

Leda Dunn Wettre, Esq.
ROBINSON, WETTRE & MILLER LLC
One Newark Center
19th Floor
Newark, New Jersey 07102
(973) 690-5400

Of Counsel:
William A. Rakoczy, Esq.
Paul J. Molino, Esq.
Theodore J. Chiacchio, Esq.
Eric R. Hunt, Esq.
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard St., Suite 500
Chicago, Illinois 60610
(312) 222-6301

Attorneys for Plaintiff Apotex Inc.

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

_____)	
APOTEX INC.,)	
)	
Plaintiff,)	Civil Action No.
)	
v.)	
)	
SHIRE LLC,)	
)	
Defendant.)	
)	
_____)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Apotex Inc. (“Apotex”) brings this action against Defendant Shire LLC (“Shire”) for a declaration that Apotex has not infringed, does not infringe, and will not infringe any valid and enforceable claim of U.S. Patent Nos. 5,326,570 and 5,912,013.

The Parties

1. Apotex Inc. is a corporation incorporated and existing under the laws of Canada with a place of business in Ontario, Canada.

2. On information and belief, Defendant Shire is a corporation incorporated and existing under the laws of the State of Kentucky, having its principal place of business at 9200 Brookfield Court, Florence, Kentucky, 41042.

3. On information and belief, Shire manufactures and sells pharmaceutical products throughout the United States, including within the State of New Jersey and this District. On information and belief, Shire has also invoked and consented to the jurisdiction of this Court by suing other generic drug manufacturers in this District, including filing patent infringement suits against two other generic manufacturers relating to Carbatrol®, and involving the very patents at issue in this action.

Jurisdiction and Venue

4. This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. The Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), because this action involves substantial claims arising under the United States Patent Act (35 U.S.C. § 1 *et seq.*), and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, because this action involves an actual controversy concerning the infringement and validity of the patents-in-suit.

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

7. This Court has personal jurisdiction over Defendant because it regularly conducts business in, and has regular and systematic contact with, the State of New Jersey, including this District, and because it has invoked and consented to the jurisdiction of this Court by suing multiple defendants in this District, including related cases involving the subject matter of this suit.

Background Allegations Common to All Counts

Shire's Carbatrol® (Carbamazepine) Extended-Release Capsules

8. Shire holds approved New Drug Application ("NDA") No. 20-712 for Carbatrol® (Carbamazepine) Extended-Release Capsules 100 mg, 200 mg and 300 mg.

9. Carbatrol® (Carbamazepine) is an anticonvulsant that is indicated for, among other things, the treatment of epilepsy.

10. On information and belief, Shire markets and sells Carbatrol® (Carbamazepine) Extended-Release Capsules 100 mg, 200 mg and 300 mg throughout the United States, including within the State of New Jersey and this District.

11. Shire's 2007 sales for Carbatrol® (Carbamazepine) Extended-Release Capsules were approximately \$72 million.

Patents-In-Suit

12. On or about July 5, 1994, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 5,326,570 ("the '570 patent"; Exhibit A hereto), entitled "Advanced Drug Delivery System and Method of Treating Psychiatric, Neurological and Other Disorders with Carbamazepine," to Edward M. Rudnic and George W. Belendiuk.

13. On or about June 15, 1999, the PTO issued U.S. Patent No. 5,912,013 ("the '013 patent"; Exhibit B hereto), entitled "Advanced Drug Delivery System and Method of

Treating Psychiatric, Neurological and Other Disorders with Carbamazepine,” to Edward M. Rudnic and George W. Belendiuk.

14. According to the electronic records of the PTO, Shire is the purported assignee and record owner of the ‘570 and ‘013 patents.

15. On information and belief, Shire purports and claims to own, and to have the right to enforce, the ‘570 and ‘013 patents.

16. On information and belief, Shire asserts and claims that the ‘570 and ‘013 patents cover or protect the use of Carbatrol® (Carbamazepine) Extended-Release Capsules from generic competition.

Apotex’s Generic Carbamazepine Extended-Release Capsules

17. Apotex has filed an Abbreviated New Drug Application (“ANDA”) seeking U.S. Food and Drug Administration (“FDA”) approval for a generic version of Carbamazepine Extended-Release Capsules 100 mg, 200 mg and 300 mg.

18. Apotex’s ANDA contains a so-called “Paragraph IV Certification” stating that the ‘570 and ‘013 patents are invalid, unenforceable and/or not infringed by Apotex’s proposed generic product that is the subject of Apotex’s ANDA.

19. Apotex intends to manufacture generic Carbamazepine Extended-Release Capsules prior to the expiration of the ‘570 and ‘013 patents.

20. Apotex has made substantial preparation to manufacture generic Carbamazepine Extended-Release Capsules prior to the expiration of the ‘570 and ‘013 patents.

21. The commercial manufacture, use, sale, offer for sale or importation of Apotex’s generic Carbamazepine Extended-Release Capsules, which are the subject of Apotex’s

ANDA, have not infringed, do not infringe, and will not infringe any valid and enforceable claim of the '570 and '013 patents.

Shire's Litigious Conduct and Delay Tactics

22. Shire is extremely litigious, and has previously exhibited an intent and willingness to aggressively assert and enforce its purported patent rights against companies seeking to market competing generic versions of Carbamazepine Extended-Release Capsules.

23. To delay generic competition, Shire has previously filed five separate actions in three different Districts against four generic drug manufacturers seeking to manufacture generic Carbamazepine Extended-Release Capsules, including Apotex, alleging infringement of the same patents at issue in this suit.

24. The bulk and oldest of the actions are pending in this District, where the Court (Chesler, J.) has already construed the disputed claims of the '570 patent; where the Courts are already the most familiar with the subject matter of the patents-in-suit; and where Apotex has consented to suit and has an agent for service of process for any action arising out of its ANDA.

25. Shire has filed suits in other Districts, including against Apotex, in a blatant display of forum-shopping designed to further delay generic competition.

Shire v. Nostrum I (D.N.J.)

26. On September 18, 2003, Shire Laboratories Inc. filed suit against Nostrum Pharmaceuticals, Inc. ("Nostrum") in the United States District Court for the District of New Jersey, alleging infringement of the '570 and '013 patents. The case is captioned *Shire Laboratories Inc. v. Nostrum Pharmaceuticals, Inc.*, Civil Action No. 3:03-cv-04436-MLC-JJH (D.N.J.), and is assigned to the Honorable Mary L. Cooper.

27. Shire did not serve the Complaint in *Shire Laboratories Inc. v. Nostrum Pharmaceuticals Inc.*, Civil Action No. 3:03-cv-04436-MLC-JJH (D.N.J.), on Nostrum until January 13, 2004.

28. On information and belief, to further delay generic competition, Shire intentionally delayed serving the Complaint in *Shire Laboratories Inc. v. Nostrum Pharmaceuticals, Inc.*, Civil Action No. 3:03-cv-04436-MLC-JJH (D.N.J.), for almost four full months. Such intentional delay is contrary to the very spirit and intent of the Hatch-Waxman statutory scheme.

29. On information and belief, to further delay generic competition, Shire moved for and obtained a stay of certain discovery in *Shire Laboratories Inc. v. Nostrum Pharmaceuticals, Inc.*, Civil Action No. 3:03-cv-04436-MLC-JJH (D.N.J.).

Shire v. Corepharma (D.N.J.)

30. On May 17, 2006, Shire Laboratories Inc. filed suit against Corepharma LLC (“Corepharma”) in the United States District Court for the District of New Jersey, alleging infringement of the ‘570 and ‘013 patents. The case is captioned *Shire Laboratories Inc. v. Corepharma LLC*, Civil Action No. 2:06-cv-02266-SRC-MAS (D.N.J.), and is assigned to the Honorable Stanley R. Chesler.

31. Shire did not serve the Complaint in *Shire Laboratories Inc. v. Corepharma LLC*, Civil Action No. 2:06-cv-02266-SRC-MAS (D.N.J.), on Corepharma until August 31, 2006.

32. On information and belief, to further delay generic competition, Shire again intentionally delayed serving the Complaint in *Shire Laboratories Inc. v. Corepharma*

LLC, Civil Action No. 2:06-cv-02266-SRC-MAS (D.N.J.), for over three months. Such intentional delay is contrary to the very spirit and intent of the Hatch-Waxman statutory scheme.

33. On March 26, 2008, Judge Chesler in *Shire Laboratories Inc. v. Corepharma LLC*, Civil Action No. 2:06-cv-02266-SRC-MAS (D.N.J.) issued an Order, together with a nineteen (19) page Opinion, construing the disputed claim terms of the '570 patent.

34. On May 21, 2008, Judge Chesler in *Shire Laboratories Inc. v. Corepharma LLC*, Civil Action No. 2:06-cv-02266-SRC-MAS (D.N.J.) issued an Order denying Shire's motion to reconsider the Court's prior claim construction Order and Opinion dated March 26, 2008.

35. Discovery in *Shire Laboratories Inc. v. Corepharma LLC*, Civil Action No. 2:06-cv-02266-SRC-MAS (D.N.J.) is complete and the final pretrial conference is set for September 15, 2008.

Shire v. Teva (S.D.N.Y.)

36. On May 2, 2007, Shire LLC filed suit against Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA (collectively, "Teva") in the United States District Court for the Southern District of New York, alleging infringement of the '570 and '013 patents. The case is captioned *Shire LLC v. Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA*, Civil Action No. 1:07-cv-03526-MGC (S.D.N.Y.), and is assigned to the Honorable Miriam Goldman Cedarbaum.

37. Shire never served the original Complaint in *Shire LLC v. Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA*, Civil Action No. 1:07-cv-03526-MGC (S.D.N.Y.).

38. On information and belief, to further delay generic competition, Shire never served the original Complaint in *Shire LLC v. Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA*, Civil Action No. 1:07-cv-03526-MGC (S.D.N.Y.). Such intentional delay is contrary to the very spirit and intent of the Hatch-Waxman statutory scheme.

39. On August 23, 2007, Shire filed an Amended Complaint in *Shire LLC v. Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA*, Civil Action No. 1:07-cv-03526-MGC (S.D.N.Y.), which was served on Teva on August 24, 2007.

40. No discovery has occurred and no substantive orders on the merits of the dispute have issued in *Shire LLC v. Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA*, Civil Action No. 1:07-cv-03526-MGC (S.D.N.Y.).

Shire v. Nostrum II (D.N.J.)

41. On July 2, 2008, Shire LLC filed suit against Nostrum in the United States District Court for the District of New Jersey, alleging infringement of the '570 and '013 patents. The case is captioned *Shire LLC v. Nostrum Pharmaceuticals, Inc. and Nostrum Pharmaceuticals, LLC*, Civil Action No. 3:08-cv-03309-MLC-TJB (D.N.J.), and is assigned to the Honorable Mary L. Cooper.

42. Shire has not served, or attempted to serve, the Complaint in *Shire LLC v. Nostrum Pharmaceuticals, Inc. and Nostrum Pharmaceuticals, LLC*, Civil Action No. 3:08-cv-03309-MLC-TJB (D.N.J.).

Shire v. Apotex (E.D. Tex.)

43. On May 19, 2008, Apotex sent Shire a "Notification of Certification for U.S. Patent Nos. 5,326,570 and 5,912,013 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act" ("Paragraph IV Notice").

44. Shire received Apotex's Paragraph IV Notice on or about May 20, 2008.

45. In its Paragraph IV Notice, Apotex explicitly consented to the jurisdiction of the Court in the District of New Jersey for any patent infringement action based on Apotex's Paragraph IV Notice and expressly identified an agent authorized to accept service of process for Apotex in this District.

46. On information and belief, to further delay generic competition, Shire engaged in blatant forum-shopping by filing suit against Apotex in Texas, rather than New Jersey where Apotex consented to suit; where Apotex's agent is located; where the bulk of the related litigation is already pending; and where the Court has already construed the disputed terms of the '570 patent.

47. On July 2, 2008, Shire LLC filed suit against Apotex Inc., Apotex Corp., and Apotex Pharmaceutical Holdings Inc. in the United States District Court for the Eastern District of Texas, alleging infringement of the '570 and '013 patents. The case is captioned *Shire LLC v. Apotex Inc., Apotex Corp., and Apotex Pharmaceutical Holdings Inc.*, Civil Action No. 2:08-cv-00265-DF (E.D. Tex.), and is assigned to the Honorable David Folsom.

48. Shire has not served, or attempted to serve, the Complaint in *Shire LLC v. Apotex Inc., Apotex Corp., and Apotex Pharmaceutical Holdings Inc.*, Civil Action No. 2:08-cv-00265-DF (E.D. Tex.).

49. The Court in *Shire LLC v. Apotex Inc., Apotex Corp., and Apotex Pharmaceutical Holdings Inc.*, Civil Action No. 2:08-cv-00265-DF (E.D. Tex.) lacks personal jurisdiction over Apotex. Apotex therefore intends to move to dismiss the Texas action for lack of personal jurisdiction or, in the alternative, to transfer the action to this District where Apotex consented to suit; where Apotex's agent is located; where the bulk of the related litigation is

already pending; and where the Court has already construed the disputed terms of the '570 patent.

Justiciable Controversy

50. There exists an actual, substantial, and continuing justiciable case or controversy between Defendant and Apotex regarding the non-infringement and invalidity of the '570 and '013 patents. Apotex accordingly is entitled by law to bring and maintain this action for declaratory judgment under, *inter alia*, the Declaratory Judgment Act.

51. Apotex is entitled to a declaration that the manufacture, use, sale, offer for sale, or importation of Apotex's generic Carbamazepine Extended-Release Capsules, which are the subject of its ANDA, have not infringed, do not infringe, and will not infringe any valid and/or enforceable claim of the '570 and '013 patents.

52. Absent the exercise of jurisdiction by this Court and such declaratory relief, Apotex and the American public will be irreparably harmed by the indefinite delay in the market entry and availability of lower-priced generic Carbamazepine Extended-Release Capsules.

COUNT I

(Declaratory Judgment of Non-Infringement of the '570 Patent)

53. Apotex repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

54. There is an actual, substantial, and continuing justiciable case or controversy between Defendant and Apotex regarding the non-infringement of the '570 patent.

55. The manufacture, use, sale, offer for sale, or importation of Apotex's generic Carbamazepine Extended-Release Capsules, which are the subject of its ANDA, have

not infringed, do not infringe, and will not infringe any valid and/or enforceable claim of the '570 patent.

56. Apotex is entitled to a declaration that the manufacture, use, sale, offer for sale, or importation of Apotex's generic Carbamazepine Extended-Release Capsules, which are the subject of its ANDA, have not infringed, do not infringe, and will not infringe any valid and/or enforceable claim of the '570 patent.

COUNT II
(Declaratory Judgment of Invalidity of the '570 Patent)

57. Apotex repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

58. There is an actual, substantial, and continuing justiciable case or controversy between Defendant and Apotex regarding the invalidity of the '570 patent.

59. The claims of the '570 patent are invalid for failure to satisfy one or more conditions for patentability in 35 U.S.C. § 1 *et seq.*

60. Apotex Inc. is entitled to a declaration that the claims of the '570 patent are invalid.

COUNT III
(Declaratory Judgment of Non-Infringement of the '013 Patent)

61. Apotex repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

62. There is an actual, substantial, and continuing justiciable case or controversy between Defendant and Apotex regarding the non-infringement of the '013 patent.

63. The manufacture, use, sale, offer for sale, or importation of Apotex's generic Carbamazepine Extended-Release Capsules, which are the subject of its ANDA, have

not infringed, do not infringe, and will not infringe any valid and/or enforceable claim of the '013 patent.

64. Apotex is entitled to a declaration that the manufacture, use, sale, offer for sale, or importation of Apotex's generic Carbamazepine Extended-Release Capsules, which are the subject of its ANDA, have not infringed, do not infringe, and will not infringe any valid and/or enforceable claim of the '013 patent.

COUNT IV
(Declaratory Judgment of Invalidity of the '013 Patent)

65. Apotex repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

66. There is an actual, substantial, and continuing justiciable case or controversy between Defendant and Apotex regarding the invalidity of the '013 patent.

67. The claims of the '013 patent are invalid for failure to satisfy one or more conditions for patentability in 35 U.S.C. § 1 *et seq.*

68. Apotex Inc. is entitled to a declaration that the claims of the '013 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Apotex respectfully requests entry of judgment:

- A. Declaring that the manufacture, use, sale, offer for sale, or importation of Apotex's generic Carbamazepine Extended-Release Capsules, which are the subject of its ANDA, have not infringed, do not infringe, and will not infringe (either literally or under the doctrine of equivalents), directly or

indirectly (either by inducement or contributorily) any valid or enforceable claim of the '570 patent;

- B. Declaring that the claims of the '570 patent are invalid;
- C. Declaring that the manufacture, use, sale, offer for sale, or importation of Apotex's generic Carbamazepine Extended-Release Capsules, which are the subject of its ANDA, have not infringed, do not infringe, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '013 patent;
- D. Declaring that the claims of the '013 patent are invalid;
- E. Declaring this case exceptional and awarding Apotex its reasonable attorneys' fees under 35 U.S.C. § 285;
- F. Awarding Apotex its reasonable costs and expenses of this action; and
- G. Awarding Apotex such further necessary or proper relief as the Court may deem just.

JURY DEMAND

Plaintiff Apotex Inc. hereby demands a trial by jury on all issues so triable.

Dated: July 17, 2008

Respectfully submitted,

APOTEX INC.

By: /s/ Leda Dunn Wettre
Leda Dunn Wettre, Esq.
ROBINSON, WETTRE & MILLER LLC
One Newark Center
19th Floor
Newark, New Jersey 07102
(973) 690-5400

Of Counsel:

William A. Rakoczy, Esq.
Paul J. Molino, Esq.
Theodore J. Chiacchio, Esq.
Eric R. Hunt, Esq.
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard St., Suite 500
Chicago, Illinois 60610
(312) 222-6301

Attorneys for Plaintiff Apotex Inc.