IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

APOTEX INC., APOTEX TECHNOLOGIES, INC., SMITHKLINE BEECHAM (CORK) LIMITED, and SMITHKLINE BEECHAM LIMITED f/k/a SMITHKLINE BEECHAM PLC, Plaintiffs, v. LUPIN LTD. and LUPIN PHARMACEUTICALS, INC., Defendants.	Civil Action No: 2:15-cv-599 **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Apotex Inc., Apotex Technologies, Inc., SmithKline Beecham (Cork) Limited, and SmithKline Beecham Limited (formerly known as SmithKline Beecham plc), (collectively, "Plaintiffs"), by and through their attorneys, for their complaint against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent No. 7,229,640 ("the '640 patent"), 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, *et seq.*

THE PARTIES

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

3. Apotex Technologies, Inc. is a corporation organized and existing under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

Apotex Technologies, Inc. is the approval holder of New Drug Application 020-936 and markets and distributes Paxil CR®, innovative paroxetine hydrochloride controlled-release tablets.

4. SmithKline Beecham (Cork) Limited is a corporation organized and existing under the laws of Ireland, having its principal office at Currabinny, Carrigaline, County Cork, Ireland.

5. SmithKline Beecham Limited (formerly known as SmithKline Beecham plc) is a company organized and existing under the laws of England, having a registered office at 980 Great West Road, Brentford, Middlesex, TW8 9GS, England.

6. On information and belief, Lupin Ltd. is a corporation organized under the laws of India with its principal place of business at Laxmi Towers "B" Wing, 5th Floor, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India, and having a registered office at 159 CST Road, Kalina Santacruz (E), Mumbai 400 098, India.

7. On information and belief, Lupin Pharmaceuticals, Inc. a wholly-owned subsidiary of Lupin Ltd., is a corporation organized and existing under the laws of the Commonwealth of Virginia, with its principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

8. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals, Inc. are in the business of manufacturing, distributing and selling generic drugs throughout the United States, including in this District.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

10. This Court has personal jurisdiction over Lupin Ltd. and Lupin Pharmaceuticals, Inc. by virtue of their systematic and continuous contacts with this jurisdiction.

11. Specifically, this Court has personal jurisdiction over Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. because they, either directly or through an agent, including each other, regularly do or solicit business in this jurisdiction, engage in other persistent courses of conduct in this jurisdiction, and/or derive substantial revenue from services or things used or consumed in this jurisdiction.

12. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals, Inc. are agents of each other and/or work in active concert with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products, including the generic paroxetine hydrochloride controlled-release tablets described in ANDA No. 20-4134 (defined below).

13. On information and belief, Lupin Ltd. is in the business of developing, formulating, manufacturing, marketing, offering to sell, selling, and commercializing generic drugs throughout the United States, including this District, through operating subsidiaries including Lupin Pharmaceuticals, Inc.

14. On information and belief, Lupin Ltd. does business in Texas through Lupin Pharmaceuticals, Inc., its wholly-owned subsidiary and agent.

15. On information and belief, various products manufactured by Lupin Ltd. appear on the Formulary Index of the Texas Medicaid/CHIP Vendor Drug Program, which provides services for over 4,000 Texas pharmacies.

16. On information and belief, various products manufactured by Lupin Ltd. appear on the Preferred Drug List for the Texas Medicaid program and are available to the millions of Texans in this District and throughout the State who participate in the Texas Medicaid program.

17. On information and belief, Lupin Ltd. has entered into arrangements with Texas entities to have its products appear on the formulary list of BlueCross BlueShield of Texas, a major managed care and health plan.

18. On information and belief, various products manufactured by Lupin Ltd. appear on the Texas Department of State Health Services' Drug Formulary.

19. On information and belief, Lupin Ltd. has previously availed itself of this forum for purposes of litigating its patent disputes regarding its ANDA products. For example, Lupin Ltd. has submitted to the jurisdiction of this Court and filed counterclaims in *Allergan, Inc. v. Lupin Ltd. & Lupin Pharmaceuticals, Inc.*, Case No. 2:11-cv-530-DF, D.I. 16 (E.D. Tex.), *Allergan, Inc. v. Lupin Ltd. & Lupin Pharmaceuticals, Inc.*, Case No. 6:11-cv-611-MHS, D.I. 21 (E.D. Tex.), and *Allergan, Inc. v. Sandoz Inc. et al.*, Case No. 6:11-cv-441-MHS, D.I. 128 (E.D. Tex.).

20. On information and belief, and consistent with their prior practice, Lupin Pharmaceuticals, Inc. is the U.S. agent for Lupin Ltd.'s ANDA No. 20-4134. Lupin Pharmaceuticals, Inc. has admitted to being Lupin Ltd.'s U.S. agent for ANDAs in multiple actions, including, among others, *Allergan, Inc. v. Lupin Ltd. & Lupin Pharmaceuticals, Inc.*, Case No. 2:11-cv-530-DF, D.I. 16 (E.D. Tex.). On information and belief, and consistent with their prior practice, Lupin Ltd. and Lupin Pharmaceuticals, Inc. acted in concert to prepare and submit ANDA No. 20-4134. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals, Inc. actively participated in the preparation of ANDA No. 20-4134 and both entities submitted ANDA No. 20-4134 to the FDA.

21. On information and belief, and consistent with their prior practice, following FDA approval of ANDA No. 20-4134, Lupin Ltd. and Lupin Pharmaceuticals, Inc. will act in concert to distribute and sell Lupin's proposed generic product, paroxetine hydrochloride controlled-

release tablets, 12.5 mg, 25 mg and 37.5 mg, throughout the United States, including in Texas and in this District. On information and belief, following the FDA approval of ANDA No. 20-4134, Lupin Ltd. and Lupin Pharmaceuticals, Inc. know and intend that Lupin Ltd.'s proposed generic paroxetine hydrochloride controlled-release tablets, 12.5 mg, 25 mg and 37.5 mg, will be distributed and sold in the United States, including in Texas.

22. On information and belief, Lupin Pharmaceuticals, Inc. is in the business of offering for sale and selling generic drugs throughout the United States, including in this District, and regularly acts as Lupin Ltd.'s U.S. agent on filings with the FDA.

23. On information and belief, Lupin Pharmaceuticals Inc. is registered to do business in Texas, has a listed registered agent in Texas, and has filed and paid taxes in Texas.

24. On information and belief, Lupin Pharmaceuticals, Inc. is a licensed wholesale distributor of prescription drugs in Texas, and offers for sale at least sixty three products in Texas, including in this District.

25. On information and belief, as a Medicaid participant, Lupin Pharmaceuticals, Inc. is required to sell products to Veterans Administration and Public Health Services facilities, of which there are over 200 in Texas. The Department of Veteran Affairs Formulary lists Lupin Ltd.'s products as being available to its participants.

26. On information and belief, Lupin Pharmaceuticals, Inc. has contracted with numerous authorized distributors, including AmerisourceBergen Drug Corp., Cardinal Health, Caremark, CVS Caremark, CVS Pharmacy Inc., McKesson Corp., Walgreens Co. and Wal-Mart, to offer for sale and to sell its drug products in Texas, including in this District. Specifically, on information and belief, Lupin Pharmaceuticals, Inc. has authorized AmerisourceBergen Drug Corp., Cardinal Health, and Randalls, a Division of Safeway, Inc., to distribute, offer for sale,

and to sell drug products manufactured by Lupin Ltd. and Lupin Pharmaceuticals, Inc. in this District.

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

BACKGROUND

28. The ’640 patent, entitled “Paroxetine Controlled Release Compositions,” issued to Graham Stanley Leonard and David Philip Elder on June 12, 2007. A copy of the ’640 patent is attached to this complaint as Exhibit A.

29. By virtue of an assignment from the inventors Graham Stanley Leonard and David Philip Elder, SmithKline Beecham plc owned the entire right, title, and interest in the ’640 patent. SmithKline Beecham plc assigned the entire right, title, and interest in the ’640 patent to SmithKline Beecham Limited.

30. SmithKline Beecham (Cork) Limited has granted Apotex Inc. a license to make, use, market, distribute, import, offer to sell, and sell paroxetine hydrochloride controlled-release tablets that are claimed in the ’640 patent.

31. Apotex Technologies, Inc. is the holder of the approved NDA No. 020-936 for paroxetine hydrochloride controlled release tablets, which is marketed under the Paxil CR® trademark.

32. In conjunction with the NDA, six patents (“the Listed Patents”) are listed with the United States Food and Drug Administration (“FDA”) that cover the approved formulation of Paxil CR®. The Listed Patents include the ’640 patent. The FDA has published the Listed Patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the “Orange Book.”

33. Paxil CR® is covered by at least one claim of the ’640 patent.

34. On March 20, 2015, Lupin Ltd. sent a letter to Apotex Technologies, Inc., SmithKline Beecham plc, and SmithKline Beecham Limited which stated that Lupin Ltd. had filed an amendment to Abbreviated New Drug Application ("ANDA") No. 20-4134 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to market a generic version of Apotex Technologies, Inc.'s Paxil CR®, 12.5 mg and 25 mg, before expiration of, *inter alia*, the '640 patent.

35. The stated purpose of the March 20, 2015 letter was to notify Apotex Technologies, Inc., SmithKline Beecham plc, and SmithKline Beecham Limited ANDA No. 20-4134 contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding, *inter alia*, the '640 patent. The letter alleged that the claims of the '640 patent are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale, or offer for sale of Lupin Ltd.'s proposed generic paroxetine hydrochloride controlled-release tablets, 12.5 mg and 25 mg.

36. Attached to the March 20, 2015 letter was detailed factual and legal basis for Lupin Ltd.'s opinion that the claims of the '640 patent is invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale, or offer for sale of Defendants' proposed generic paroxetine hydrochloride controlled-release tablets, 12.5 mg and 25 mg.

37. Defendants also seek FDA approval of a 37.5 mg dosage strength paroxetine hydrochloride controlled-release tablet under ANDA No. 20-4134.

38. Defendants had knowledge of the '640 patent since the date on which ANDA No. 20-4134 was filed with the FDA because Defendants' ANDA contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the '640 patent.

39. In filing its ANDA, Defendants have requested the FDA's approval to market a generic version of Apotex Technologies, Inc.'s Paxil CR® (paroxetine hydrochloride controlled-release tablet) drug product throughout the United States, including in Texas.

COUNT I
(Infringement of the '640 Patent Under 35 U.S.C. § 271(e)(2) by Defendants' Proposed Generic Paroxetine Hydrochloride Product, 37.5 mg)

40. Paragraphs 1-39 are incorporated herein as set forth above.

41. Lupin Ltd. and Lupin Pharmaceuticals, Inc. submitted ANDA No. 20-4134 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of their proposed generic 37.5 mg paroxetine hydrochloride controlled-release tablet product throughout the United States. By submitting ANDA No. 20-4134 to the FDA, Defendants have committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

42. The commercial use of Defendants' proposed generic 37.5 mg paroxetine hydrochloride controlled-release tablet product described in ANDA No. 20-4134 will constitute an act of direct infringement of the '640 patent.

43. The commercial manufacture, offer for sale, sale and/or importation of Defendants' proposed generic 37.5 mg paroxetine hydrochloride controlled-release tablet product, in conjunction with Defendants' labeling and instructions for the use thereof, will constitute an act of inducement of infringement of the '640 patent by doctors and/or patients, including in this District.

44. The commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic 37.5 mg generic paroxetine hydrochloride product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

COUNT II
(Declaratory Judgment of Infringement of the '640 Patent Under 35 U.S.C. § 271(a)-(b) by Defendants' Proposed Generic Paroxetine Hydrochloride Products, 37.5 mg)

45. Paragraphs 1-44 are incorporated herein as set forth above.

46. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

47. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

48. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import Defendants' proposed generic 37.5 mg paroxetine hydrochloride controlled-release tablet product.

49. Defendants' actions indicate a refusal to change the course of their actions in the face of acts by Plaintiffs.

50. The commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic 37.5 mg paroxetine hydrochloride controlled-release tablet product will constitute an act of direct infringement of the '640 patent.

51. The commercial use, offer for sale, and sale of Defendants' proposed generic 37.5 mg paroxetine hydrochloride controlled-release tablet product in conjunction with Defendants' labeling and instructions for the use thereof, will constitute an act of inducement of infringement of the '640 patent by doctors and/or patients, including in this District.

52. Defendants had knowledge of the '640 patent at least since the date on which ANDA No. 20-4134 was filed with the FDA because Defendants' ANDA contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the '640 patent.

53. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic 37.5 mg paroxetine hydrochloride controlled-release tablet product by any or all of Defendants will infringe the '640 patent.

COUNT III
(Infringement of the '640 Patent Under 35 U.S.C. § 271(e)(2) by Defendants' Proposed Generic Paroxetine Hydrochloride Products, 12.5 mg and 25 mg)

54. Paragraphs 1-53 are incorporated herein as set forth above.

55. Lupin Ltd. and Lupin Pharmaceuticals, Inc. submitted ANDA No. 20-4134 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of their proposed generic 12.5 mg and 25 mg paroxetine hydrochloride controlled-release tablet products throughout the United States. By submitting ANDA No. 20-4134 to the FDA, Defendants have committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

56. The commercial use of Defendants' proposed generic 12.5 mg and 25 mg paroxetine hydrochloride controlled-release tablet products described in ANDA No. 20-4134 will constitute an act of direct infringement of the '640 patent.

57. The commercial manufacture, offer for sale, sale and/or importation of Defendants' proposed generic 12.5 mg and 25 mg paroxetine hydrochloride controlled-release tablet products, in conjunction with Defendants' labeling and instructions for the use thereof, will constitute an act of inducement of infringement of the '640 patent by doctors and/or patients, including in this District.

58. The commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic 12.5 mg and 25 mg paroxetine hydrochloride controlled-release

tablet products in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

COUNT IV
(Declaratory Judgment of Infringement of the '640 Patent Under 35 U.S.C. § 271(a)-(b) by Defendants' Proposed Generic Paroxetine Hydrochloride Products, 12.5 mg and 25 mg)

59. Paragraphs 1-58 are incorporated herein as set forth above.

60. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

61. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

62. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import Defendants' proposed generic 12.5 mg and 25 mg paroxetine hydrochloride controlled-release tablet products.

63. Defendants' actions indicate a refusal to change the course of their actions in the face of acts by Plaintiffs.

64. The commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic 12.5 mg and 25 mg paroxetine hydrochloride controlled-release tablet products will constitute an act of direct infringement of the '640 patent.

65. The commercial use, offer for sale, and sale of Defendants' proposed generic 12.5 mg and 25 mg paroxetine hydrochloride controlled-release tablet products in conjunction with Defendants' labeling and instructions for the use thereof, will constitute an act of inducement of infringement of the '640 patent by doctors and/or patients, including in this District.

66. Defendants had knowledge of the ’640 patent at least since the date on which ANDA No. 20-4134 was filed with the FDA because Defendants’ ANDA contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the ’640 patent.

67. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ proposed generic 12.5 mg and 25 mg paroxetine hydrochloride controlled-release tablet products by any or all of Defendants will infringe the ’640 patent.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Defendants have infringed and that Defendants’ making, using, selling, offering to sell, marketing, distributing, or importing the proposed generic paroxetine hydrochloride controlled-release tablet products (12.5 mg, 25 mg and 37.5 mg) described in ANDA No. 20-4134 will constitute infringement and active inducement of infringement of the ’640 patent;

B. A declaration that Defendants’ commercial manufacture, distribution, use, and sale of the proposed generic paroxetine hydrochloride controlled-release tablet products (12.5 mg, 25 mg and 37.5 mg) would infringe the ’640 patent;

C. An order that Defendants are not entitled to obtain FDA approval of ANDA No. 20-4134 before expiration of the ’640 patent, including any extensions and/or exclusivity period associated therewith;

D. An injunction enjoining Defendants and Defendants' officers, agents, servants, employees, and those persons in active concert or participation with any of them from making, using, selling, offering to sell, marketing, distributing, or importing products made under the ANDA No. 20-4134 before expiration of the '640 patent, including any extensions and/or exclusivity period associated therewith;

E. If Defendants attempt to engage in the commercial manufacture, use, offer for sale, sale, or importation of Defendants' generic products described in ANDA No. 20-4134 prior to the expiration of the '640 patent, including any extensions and/or exclusivity period associated therewith, that judgment be entered awarding Plaintiffs damages, including prejudgment interest, resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

F. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to U.S.C. § 285;

G. Costs and expenses in this action; and

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

Dated: May 1, 2015

Respectfully submitted,

By: /s/ William E. Davis, III

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