UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DAIICHI SANKYO CO., LTD. and DAIICHI SANKYO, INC. Plaintiffs, v. APOTEX INC. and APOTEX CORP. Defendants.	)	Civil Action No. 1:09-cv-470-JBS Jury Trial Demanded

APOTEX INC. AND APOTEX CORP.'S
ANSWER, DEFENSES, COUNTERCLAIM AND JURY DEMAND

Defendants Apotex Inc. and Apotex Corp. (hereinafter collectively, "Defendants") hereby answer the Complaint of Plaintiffs Daiichi Sankyo Co., Ltd. and Daiichi Sankyo, Inc. (hereinafter collectively, "Plaintiffs"), as follows:

NATURE OF ACTION

1. Paragraph 1 contains legal conclusions to which no answer is required. To the extent that an answer is required, Defendants admit that this is an action for alleged patent infringement. Defendants deny the remaining allegations of Paragraph 1.

PARTIES

2. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2, and therefore deny these allegations.

3. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3, and therefore deny these allegations.

4. Paragraph 4 contains a statement not susceptible to an admission or denial from Defendants. To the extent an answer is required, Defendants deny all allegations of Paragraph 4.

5. Defendants admit that Apotex Inc. is a corporation existing solely under the laws of Canada with its only places of business located in Canada, including at 150 Signet Drive, Weston, Ontario M9L 1T9, Canada. Defendants deny any remaining allegations of Paragraph 5.

6. Denied.

7. Defendants admit that Apotex Corp. is a Delaware corporation with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Defendants deny the remaining allegations of Paragraph 7. Defendants further deny that Apotex Corp. is a proper party to this suit, and also deny that the Court has subject matter jurisdiction for any claims asserted against Apotex Corp.

8. Denied.

9. Paragraph 9 contains a statement not susceptible to an admission or denial from Defendants. To the extent an answer is required, Defendants deny all allegations of Paragraph 9.

JURISDICTION AND VENUE

10. Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit subject matter jurisdiction for the claim asserted against Apotex Inc. under 35 U.S.C. § 271(e)(2)(A) only. Defendants deny subject matter jurisdiction for any claim against Apotex Corp. Defendants deny the remaining allegations of Paragraph 10.

11. Paragraph 11 contains legal conclusions to which no answer is required. To the extent that an answer is required, Defendants deny the allegations of Paragraph 11. Further answering, to conserve the resources of the parties and the Court and for purposes of judicial efficiency, Defendants do not contest personal jurisdiction in this District for purposes of this action only. Further answering, Defendants deny that Apotex Corp. is a proper party to this action.

12. Denied.

13. Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 13. Further answering, to conserve the resources of the parties and the Court and for purposes of judicial efficiency, Defendants do not contest venue for the purpose of this action only. Defendants deny that Apotex Corp. is a proper party to this action. Defendants deny all remaining allegations of Paragraph 14.

CLAIM FOR RELIEF - PATENT INFRINGEMENT

14. Defendants admit that the electronic version of the U.S. Food and Drug Administration's ("FDA") publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), identifies "DAIICHI SANKYO CO" as the "Applicant" for approved New Drug Application ("NDA") No. 020989 for EVOXAC® Capsules (cevimeline hydrochloride), 30 mg. Further answering, Defendants admit that, according to the electronic version of FDA's Orange Book, FDA approved NDA No. 020989 for EVOXAC® Capsules (cevimeline hydrochloride), 30 mg, on or about January 11, 2000. Further answering, Defendants admit that the current FDA-approved labeling for EVOXAC® Capsules (cevimeline hydrochloride), 30 mg, sets forth any approved indications or uses for said capsules. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 14, and therefore deny these allegations.

15. Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that, according to the electronic records of the United States Patent and Trademark Office ("PTO"), the PTO issued United States Patent No. 5,340,821 ("'821 patent"), entitled "Composition and Method for Treating Sjoegren

Syndrome," on or about August 23, 1994; that the cover page of the '821 patent identifies "Snow Brand Milk Products Co., Ltd." as the purported "Assignee"; and that what purports to be a copy of the '821 patent is attached to the Complaint as Exhibit A. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 15, and therefore deny these allegations.

16. Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 16.

17. Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that the cover page of the '821 patent identifies "Snow Brand Milk Products Co., Ltd." as the purported "Assignee." Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 17, and therefore deny these allegations.

18. Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that the cover page of the '821 patent identifies "Snow Brand Milk Products Co., Ltd." as the purported "Assignee"; and that the Orange Book identifies "DAIICHI SANKYO CO" as the "Applicant" for approved New Drug Application ("NDA") No. 020989 for EVOXAC® Capsules (cevimeline hydrochloride), 30 mg. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 18, and therefore deny these allegations.

19. Defendants admit that Apotex Inc. submitted an Abbreviated New Drug Application ("ANDA") to FDA for cevimeline hydrochloride capsules, 30 mg. Defendants deny the remaining allegations of Paragraph 19.

20. Defendants admit that Apotex Inc. submitted an ANDA to FDA seeking approval for cevimeline hydrochloride capsules, 30 mg, prior to the expiration of the '821 patent. Defendants deny the remaining allegations of Paragraph 20.

21. Denied.

22. Denied.

* * *

Defendants deny every allegation not expressly admitted herein. Defendants further deny that Plaintiffs are entitled to any of the relief requested, or to any relief whatsoever. Defendants demand judgment dismissing Plaintiffs' Complaint with prejudice, awarding Defendants' attorney fees and costs incurred defending this action under 35 U.S.C. § 285, and granting such further relief as this Court may deem just and proper.

DEFENSES

Without undertaking any of the burdens imposed by law on Plaintiffs Daiichi Sankyo Co., Ltd. and Daiichi Sankyo, Inc. (hereinafter collectively, "Plaintiffs"), and without admitting any of the allegations in the Complaint not otherwise admitted, Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") assert the following defenses:

First Defense

The Complaint fails to state a claim upon which relief can be granted.

Second Defense

The manufacture, use, sale, offer for sale, or importation of the 30 mg cevimeline hydrochloride capsules that are the subject of Apotex Inc.'s Abbreviated New Drug Application ("ANDA") have not infringed, do not infringe, and would not, if made, imported, or marketed,

infringe any valid and/or enforceable claim of United States Patent No. 5,340,821 ("'821 patent").

Third Defense

The claims of the '821 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code.

Fourth Defense

Apotex has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and/or enforceable claim of the '821 patent.

Fifth Defense

The Court lacks subject matter jurisdiction for any claims asserted against Apotex Corp.

Sixth Defense

Apotex Corp. is not a proper party to this suit.

Seventh Defense

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIM

Defendants/Counterclaim-Plaintiffs, Apotex Inc. and Apotex Corp. (collectively, "Apotex"), for their Counterclaim against Plaintiffs/Counterclaim-Defendants, Daiichi Sankyo Co., Ltd. and Daiichi Sankyo, Inc. (collectively referred to as "Daiichi"), allege as follows:

The Parties

1. Defendant/Counterclaim-Plaintiff Apotex Inc. is a corporation organized and existing solely under the laws of Canada and having its only places of business in Canada.

2. Defendant/Counterclaim-Plaintiff Apotex Corp. is a Delaware corporation with offices in Florida.

3. Upon information and belief, Plaintiff/Counterclaim-Defendant Daiichi Sankyo Co., Ltd. purports to be a corporation organized and existing under the laws of Japan, having a place of business at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan.

4. Upon information and belief, Plaintiff Daiichi Sankyo, Inc. purports to be a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Two Hilton Court, Parsippany, New Jersey 07054.

Jurisdiction and Venue

5. This Counterclaim arises under 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.

6. This Court has original jurisdiction over the subject matter of this Counterclaim under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because they have availed themselves of the rights and privileges of this forum by suing Apotex in this District, and because Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular and systematic contacts with, this District.

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

Factual Background

9. On or about August 23, 1994, the U.S. Patent and Trademark Office ("PTO") issued U.S. Patent No. 5,340,821 ("'821 patent"), entitled "Composition and Method for Treating Sjoegren Syndrome Disease," to Nobuaki Abe and Yasuyoshi Takeshita.

10. Plaintiffs/Counterclaim-Defendants purport and claim to own, and to have the right to enforce, the '821 patent.

11. On July 2, 2009, Plaintiffs/Counterclaim-Defendants sued Apotex in this District alleging infringement of the '821 patent under 35 U.S.C. § 271(e)(2)(A).

Count I
(Declaratory Judgment of Non-Infringement of the '821 Patent)

12. Apotex re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

13. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Plaintiffs/Counterclaim-Defendants regarding non-infringement of the '821 patent.

14. The manufacture, use, sale, offer for sale, or importation of the drug product that is described in Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '821 patent, either literally or under the doctrine of equivalents.

15. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the drug product that is described in Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '821 patent, either literally or under the doctrine of equivalents.

Count II
(Declaratory Judgment of Invalidity of the '821 Patent)

16. Apotex re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

17. There is an actual, substantial, and continuing justiciable case or controversy between both Apotex and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the '821 patent.

18. The claims of the '821 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

19. Apotex is entitled to a judicial declaration that the claims of the '821 patent are invalid.

Prayer for Relief

WHEREFORE, Apotex respectfully prays for judgment in its favor and against Plaintiffs/Counterclaim-Defendants:

a. Declaring that the manufacture, use, sale, offer for sale or importation of the drug product that is described in Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '821 patent, either literally or under the doctrine of equivalents;

b. Declaring that the claims of the '821 patent are invalid;

c. Ordering that Plaintiffs/Counterclaim-Defendants Complaint be dismissed with prejudice and judgment entered in favor of Apotex;

d. Awarding Apotex its costs;

e. Declaring this case exceptional and awarding Apotex its reasonable attorney fees and costs under 35 U.S.C. § 285; and

f. Awarding Apotex such other and further relief as the Court may deem just and proper.

JURY DEMAND

Apotex Inc. and Apotex Corp. hereby demand trial by jury as to all issues so triable.

Respectfully submitted,

Dated: August 21, 2009

By: _____

John C. Phillips, Jr. (#110)
PHILLIPS, GOLDMAN & SPENCE, P.A.
1200 North Broom Street
Wilmington, Delaware 19806
(302) 655-4200 (telephone)
(302) 655-4210 (facsimile)
jcp@pgslaw.com (e-mail)

-and-

William A. Rakoczy
Paul J. Molino
Deanne M. Mazzochi
Andrew M. Alul
Brian A. Garcia
Eric R. Hunt
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street
Suite 500
Chicago, IL 60654
(312) 222.6301 (telephone)
(312) 222.6321 (facsimile)
wrakoczy@rmmslegal.com (e-mail)

Attorneys for Defendants Apotex Inc. and Apotex Corp.