

**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. _____
)	
PERRIGO CO. and PERRIGO ISRAEL)	
PHARMACEUTICALS LTD.,)	
)	
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 Perrigo 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, Perrigo Company (“Perrigo Co.”) is a corporation organized and existing under the laws of Michigan, having its principal place of business at 515 Eastern Ave., Allegan, MI 49010. Upon information and belief, Perrigo Co. is in the business of, among other things, manufacturing, distributing, and/or selling generic versions of branded pharmaceutical products throughout the United States market through various operating subsidiaries, including Perrigo Israel Pharmaceuticals Ltd.

5. Upon information and belief, Perrigo Israel Pharmaceuticals Ltd. (“Perrigo Israel”) is a corporation organized and existing under the laws of Israel, having its principal place of business at 29 Lehi St., Bnei Brak 51200, Israel. Upon information and belief, Perrigo Israel is in the business of, among other things, manufacturing and/or selling generic versions of branded pharmaceutical products for the United States market. Perrigo Israel is a wholly-owned subsidiary of Perrigo Co. Upon information and belief, Perrigo Israel is controlled by and/or is an agent of Perrigo Co.

6. Except where otherwise noted, Perrigo Co. and Perrigo Israel are referred to collectively herein as “Perrigo.”

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, Perrigo is subject to personal jurisdiction in the State of 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. Perrigo 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, Perrigo Co., itself and/or through its wholly-owned subsidiary Perrigo Israel, is engaged in the manufacture, distribution, and/or sale of generic versions of branded pharmaceutical products within the United States, including the State of Texas and the Northern District of Texas. Upon information and belief, as reported in its 2010 Annual Report, Perrigo Co., itself and/or through its wholly-owned subsidiary Perrigo Israel, manufactures, distributes, markets, and/or sells its products to major national and regional retail drug, supermarket and mass merchandise chains located within the State of Texas and the Northern District of Texas, including Wal-Mart, CVS, Walgreens, Kroger, and Safeway (operating in Northern Texas as “Tom Thumb”), as well as to major wholesalers located within the State of Texas the Northern District of Texas, including McKesson, Cardinal Health, and AmerisourceBergen.

11. Upon information and belief, Perrigo Co., itself and/or through its wholly-owned subsidiary Perrigo Israel, is a party to one or more contractual agreements regarding the distribution of generic pharmaceutical products into the State of Texas and the Northern District of Texas.

12. Upon information and belief, Perrigo Co., itself and/or through its wholly-owned subsidiary Perrigo Israel, earns revenue from the distribution of generic pharmaceutical products in the State of Texas and the Northern District of Texas.

13. Upon information and belief, Perrigo Co. has consented to personal jurisdiction in the Northern District of Texas in other litigations, including *Galderma Labs., L.P. et al. v. Perrigo Co. et al.*, No. 4:10-cv-00584-Y, and *Galderma Labs., L.P. et al. v. Perrigo Co. et al.*, No. 3:09-cv-02322-M.

14. In addition, upon information and belief, Perrigo Co. is subject to personal jurisdiction in the State of Texas and the Northern District of Texas on the basis of its inducement of and/or contribution to Perrigo Israel's acts of infringement in the State of Texas and the Northern District of Texas. Upon information and belief, Perrigo Co. controls and dominates Perrigo Israel and therefore the activities of Perrigo Israel in this jurisdiction are attributed to Perrigo Co.

15. Upon information and belief, Perrigo Israel submits ANDAs and develops and manufactures generic topical drugs for the United States market, including within the State of Texas and the Northern District of Texas. Upon information and belief, according to Dun & Bradstreet Israel Ltd., Perrigo Israel develops and manufactures products for large retail chains located within the State of Texas and the Northern District of Texas, including Wal-Mart, CVS, Walgreens, Albertson's, Kroger, and Safeway (operating in Northern Texas as "Tom Thumb"), as well as for major wholesalers within the State of Texas and the Northern District of Texas, including Cardinal, McKesson, and AmerisourceBergen.

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

17. Upon information and belief, Perrigo Israel earns revenue from the distribution of generic pharmaceutical products in the State of Texas and the Northern District of Texas.

18. Upon information and belief, Perrigo Israel has consented to personal jurisdiction in the Northern District of Texas in other litigations, including *Galderma Labs., L.P. et al. v. Perrigo Co. et al.*, No. 4:10-cv-00584-Y, and *Galderma Labs., L.P. et al. v. Perrigo Co. et al.*, No. 3:09-cv-02322-M. Upon information and belief, Perrigo Israel has also brought suit as a counterclaim plaintiff in the Northern District of Texas in other litigations, including *Galderma Labs., L.P. et al. v. Perrigo Co. et al.*, No. 4:10-cv-00584-Y, and *Galderma Labs., L.P. et al. v. Perrigo Co. et al.*, No. 3:09-cv-02322-M.

19. Upon information and belief, and consistent with their practice with respect to other generic products, Perrigo Co. and Perrigo Israel acted in concert to prepare and submit ANDA No. 202853. Upon information and belief, and consistent with their practice with respect to other generic products, Perrigo Co. and Perrigo Israel each actively participated in the preparation and submission of ANDA No. 202853. Upon information and belief, Perrigo Israel acted as the agent of Perrigo Co. in submitting ANDA No. 202853 to the FDA.

20. Upon information and belief, following any FDA approval of ANDA No. 202853, Perrigo Co. and Perrigo Israel will act in concert to manufacture, distribute, market, and/or sell Perrigo's Olopatadine Hydrochloride Nasal Spray, 0.665% ("Perrigo'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. 202853,

Perrigo Co. and Perrigo Israel know and intend that Perrigo's ANDA Product will be distributed, marketed, and/or sold in the United States, including within the State of Texas and the Northern District of Texas.

BACKGROUND

21. 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

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

23. 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.

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

25. Alcon Pharmaceuticals, Ltd. owns the ’376 patent.

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

27. Plaintiffs will be substantially and irreparably damaged by infringement of the ’376 patent.

28. 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

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.

29. 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.

30. 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*.

31. Perrigo has knowledge of the '376 patent.

32. By letter dated September 2, 2011 (the "Notice Letter"), Perrigo notified Plaintiffs that Perrigo had submitted ANDA No. 202853 to the FDA for Perrigo's ANDA Product. The purpose of ANDA No. 202853 was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use or sale of Perrigo's ANDA Product prior to the expiration of the '376 patent.

33. In the Notice Letter, Perrigo also notified Plaintiffs that, as part of its ANDA, Perrigo 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, Perrigo submitted ANDA No. 202853 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 commercial manufacture, use or sale of Perrigo's ANDA Product.

34. Perrigo was required to state in its Notice Letter its bases for any contention that Perrigo's ANDA Product will not infringe the patent-in-suit. Perrigo did not assert in the September 2, 2011, Notice Letter that Perrigo's ANDA Product does not infringe claim 1 of the '376 patent.

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

36. Perrigo's filing of ANDA No. 202853 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo'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).

37. Upon information and belief, Perrigo will engage in the manufacture, use, offer for sale, sale, and/or importation of Perrigo's ANDA Product immediately and imminently upon approval of ANDA No. 202853.

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

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

40. Upon information and belief, Perrigo 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.

41. Notwithstanding Perrigo's knowledge of the claims of the '376 patent, Perrigo has continued to assert its intent to manufacture, offer for sale, sell, and/or import Perrigo's ANDA Product with its proposed labeling following FDA approval of ANDA No. 202853 prior to the expiration of the '376 patent.

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

43. Upon information and belief, Perrigo 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.

44. Unless Perrigo 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

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

46. 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 Perrigo on the other regarding Perrigo's infringement and active inducement of infringement of the '376 patent.

47. 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 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.

48. 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.

49. Patanase[®] is covered by one or more of the claims of the '376 patent.

50. Perrigo has knowledge of the '376 patent.

51. In the Notice Letter described in paragraph 32 above, Perrigo notified Plaintiffs that Perrigo had submitted ANDA No. 202853 to the FDA for Perrigo's ANDA Product. The

purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use or sale of Perrigo's ANDA Product prior to the expiration of the '376 patent.

52. In the Notice Letter, Perrigo also notified Plaintiffs that, as part of its ANDA, Perrigo 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, Perrigo submitted ANDA No. 202853 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 commercial manufacture, use or sale of Perrigo's ANDA Product.

53. Perrigo was required to state in its Notice Letter its bases for any contention that Perrigo's ANDA Product will not infringe the patent-in-suit. Perrigo did not assert in the September 2, 2011, Notice Letter that Perrigo's ANDA Product will not infringe the claim 1 of the '376 patent.

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

55. Upon information and belief, Perrigo will engage in the manufacture, use, offer for sale, sale, and/or importation of Perrigo's ANDA Product immediately and imminently upon approval of ANDA No. 202853.

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

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

58. Upon information and belief, Perrigo 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.

59. Notwithstanding Perrigo's knowledge of the claims of the '376 patent, Perrigo has continued to assert its intent to manufacture, offer for sale, sell, and/or import Perrigo's ANDA Product with its proposed labeling following FDA approval of ANDA No. 202853 prior to the expiration of the '376 patent.

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

61. Upon information and belief, Perrigo 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.

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

63. The Court should declare that the commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo'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 Perrigo's submission to the FDA of its ANDA

No. 202853 and will be infringed by the manufacture, use, offer for sale, sale, and/or importation of Perrigo's ANDA Product.

(b) A judgment providing that the effective date of any FDA approval for Perrigo to manufacture, use, offer for sale, sell, and/or import Perrigo'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 that the '376 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Perrigo, and all persons acting in concert with Perrigo, from the manufacture, use, offer for sale, sale, and/or importation of Perrigo'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 Perrigo's manufacture, use, offer for sale, sale, and/or importation of Perrigo'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,

s/ Michael D. Anderson

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