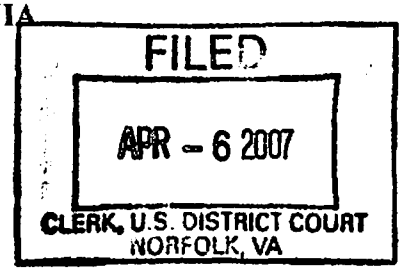
UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
~~Norfolk~~ Alexandria Division



EXELA PHARMSCI, INC.,

Plaintiff,

v.

ALLERGAN, INC.,

Defendant.

Civil Action No. 1:07cv338 TSE/TCB

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Exela PharmSci, Inc. ("Exela"), by way of its Complaint against Allergan, Inc. ("Allergan"), alleges as follows:

Statement of the Case

1. This is a declaratory-judgment action seeking a declaration of noninfringement, unenforceability, or invalidity of United States Patents Nos. 5,424,078 ("the '078 patent"), 6,562,873 ("the '873 patent"), 6,627,210 ("the '210 patent"), 6,641,834 ("the '834 patent"), and 6,673,337 ("the '337 patent") (attached as Exhibits 1-5). Allergan listed the above five patents with the Food and Drug Administration ("the FDA") in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"), as patents that could reasonably be asserted against anyone marketing or seeking to market a generic product in competition with Allergan's 0.15% brimonidine tartrate ophthalmic solution, which Allergan sells under the brand name Alphagan® P. Exela has filed an Abbreviated New Drug Application ("ANDA") with the FDA, seeking approval to market a 0.15% brimonidine tartrate ophthalmic solution. As part of

that application, Exela certified that that it did not infringe any of the above five patents and that the patents were unenforceable or invalid. Exela also provided Allergan with notice of its certification.

2. On March 26, 2007, Allergan sued Exela alleging infringement of the '834 patent. *See Allergan, Inc. v. Exela PharmSci, Inc. and Exela PharmSci Pvt. Ltd.*, No. 07-6196 (R)(RC) (Mar. 26, 2007) ("the California Complaint"). By suing on the '834 patent within 45 days after receiving Exela's notice, Allergan invoked statutory provisions that prevent the FDA from approving Exela's ANDA for up to 30 months under certain conditions. 21 U.S.C. § 355(j)(5)(B)(iii). Because Allergan did not sue Exela on the remaining four patents listed in the Orange Book and Exela remains faced with the threat of suit on those patents, Exela has a reasonable apprehension that Allergan will sue Exela on the remaining patents listed in the Orange Book, and a justiciable controversy exists under the Declaratory Judgment Act. Allergan's conduct impairs Exela's ability to bring its brimonidine drug product to market. Exela thus seeks a declaratory judgment that it does not infringe the '078, '873, '210, '834, and '337 patents, and that those patents are invalid and/or unenforceable.

3. Exela is a Virginia corporation and is not subject to the jurisdiction of California. Exela intends to challenge jurisdiction in the California Complaint and properly brings this declaratory-judgment action in Virginia.

Parties

4. Exela is a Virginia corporation, and has its principal place of business at 11710 Plaza America Drive, Suite 2000, Reston, Virginia 20190. Among other things, Exela develops generic pharmaceutical products for distribution and sale in the United States.

5. On information and belief, Allergan is a Delaware corporation with its principal place of business at 2525 Dupont Drive, Irvine, California 92612.

Jurisdiction and Venue

6. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and 21 U.S.C. § 355(j)(5)(C)(i)(II).

7. This Court has subject-matter jurisdiction based on 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 and 21 U.S.C. § 355(j)(5)(C)(i)(II).

8. This Court has personal jurisdiction over Allergan because, for example, Allergan is doing business within this district.

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

10. Venue is proper because Exela is a Virginia corporation and a substantial part of the events giving rise to the claim occurred in Virginia.

11. Venue is proper because Allergan resides in this district, is subject to personal jurisdiction in this district in that it is doing and transacting business in this district, and has substantial contacts in this district.

Allergan's NDA and Exela's ANDA

12. On information and belief, Allergan is the current holder of New Drug Application ("NDA") No. 21-262 for 0.15% brimonidine tartrate ophthalmic solution, which Allergan markets under the brand name Alphagan® P in the United States. Alphagan® P is indicated to treat glaucoma.

13. On information and belief, in 2001 the FDA approved Allergan's NDA 21-262. This permitted Allergan to market its 0.15% brimonidine tartrate ophthalmic solution.

14. Brimonidine has been approved by the FDA as an ophthalmic solution since 1996 and has been sold by several drug companies, including Alcon, Inc. ("Alcon"), Akorn, Inc., Bausch and Lomb, Inc., and Ivax Pharmaceuticals, Inc.

15. On information and belief, the FDA has approved Alcon's NDA No. 21-764 for 0.15% brimonidine tartrate ophthalmic solution, but Alcon may not market its product until September 30, 2009, due to a settlement agreement with Allergan, unless certain market conditions occur, the primary condition being a trigger based on the extent to which prescriptions of Allergan's 0.15% brimonidine tartrate ophthalmic solution have been converted to other brimonidine-containing products.

16. The FDA rated Alcon's NDA 21-764 product with an "AT" Therapeutic Evaluation Code, which means that it is considered therapeutically equivalent (same active ingredient) but not pharmaceutically equivalent (not generically substitutable). As a result, there is currently no generic product that can be sold in competition with Allergan's 0.15% brimonidine product.

17. The Federal Food, Drug and Cosmetic Act ("FFDCA") authorizes a generic company to file an ANDA, which the FDA will approve if the generic company shows that its product has the same active ingredient as, and is bioequivalent to, a product that the FDA has already approved. Typically, the ANDA applicant submits data showing that its product is bioequivalent to a product that has been the subject of an approved NDA.

18. The FFDCA requires NDA holders to submit to the FDA the patent number and expiration date of any patent(s) that the NDA holder believes "a claim of patent infringement could reasonably be asserted if a person not licensed by the [NDA] owner engaged in the

manufacture, use or sale of the drug." 21 U.S.C. § 355(b)(1). The FDA—with no substantive review of the patents—lists the patent number(s) and expiration date(s) in the Orange Book.

19. If an ANDA applicant seeks approval to market its generic product before the patents listed in the Orange Book expire, the applicant must include in its ANDA a certification that its proposed product would not infringe those patents, and/or that the patents are invalid or unenforceable. The applicant must then send a notice letter to the NDA holder and patent owner that includes a detailed statement of the factual and legal bases of the applicant's opinion that the patent is invalid, unenforceable, or would not be infringed.

20. If the patent owner sues the ANDA applicant for infringement within 45 days of receiving the notice letter, on that basis alone the FDA is prohibited by statute from approving the ANDA for 30 months or until the infringement action is over, absent a court order shortening the period.

21. Upon information and belief, Allergan, as the NDA holder for Alphagan® P (NDA 21-262), filed with the FDA a patent certification pursuant to 21 U.S.C. § 355(b)(1) requesting that five patents be listed by the FDA in the Orange Book, namely the '078, '873, '210, '834, and '337 patents.

22. Allergan's listing of these five patents means that Allergan asserts that any one of these patents is a "patent which claims the drug for which the application was submitted [i.e., Alphagan® P, NDA No. 21-262] . . . and 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." *See* 21 U.S.C. § 355(b)(1).

23. All patents covering the active ingredient brimonidine expired long ago. The Orange Book patents all relate to formulations of brimonidine.

24. To engage in the commercial manufacture, use, or sale of 0.15% brimonidine tartrate ophthalmic solution, Exela filed with the FDA an ANDA for Exela's product, and the FDA assigned Exela's application ANDA No. 78-590.

25. Exela's ANDA seeks approval to market generic 0.15% brimonidine tartrate ophthalmic solution based on Allergan's NDA No. 21-262. By preparing and filing this ANDA, Exela has made substantial preparation to make, use, import, offer to sell, and sell generic 0.15% brimonidine tartrate ophthalmic solution in the United States before expiration of the patents Allergan listed in the Orange Book. Exela certified to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (hereinafter "Paragraph IV certification(s)"), that Exela's 0.15% brimonidine tartrate ophthalmic solution will not infringe any claim of the patents listed in the Orange Book, and that those patents are invalid and unenforceable.

26. On February 8, 2007, Exela, in accordance with 21 U.S.C. § 355(j)(2)B)(i) and (ii), mailed Allergan a notice that it had filed an ANDA for its 0.15% brimonidine tartrate ophthalmic solution informing Allergan that its ANDA contained Paragraph IV certifications regarding the '078, '873, '210, '834, and '337 patents. The notice provided the factual and legal bases as to why the '078, '873, '210, '834, and '337 patents were invalid, unenforceable, or will not be infringed, by the commercial manufacture, use, or sale of Exela's 0.15% brimonidine tartrate ophthalmic solution before expiration of the '078, '873, '210, '834, and '337 patents. The notice also included an offer of confidential access to Exela's ANDA, as provided for in 21 U.S.C. § 355 (j)(5)(C)(I)(cc), (j)(5)(C)(III).

27. Upon information and belief, Allergan has stated that it received notice on February 12, 2007, that Exela had filed an ANDA for 0.15% brimonidine tartrate ophthalmic

solution with Paragraph IV certifications as to the five listed Orange Book patents, as provided by § 505(j)(2)(B)(ii) of the FFDCA and 21 C.F.R. § 314.95.

28. On March 26, 2007, Allergan filed the California Complaint alleging "Exela's proposed generic Brimonidine Tartrate Ophthalmic Solution 0.15% will infringe the '834 patent."

29. In the California Complaint, however, Allergan did not sue Exela for infringement of the '078, '873, '210, and '337 patents. Because those patents are listed in the Orange Book for 0.15% brimonidine tartrate ophthalmic solution, Exela remains faced with the threat of litigation concerning these four patents, and that threat is impairing Exela's ability to bring to market its brimonidine drug product. The 45-day period after the date on which Allergan received Exela's notice that Exela had filed an ANDA for its brimonidine drug product containing Paragraph IV certifications as to the five listed Orange Book patents has expired, as provided by § 505(j)(5)(B)(iii) of the FFDCA. Exela thus seeks a declaratory judgment of noninfringement, invalidity, and/or unenforceability of the '078, '873, '210, and '337 patents, pursuant the Declaratory Judgment Act and 21 U.S.C. § 355(j)(5)(C)(i)(II).

30. Allergan did not accept Exela's offer of access to Exela's ANDA before filing the California Complaint.

31. Allergan has not provided Exela with a covenant not to sue based on the five Orange Book patents, nor any other assurance that it would not assert a case for infringement for the remaining four patents listed in the Orange Book against Exela.

32. Allergan has demonstrated an intention to prevent generic competition for its products by attempting to enforce Orange Book-listed patents against one or more generic companies in numerous instances. With regard to 0.15% brimonidine tartrate ophthalmic

solution, Allergan sued Alcon Laboratories for its brimonidine drug product (under 505(b)(2)), based on the '834 and '337 patents and settled this case on or about March 9, 2006. *See Allergan, Inc. v. Alcon Labs.*, No. 04-968 (D. Del. filed Aug. 24, 2004).

33. The five Orange Book patents include claims for 0.15% brimonidine tartrate ophthalmic solutions that are closely related to the formulation claims in the '834 patent and involve the same technology. The '834 patent, moreover, is a continuation patent of the '210 patent. The '873 patent, the '210 patent, and the '337 patent all share a history to Provisional Application No. 60/218,200 and share many common components in their substantive specifications.

34. Allergan's selection of the '834 patent to initiate its infringement suit creates uncertainty as to Exela's legal rights under its ANDA.

35. Exela suffers a direct legal injury from the actions Allergan has already taken—Allergan's listing of the five Alphagan® P patents in the Orange Book and Allergan's suit against Exela challenging the validity of Exela's ANDA—which requires judicial relief. *See* 21 U.S.C. § 355(j)(5)(C).

36. Exela suffers from the possibility of future litigation created by Allergan electing to challenge Exela's ANDA on only one of the five listed Orange Book patents for Alphagan® P. Allergan's suit on the '834 patent alone leaves open the possibility of future litigation regardless of whether Exela wins or loses the '834 patent-infringement suit. The possibility that Exela will be subject to multiple infringement suits from Allergan over a protracted litigation on the submission of its single ANDA containing five Paragraph IV certifications is an injury relevant to finding a justiciable controversy.

37. Exela suffers from Allergan improperly bringing suit on the '834 patent in California, forcing Exela to challenge personal jurisdiction and further protract its litigation concerning its ANDA product because Exela is a Virginia corporation and a substantial part of the events giving rise to the claim occurred in Virginia.

38. Exela, therefore, has a reasonable apprehension and justiciable controversy under the Declaratory Judgment Act that Allergan would likely assert the five listed Orange Book patents against Exela if Exela commercially marketed its generic 0.15% brimonidine tartrate ophthalmic solution.

The Presence of a Case or Controversy

39. Under 35 U.S.C. § 271(e)(2)(A), Exela's submission of an ANDA to the FDA constitutes a "technical" act of infringement for subject-matter jurisdiction purposes for each of the patents listed in the Orange Book. Moreover, 35 U.S.C. § 271(e)(5) provides that the Court has subject-matter jurisdiction under 28 U.S.C. §§ 2201 for a declaratory judgment that any unasserted Orange Book patents are invalid or not infringed. *See also Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, No. 06-1181, 2007 WL 942201 (Fed. Cir. Mar. 30, 2007).

40. Because Allergan filed the California Complaint alleging that Exela has infringed the '834 patent, Allergan has demonstrated an intent to enforce its patents concerning 0.15% brimonidine tartrate ophthalmic solution.

41. The California Complaint gives rise to an actual controversy with respect to the '834 patent.

42. Allergan has never disavowed, in the California Complaint or elsewhere, an intent to assert that Exela infringes the '078, '873, '210, and '337 patents.

43. Exela has made, and will continue to make, substantial preparation in the United States to manufacture, sell, and offer to sell Exela's 0.15% brimonidine tartrate ophthalmic solution.

44. Allergan caused the FDA to list the '078, '873, '210, and '337 patents in the Orange Book but did not assert those patents in the California Complaint, even though those patents involve the same technology and share substantial content with the '834 patent.

45. The totality of the circumstances support that a case or controversy exists with respect to the infringement, invalidity, and/or unenforceability of the '078, '873, '210, '834 and '337 patents.

46. To avoid legal uncertainty and to protect its substantial investment (and anticipated future investment) in Exela's 0.15% brimonidine tartrate ophthalmic solution, Exela seeks declaratory-judgment relief with respect to the '078, '873, '210, '834 and '337 patents in Virginia.

COUNT I
Declaratory Judgment of
Noninfringement of the '078 Patent

17. Exela repeats and realleges each of the foregoing paragraphs of this Complaint for Declaratory Judgment.

18. A case or controversy exists between Exela and Allergan concerning the noninfringement of the '078 patent, which requires a declaration of rights by this Court.

19. Exela's 0.15% brimonidine tartrate ophthalmic solution does not infringe any valid or enforceable claim of the '078 patent.

20. Exela is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale, or importation of Exela's 0.15% brimonidine tartrate ophthalmic solution does not infringe any valid or enforceable claim of the '078 patent.

COUNT II
Declaratory Judgment of
Invalidity of the '078 Patent

21. Exela repeats and realleges each of the foregoing paragraphs of this Complaint for Declaratory Judgment.

22. A case or controversy exists between Exela and Allergan concerning the invalidity of the '078 patent, which requires a declaration of rights by this Court.

23. The '078 patent is invalid for failure to meet the patentability requirements under 35 U.S.C. § 101, *et seq.*

24. Exela is entitled to a declaratory judgment that the '078 patent is invalid.

COUNT III
Declaratory Judgment of
Noninfringement of the '873 Patent

25. Exela repeats and realleges each of the foregoing paragraphs of this Complaint for Declaratory Judgment.

26. A case or controversy exists between Exela and Allergan concerning the noninfringement of the '873 patent, which requires a declaration of rights by this Court.

27. Exela's 0.15% brimonidine tartrate ophthalmic solution does not infringe any valid or enforceable claim of the '873 patent.

28. Exela is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale, or importation of Exela's 0.15% brimonidine tartrate ophthalmic solution does not infringe any valid or enforceable claim of the '873 patent.

COUNT IV
Declaratory Judgment of
Invalidity of the '873 Patent

29. Exela repeats and realleges each of the foregoing paragraphs of this Complaint for Declaratory Judgment.

30. A case or controversy exists between Exela and Allergan concerning the invalidity of the '873 patent, which requires a declaration of rights by this Court.

31. The '873 patent is invalid for failure to meet the patentability requirements under 35 U.S.C. § 101, *et seq.*

32. Exela is entitled to a declaratory judgment that the '873 patent is invalid.

COUNT V
Declaratory Judgment of
Noninfringement of the '210 Patent

33. Exela repeats and realleges each of the foregoing paragraphs of this Complaint for Declaratory Judgment.

34. A case or controversy exists between Exela and Allergan concerning the noninfringement of the '210 patent, which requires a declaration of rights by this Court.

35. Exela's 0.15% brimonidine tartrate ophthalmic solution does not infringe any valid or enforceable claim of the '210 patent.

36. Exela is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale, or importation of Exela's 0.15% brimonidine tartrate ophthalmic solution does not infringe any valid or enforceable claim of the '210 patent.

COUNT VI
Declaratory Judgment of Invalidity of the '210 Patent

37. Exela repeats and realleges each of the foregoing paragraphs of this Complaint for Declaratory Judgment.

38. A case or controversy exists between Exela and Allergan concerning the invalidity of the '210 patent, which requires a declaration of rights by this Court.

39. The '210 patent is invalid for failure to meet the patentability requirements under 35 U.S.C. § 101, *et seq.*

40. Exela is entitled to a declaratory judgment that the '210 patent is invalid.

COUNT VII
Declaratory Judgment of Noninfringement of the '834 Patent

41. Exela repeats and realleges each of the foregoing paragraphs of this Complaint for Declaratory Judgment.

42. A case or controversy exists between Exela and Allergan concerning the noninfringement of the '834 patent, which requires a declaration of rights by this Court.

43. Exela's 0.15% brimonidine tartrate ophthalmic solution does not infringe any valid or enforceable claim of the '834 patent.

44. Exela is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale, or importation of Exela's 0.15% brimonidine tartrate ophthalmic solution does not infringe any valid or enforceable claim of the '834 patent.

COUNT VIII
Declaratory Judgment of Invalidity of the '834 Patent

45. Exela repeats and realleges each of the foregoing paragraphs of this Complaint for Declaratory Judgment.

46. A case or controversy exists between Exela and Allergan concerning the invalidity of the '834 patent, which requires a declaration of rights by this Court.

47. The '834 patent is invalid for failure to meet the patentability requirements under 35 U.S.C. § 101, *et seq.*

48. Exela is entitled to a declaratory judgment that the '834 patent is invalid.

COUNT IX
Declaratory Judgment of Noninfringement of the '337 Patent

49. Exela repeats and realleges each of the foregoing paragraphs of this Complaint for Declaratory Judgment.

50. A case or controversy exists between Exela and Allergan concerning the noninfringement of the '337 patent, which requires a declaration of rights by this Court.

51. Exela's 0.15% brimonidine tartrate ophthalmic solution does not infringe any valid or enforceable claim of the '337 patent.

52. Exela is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale, or importation of Exela's 0.15% brimonidine tartrate ophthalmic solution does not infringe any valid or enforceable claim of the '337 patent.

COUNT X
Declaratory Judgment of Invalidity of the '337 Patent

53. Exela repeats and realleges each of the foregoing paragraphs of this Complaint for Declaratory Judgment.

54. A case or controversy exists between Exela and Allergan concerning the invalidity of the '337 patent, which requires a declaration of rights by this Court.

55. The '337 patent is invalid for failure to meet the patentability requirements under 35 U.S.C. § 101, *et seq.*

56. Exela is entitled to a declaratory judgment that the '337 patent is invalid.

PRAYER FOR RELIEF

WHEREFORE, Exela respectfully requests that the Court enter a Judgment and Order declaring that:

A. Exela's 0.15% brimonidine tartrate ophthalmic solution as described in ANDA No. 78-590 does not infringe claims 1-18 of United States Patent No. 5,424,078;

B. the claims of United States Patent No. 5,424,078 are invalid;

C. the claims of United States Patent No. 5,424,078 are unenforceable;

D. Exela's 0.15% brimonidine tartrate ophthalmic solution as described in ANDA No. 78-590 does not infringe claims 1-49 of United States Patent No. 6,562,873;

E. the claims of United States Patent No. 6,562,873 are invalid;

F. the claims of United States Patent No. 6,562,873 are unenforceable;

G. Exela's 0.15% brimonidine tartrate ophthalmic solution as described in ANDA No. 78-590 does not infringe claims 1-34 of United States Patent No. 6,627,210;

H. the claims of United States Patent No. 6,627,210 are invalid;

I. the claims of United States Patent No. 6,627,210 are unenforceable;

J. Exela's 0.15% brimonidine tartrate ophthalmic solution as described in ANDA No. 78-590 does not infringe claims 1-22 of United States Patent No. 6,641,834;

K. the claims of United States Patent No. 6,641,834 are invalid;

L. the claims of United States Patent No. 6,641,834 are unenforceable;

M. Exela's 0.15% brimonidine tartrate ophthalmic solution as described in ANDA No. 78-590 does not infringe claims 1-10 of United States Patent No. 6,673,337;

N. the claims of United States Patent No. 6,673,337 are invalid;

O. the claims of United States Patent No. 6,673,337 are unenforceable;

P. this case is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Exela its attorneys' fees, costs, and expenses; and

Q. Exela is entitled to any further relief that this Court may deem just, proper, and equitable.

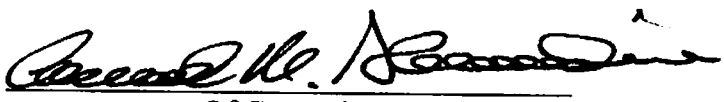
DEMAND FOR JURY TRIAL

Exela demands a jury trial of all issues in this action so triable pursuant to Rule 38 of the Federal Rules of Civil Procedure.

Dated: April 6, 2007

Respectfully submitted,

EXELA PHARMSCI, INC.

By: 

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