

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

ALLERGAN SALES, LLC,

Plaintiff,

v.

AKORN, INC.,

Defendant.

Civil Action No. 2:12-cv-175

Jury Trial Demanded

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Allergan Sales, LLC (“Allergan” or “Plaintiff”), for its complaint against Defendant Akorn, Inc. (“Akorn” or “Defendant”), 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 Akorn is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 1925 West Field Court, Suite 300, Lake Forest, Illinois 60045.

5. On information and belief, Akorn 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.

6. On information and belief, and consistent with its prior practice, since at least November 2009, Akorn has acted to distribute and sell its generic ketorolac tromethamine ophthalmic solution, 0.4%, throughout the United States, including in Texas.

7. On information and belief, Akorn knows and intends that its generic ketorolac tromethamine ophthalmic solution, 0.4%, will continue to be distributed and sold in the United States, including in Texas.

JURISDICTION AND VENUE

8. 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.

9. This Court has personal jurisdiction over Akorn 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.

10. Specifically, this Court has personal jurisdiction over defendant Akorn because it, either directly or through an agent, regularly does or solicits business in this jurisdiction, engages in other persistent courses of conduct in this jurisdiction, and/or derives substantial revenue from services or things used or consumed in this jurisdiction.

11. On information and belief, Akorn is a licensed drug distributor of prescription drugs by the State of Texas.

12. On information and belief, Akorn manufactures and sells numerous generic drugs throughout the United States, including this judicial district.

13. On information and belief, during the past thirty-six months, Akorn sold nearly \$8 million worth of Akorn's products in Texas, nearly \$350,000 of which were sold in this judicial district.

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

15. On information and belief, Akorn 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.

16. On information and belief, Akorn has authorized numerous customers in Texas to distribute Akorn generic products, including AmerisourceBergen Drug Corp., Cardinal Health, Inc., McKesson Corp., and Walgreen Co.

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

BACKGROUND

18. 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.

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

20. 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.

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

22. 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."

23. The '338 patent is listed on the package insert for ACULAR LS®.

24. ACULAR LS® is covered by at least one claim of the '338 patent.

25. On information and belief, in July 2006, Akorn filed Abbreviated New Drug Application ("ANDA") No. 07-8399 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.

26. By filing ANDA No. 07-8399, Akorn requested the FDA's approval to market a generic version of Allergan's ACULAR LS® product throughout the United States, including in Texas.

27. On information and belief, in November 2009, the FDA approved ANDA No. 07-8399, allowing Akorn 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.

28. On information and belief, since November 2009, Akorn has manufactured, used, sold, and/or offered to sell its generic ketorolac tromethamine ophthalmic solution, 0.4%, throughout the United States, including in Texas.

29. On information and belief, Akorn has continued to sell its 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 Akorn's Generic Ketorolac Tromethamine Ophthalmic Solution, 0.4%)

30. Paragraphs 1 to 29 are incorporated herein as set forth above.

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

32. Akorn is infringing one or more claims of the '338 Patent, by making, using, selling, or offering to sell its generic ketorolac tromethamine ophthalmic solution, 0.4%, throughout the United States.

33. The foregoing actions by Akorn constitute infringement of the '338 patent.

34. Akorn continues such infringing activities to the ongoing injury of Allergan.

35. Akorn is committing these acts of infringement without license or authorization.

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

37. On information and belief, Akorn 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.

38. The commercial manufacture, use, offer for sale, and/or sale of Akorn'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.

39. As a result of Akorn'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. Akorn is therefore liable to Allergan under 25 U.S.C. § 284 for damages in an amount that adequately compensates Allergan for Akorn's infringing conduct.

40. Despite having notice of the '338 patent since at least the first marking of the product, Akorn 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.

COUNT II

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

41. Paragraphs 1 to 40 are incorporated herein as set forth above.

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

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

44. On information and belief, Akorn 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.

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

46. As a result of Akorn'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. Akorn is therefore liable to Allergan under 25 U.S.C. § 284 for damages in an amount that adequately compensates Allergan for Akorn's infringing conduct.

47. Despite having notice of the '338 patent since at least the first marking of the product, Akorn 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 Akorn as follows:

- a. a judgment that Akorn 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 Akorn's generic ketorolac tromethamine ophthalmic solution, 0.4%;
- b. an injunction enjoining and restraining Akorn, 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 Akorn's generic ketorolac tromethamine ophthalmic solution, 0.4%;
- c. an award of damages resulting from Akorn's infringement, including lost profits;
- d. a judgment that Akorn'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)

Wesley Hill
Texas Bar No. 24032294
wh@wsfirm.com
WARD & SMITH LAW FIRM
111 W. Tyler Street
Longview, TX 75601

Telephone: (903) 757-6400
Facsimile: (903) 757-2323

W. Chad Shear
Texas Bar No. 24013493
shear@fr.com
Grace L. Wang
gwang@fr.com
FISH & RICHARDSON P.C.
222 Delaware Avenue, 17th Floor
Wilmington, DE 19801
Telephone: (302) 652-5070
Facsimile: (302) 652-0607

Jonathan E. Singer – Lead Attorney
singer@fr.com
Deanna J. Reichel
reichel@fr.com
FISH & RICHARDSON P.C.
60 South Sixth St., #3200
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

Ellen A. Scordino
scordino@fr.com
Gauri M. Dhavan
dhavan@fr.com
FISH & RICHARDSON P.C.
One Marina Park Drive
Boston, MA 02210
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

Juanita R. Brooks
brooks@fr.com
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, CA 92130
Telephone: (858) 678-5070
Facsimile: (858) 678-5099

*Attorneys for Plaintiff
Allergan Sales, LLC*