

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

ALLERGAN SALES, LLC,

Plaintiff,

v.

APOTEX, INC. and APOTEX CORP.,

Defendants.

Civil Action No. 2:12-cv-178

Jury Trial Demanded

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Allergan Sales, LLC (“Allergan” or “Plaintiff”), for its complaint against Defendants Apotex, Inc. and Apotex Corp. (collectively “Apotex” or “Defendants”), by its attorneys, alleges as follows:

THE NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 8,008,338 (“the ‘338 patent”) under 35 U.S.C. § 271, *et seq.*

THE PARTIES

2. Allergan is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.

3. Allergan operates a facility in Waco, Texas where it develops and manufactures numerous pharmaceutical products, including Allergan’s product at issue in this case, ACULAR LS®. Allergan employs approximately 600 individuals in Texas, more than in any other U.S. state except California.

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

5. On information and belief, Apotex, Inc. is in the business of developing, formulating, manufacturing, marketing, offering to sell, selling, and commercializing generic drugs throughout the United States, including in this judicial district, through operating subsidiaries, including Apotex Corp.

6. On information and belief, defendant 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.

7. On information and belief, Apotex Corp. is in the business of offering for sale and selling generic drugs throughout the United States, including in this judicial district, and regularly acts as Apotex, Inc.'s U.S. agent on filings with the U.S. Food and Drug Administration ("FDA").

8. On information and belief, defendant Apotex Corp. operates as a subsidiary of Apotex, Inc.

9. On information and belief, and consistent with their prior practice, since at least November 2009, Apotex, Inc. and Apotex Corp. have acted in concert to distribute and sell Apotex's generic ketorolac tromethamine ophthalmic solution, 0.4%, throughout the United States, including in Texas.

10. On information and belief, Apotex, Inc. and Apotex Corp. know and intend that Apotex's generic ketorolac tromethamine ophthalmic solution, 0.4%, will continue to be distributed and sold in the United States, including in Texas.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.* This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338.

12. This Court has personal jurisdiction over Apotex by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein, as well as because of the injury to Allergan, and the cause of action Allergan has raised, as alleged herein.

13. Specifically, this Court has personal jurisdiction over defendants Apotex, Inc. and Apotex Corp. 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.

14. On information and belief, Apotex, Inc. and Apotex Corp. 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 ketorolac tromethamine ophthalmic solution, 0.4%, described in ANDA No. 07-7308 (defined below).

15. On information and belief, Apotex Corp. is a licensed drug distributor of prescription drugs by the State of Texas.

16. On information and belief, during the past thirty-six months, Apotex Corp. sold over \$816 million worth of Apotex, Inc.'s products in Texas, nearly \$62 million of which were sold in this judicial district.

17. On information and belief, Apotex Corp. sells numerous generic drugs, manufactured and supplied by Apotex, Inc., throughout the United States, including this judicial district.

18. On information and belief, various Apotex drug products appear on the Formulary Index of the Texas CHIP/Medicaid Vendor Drug Program, which provides services for over 4,000 Texas pharmacies.

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

20. On information and belief, Apotex has authorized numerous customers in Texas to distribute both Apotex branded and generic products, including Cardinal Health, Inc., McKesson Corp., and Walgreen Co.

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

BACKGROUND

22. The '338 patent, entitled "Ketorolac Tromethamine Compositions For Treating Or Preventing Ocular Pain," issued to Christopher A. Muller, Janet K. Cheetham, Teresa H. Kuan and David F. Power on August 30, 2011, and was assigned to Allergan, Inc. A copy of the '338 patent is attached to this complaint as Exhibit A.

23. The '338 patent is valid and enforceable and was duly issued in full compliance with Title 35 of the United States Code.

24. Allergan Sales, LLC, as the current assignee, owns the entire right, title, and interest in the '338 patent, including the right to sue for past and future infringement and all other substantial rights.

25. New Drug Application (“NDA”) No. 21-528 covers ketorolac tromethamine ophthalmic solution, 0.4% sold under the ACULAR LS® trademark.

26. The ’338 patent, which covers the approved formulation of ACULAR LS®, is listed with the FDA in conjunction with NDA No. 21-528. The FDA has published the ’338 patent in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the “Orange Book.”

27. The ’338 patent is listed on the package insert for ACULAR LS®.

28. ACULAR LS® is covered by at least one claim of the ’338 patent.

29. On information and belief, in October 2004, Apotex, Inc. and Apotex Corp. filed Abbreviated New Drug Application (“ANDA”) No. 07-7308 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), seeking approval to engage in the commercial manufacture, use, offer for sale, or sale of a generic version of Allergan’s ACULAR LS® product.

30. On information and belief, Apotex Corp. is designated as Apotex, Inc.’s U.S. agent on ANDA No. 07-7308, as it has been on numerous ANDAs in the past.

31. By filing ANDA No. 07-7308, Apotex requested the FDA’s approval to market a generic version of Allergan’s ACULAR LS® product throughout the United States, including in Texas.

32. On information and belief, in November 2009, the FDA approved ANDA No. 07-7308, allowing Apotex to engage in the commercial manufacture, use, sale, or offer for sale of ketorolac tromethamine ophthalmic solution, 0.4%, a generic version of Allergan’s ACULAR LS® product.

33. On information and belief, since November 2009, Apotex, Inc. and Apotex Corp., acting jointly, have manufactured, used, sold, and/or offered to sell Apotex's generic ketorolac tromethamine ophthalmic solution, 0.4%, throughout the United States, including in Texas.

34. On information and belief, Apotex has continued to sell Apotex's generic ketorolac tromethamine ophthalmic solution, 0.4%, throughout the United States, including in Texas, after the FDA published the '338 patent in the Orange Book.

COUNT I

(Infringement of the '338 Patent under 35 U.S.C. § 271 (a) by Apotex's Generic Ketorolac Tromethamine Ophthalmic Solution, 0.4%)

35. Paragraphs 1 to 34 are incorporated herein as set forth above.

36. The commercial manufacture, use, offer for sale, and/or sale of Apotex's generic ketorolac tromethamine ophthalmic solution, 0.4%, constitutes an act of direct infringement of one or more claims of the '338 patent.

37. Apotex, Inc. and Apotex Corp. are infringing one or more claims of the '338 Patent, by making, using, selling, or offering to sell their generic ketorolac tromethamine ophthalmic solution, 0.4%, throughout the United States.

38. On information and belief, Apotex became aware of the '338 patent no later than the date on which ACULAR LS® was first marked.

39. The foregoing actions by Apotex constitute infringement of the '338 patent.

40. Apotex continues such infringing activities to the ongoing injury of Allergan.

41. Apotex is committing these acts of infringement without license or authorization.

42. On information and belief, Apotex has acted and is acting with full knowledge of the '338 patent and without a reasonable basis for believing that it would not be liable for infringing the '338 patent.

43. The commercial manufacture, use, offer for sale, and/or sale of Apotex's generic ketorolac tromethamine ophthalmic solution, 0.4%, in violation of Allergan's patent rights has caused and will continue to cause harm to Allergan unless enjoined by this Court.

44. As a result of Apotex's infringement of the '338 patent, Allergan has suffered, and continues to suffer, damages, in an amount not yet determined, of at least a reasonable royalty and/or lost profits. Apotex is therefore liable to Allergan under 25 U.S.C. § 284 for damages in an amount that adequately compensates Allergan for Apotex's infringing conduct.

45. Despite having actual notice of the '338 patent since at least the first marking of the product, Apotex continues to willfully, wantonly, and deliberately infringe the '338 patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to increased damages and reasonable attorneys' fees pursuant to 35 U.S.C. §§ 284 and 285.

COUNT II

(Infringement of the '338 Patent under 35 U.S.C. § 271 (b) and (c) by Apotex's Generic Ketorolac Tromethamine Ophthalmic Solution, 0.4%)

46. Paragraphs 1 to 45 are incorporated herein as set forth above.

47. On information and belief, Apotex knows or should know that its commercial manufacture, use, offer for sale, and/or sale of Apotex's generic ketorolac tromethamine ophthalmic solution, 0.4%, will actively induce the actual infringement of the '338 patent.

48. On information and belief, Apotex encourages another's infringement of the '338 patent by and through its sale of Apotex's generic ketorolac tromethamine ophthalmic solution, 0.4%, for uses covered by certain claims of the '338 patent.

49. On information and belief, Apotex knows or should know that its proposed generic ketorolac tromethamine ophthalmic solution, 0.4% is especially made or especially adapted for use in an infringement of the '338 patent, and is not a staple article or commodity of

commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic ketorolac tromethamine ophthalmic solution, 0.4% will actively contribute to the actual infringement of the '338 patent.

50. Apotex's acts of infringement were done with knowledge of the '338 patent and with the intent to encourage infringement.

51. As a result of Apotex's infringement of the '338 patent, Allergan has suffered, and continues to suffer, damages, in an amount not yet determined, of at least a reasonable royalty and/or lost profits. Apotex is therefore liable to Allergan under 25 U.S.C. § 284 for damages in an amount that adequately compensates Allergan for Apotex's infringing conduct.

52. Despite having notice of the '338 patent since at least the first marking of the product, Apotex continue to willfully, wantonly, and deliberately infringe the '338 patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to increased damages and reasonable attorneys' fees pursuant to 35 U.S.C. §§ 284 and 285.

JURY TRIAL DEMAND

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

PRAYER FOR RELIEF

WHEREFORE, Allergan respectfully prays that the Court enter judgment against Apotex as follows:

a. a judgment that Apotex has infringed the '338 patent under 35 U.S.C. § 271(a), (b), and/or (c) by the commercial manufacture, use, offer to sell, or sale within the United States of Apotex's generic ketorolac tromethamine ophthalmic solution, 0.4%;

- b. an injunction enjoining and restraining Apotex, and its successors, assigns, officers, agents, servants, employees, attorneys, and persons in active concert or participation with them, including any affiliated entities, during the term of the '338 patent, from infringing and from inducing, contributing to, or otherwise causing the infringement of the '338 patent by making, using, selling, or offering to sell in the United States Apotex's generic ketorolac tromethamine ophthalmic solution, 0.4%;
- c. an award of damages resulting from Apotex's infringement, including lost profits;
- d. a judgment that Apotex's infringement was willful, making this is an exceptional case under 35 U.S.C. § 285;
- e. an award of treble damages pursuant to 35 U.S.C. § 284;
- f. an award of reasonable attorneys' fees and costs pursuant to 35 U.S.C. § 285;
- g. an accounting for infringing sales not presented at trial and an award of additional damages for any such infringing sales; and
- h. such other and further relief, at law or in equity, as it may deem just and proper.

Dated: April 4, 2012

Respectfully submitted,

By: /s/ Wesley Hill (by perm. of Lead Atty)

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