IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

ALCON PHARMACEUTICALS, LTD., and ALCON RESEARCH, LTD.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. _____
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Alcon Pharmaceuticals, Ltd. and Alcon Research, Ltd. (collectively "Plaintiffs"), by their attorneys, for their Complaint, allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Apotex of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Patanase® nasal spray, a drug product containing olopatadine hydrochloride, prior to the expiration of United States Patent No. 7,977,376.

PARTIES

2. Alcon Pharmaceuticals, Ltd. is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Route des Arsenaux 41, 1701 Fribourg, Switzerland.

3. Alcon Research, Ltd. is a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

4. Upon 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 Dr., Weston, Ontario M9L 1T9, Canada. Upon information and belief, Apotex Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market through various operating subsidiaries, including Apotex Corp.

5. Upon information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326. Upon information and belief, Apotex Corp. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the United States market. Apotex Corp. is a wholly-owned subsidiary of Apotex Inc.

6. Except where otherwise noted, Apotex Inc. and Apotex Corp. are referred to collectively herein as "Apotex."

JURISDICTION AND VENUE

7. This court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Venue in this district is proper pursuant to 28 U.S.C. §§ 1391 and 1400(b).

9. Upon information and belief, Apotex is subject to personal jurisdiction in Texas and the Northern District of Texas because, among other things, it is in the business of manufacturing pharmaceutical products, which it distributes, markets, and sells throughout the

United States, including the State of Texas and the Northern District of Texas. Apotex therefore regularly transacts and/or solicits business in the State of Texas and the Northern District of Texas, and has purposefully availed itself of this forum such that it should reasonably anticipate being haled into court here.

10. Upon information and belief, Apotex Inc. submits ANDAs and manufactures generic copies of branded pharmaceutical products for the United States market. Upon information and belief, Apotex Inc., itself and through its wholly-owned subsidiary Apotex Corp., distributes, markets, and/or sells those generic pharmaceutical products throughout the United States and within the State of Texas and the Northern District of Texas.

11. Upon information and belief, Apotex Inc., itself and through its wholly-owned subsidiary Apotex Corp., is a party to one or more contractual agreements regarding the distribution of generic pharmaceutical products in the State of Texas and the Northern District of Texas.

12. Upon information and belief, Apotex Inc., itself and through its wholly-owned subsidiary Apotex Corp., earns revenue from the distribution of generic pharmaceutical products in the State of Texas and the Northern District of Texas.

13. In addition, on information and belief, Apotex Inc. is subject to personal jurisdiction in Texas on the basis of its inducement of and/or contribution to Apotex Corp.'s acts of infringement in Texas. On information and belief, Apotex Inc. controls and dominates Apotex Corp. and therefore the activities of Apotex Corp. in this jurisdiction are attributed to Apotex Inc.

14. Upon information and belief, Apotex Corp. distributes, markets, and sells those generic pharmaceutical products for which Apotex Inc. holds an ANDA, including selling such products in the State of Texas and the Northern District of Texas.

15. Upon information and belief, Apotex Corp. is a corporation licensed with the Texas Department of Health to distribute pharmaceutical products in the State of Texas and sell such pharmaceutical products wholesale therein.

16. Upon information and belief, Apotex Corp. is a party to one or more contractual agreements regarding the distribution of generic pharmaceutical products in the State of Texas and the Northern District of Texas.

17. Upon information and belief, Apotex Corp. earns revenue from the distribution of generic pharmaceutical products, including products for which Apotex Inc. holds the ANDA, in the State of Texas and the Northern District of Texas.

18. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 91-572, Apotex Inc. and Apotex Corp. will act in concert to distribute, market, and sell Apotex's olopatadine hydrochloride nasal spray solution ("Apotex's ANDA Product"), throughout the United States, including within the State of Texas and the Northern District of Texas. Upon information and belief, following any FDA approval of ANDA No. 91-572, Apotex Inc. and Apotex Corp. intend that Apotex's ANDA product will be distributed, marketed, and sold in the United States, including within the State of Texas and the Northern District of Texas.

19. Upon information and belief, and consistent with their practice with respect to other generic products, Apotex Inc. and Apotex Corp. acted in concert to prepare and submit ANDA No. 91-572. Upon information and belief, and consistent with their practice with respect

to other generic products, Apotex Inc. and Apotex Corp. actively participated in the preparation of ANDA No. 91-572. Upon information and belief, Apotex Corp. acted as the agent of Apotex Inc. in submitting ANDA No. 91-572 to the FDA.

BACKGROUND

20. Patanase® is a nasal spray indicated for the relief of the symptoms of seasonal allergic rhinitis in adults and children 6 years of age and older.

COUNT I – INFRINGEMENT OF UNITED STATES PATENT NO. 7,977,376

21. Plaintiffs incorporate each of the preceding paragraphs 1-20 as if fully set forth herein.

22. United States Patent No. 7,977,376 ("the '376 patent"), entitled "Olopatadine Formulations for Topical Nasal Administration" (Exhibit A hereto), was duly and legally issued on July 12, 2011, to Novartis AG as assignee of Onkar N. Singh, G. Michael Wall, Rajni Jani, Masood A. Chowhan, and Wesley Wehsin Han.

23. Novartis AG subsequently assigned its interest in the '376 patent to Alcon Pharmaceuticals, Ltd.

24. Alcon Pharmaceuticals, Ltd. owns the '376 patent.

25. Alcon Research, Ltd. holds an exclusive license under the '376 patent and is the holder of approved New Drug Application 02-1861 for Patanase®.

26. Plaintiffs will be substantially and irreparably damaged by infringement of the '376 patent.

27. The '376 patent claims, *inter alia*, a topically administrable, aqueous, nasal spray solution composition consisting of 0.665% (w/v) olopatadine hydrochloride; a phosphate salt in an amount equivalent to 0.4-0.6% (w/v) dibasic sodium phosphate, wherein the phosphate salt is

selected from the group consisting of monobasic sodium phosphate, dibasic sodium phosphate, tribasic sodium phosphate, monobasic potassium phosphate, dibasic potassium phosphate, and tribasic potassium phosphate; 0.35-0.45% (w/v) NaCl; one or more pH-adjusting agents in an amount sufficient to cause the composition to have a pH of 3.6-3.8, wherein the pH-adjusting agents are selected from the group consisting of HCl and NaOH; 0.005-0.015% (w/v) benzalkonium chloride; 0.005-0.015% (w/v) edetate disodium; and water; wherein the composition has an osmolality of 260-330 mOsm/kg.

28. The ’376 patent also claims, *inter alia*, a topically administrable, aqueous, nasal spray solution composition consisting of 0.665% (w/v) olopatadine hydrochloride; 0.4-0.6% (w/v) dibasic sodium phosphate; 0.35-0.45% (w/v) NaCl; one or more pH-adjusting agents in an amount sufficient to cause the composition to have a pH of 3.6-3.8, wherein the pH-adjusting agents are selected from the group consisting of HCl and NaOH; 0.01% (w/v) benzalkonium chloride; 0.01% (w/v) edetate disodium; and water; wherein the composition has an osmolality of 260-330 mOsm/kg.

29. Patanase® is covered by the claims of the ’376 patent, and the ’376 patent has been listed in connection with that drug product in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*.

30. Apotex has knowledge of the ’376 patent.

31. By letter dated July 12, 2011 (the “Notice Letter”), Apotex notified Plaintiffs that Apotex had submitted ANDA No. 91-572 to the FDA for Apotex’s ANDA Product. Apotex sent subsequent letters after July 12, 2011, which make the same substantive assertions as the July 12, 2011, letter. The purpose of ANDA No. 91-572 was to obtain approval under the Federal Food,

Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product prior to the expiration of the '376 patent.

32. In the Notice Letter, Apotex also notified Plaintiffs that, as part of its ANDA, Apotex had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '376 patent. Upon information and belief, Apotex submitted ANDA No. 91-572 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '376 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product.

33. Apotex was required to state in its Notice Letter its bases for any contention that its ANDA Product will not infringe the patent-in-suit. Apotex did not assert in the July 12, 2011, Notice Letter or any of the subsequent letters it sent to Plaintiffs that its ANDA product does not infringe the claims of the '376 patent.

34. Upon information and belief, Apotex's ANDA Product is covered by one or more claims of the '376 patent.

35. Apotex's filing of ANDA No. 91-572 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product before the expiration of the '376 patent is an act of infringement of the '376 patent under 35 U.S.C. § 271(e)(2)(A).

36. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product immediately and imminently upon approval of ANDA No. 91-572.

37. The manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product would infringe one or more claims of the '376 patent.

38. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product in accordance with and as directed by Apotex's proposed labeling for that product would infringe one or more claims of the '376 patent.

39. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '376 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

40. Notwithstanding Apotex's knowledge of the claims of the '376 patent, Apotex has continued to assert its intent to manufacture, offer for sale, sell, and/or import Apotex's ANDA Product with its proposed labeling following FDA approval of ANDA No. 91-572 prior to the expiration of the '376 patent.

41. The foregoing actions by Apotex constitute and/or will constitute infringement and active inducement of infringement of the '376 patent.

42. Upon information and belief, Apotex has acted with full knowledge of the '376 patent and without a reasonable basis for believing that it would not be liable for infringement and active inducement of infringement of the '376 patent.

43. Unless Apotex is enjoined from infringing and actively inducing infringement of the '376 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 7,977,376

44. Plaintiffs incorporate each of the preceding paragraphs 1-43 as if fully set forth herein.

45. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Apotex on the other regarding Apotex's infringement and active inducement of infringement of the '376 patent.

46. The '376 patent claims, *inter alia*, a topically administrable, aqueous, nasal spray solution composition consisting of 0.665% (w/v) olopatadine hydrochloride; a phosphate salt in an amount equivalent to 0.4-0.6% (w/v) dibasic sodium phosphate, wherein the phosphate salt is selected from the group consisting of monobasic sodium phosphate, dibasic sodium phosphate, tribasic sodium phosphate, monobasic potassium phosphate, dibasic potassium phosphate, and tribasic potassium phosphate; 0.35-0.45% (w/v) NaCl; one or more pH-adjusting agents in an amount sufficient to cause the composition to have a pH of 3.6-3.8, wherein the pH-adjusting agents are selected from the group consisting of HCl and NaOH; 0.005-0.015% (w/v) benzalkonium chloride; 0.005-0.015% (w/v) edetate disodium; and water; wherein the composition has an osmolality of 260-330 mOsm/kg.

47. The '376 patent also claims, *inter alia*, a topically administrable, aqueous, nasal spray solution composition consisting of 0.665% (w/v) olopatadine hydrochloride; 0.4-0.6% (w/v) dibasic sodium phosphate; 0.35-0.45% (w/v) NaCl; one or more pH-adjusting agents in an amount sufficient to cause the composition to have a pH of 3.6-3.8, wherein the pH-adjusting agents are selected from the group consisting of HCl and NaOH; 0.01% (w/v) benzalkonium chloride; 0.01% (w/v) edetate disodium; and water; wherein the composition has an osmolality of 260-330 mOsm/kg.

48. Patanase® is covered by one or more of the claims of the '376 patent.

49. Apotex has knowledge of the '376 patent.

50. In the Notice Letter described in paragraph 31 above, Apotex notified Plaintiffs that Apotex had submitted ANDA No. 91-572 to the FDA for Apotex's ANDA Product. The purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product prior to the expiration of the '376 patent.

51. In the Notice Letter, Apotex also notified Plaintiffs that, as part of its ANDA, Apotex had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '376 patent. Upon information and belief, Apotex submitted ANDA No. 91-572 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '376 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product.

52. Apotex was required to state in its Notice Letter its bases for any contention that its ANDA Product will not infringe the patent-in-suit. Apotex did not assert in the July 12, 2011, Notice Letter or any of the subsequent letters it sent to Plaintiffs that its ANDA product will not infringe the claims of the '376 patent.

53. Upon information and belief, Apotex's ANDA Product is covered by one or more of the claims of the '376 patent.

54. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product immediately and imminently upon approval of ANDA No. 91-572.

55. The manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product would infringe one or more of the claims of the '376 patent.

56. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product in accordance with and as directed by Apotex's proposed labeling for that product would infringe one or more of the claims of the '376 patent.

57. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '376 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

58. Notwithstanding Apotex's knowledge of the claims of the '376 patent, Apotex has continued to assert its intent to manufacture, offer for sale, sell, and/or import Apotex's ANDA Product with its proposed labeling following FDA approval of ANDA No. 91-572 prior to the expiration of the '376 patent.

59. The foregoing actions by Apotex constitute and/or will constitute infringement and active inducement of infringement of the '376 patent.

60. Upon information and belief, Apotex has acted with full knowledge of the '376 patent and without a reasonable basis for believing that it would not be liable for infringement and active inducement of infringement of the '376 patent.

61. Unless defendant Apotex is enjoined from infringing and actively inducing infringement of the '376 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

62. The Court should declare that Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product, or any other drug product which infringes United States Patent No. 7,977,376, will infringe the '376 patent and/or will induce the infringement of that patent.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that United States Patent No. 7,977,376 is valid and enforceable, and has been infringed under 35 U.S.C. § 271(e)(2) by Apotex's submission to the FDA of its ANDA No. 91-572 and will be infringed by the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product.

(b) A judgment providing that the effective date of any FDA approval for Apotex to manufacture, use, offer for sale, sell, and/or import Apotex's ANDA Product, or any other drug product that infringes United States Patent No. 7,977,376, be not earlier than the expiration date of the '376 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Apotex, and all persons acting in concert with Apotex, from the manufacture, use, offer for sale, sale, and/or importation into the United States of Apotex's ANDA Product, or any other drug product that infringes United States Patent No. 7,977,376, prior to the expiration of the '376 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that Apotex's manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product, or any other drug product that infringes United States Patent No. 7,977,376, will infringe and/or will induce infringement of the '376 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

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

Respectfully submitted,

Dated: August 25, 2011

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