IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

ABBOTT LABORATORIES, INC., and ABBOTT GMBH & CO. KG Plaintiff, - vs. - APOTEX INC. and APOTEX CORP. Defendants	Case No. 1:09-CV-07968

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Abbott Laboratories, Inc. and Abbott GmbH & Co. KG (collectively "Plaintiffs" and "Abbott") for their complaint against Apotex Inc. and Apotex Corp. (collectively "Defendants" and "Apotex") allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 5,436,272. This action arises out of Apotex's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell a generic copy of Abbott's highly successful drug Meridia® prior to the expiration of the patent owned by Abbott.

THE PARTIES

2. Abbott Laboratories, Inc. is a corporation organized under the laws of the state of Delaware, having its headquarters and principal place of business at 100 Abbott Park Road, Abbott Park, Illinois, 60064.

3. Abbott GmbH & Co. KG is a limited partnership organized and existing under the laws of Germany, having a principal place of business at Max-Planck-Ring 2,65205 Wiesbaden, Germany. Abbott GmbH & Co. KG is a wholly owned subsidiary of Abbott Laboratories.

4. On information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

5. On information and belief, Apotex Corp. is a corporation organized under the laws of the State of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

JURISDICTION AND VENUE

6. This is a civil action for patent infringement and declaratory judgment arising 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. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. On information and belief, Apotex Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. On information and belief, Apotex Inc. directly, or through its affiliates and agents, including Apotex Corp., manufactures, markets and sells drug products throughout the United States and in this judicial district. Thus, Apotex Inc. is subject to personal jurisdiction in this judicial district under 735 ILCS 5/2-209 because it regularly and continuously transacts business within the State of Illinois.

8. On information and belief, Apotex Corp. directly, or indirectly, manufactures, markets or sells drug products, including generic drug products manufactured by Apotex Inc., throughout the United States and in this judicial district. On information and belief, Apotex Corp. purposefully has conducted and continues to conduct business in this judicial district. On information and belief, Apotex Corp. has at least places of business in Lincolnshire, IL 60069 and in Vernon Hills, Illinois 60061. Thus, Apotex Corp. is subject to personal jurisdiction in this judicial district under 735 ILCS 5/2-209 because it regularly and continuously transacts business within the State of Illinois.

9. Apotex Inc. and Apotex Corp. have designated Keith D. Parr, Esq., Locke Lord

Bissell & Liddell LLP, 111 South Wacker Drive, Chicago, Illinois 60606, as Apotex's agent authorized to accept service of process for Apotex Inc. and Apotex Corp. in this action, and have thereby consented to personal jurisdiction in this district for both Apotex Inc. and Apotex Corp.

10. On information and belief, Apotex Inc. and Apotex Corp. regularly seek approval from the United States Food and Drug Administration ("FDA") to market, distribute, and sell their generic pharmaceutical products throughout the United States, including the State of Illinois. Apotex Inc. and Apotex Corp. have filed applications with the FDA for approval of at least 144 pharmaceutical products.

11. On information and belief, Apotex Corp., and Apotex Inc., alone or through Apotex Corp., markets, sells and/or distributes at least 107 generic pharmaceutical products throughout the United States, including the State of Delaware. These products include generic versions of Lotensin®, Norvasc®, Risperdal®, Topamax®, Depakote®, Wellbutrin®, Fosamax®, and Cellcept®, with sales in significant U.S. markets, *e.g.*, Cellcept® ($700 mil. total market), Depakote® ($450 mil. total market), Norvasc® ($2.2. bil. total market), Risperdal® ($1.2 bil. total market), and Topamax® ($2.1 bil. total market).

12. On information and belief, according to the FDA's website, the Abbreviated New Drug Applications for generic Lotensin, Risperdal, Topamax, and Wellbutrin are held by Apotex Inc. Thus, Apotex Inc. holds approvals to sell large dollar values of these drugs throughout the United States, including in the State of Illinois and this District.

13. On information and belief, Apotex Corp. and Apotex Inc., alone or through Apotex Corp., distributes and/or has distributed pharmaceutical products throughout the United States, including throughout the State of Illinois, through large retail stores and distributors such as Wal-Mart (trazodone hydrochloride (generic Desyrel®) and doxazosin (generic Cardura®)), Walgreens (midodrine (generic Proamatine®) and fluoxetine (generic Prozac®)), Amazon.com (cetirizine hydrochloride (generic Zyrtec®)) and HealthWarehouse.com (loratidine (generic Claritin®); and midodrine (generic Proamatine®)).

14. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), (c) and (d), and

1400(b).

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

15. On July 25, 1995 the United States Patent and Trademark Office issued U.S. Patent No. 5,436,272 ("the '272 Patent") to The Boots Company (USA), Inc., the assignee of the named inventor Monte L. Scheinbaum. The Boots Company assigned the '272 Patent to the Knoll Pharmaceutical Company. Subsequently, the Knoll Pharmaceutical Company assigned '272 Patent to Abbott GmbH & Co. KG. Abbott Laboratories, Inc. has an exclusive license to the '272 patent. A copy of the '272 Patent is attached hereto as Exhibit A.

16. The expiration date of the '272 Patent is July 25, 2012.

17. The '272 Patent is listed in an FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (known as the "Orange Book") as covering sibutramine hydrochloride capsules, which are marketed by Abbott under the brand name Meridia®.

18. Meridia® has also received pediatric exclusivity of 6 months beginning from the expiration of the '272 Patent, during which no ANDA covering sibutramine hydrochloride capsules can be approved. Thus, no ANDA that infringes the '272 Patent can be approved prior to January 25, 2013.

19. On information and belief, Apotex Inc. and Apotex Corp. continuously seek to expand the range of generic products they sell, and actively review pharmaceutical patents held by Abbott to seek opportunities to challenge those patents. For this reason, Apotex would be aware of the '272 patent when it filed its ANDA.

20. On information and belief, Apotex Inc. and Apotex Corp. submitted to the FDA Abbreviated New Drug Application No. 91-696, seeking approval to engage in the commercial manufacture, use and sale of their generic 5, 10, and 15 milligram sibutramine hydrochloride capsules, prior to the expiration of the '272 Patent.

21. Abbott received a letter dated November 9, 2009, along with an "Attachment 1" referenced therein, informing Abbott that Apotex Inc. and Apotex Corp. had filed ANDA No.

91-696, which includes a certification under 21 U.S.C. § 355(j)(2)(A) with a "Paragraph IV certification" to obtain approval to engage in the commercial manufacture, use or sale of sibutramine hydrochloride product before the expiration of the '272 Patent.

22. On information and belief, Apotex Inc. and Apotex Corp. were necessarily aware of the '272 Patent when they filed ANDA No. 91-696 and the Paragraph IV certification.

23. Plaintiffs commenced this action within 45 days of the date they received Apotex's notice of ANDA No. 91-696 containing the Paragraph IV certification.

24. The submission of Apotex's ANDA and Apotex's intention to engage in the commercial manufacture, use, or sale of Apotex's sibutramine hydrochloride capsules upon receiving FDA approval creates an actual case or controversy with respect to infringement of the '272 Patent.

25. Plaintiffs will be substantially and irreparably damaged and harmed if Apotex's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

FIRST CLAIM FOR RELIEF
(Direct Infringement of the '272 Patent by Apotex Inc and Apotex Corp.)

26. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 25, as if fully set forth herein.

27. Through the conduct alleged above, Apotex Inc. and Apotex Corp. directly infringe, and continue to directly infringe, claims 1-3, and claims 5-8, of the '272 Patent.

28. By filing ANDA No. 91-696 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of a generic sibutramine hydrochloride capsule, prior to the expiration of the '272 Patent, Apotex Inc. and Apotex Corp. jointly infringe claims 1-3, and claims 5-8, of the '272 Patent under 35 U.S.C. § 271(e)(2).

29. Apotex Inc. and Apotex Corp. were aware of the existence of the '272 Patent prior to filing ANDA No. 91-696 but took such action knowing that it would constitute an infringement of the '272 Patent.

30. Moreover, in their Paragraph IV notification letter dated November 9, 2009, along

with an "Attachment 1" referenced therein, Apotex did not offer any contentions that it did not infringe claims 1-3 and claims 5-8.

31. Apotex had a legal obligation to make such non-infringement contentions if it were aware of any. 21 U.S.C. § 355(j)(2)(B).

32. On information and belief, Apotex Inc. and Apotex Corp. acted without a reasonable basis or a good faith belief that they would not be liable for infringing the '272 Patent.

33. Apotex Inc.'s and Apotex Corp.'s conduct renders this case "exceptional" as described in 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

34. Plaintiffs will be irreparably harmed if Apotex Inc. and Apotex Corp. are not enjoined from infringing the '272 Patent.

SECOND CLAIM FOR RELIEF
(Declaratory Judgment as to Inducement of Infringement of the '272 Patent by Apotex Inc and Apotex Corp.)

35. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 34 hereof, as if fully set forth herein.

36. Through the conduct alleged above, Apotex Inc. and Apotex Corp. knowingly and actively induce those members of the medical community to whom Apotex Inc. and Apotex Corp. intend to market the generic sibutramine hydrochloride capsules that Apotex Inc. and Apotex Corp. intend to manufacture and distribute – and who encompass but are not limited to physicians, pharmacists, pharmacies, and/or pharmaceutical wholesalers (collectively, "the medical community") – to infringe, and continue to infringe, claims 1-3, and claims 5-8, of the '272 Patent.

37. Apotex Inc.'s and Apotex Corp.'s activities have placed Plaintiffs under a reasonable apprehension that Apotex Inc. and Apotex Corp. will induce the medical community to directly infringe the '272 Patent. There now exists a justiciable case and controversy for adjudication by the Court.

38. By reason of Apotex Inc.'s and Apotex Corp.'s inducement of the medical

community's direct infringement of the '272 Patent, Apotex Inc. and Apotex Corp. will cause and continue to cause irreparable harm to Plaintiffs.

39. On information and belief, Apotex Inc.'s and Apotex Corp.'s inducement of the medical community's direct infringement of the '272 Patent before this patent expires will continue unless enjoined by this Court.

40. Plaintiffs have no adequate remedy at law for Apotex Inc.'s and Apotex Corp.'s joint inducement of the medical community's direct infringement of the '272 Patent.

41. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

THIRD CLAIM FOR RELIEF
(Declaratory Judgment as to Contributory Infringement of the '272 Patent by Apotex Inc and Apotex Corp.)

42. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 41, as if fully set forth herein.

43. Through the proposed sale and marketing of sibutramine hydrochloride capsules and the conduct alleged above, Apotex Inc. and Apotex Corp. will contribute to the medical community's infringement, and continued infringement, of claims 1-3, and claims 5-8, of the '272 Patent.

44. Apotex Inc.'s and Apotex Corp.'s activities have placed Plaintiffs under a reasonable apprehension that Apotex Inc. and Apotex Corp. will contribute to the medical community's direct infringement of the '272 Patent. There now exists a justiciable case and controversy for adjudication by the Court.

45. By reason of Apotex Inc.'s and Apotex Corp.'s contribution to the medical community's direct infringement of the '272 Patent, Apotex Inc. and Apotex Corp. will cause and continue to cause irreparable harm to Plaintiffs.

46. On information and belief, Apotex Inc.'s and Apotex Corp.'s contribution to the medical community's direct infringement of the '272 Patent before this patent expires will continue unless enjoined by this Court.

47. Plaintiffs have no adequate remedy at law for Apotex Inc.'s and Apotex Corp.'s joint contribution to the medical community's direct infringement of the '272 Patent.

48. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

WHEREFORE, Plaintiffs respectfully request the following relief:

A. An order adjudging and decreeing that Apotex Inc. directly infringes the '272 Patent;

B. An order adjudging and decreeing that Apotex Corp. directly infringes the '272 Patent;

C. An order adjudging and decreeing that Apotex Inc. and Apotex Corp. induce the direct infringement of the '272 Patent;

D. An order adjudging and decreeing that Apotex Inc. and Apotex Corp. contribute to the direct infringement of the '272 Patent;

E. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 91-696 be no earlier than 6 months after the expiration date of the '272 Patent, including any future additional extensions;

F. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Apotex Inc. and Apotex Corp., their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the generic sibutramine hydrochloride capsules described in ANDA No. 91-696 or any other ANDA not colorably different from ANDA No. 91-696 until 6 months after the expiration date of the '272 Patent, including any future additional extensions;

G. A declaration that this case is exceptional and an award of attorneys' fees under 35 U.S.C. § 285 and costs and expenses in this action; and

H. Such other and further relief as the Court may deem just and proper.

Dated: December 23, 2009

s/ Raj N. Shah

Raj N. Shah
DLA Piper LLP (US)
203 North LaSalle Street
Suite 1900
Chicago, IL 60601-1293
Phone: (312) 368-8904
Fax: (312) 251-5714

Of Counsel
Stuart E. Pollack
DLA Piper LLP (US)
1251 Avenue of the Americas
New York, New York 10020-1104
Phone: 212.335.4964
Fax: 212.884.8464

pro hac vice application anticipated:
John Allcock
Rick Mulloy
Erica Pascal
DLA Piper LLP (US)
401 B street, Suite 1700
San Diego, CA 92101-4297
Phone: (619) 699 2700
Fax: (619) 699 2701

Sarita Pendurthi
Dianne Casuto
Abbott Laboratories
100 Abbott Park Road
Abbott Park, Illinois, 60064