

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

.....
SHIRE LLC,
SHIRE DEVELOPMENT LLC,
and
SUPERNUS PHARMACEUTICALS, INC.,

Plaintiffs,

v.

APOTEX, INC. and APOTEX CORP.,

Defendants.
.....

C.A. No. _____

COMPLAINT

Plaintiffs Shire LLC (“Shire”), Shire Development LLC (“Shire Development”), and Supernus Pharmaceuticals, Inc. (“Supernus”) (collectively “Plaintiffs”), by their undersigned attorneys, for their Complaint against Defendants Apotex, Inc. and Apotex Corp. (collectively “Defendants” or “Apotex”) herein, allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 6,287,599 (“the ’599 patent”) and 6,811,794 (“the ’794 patent”) (attached as Exhibits A and B respectively hereto) (collectively “the patents-in-suit”).

THE PARTIES

2. Plaintiff Shire is a corporation organized and existing under the laws of the State of Kentucky, having its principal place of business at 9200 Brookfield Court, Florence, Kentucky 41042.

3. Plaintiff Shire Development is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 725 Chesterbrook Boulevard, Wayne, Pennsylvania 19087.

4. Plaintiff Supernus is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1550 East Gude Drive, Rockville, Maryland 20850.

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

6. Upon information and belief, Apotex, Inc. develops and manufactures generic pharmaceutical products that are sold throughout the United States, including the state of Delaware.

7. Upon information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

8. Upon information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex, Inc. Upon information and belief, Apotex Corp. acts at the direction of, under the control of, and for the direct benefit of Apotex, Inc. and is controlled and/or dominated by Apotex, Inc.

9. Upon information and belief, Apotex Corp. is an agent, affiliate, or subsidiary of Apotex, Inc., including for Abbreviated New Drug Application (“ANDA”) No. 205430 (“the Apotex ANDA”). Apotex’s ANDA states that Apotex Corp. is the “authorized US agent” for communications with respect to Apotex’s ANDA.

10. Upon information and belief, Apotex Corp. is authorized to accept service of process for Apotex, Inc. in the United States.

11. Upon information and belief, Apotex Corp. serves as Apotex, Inc.'s United States distributor and sells and offers for sale Apotex, Inc.'s drug product throughout the United States including Delaware.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. This Court has personal jurisdiction over Defendants Apotex.

14. Upon information and belief, Apotex, Inc. markets and sells generic drugs throughout the United States and within the state of Delaware.

15. Upon information and belief, Apotex, Inc. is the applicant for Apotex's ANDA which was filed with the U.S. Food and Drug Administration ("FDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to manufacture, use, sell, offer for sale, and/or import a 1, 2, 3, and 4 mg Guanfacine Hydrochloride Extended-Release Oral Tablets for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD") in the United States.

16. Upon information and belief, Apotex, Inc. resides and is doing business within this judicial district through its agent, Apotex Corp.

17. Upon information and belief, Apotex Corp. is a Delaware corporation with a registered agent in Delaware.

18. Upon information and belief, Apotex Corp. avails itself to the laws of the state of Delaware. For example, upon information and belief, Apotex Corp. is registered with the Delaware Board of Pharmacy pursuant to 24 Del. C. § 2540.

19. Upon information and belief, Apotex Corp. operated as an instrumentality for the preparation and submission of Apotex's ANDA, which seeks approval to engage in the

commercial manufacture, use, sale, offer for sale and/or importation into the United States of Apotex's Proposed Products.

20. Upon information and belief, Apotex has a continuous and systematic business presence within this judicial district and/or substantial events giving rise to acts of infringement that have occurred and/or will occur within this judicial district including its preparation of and/or contribution to the submission and/or filing of Apotex's ANDA seeking approval to sell or offer to sell Apotex's Proposed Products in the United States including the state of Delaware.

21. Upon information and belief, Apotex's business includes developing, manufacturing, distributing, and/or selling generic drug products for sale and use throughout the United States including for sale and use in the state of Delaware.

22. Upon information and belief, Apotex has derived revenue from generic drug products distributed and/or sold in the state of Delaware.

23. Upon information and belief, Apotex has previously submitted to the jurisdiction of this Court and has previously availed itself of this Court by filing suit in this jurisdiction and/or by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., In re Armondafinil Patent Lit.*, 2013 U.S. Dist. LEXIS 46572 (D. Del. March 30, 2013); *Apotex v. Senju Pharm.*, 921 F. Supp. 2d 308 (D. Del. 2013).

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

FACTS COMMON TO ALL COUNTS

25. Shire Development is the owner of New Drug Application ("NDA") No. 022037, which was approved by the FDA for the manufacture and sale of Guanfacine Hydrochloride Extended Release Tablets, Eq. 1 mg Base, Eq. 2 mg Base, Eq. 3 mg Base and Eq. 4 mg Base, which Shire markets under the name of Intuniv[®]. Intuniv[®] is indicated for the treatment of Attention Deficit Hyperactivity Disorder.

26. The '599 patent is entitled "Sustained release pharmaceutical dosage forms with minimized pH dependent dissolution profiles" and was duly and legally issued on September 11, 2001.

27. The '794 patent is also entitled "Sustained release pharmaceutical dosage forms with minimized pH dependent dissolution profiles" and was duly and legally issued on November 2, 2004.

28. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit are listed in FDA's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering Intuniv[®].

29. Upon information and belief, Apotex filed its ANDA with the FDA under § 505(j) of the FDCA seeking approval to engage in the manufacture, use, sale, offer for sale, and/or importation of generic guanfacine hydrochloride extended-release tablets, 1 mg, 2 mg, 3 mg, and 4 mg ("Apotex's Proposed Products") before the expiration of the '599 and '794 patents.

30. Upon information and belief, Apotex sent Shire a letter purporting to include a notice of certification for the '599 and '794 patents under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. 505(j)(2)(B)(ii) of the FDCA regarding Apotex's Product ("Apotex's Notice Letter"). This letter was received by Shire on October 8, 2013.

FIRST COUNT

(Infringement of the '599 patent by Apotex)

31. Plaintiff repeats and incorporates by reference each paragraph above.

32. The '599 patent, entitled "Sustained release pharmaceutical dosage forms with minimized pH dependent dissolution profiles," was duly and legally issued on September 11, 2001 to Shire Laboratories Inc. ("Shire Labs") upon assignment from Beth A. Burnside, Ron-Kun Chang, and Xiaodi Guo. Supernus became the owner of the '599 patent upon assignment

from Shire Labs. Supernus granted Shire an exclusive license under the '599 patent with respect to, *inter alia*, drug products containing the active ingredient guanfacine or salts thereof.

33. Upon information and belief, Apotex seeks FDA approval for the manufacture and/or distribution of Apotex's Proposed Products.

34. Upon information and belief, Apotex's ANDA includes a paragraph IV certification to the '599 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's Proposed Products before the expiration of the '599 patent.

35. Upon information and belief, Apotex will commercially manufacture, sell, offer for sale, and/or import Apotex's Proposed Products immediately upon FDA approval.

36. Upon information and belief, as of the date of Apotex's Notice Letters, Apotex was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

37. The submission and filing of Apotex's ANDA with a paragraph IV certification to the '599 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Apotex's Proposed Products before the expiration of the '599 patent is an act of infringement of one or more claims of the '599 patent under 35 U.S.C. § 271(e)(2)(A).

38. Upon information and belief, Apotex's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's Proposed Products that are the subject of Apotex's ANDA will infringe one or more claims of the '599 patent.

39. Upon information and belief, as of the date of Apotex's Notice Letters, Apotex was aware of the existence of the '599 patent and acted without reasonable basis for believing that they would not be liable for infringement of the '599 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

SECOND COUNT

(Infringement of the '794 patent by Apotex)

40. Plaintiffs repeat and incorporate by reference each paragraph above.

41. The '794 patent, entitled "Sustained release pharmaceutical dosage forms with minimized pH dependent dissolution profiles," was duly and legally issued on November 2, 2004 to Shire Laboratories Inc. ("Shire Labs") upon assignment from Beth A. Burnside, Ron-Kun Chang, and Xiaodi Guo. Supernus became the owner of the '794 patent upon assignment from Shire Labs. Supernus granted Shire an exclusive license under the '794 patent with respect to, *inter alia*, drug products containing the active ingredient guanfacine or salts thereof.

42. Upon information and belief, Apotex seeks FDA approval for the manufacture and/or distribution of Apotex's Proposed Products.

43. Upon information and belief, Apotex's ANDA includes a paragraph IV certification to the '794 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Apotex's Proposed Products before the expiration of the '794 patent.

44. Upon information and belief, Apotex will commercially manufacture, sell, offer for sale, and/or import Apotex's Proposed Products immediately upon FDA approval.

45. Upon information and belief, as of the date of Apotex's Notice Letters, Apotex was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

46. The submission and filing of Apotex's ANDA with a paragraph IV certification to the '794 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's Proposed Products before the expiration of the '794 patent is an act of infringement by Apotex before the expiration of the '794 patent is

an act of infringement by Apotex of one or more claims of the '794 patent under 35 U.S.C. § 271(e)(2)(A).

47. Upon information and belief, Apotex's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's Proposed Products that are the subject of Apotex's ANDA will infringe one or more claims of the '794 patent.

48. Upon information and belief, as of the date of Apotex's Notice Letters, Apotex was aware of the existence of the '794 patent and acted without reasonable basis for believing that they would not be liable for infringement of the '794 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

THIRD COUNT

(Induced and/or Contributory Infringement of the '599 Patent.)

49. Plaintiffs repeat and incorporate by reference each paragraph above.

50. Apotex Corp. is jointly and severally liable for Apotex, Inc.'s infringement of one or more claims of the '599 patent.

51. Upon information and belief, Apotex, Inc. knowingly induced and/or will induce Apotex Corp. to infringe and/or contributed and/or will contribute to Apotex Corp.'s infringement of one or more claims of the '599 patent.

52. Upon information and belief, Apotex, Inc. has, continues to, and will actively induce, encourage, aid, or abet Apotex Corp.'s infringement of the '599 patent with knowledge that it is in contravention of the rights of Plaintiffs.

53. Upon information and believe, Apotex Corp. is a wholly owned subsidiary of Apotex, Inc. Upon information and belief, Apotex Corp. serves as Apotex, Inc.'s United States distributor and sells and offers for sale Apotex, Inc.'s drug product throughout the United States including Delaware. Apotex's ANDA indicates that Apotex Corp. is the United States agent for Apotex, Inc. with respect to Apotex's ANDA.

54. Upon information and belief, Apotex, Inc. actively induced, encouraged, aided, and/or abetted Apotex Corp.'s participation and/or preparation and/or submission and/or filing of Apotex's ANDA.

55. Apotex, Inc. will induce and/or contribute to Apotex Corp.'s infringement of the '599 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c) by virtue of commercial use, sale, offer for sale and/or importation of Apotex's Proposed Products.

56. Upon information and belief, Apotex, Inc. and Apotex Corp. will induce and/or contribute to infringement by third parties of the '599 patent under 35 U.S.C. § 271 by virtue of their inducement, encouragement, aiding, and/or abetting of the sale or offer for sale of Apotex's Proposed Products.

57. Upon information and belief, Apotex, Inc. has, continues to, and will actively induce, encourage, aid, or abet Apotex Corp.'s infringement of the '599 patent with knowledge that it is in contravention of the rights of Plaintiffs.

58. Upon information and belief, as of the date of Apotex's Notice Letters, Apotex, Inc. was aware of the existence of the '599 patent and acted without a reasonable basis for believing that it would not be liable for inducing and/or contributing to Apotex Corp.'s infringement, thus rendering this case "exceptional" under 35 U.S.C. § 285.

59. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which neither has adequate remedy at law, unless Apotex Corp. is preliminarily and permanently enjoined by this Court.

FOURTH COUNT

(Induced and/or Contributory Infringement of the '794 Patent.)

60. Plaintiffs repeat and incorporate by reference each paragraph above.

61. Apotex Corp. is jointly and severally liable for Apotex, Inc.'s infringement of one or more claims of the '794 patent.

62. Upon information and belief, Apotex, Inc. knowingly induced and/or will induce Apotex Corp. to infringe and/or contributed and/or will contribute to Apotex Corp.'s infringement of one or more claims of the '794 patent.

63. Upon information and belief, Apotex, Inc. has, continues to, and will actively induce, encourage, aid, or abet Apotex Corp.'s infringement of the '794 patent with knowledge that it is in contravention of the rights of Plaintiffs.

64. Upon information and believe, Apotex Corp. is a wholly owned subsidiary of Apotex, Inc. Upon information and belief, Apotex Corp. serves as Apotex, Inc.'s United States distributor and sells and offers for sale Apotex, Inc.'s drug product throughout the United States including Delaware. Apotex's ANDA indicates that Apotex Corp. is the United States agent for Apotex, Inc. with respect to Apotex's ANDA.

65. Upon information and belief, Apotex, Inc. actively induced, encouraged, aided, and/or abetted Apotex Corp.'s participation and/or preparation and/or submission and/or filing of Apotex's ANDA.

66. Apotex, Inc. will induce and/or contribute to Apotex Corp.'s infringement of the '794 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c) by virtue of commercial use, sale, offer for sale, and/or importation of Apotex's Proposed Products.

67. Upon information and belief, Apotex, Inc. and Apotex Corp. will induce and/or contribute to infringement by third parties of the '794 patent under 35 U.S.C. § 271 by virtue of their inducement, encouragement, aiding, and/or abetting of the sale or offer for sale of Apotex's Proposed Products.

68. Upon information and belief, Apotex, Inc. has, continues to, and will actively induce, encourage, aid, or abet Apotex Corp.'s infringement of the '794 patent with knowledge that it is in contravention of the rights of Plaintiffs.

69. Upon information and belief, as of the date of Apotex's Notice Letters, Apotex, Inc. was aware of the existence of the '794 patent and acted without a reasonable basis for believing that it would not be liable for inducing and/or contributing to Apotex Corp.'s infringement, thus rendering this case "exceptional" under 35 U.S.C. § 285.

70. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which neither has adequate remedy at law, unless Apotex Corp. is preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

- (a) A judgment declaring that the '599 patent is valid and enforceable;
- (b) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission and filing of Apotex's ANDA with a paragraph IV certification to the FDA to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the products that are the subject of Apotex's ANDA prior to the expiration of the '599 patent was an act of infringement;
- (c) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A) and/or 35 U.S.C. § 271(a), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the products that are the subject of Apotex's ANDA prior to the expiration of the '599 patent will constitute an act of infringement of the '599 patent by Apotex, Inc. and Apotex Corp., individually and collectively;
- (d) An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of Apotex's ANDA shall be no earlier than the date on which the '599 patent expires;
- (e) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Apotex, their officers, agents, servants, employees and attorneys, and those persons in

active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sell, and/or importation in the United States of the product that is the subject of Apotex's until the expiration of the '599 patent;

(f) A judgment awarding Plaintiffs damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Apotex commercially manufactures, uses, sells, offers to sell, and/or imports any products that are the subject of Apotex's ANDA prior to the expiration of the '599 patent;

(g) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Apotex, Inc. would induce and/or contribute to Apotex Corp.'s infringement of the '599 patent and that both defendants would induce and/or contribute to third party infringement of the '599 patent based on the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's Proposed Products that are the subject of Apotex's ANDA prior to the expiration of the '599 patent.

(h) A judgment declaring that Apotex's infringement of the '599 patent based on Apotex's ANDA is willful if Apotex commercially manufactures, uses, sells, offers to sell, and/or imports any products that are the subject of Apotex's ANDA prior to the expiration of the '599 patent;

(i) A judgment declaring that the '794 patent is valid and enforceable;

(j) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission and filing of Apotex's ANDA with a paragraph IV certification to the FDA to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the products that are the subject of Apotex's ANDA prior to the expiration of the '794 patent was an act of infringement;

(k) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A) and/or 35 U.S.C. § 271(a), the commercial manufacture, use, sale, offer for sale, and/or importation in the United

States of the products that are the subject of Apotex's ANDA prior to the expiration of the '794 patent will constitute an act of infringement of the '794 patent by Apotex, Inc. and Apotex Corp., individually and collectively;

(l) An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of Apotex's ANDA shall be no earlier than the date on which the '794 patent expires;

(m) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Apotex, their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sell, and/or importation in the United States of the products that are the subject of Apotex's ANDA until the expiration of the '794 patent;

(n) A judgment awarding Plaintiffs damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Apotex commercially manufactures, uses, sells, offers to sell, and/or imports any products that are the subject of Apotex's ANDA prior to the expiration of the '794 patent;

(o) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Apotex, Inc. would induce and/or contribute to Apotex Corp.'s infringement of the '794 patent and that both defendants would induce and/or contribute to third party infringement of the '794 patent based on the commercial manufacture, use, sale, offer for sell, and/or importation into the United States of Apotex's Proposed Products that are the subject of Apotex's ANDA prior to the expiration of the '794 patent.

(p) A judgment declaring that Apotex's infringement of the '794 patent based on Apotex's ANDA is willful if Apotex commercially manufactures, uses, sells, offers to sell, and/or imports any products that are the subject of Apotex's ANDA prior to the expiration of the '794 patent;

(q) A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Shire its attorneys' fees and costs;

(r) Such other and further relief as this Court may deem just and proper.

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