IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
CASE NO. 1:09-CV-00477

APOTEX INC.,	)	
	)	
Plaintiff,	)	
	)	**COMPLAINT**
v.	)	**JURY TRIAL DEMANDED**
	)	
EISAI INC. and	)	
EISAI CO., LTD.,	)	
	)	
Defendants.	)	

Plaintiffs Apotex Inc. ("Plaintiff" or "Apotex"), by and through its attorneys, for its Complaint against defendants Eisai Co., Ltd. and Eisai Inc. ("Defendants" or "Eisai") complain as follows:

NATURE OF THE ACTION

1. Apotex brings claims for declaratory relief that Eisai's United States Patent Nos. 5,985,864 ("the '864 patent"), 6,140,321 (the "321 patent"), 6,245,911 (the "911 patent"), and 6,372,760 (the "760 patent") are not infringed by Apotex thereby allowing the Federal Food and Drug Administration ("FDA") to finally approve Apotex's application to market its generic version of donepezil hydrochloride that is bio-equivalent to Eisai's drug ARICEPT®.

PARTIES

2. Apotex Inc. is a corporation organized and existing under the laws of Canada, whose principal place of business is located at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

3. Upon information and belief, Eisai Co., Ltd. is a corporation incorporated and existing under the laws of Japan, having its principal place of business at 4-6-10 Koishikawa, Bunkyo-ku, Tokyo 112-8008, Japan.

4. Upon information and belief, Eisai Inc. is a United States subsidiary of Eisai Co., Ltd. and a corporation incorporated under the laws of the State of Delaware, having its principal place of business at 500 Frank W. Burr Blvd., Teaneck, New Jersey 07666.

JURISDICTION AND VENUE

5. This Complaint arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.; the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq*., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (hereinafter "Hatch-Waxman Amendments"), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003) (hereinafter "MMA"); and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court has subject matter jurisdiction over this Complaint pursuant to 28 U.S.C. §§ 1331, and 1338(a).

7. This Court has personal jurisdiction over Eisai Inc. and Eisai Co., Ltd. because Defendants transact business in this district, at least by selling and/or distributing pharmaceuticals in this district including Eisai's donepezil HCl product ARICEPT® and/or maintaining a research and development facility at 900 Davis Drive, Research Triangle Park, North Carolina 27709.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(c) and 1391(d).

FACTUAL ALLEGATIONS

A. THE REGULATORY BACKGROUND PURSUANT TO WHICH GENERIC SUBSTITUTES FOR BRAND NAME DRUGS ARE APPROVED

9. In 1984, Congress amended the Federal Food, Drug, and Cosmetic Act by adding the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. *See* Pub.L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 2l U.S. § 355 and 35 U.S.C. § 271(e)). The Hatch-Waxman Amendments were designed to stem the rising cost of prescription drugs by bringing less expensive generic drugs to market faster.

10. Under the Federal Food, Drug, and Cosmetics Act (21 U.S.C. §§ 301-392), manufacturers wanting to sell a new drug compound must obtain approval to sell from the FDA by filing a New Drug Application ("NDA"). An NDA must include specific

data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

11. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need to file a lengthy and costly NDA in order to obtain FDA approval to sell a generic equivalent of a marketed drug. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA").

12. The ANDA relies on the scientific findings of safety and effectiveness included by the brand name drug manufacturer in the original NDA. The ANDA filer must demonstrate to the FDA that the proposed generic product is bio-equivalent to the branded drug.

13. As a counter-balance to this abbreviated process for bio-equivalent generic drugs, Hatch-Waxman provided brand drug manufacturers certain non-patent exclusivities, such as Orphan Drug and New Chemical Entity ("NCE") exclusivities.

14. When the FDA approves a brand name manufacturer's NDA, the FDA publishes in the "Approved Drug Products with Therapeutic Equivalence Evaluations", or the "Orange Book", any patents the brand manufacturer alleges can be reasonably asserted against a generic equivalent. 21 U.S.C. § 355(j)(7)(A)(iii). The listing of patents in the Orange Book by the FDA is a ministerial act. The FDA does not check the facts supplied to it by the brand manufacturer.

15. After an NDA is approved by the FDA, a brand manufacturer may list additional new patents in the Orange Book as being related to the drug the subject of its NDA. The brand manufacturer must certify, *inter alia,* that the new patents claim either the approved drug (for compound patents) or that the patents claim approved methods of using the drug (for method-of-use patents).

16. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a branded drug without receiving a license by the branded drug manufacturer), a generic manufacturer must make specific certifications with respect to patents that may be listed in the Orange Book as claiming the subject drug or method of using the drug. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand name drug has expired (a "Paragraph II certification");

iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturers proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

17. If a generic manufacturer files a Paragraph IV certification claiming a patent listed in the Orange Book is invalid or will not be infringed, a brand manufacturer

has an opportunity to delay the final FDA approval of the ANDA and the sale of the competing generic drug on the market.

18. When a generic drug manufacturer files a Paragraph IV certification with its ANDA, the generic manufacturer must promptly give notice of its certification to both the NDA-holder and the owner of the patent(s) at issue. Pursuant to 35 U.S.C. § 271(e)(2), submitting a Paragraph IV certification is an artificial act of infringement. If the NDA-holder initiates a patent infringement action against the ANDA filer within 45 days of receiving the Paragraph IV certification, then the FDA may not grant final approval to the ANDA until the earlier of either: (a) 30 months from the date the ANDA is filed; or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii).

19. The first ANDA holder (first-to-file generic) to file a Paragraph IV certification can obtain a 180-day period of exclusivity, during which time the FDA will not approve any other ANDAs containing Paragraph IV certifications that list the same pioneer drug.

20. Pursuant to the statutory framework applicable to the ANDA applications the subject of the present complaint, the FDA has interpreted Hatch-Waxman to provide first-to-file generics with a 180 day exclusivity period that can be triggered by (1) a court decision of invalidity or non-infringement or (2) by one of the first-to-file generics entering the market. 21 U.S.C. § 355(j)(5)(B)(iv). Until one of these triggers occurs, the FDA will not grant a generic that files its Paragraph IV Certification after the first-to-file

generic to obtain final approval to enter the market. The court decision of invalidity or non-infringement, however, can be from any case, including cases that do not arise from litigation against the first-filing generic.

21. In the case of ANDAs filed prior to the MMA amendments to the Hatch Waxman Act (*e.g.* the ANDA applications discussed herein), a bottleneck can occur when the first-to-file generic does not enter the market and the brand drug manufacturer refuses to sue subsequent Paragraph IV filers, thereby preventing a finding of invalidity or non-infringement. Because there is no trigger of the first-to-file generic's 180 day exclusivity period, generic drug entry can be delayed indefinitely. In *Caraco Pharm. Labs., Inc. v. Forest Labs., Inc.*, the Federal Circuit held courts have declaratory judgment jurisdiction over complaints filed by second-to-file generic manufacturers when a bottleneck is formed because the first-to-file generic manufacturer will not enter the market and subsequent Paragraph IV filing generics have not been sued. 527 F.3d 1278 (Fed. Cir. 2008).

22. The Hatch-Waxman Act provides for civil actions to obtain patent certainty through the Declaratory Judgment Act where (1) the patentee and/or the holder of the NDA has not brought a civil action for infringement of the certified patents and (2) the ANDA applicant has included an offer of confidential access to its ANDA application in its notice letter. 21 U.S.C. § 355(j)(5)(C).

B. THE SPECIFIC DRUG AT ISSUE HERE.

23. ARICEPT® is a branded drug manufactured by Eisai. ARICEPT® is marketed and prescribed for the treatment of mild to moderate dementia of the Alzheimer's type. The active pharmaceutical ingredient in ARICEPT® is donepezil hydrochloride.

24. The FDA approved Eisai's NDA No. 20-690 to sell 5 mg and 10 mg tablets including the active ingredient donepezil hydrochloride (*i.e.* ARICEPT®) on or around Oct. 18, 2004, and Eisai began selling ARICEPT® shortly thereafter.

25. Upon information and belief, Eisai Co., Ltd. is the assignee of U.S. Patent No. 4,895,841 ("the '841 patent"), titled "Cyclic Amine Compounds With Activity Against Acetylcholinesterase" and issued on Jan. 23, 1990. The '841 patent expires on November 25, 2010. The '841 patent has been listed in the FDA's Orange Book as a patent that could reasonably be asserted against a generic manufacturer of ARICEPT® and is attached hereto as **Exhibit A**.

26. Upon information and belief, Eisai Co., Ltd. is the assignee of the '864 patent, titled "Polymorphs Of Donepezil Hydrochloride And Process For Production" and issued on November 16, 1999. The '864 patent will expire on December 30, 2016. The '864 patent has been listed in the FDA's Orange Book as a patent that could reasonably be asserted against a generic manufacturer of ARICEPT®. The '864 patent is attached hereto as **Exhibit B**.

27. Upon information and belief, Eisai Co., Ltd. is the assignee of the '321 patent, titled "Polymorphs Of Donepezil Hydrochloride And Process For Production" and issued on Oct. 31, 2000. The '321 patent expires on December 30, 2016. The '321 patent has been listed in the FDA's Orange Book as a patent that could reasonably be asserted against a generic manufacturer of ARICEPT®. The '321 patent is attached hereto as **Exhibit C**.

28. Upon information and belief, Eisai Co., Ltd. is the assignee of the '911 patent, titled "Donepezil Polycrystals And Process For Producing The Same" and issued on Jun. 12, 2001. The '911 patent will expire on December 1, 2018. The '911 patent has been listed in the FDA Orange Book as a patent that could reasonably be asserted against a generic manufacturer of ARICEPT®. The '911 patent is attached hereto as **Exhibit D**.

29. Upon information and belief, Eisai Co., Ltd. is the assignee of the '760 patent, titled "Stabilized Composition Comprising Antidementia Medicament" and issued Apr. 16, 2002. The '760 patent expires on Mar. 31, 2019. The '760 patent has been listed in the FDA Orange Book as a patent that could reasonably be asserted against a generic manufacturer of ARICEPT®. Upon information and belief, formed after an investigation reasonable under the circumstances, Eisai has requested the '760 patent be "de-listed", *i.e.* removed from the FDA's Orange Book. At this time the FDA has not complied with Eisai's request. The '760 patent is attached hereto as **Exhibit E**.

C. GENERIC MANUFACTURERS OTHER THAN APOTEX WITH PARAGRAPH IV CERTIFICATIONS TO EISAI'S PATENTS

30. Upon information and belief, Ranbaxy Laboratories, Ltd. and/or Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy") filed with the FDA ANDA No. 07-6786 with a Paragraph IV certification asserting the '864, '321, '911 and '760 patents were invalid and/or not infringed by the proposed generic ARICEPT® product described in its application. Ranbaxy was the first-to-file generic manufacturer pursuant to the Hatch-Waxman Act. Eisai did not sue Ranbaxy for the statutory act of infringement of Eisai's patents.

31. Upon information and belief, Ranbaxy obtained tentative approval (pending the expiry of Eisai's '841 patent on November 25, 2010) on February 23, 2005 and again on December 5, 2007. "Tentative approval" means the generic product the subject of the ANDA is deemed by the FDA to be safe, effective and bio-equivalent to its brand name counterpart, but the existence of some legal or regulatory barrier precludes the FDA from granting final approval to sell.

32. In September 2008, and after obtaining tentative approval, the FDA sent letters of deficiency to Ranbaxy because certain of its manufacturing facilities in India failed to comply with U.S. current Good Manufacturing Practices ("cGMP"). As a result, Ranbaxy was informed applications describing pharmaceuticals manufactured at its deficient facilities would not be approved and shipments of pharmaceuticals from these facilities would be denied entry into the U.S.

33. In February 2009, Ranbaxy was informed the FDA had determined it had submitted untrue statements of material fact in ANDA applications it filed with the FDA. The untrue statements related to tests performed and described in Ranbaxy's ANDA submissions. Ranbaxy was informed applications describing tests similar to those found to be untrue would not be approved pending investigations.

34. Upon information and belief, a reasonable opportunity for further investigation and discovery will show Ranbaxy's tentative approval has been revoked because Ranbaxy failed to comply or conform with accepted regulatory (*i.e.* cGMP) and legal requirements relating to its generic drug products and ANDA submissions. The FDA's revocation of Ranbaxy's tentative approval is unrelated to any patent Eisai asserts covers its donepezil hydrochloride ARICEPT® product. Ranbaxy will not be able to enter the market for generic donepezil hydrochloride on November 25, 2010 (the expiration date of the '841 patent) without final approval of the safety and efficacy content of its ANDA. Generic entry will be delayed indefinitely if Ranbaxy does not launch on November 25, 2010.

35. Upon information and belief, subsequent to Ranbaxy's filing its ANDA application, Par Pharmaceuticals, Inc. ("Par"), Roxane Laboratories, Inc. ("Roxane"), and Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. ("Teva") each filed ANDA applications to sell generic donepezil hydrochloride with Paragraph IV certifications to Eisai's '864, '321, '911 and '760 patents. Teva also filed a Paragraph IV

certification asserting Eisai's '841 patent was either invalid or not infringed by the proposed donepezil hydrochloride product described in its ANDA.

36. Eisai has not asserted any of the '864, '321, '911 or '760 patents against any of the aforementioned Paragraph IV filing applicants. Eisai sued Teva for infringement of the '841 patent and that litigation is currently pending in the District of New Jersey (Civil Action No. 05-5727).

37. Upon information and belief, Par, Roxane and Teva are not first-to-file generic manufacturers and are not entitled to 180 days of exclusivity for selling generic ARICEPT®. Neither Par, Roxane nor Teva can enter the market to sell generic donepezil hydrochloride until (1) Ranbaxy enters the market or (2) each of Eisai's '841, '864, '321, '911 and '760 patents are found invalid, not-infringed or otherwise expire. Because Eisai has not sued any generic manufacturer for statutory infringement of Eisai's '864, '321, '911 and '760 patents, no generic manufacturer can enter the market in the event the court finds the '841 patent invalid or not infringed in the action Eisai brought against Teva (or when the '841 patent expires because Ranbaxy cannot obtain FDA final approval). Each generic manufacturer would be indefinitely blocked by Eisai's unasserted patents and Ranbaxy's failure to enter the market.

38. On information and belief, a reasonable opportunity for further investigation or discovery will show the FDA is erroneously identifying Teva as the first-to-file generic manufacturer for donepezil hydrochloride. Until and unless the FDA is made aware and corrects its mistake, Teva is poised to illegally obtain final approval to

sell its generic donepezil hydrochloride product on or around November 25, 2010, the date Eisai's '841 patent expires. Any attempt by the FDA to finally approve Teva's application prior to Ranbaxy's 180 days of exclusivity, however, is not likely to be successful.

39. Ranbaxy's inability to obtain approval of its ANDA and the FDA's erroneous identification of Teva as the first-to-file generic has created substantial uncertainty in the generic market for donepezil hydrochloride products bio-equivalent to ARICEPT®. While there are a number of generic manufacturers willing and able to enter the market for generic donepezil hydrochloride, the uncertainty prevents each from planning a launch.

D. APOTEX'S ANDA AND INJURY RESULTING FROM BEING HELD OUT OF THE MARKET BY EISAI'S LISTING OF THE '864, '321, '911 and '760 PATENTS.

40. Apotex manufactures generic drug products for sale in Canada and the United States. Apotex is familiar with the regulatory requirements for filing an ANDA and the benefits the first-to-file generic manufacturer receives.

41. Apotex filed ANDA No. 78-841 for a generic donepezil hydrochloride product bio-equivalent to Eisai's ARICEPT®. Apotex included a Paragraph III certification to Eisai's '841 patent stating it would not sell its generic product until, at least, the date the '841 patent expired, namely November 25, 2010. Apotex filed Paragraph IV certifications stating the '864, '321, '911 and '760 patents would not be infringed by Apotex's proposed generic donepezil hydrochloride product.

42. On or around July 5, 2007, Apotex submitted a notice letter to Eisai informing it Apotex had filed ANDA No. 78-841 with Paragraph IV certifications to Eisai's '864, '321, '911 and '760 patents. Apotex's notice letter contained an offer for confidential access to Apotex's ANDA.

43. More than 45 days have passed since Apotex provided Eisai notice of its ANDA containing Paragraph IV certifications. Eisai has not filed a lawsuit in response to those certifications.

44. Apotex expended considerable effort and resources to develop a generic version of donepezil hydrochloride therapeutically bio-equivalent to Eisai's ARICEPT®. Apotex has also spent considerable resources in preparing to market and launch its generic product.

45. By filing a substantially complete ANDA for donepezil hydrochloride with the FDA, Apotex has taken all regulatory actions necessary to obtain FDA approval of its ANDA thereby allowing it to sell generic ARICEPT® in the United States.

46. Apotex has obtained tentative approval from the FDA to sell donepezil hydrochloride tablets, 5 mg and 10 mg. The FDA granted tentative approval based on Apotex's submissions to the FDA. The FDA determination was based on the status of cGMP of Apotex's facilities used in the manufacture and testing of donepezil hydrochloride.

47. Even though Apotex has tentative approval, Apotex does not have final approval for its ANDA and cannot sell a generic version of ARICEPT®.

48. Apotex will be unable to obtain final approval of its generic product on or around 180 days following the expiry of the '841 patent until such time as the bottleneck created by Ranbaxy's inability to obtain FDA approval and Eisai's refusal to sue second to file generic manufacturers is eliminated.

49. The FDA will not give final approval to Apotex's ANDA unless (1) Ranbaxy enters the market or (2) there is a court decision finding, *inter alia*, the '864, '321, '911 and '760 patents invalid or not infringed.

50. Apotex is injured because Ranbaxy will not be able to launch its generic product Eisai's '841 patent expires and Eisai has refused to sue any generic Paragraph IV filer for infringement of its '864, '321, '911 and '760 patents. As such, there is no opportunity for a triggering event and subsequent generic entry to the market. Furthermore, even if Ranbaxy were to enter the market, Apotex needs a finding of invalidity or non-infringement of the '864, '321, '911 and '760 patents to have certainty that it does not infringe these patents.

51. Patent uncertainty and the bottleneck caused by Ranbaxy's inability to obtain final approval and Eisai's refusal to sue Paragraph IV filing generics for statutory infringement of the '864, '321, '911 and '760 patents has caused, and is causing, substantial damage to Apotex.

E. FACTS DEMONSTRATING APOTEX STATES A JUSTICIABLE CLAIM OR CONTROVERSY.

52. Upon receiving final approval of its ANDA for donepezil hydrochloride from the FDA, Apotex is prepared and fully intends to enter the U.S. market with a generic version of ARICEPT®.

53. Apotex's generic ARICEPT® drug would not infringe any valid and enforceable claim of the '864, '321, '911 and '760 patents. Apotex suffers the injury of the restraint on the free exploitation of its non-infringing generic version of ARICEPT®.

54. Apotex has the right to enter the generic donepezil hydrochloride market 180 days after the '841 patent expires, namely 180 days after November 25, 2010, because it does not infringe any valid claim of the '864, '321, '911 and '760 patents.

55. Apotex will be excluded from entering the market when it has a right to do so because Eisai refuses to bring suit for the statutory infringement of its '864, '321, '911 and '760 patents.

56. Apotex has a complete generic drug product application and there are no additional facts required to determine whether Apotex's ANDA infringes a valid and enforceable claim of Eisai's '864, '321, '911 and '760 patents.

57. The Hatch-Waxman Act provides for declaratory judgment jurisdiction here because more than 45 days have passed since Apotex provided Eisai with its notice letter containing an offer of confidential access to Apotex's ANDA and Eisai has not sued Apotex for infringement of the certified patents.

58. If the Court withheld consideration of Apotex's declaratory judgment claims, it would have the immediate and substantial impact of forestalling Apotex's ability to trigger the 180-day exclusivity period by obtaining a finding of non-infringement of the claims of the '864, '321, '911 and '760 patents.

59. Eisai has not offered a covenant not to sue. However, even if Eisai were to make such an offer, it would not moot this action because Apotex's injury of being unable to sell a non-infringing generic version of donepezil hydrochloride would not be alleviated.

COUNT I

DECLARATORY JUDGMENT OF NON-INFRINGEMENT AGAINST EISAI

60. Paragraphs 1-59 above are hereby adopted by reference as though they were fully set forth herein.

61. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(C).

62. Apotex has filed an ANDA with a Paragraph IV certification stating the '864, '321, '911, and '760 patents are not infringed by Apotex.

63. Apotex intends to sell donepezil hydrochloride when it obtains FDA approval to sell.

64. There is a real, actual, and continuing justiciable case and controversy between Apotex on the one hand and Eisai on the other hand regarding the infringement of the '864, '321, '911, and '760 patents.

65. The '864, '321, '911, and '760 patents will not be infringed by the manufacture, use, or sale of generic donepezil hydrochloride for which Apotex has submitted an ANDA.

66. Apotex is entitled to a judicial declaration that the manufacture, sale or use of Apotex's donepezil hydrochloride product, that is the subject of ANDA No. 78-841, will not infringe, directly or indirectly, any valid claim of the '864, '321, '911 and '760 patents.

DEMAND FOR JUDGMENT AND PRAYER FOR RELIEF

WHEREFORE, Apotex prays for judgment:

a. Finding Apotex has not infringed the '864, '321, '911 and '760 patents;

b. Finding this to be an exceptional case under 35 U.S.C. § 285;

c. Awarding Apotex its costs, expenses, and reasonable attorneys' fees and other relief the Court deems just.

DEMAND FOR JURY TRIAL

Apotex demands trial by jury for all issues triable by jury as a matter of right.

This the 1st day of July, 2009.

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