THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
CASE NO. 1:09-CV-00485

APOTEX INC.,	)	
	)	
Plaintiff,	)	
	)	**COMPLAINT FOR**
v.	)	**DECLARATORY JUDGMENT**
	)	**JURY TRIAL DEMANDED**
GLAXO WELLCOME INC. and SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,	)	
	)	
Defendants.	)	

Plaintiff Apotex Inc. ("Apotex") alleges as follows for its Complaint against Defendants, Glaxo Wellcome Inc. and SmithKline Beecham Corporation d/b/a GlaxoSmithKline (collectively "Glaxo"):

Nature of the Action

1. Apotex brings this action for declaratory judgment of patent non-infringement under the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 and 2202, and sections of the Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(5)(C)(i), as amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173 (2003) ("MMA").

2. This action arises out of, *inter alia*, Apotex's submission of Abbreviated New Drug Application ("ANDA") No. 90-500 to the U.S. Food and Drug Administration

("FDA") seeking approval to market a generic version of Glaxo's brand-name drug Valtrex, known generically as valacyclovir.

3. On information and belief, Glaxo owns U.S. Patent Nos. 5,879,706 ("the '706 patent") and 6,107,302 ("the '302 patent"), copies of which are attached hereto as Exhibits A and B respectively. Upon submission by Glaxo, the '706 and '302 patents were listed in FDA's compilation of approved drugs and their respective patents, commonly referred to as "the Orange Book."

4. As a consequence of such listing, Glaxo maintains, and has affirmatively represented to the world, that the '706 and '302 patents claim the approved drug, Valtrex, and that a claim for patent infringement could reasonably be asserted against any generic ANDA applicant, including Apotex, attempting to market a generic valacyclovir product prior to expiry of the '706 or '302 patents.

5. Apotex has designed around the '706 and '302 patents with its proposed generic valacyclovir ANDA product and, as required by statute, has certified to FDA that Apotex's ANDA product will not infringe the '706 or '302 patents. Apotex has further notified Glaxo of the legal and factual bases for that certification. Apotex's submission of this "Paragraph IV" certification to the '706 and '302 patents constitutes an artificial act of patent infringement under 35 U.S.C. § 271(e)(2). Apotex is thus at considerable risk of being sued by Glaxo both before and after market entry.

6. Glaxo's act of causing the '706 and '302 patents to be listed in the Orange Book and Apotex's subsequent filing of an ANDA containing Paragraph IV certifications

to each of those patents creates a case or controversy allowing Apotex to file and maintain an action for declaratory judgment of patent non-infringement under the statute. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc).

7. Apotex reasonably believes and apprehends that Glaxo intends to sue Apotex for infringement of the '706 and '302 patents. There is an actual, substantial, and continuing justiciable case and controversy between Apotex and Glaxo regarding infringement of the '706 and '302 patents, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

8. Apotex is entitled by law to bring and maintain this action for declaratory judgment of patent non-infringement under the MMA where, as here, Glaxo did not sue Apotex within 45 days of receipt of Apotex's notice of Paragraph IV certification to the '706 and '302 patents and Apotex has provided Glaxo an Offer of Confidential Access to Apotex's ANDA No. 90-500.

9. Apotex is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of Apotex's proposed generic valacyclovir product does not and will not infringe the '706 or '302 patents. Absent the exercise of jurisdiction by this Court and such declaratory relief, Apotex will be irreparably harmed by the indefinite delay in the market entry of Apotex's generic valacyclovir product.

The Parties

10. Plaintiff Apotex Inc. is a corporation organized and existing under the laws of Canada and having a place of business at 150 Signet Drive, Toronto, Ontario, Canada

M9L 1T9. Apotex, Inc. develops and manufactures quality, lower-priced generic medicines.

11. On information and belief, Defendant Glaxo Wellcome Inc. is a North Carolina corporation with a principal place of business within this District at 5 Moore Drive, Research Triangle Park, North Carolina 27709 that has merged into Defendant SmithKline Beecham Corporation.

12. On information and belief, Defendant SmithKline Beecham Corporation is a Pennsylvania corporation doing business as GlaxoSmithKline with a place of business at 1 Franklin Plaza, 200 North 16th Street, Philadelphia, Pennsylvania 19102.

Jurisdiction and Venue

13. This action arises under *inter alia*, the Patent Act, 35 U.S.C. §§ 1 *et seq*., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the MMA, 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5).

14. This Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a) because it involves claims arising under the United States Patent Act, 35 U.S.C. §§ 1 *et seq*., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(5)(C)(i).

15. Apotex has a statutory right to bring and maintain this declaratory judgment action under 21 U.S.C. § 355(j)(5)(C)(i). This Court can and should exercise its

declaratory judgment jurisdiction over Apotex's claims pursuant to 35 U.S.C. § 271(e)(5).

16. This Court has personal jurisdiction over the Glaxo defendants because they conduct substantial business in, and have regular and systematic contact with, this District, including selling and/or manufacturing pharmaceuticals such as Glaxo's valacyclovir hydrochloride product, VALTREX® within this District and operating an administrative headquarters within this District. *See* http://us.gsk.com/html/career/career-working-locations.html.

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

Background

Hatch-Waxman statutory scheme

18. Approval of new and generic drugs by FDA is governed by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, as amended by the Hatch-Waxman Act and the MMA of 2003.

19. Before marketing an original new drug in the United States, an applicant must submit, and the FDA approve, a new drug application ("NDA") under 21 U.S.C. § 355(b).

20. An NDA applicant is required, as part of the NDA, to submit information regarding each patent that claims the drug or method of using the drug that is the subject of the NDA and for which a claim of patent infringement could reasonably be asserted

against a person not authorized by the patent owner to manufacture, use, sell, or import the drug product. 21 U.S.C. § 355(b)(1), (c)(2).

21. For approved NDAs, FDA publishes patent information submitted by an NDA-holder in a publication called *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book").

22. By filing an NDA and submitting a patent for listing in the Orange Book, the NDA-holder necessarily maintains that the listed patent claims the approved NDA drug, or a method of using that drug, and that an infringement suit could reasonably be asserted against anyone who engages in the manufacture, use, or sale of the drug, and in particular, against any company that is seeking to make a generic bioequivalent of the NDA drug before patent expiration.

23. Thus, the NDA-holder necessarily puts all prospective generic ANDA applicants on notice that a suit for infringement can and will be asserted against any ANDA applicant that attempts to seek approval for and market a generic version of the NDA drug before patent expiration.

Abbreviated New Drug Application (ANDA) Process

24. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, which simplified and expedited the procedure for obtaining approval of generic drugs by permitting a company seeking to market a generic drug to submit an Abbreviated New Drug Application ("ANDA").

25. The ANDA approval process is a streamlined version of the full NDA procedure and requires the applicant to show that its generic drug product is "bioequivalent" to the reference NDA drug. An applicant may invoke this procedure for expedited FDA approval of a generic version of an already-approved NDA drug by submitting an ANDA to FDA under 21 U.S.C. § 355(j).

26. An ANDA also must contain a "certification" to each patent properly listed in the Orange Book in connection with the approved NDA drug. More specifically, an ANDA applicant must submit one of four types of patent certifications for each listed patent: (I) that the NDA-holder/patent owner has not submitted any patent information to FDA; (II) that the listed patent has expired; (III) that the patent will expire on a future date, and that the generic applicant will not market its product until after the expiration date ("Paragraph III certification"); or (IV) that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted ("Paragraph IV certification").

27. A Paragraph IV certification signifies that the ANDA applicant intends to market its generic product prior to expiration of the listed patent. Such certification constitutes an act of patent infringement. 35 U.S.C. § 271(e)(2).

28. When an ANDA applicant makes a Paragraph IV certification, the applicant must notify the NDA-holder and the patent owner that it has filed an ANDA to obtain regulatory approval of a generic version of the NDA drug, and that the ANDA contains a Paragraph IV certification for a listed patent. 21 U.S.C. § 355(j)(2)(B). This notice must

include a detailed statement of the factual and legal bases for the ANDA applicant's certification that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the ANDA applicant's generic drug product. 21 U.S.C. § 355(j)(2)(B)(iv).

29. The submission of a Paragraph IV certification constitutes an artificial act of infringement that creates the necessary case or controversy and subject matter jurisdiction to enable an NDA-holder and patent holder to file an action for patent infringement before the drug is actually made, used, or sold in the United States.

30. The submission of a Paragraph IV certification likewise creates the necessary case or controversy and subject matter jurisdiction for an ANDA applicant to file a declaratory judgment action against the NDA-holder and patent owner if the ANDA applicant is not sued within 45 days after the patent owner receives the notice of Paragraph IV certification from the ANDA applicant.

Declaratory Judgment Actions by ANDA Applicants

31. In 2003, Congress amended the Hatch-Waxman provisions of the Federal Food, Drug, and Cosmetic act to explicitly entitle an ANDA applicant to bring and maintain a declaratory judgment action against an NDA holder or patent owner if: (1) 45 days have passed since the Paragraph IV notification was received by the NDA-holder/patent owner, (2) neither the patent owner nor the NDA-holder brought an action for infringement of the patent within the 45-day period, and (3) the notice of Paragraph

IV certification includes an Offer of Confidential Access to the ANDA. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc).

32. Congress amended 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5) to allow ANDA applicants to obtain patent certainty before marketing their generic products and to allow ANDA applicants to obtain court decisions that would expedite introduction of generic drugs into the marketplace in the United States.

33. The 2003 amendments explicitly giving ANDA applicants the right to bring declaratory judgment actions applies to Apotex's ANDA No. 90-500, which was filed in 2008.

34. Congress explicitly mandated that an ANDA applicant is entitled to maintain a declaratory judgment action when it is not sued. 21 U.S.C. § 355(j)(5)(C).

Glaxo's Orange Book Listings

35. Glaxo is the holder of approved NDA No. 20-487 and 20-550 for valacyclovir tablets which are sold under the trade name Valtrex®.

36. Valtrex (valacyclovir) is an anti-viral medication used, among other things, in the treatment of herpes infections. FDA approved Valtrex in 1995. Valtrex is the only valacyclovir product available on the market in the United States.

37. Glaxo submitted information to FDA for three patents to be listed under the Valtrex NDA: U.S. Patent No. 4,957,924 ("the '924 patent") which expired on June 23, 2009, the '706 patent which expires on January 19, 2016, and the '302 patent which also expires on January 19, 2016.

38. On information and belief, Glaxo Wellcome is the owner of the '706 and '302 patents.

39. By listing these patents in the Orange Book, Glaxo affirmatively represented that the '924 patent, the '706 patent, and the '302 patent claims Valtrex tablets, or a method for using Valtrex, and that an infringement suit could reasonably be asserted against any generic ANDA applicant, including Apotex, that attempts to seek approval for, and market, a generic version of Valtrex before patent expiration.

Facts Demonstrating a Justiciable Controversy Regarding Apotex's ANDA for Valacyclovir Tablets

40. Apotex has submitted an ANDA (No. 90-500) to FDA seeking approval to market a valacyclovir tablet product.

41. In its ANDA No. 90-500, Apotex included a Paragraph IV certification to the '706 and '302 patents, stating that the '706 and '302 patents will not be infringed by the manufacture, use, offer for sale, sale, or importation of Apotex's generic valacyclovir tablets and/or that the '706 and '302 patent claims are invalid. This certification signified that Apotex intends to market its generic valacyclovir product before expiration of the '706 and '302 patents in 2016.

42. Apotex's ANDA is substantially complete and was accepted for filing by FDA. Upon receiving final approval, Apotex is prepared and fully intends to market its generic valacyclovir product before expiration of the '706 and '302 patents.

43. In accordance with 21 U.S.C. § 355(j)(2)(B), Apotex provided Glaxo with notice that it had submitted ANDA No. 90-500 to FDA containing a Paragraph IV

certification to the '706 and '302 patents. The notice include a detailed statement of the factual and legal bases why the '706 and '302 patent claims will not be infringed by the manufacture, use, offer for sale, sale, or importation of Apotex's generic valacyclovir tablets.

44. This Notice of Paragraph IV certification was sent by Apotex to Glaxo on August 13, 2008 by United States Mail.

45. On information and belief, Glaxo received the notice of Paragraph IV certification on or about August 16, 2008.

46. More than 45 days have passed since Glaxo received the Notice of Paragraph IV certification from Apotex.

47. Although a case or controversy exists between the parties regarding the '706 and '302 patents, Glaxo has not brought a civil action against Apotex for infringement of either the '706 patent or the '302 patent.

48. Attached to the notice of Paragraph IV certification, Apotex included an offer of confidential access to ANDA No. 90-500 as required by 21 U.S.C. § 355(j)(5)(D) for the sole and exclusive purpose of determining whether an infringement action should be brought.

49. The submission of a Paragraph IV certification constitutes an artificial act of infringement creating the necessary case or controversy and subject matter jurisdiction for an NDA-holder to maintain an action for patent infringement and for the ANDA

applicant to maintain a declaratory judgment action against the NDA-holder and patent owner.

50. Apotex is statutorily entitled to bring and maintain this declaratory judgment action against Glaxo because (1) more than 45 days have passed since Glaxo received Apotex's notice of Paragraph IV certification, (2) Glaxo has not brought a civil action against Apotex for infringement of the '706 or '302 patents, and (3) Apotex provided Glaxo with an offer of confidential access to ANDA No. 90-500.

51. Though Apotex has not yet received tentative approval of ANDA No. 90-500, on information and belief, the ANDA is in satisfactory condition for approval and tentative approval of the ANDA is expected to be forthcoming.

Apotex's Need to Obtain Declaratory Judgment on the '706 and '302 patents

52. Apotex requires a declaratory judgment to obtain patent and market certainty and to avoid indefinite delays in FDA's approval of ANDA No. 90-500.

53. Unless and until Apotex obtains a court decision of non-infringement and/or invalidity on the '706 and '302 patents, it faces the uncertainty of potentially enormous infringement liability if it commences marketing its valacyclovir ANDA product before the '706 and '302 patents expire.

54. On information and belief, Apotex is not the first ANDA applicant to provide a Paragraph IV certification with respect to either the '706 or '302 patents.

55. On information and belief, Ranbaxy Laboratories, Ltd. was the first applicant to file an ANDA containing a Paragraph IV certification to the '924 patent, the '706 patent, and the '302 patent.

56. On information and belief, after an investigation reasonable under the circumstances, FDA has granted and/or will grant Ranbaxy, as the first-filer, 180 days of generic market exclusivity. Until the 180-day first-to-file exclusivity period expires, Apotex is prevented from obtaining final approval to commercially market its valacyclovir ANDA product. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

57. Because, on information and belief, Ranbaxy holds the 180-day first-to-file generic exclusivity, Apotex will be prevented from marketing its product until the earlier of 180 days after Ranbaxy's first commercial marketing of its valacyclovir product or 180 days after obtaining a judgment of non-infringement or invalidity against the '706 and '302 patents.

58. In May 2003, Glaxo sued Ranbaxy for infringement of the '924 patent but not on the '706 and '302 patents.

59. Glaxo and Ranbaxy eventually settled that lawsuit. According to the terms of the agreed Stipulation and Order in that case, Ranbaxy would be allowed to commercially market its valacyclovir tablets product before expiration of the three patents listed in the Orange Book.

60. On information and belief, after a reasonable investigation under the circumstances, Glaxo and Ranbaxy reached an agreement whereby Ranbaxy would be

allowed to commercially market its generic valacyclovir product sometime near the end of 2009.

61. On information and belief, at least 5 other companies have filed ANDAs for valacyclovir tablets. Glaxo has not brought a civil action against any company other than Ranbaxy asserting infringement of the '924 patent, 'the '706 patent, or the '302 patent.

62. Glaxo's purposeful decision not to file suit against any of the subsequent ANDA filers is preventing all of those ANDA applicants, including Apotex from obtaining a judgment of non-infringement or invalidity that would start the 180-day generic market exclusivity period.

63. After Ranbaxy settled its case with Glaxo, FDA took action against Ranbaxy that upon information and belief will prevent it from commercially marketing a generic valacyclovir product for an indefinite period of time in the future. On September 16, 2008, FDA sent warning letters to Ranbaxy detailing several significant deviations from current good manufacturing practices at Ranbaxy's facilities in Dewas, India and Paonta Sahib, India.

64. Ranbaxy's valacyclovir active pharmaceutical ingredient ("API") is included on a list from the FDA of drugs manufactured at the Dewas and Paonta Sahib facilities subject to the FDA warning letters. An API is the active drug product contained within a pharmaceutical composition, such as a tablet, capsule or solution. The API in Glaxo's Valtrex and any generic therapeutic equivalent, such as Ranbaxy's and Apotex's

generic valacyclovir tablet products, is valacyclovir. On information and belief, after an investigation reasonable under the circumstances, Ranbaxy's valacyclovir API is manufactured at the Dewas facility.

65. FDA's warning letters state that "[S]hipments of articles manufactured by your firm are subject to refusal of admission under Section 801 of the FD&C Act in that, the methods and controls used in their manufacture do not appear to conform to current good manufacturing practice within the meaning of Section 501(a)(2)(B) of the FD&C Act."

66. In February 2009, FDA took further action against Ranbaxy after finding that Ranbaxy had submitted untrue statements of material fact in abbreviated and new drug applications (ANDAs and NDAs) filed with FDA and had engaged in a pattern of making false statements and misrepresentations to FDA.

67. Unless and until Ranbaxy cures its problems with FDA, Ranbaxy will not be able to commercially market its valacyclovir product, thus preventing the start of its 180-day first-to-file exclusivity period and consequently preventing all other applicants who have filed an ANDA for valacyclovir, including Apotex, from commercially marketing their generic valacyclovir products.

68. It is unclear when, if ever, Ranbaxy will be in a position to sufficiently cure its regulatory issues prohibiting marketing of its valacyclovir, allowing Ranbaxy the opportunity for market entry.

69. Therefore, the date upon which Apotex (or any other ANDA filer) will be allowed to market its generic valacyclovir product has been indefinitely delayed, and Apotex cannot be certain that it will be provided the opportunity to market its generic valacyclovir product prior to the expiration of the '706 and '302 patents.

70. Further, without obtaining certainty as to when final approval will be available, Apotex cannot adequately prepare for any marketing launch or undertake necessary pre-launch activities for its generic valacyclovir product including: (1) manufacturing scale-up; (2) obtaining clearance on governmental and private insurance formularies for sale; (3) submitting final paperwork to government environmental and health regulatory agencies; (4) validating product specifications for shipping and handling; and (5) manufacturing packaging and labeling.

71. As a result, unless and until the Court adjudicates the issues raised in this declaratory judgment action the American public may not be afforded the opportunity to purchase a lower-priced generic alternative to Glaxo's Valtrex product prior to the expiration of the '706 and '302 patents.

72. The only way that Apotex (or any other ANDA filer) can obtain certainty that it will be able to market its product before the expiration of the '706 and '302 patents is to obtain a judgment of non-infringement or invalidity of the '706 and '302 patents through a declaratory judgment action that will start the running of Ranbaxy's 180-day exclusivity period, even if Ranbaxy has yet to market its product.

73. Thus, Apotex requires a declaratory judgment of non-infringement or invalidity of the ’706 and ‘302 patents to avoid a continuing indefinite delay in its ability to commercially market its valacyclovir ANDA product.

Apotex’s Injury Traceable to Glaxo and Redressable by the Court

74. Apotex has been and is continuing to be harmed by being indefinitely delayed from obtaining final approval to market its non-infringing valacyclovir ANDA product and by enduring substantial uncertainty as to whether its ANDA product described in ANDA No. 90-500 infringes either the ‘706 patent or the ‘302 patent.

75. Each day that this uncertainty remains is another day that Apotex is unable to plan and conduct the pre-launch activities necessary for marketing its generic valacyclovir product.

76. Moreover, the injury from this uncertainty impacts not only Apotex, but also the other ANDA holders and the American public, because lower-priced and therapeutically equivalent generic valacylovir products, such as Apotex’s, are indefinitely delayed from commercial marketing.

77. That delay and uncertainty is traceable to Glaxo’s submission to FDA of the ‘706 and ‘302 patents for inclusion in the Orange Book which constituted an affirmative representation that “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.” *See* 21 U.S.C. § 355(b)(1).

78. The delay and uncertainty being suffered by Apotex can be redressed by this Court through a declaratory judgment that Apotex does not infringe any valid and enforceable claim of either the '706 or '302 patents.

Count I

Declaratory Judgment of Non-Infringement

79. Apotex realleges and incorporates by reference the allegations of paragraphs 1 through 78 above as if fully set forth herein.

80. This declaratory action arises under the United States Patent Act, 35 U.S.C. § 1 *et seq*. and the Declaratory Judgment act, 28 U.S.C. § 2201 and 2202, pursuant to 21 U.S.C. § 355(j)(5)(C), and seeks a declaration that one or more claims of the '706 and '302 patents are not infringed by the manufacture, use, or sale of Apotex's ANDA product.

81. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Glaxo regarding, *inter alia*, non-infringement of the '706 and '302 patents.

82. The manufacture, use, offer for sale, sale, or importation of Apotex's valacyclovir product in ANDA No. 90-500 does not and will not infringe any valid and enforceable claim of the '706 patent or the '302 patent.

83. Apotex intends to sell its valacyclovir product when it receives final approval from the FDA.

84. Apotex is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Apotex's valacyclovir product in ANDA No. 90-500 does not and will not infringe any valid and enforceable claim of the '706 patent or the '302 patent.

Prayer for Relief

Wherefore, Apotex Inc., respectfully prays for judgment in its favor and against Glaxo Wellcome Inc. and SmithKline Beechem Corporation d/b/a GlaxoSmithKline:

(a) Declaring that the manufacture, use, offer for sale, sale, or importation of Apotex's valacyclovir product in ANDA No. 90-500 does not and will not infringe any valid and enforceable claim of the '706 patent or the '302 patent;

(b) Awarding Apotex its reasonable costs, expenses and attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285; and

(c) Awarding all such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Apotex demands trial by jury for any issues so triable.

This the 6th day of July, 2009.

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