 patent under 35 U.S.C. § 271(e)(2)(A).

56. Any commercial manufacture, use, offer for sale, sale and/or importation of the Apotex Generic Products prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the '121 patent.

57. The commercial manufacture, use, offer for sale, sale and/or importation of the Apotex Generic Products prior to patent expiry will infringe at least one claim of the '121 patent, literally or under the doctrine of equivalents.

COUNT IV

(Declaratory Judgment of Infringement of the '121 Patent

Under 35 U.S.C. § 271(b) and (c))

58. Paragraphs 1 to 57 are incorporated herein as set forth above.

59. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

60. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

61. Defendants have made, and will continue to make, substantial preparation in the United States, including Delaware, to manufacture, sell, offer to sell and/or import the Apotex Generic Products.

62. Defendants' actions indicate a refusal to change the course of their action in the face of acts by Plaintiffs.

63. Any commercial manufacture, use, offer for sale, sale and/or importation of the Apotex Generic Products prior to patent expiry will constitute contributory infringement and/or active inducement of the '121 patent.

64. The commercial manufacture, use, offer for sale, sale and/or importation of the Apotex Generic Products prior to patent expiry will infringe at least one claim of the '121 patent, literally or under the doctrine of equivalents.

65. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of the Apotex Generic Products by Defendants prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the '121 patent.

EXCEPTIONAL CASE

66. Defendants were aware of the '199 and '121 patents prior to filing ANDA No. 206703.

67. The actions of Defendants render this an exceptional case under 35 U.S.C. § 285.

INJUNCTIVE RELIEF

68. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

a. That judgment be entered that Defendants have infringed the '199 and '121 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 206703 under the FFDCA, and that the commercial manufacture, use, offer for sale, sale and/or importation of the Apotex Generic Products prior to patent expiry will constitute an act of infringement of the '199 and '121 patents;

b. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 206703 shall be a date that is not earlier than the expiration date of the '199 and '121 patents including any extensions or exclusivities;

c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sale or sale within the United States, or importation into the United States, of any drug product covered by the '199 and '121 patents, prior to the expiration date of those patents, including any extensions or exclusivities;

d. That a declaration be issued under 28 U.S.C. § 2201 that if Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Apotex Generic Products prior to patent expiry, it will constitute an act of direct and/or indirect infringement of the '199 and '121 patents;

e. That damages or other monetary relief be awarded to Plaintiffs under 35 U.S.C. §§ 271(a), (b), (c) and (e)(4)(C), and/or 35 U.S.C. § 284 as appropriate;

f. That this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs; and

g. That this Court award such other and further relief as it may deem just and proper.

Dated: August 11, 2014

FISH & RICHARDSON P.C.

By: */s/ Robert M. Oakes*

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