IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC. and VISTAKON PHARMACEUTICALS, LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
WILSHIRE PHARMACEUTICALS, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Allergan, Inc., and Vistakon Pharmaceuticals, LLC, by way of Complaint against Wilshire Pharmaceuticals, Inc., allege as follows:

THE PARTIES

1. Allergan, Inc. ("Allergan") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2525 Dupont Drive, Irvine, California, 92612. Allergan is a global, research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve human health.

2. Vistakon Pharmaceuticals, LLC ("Vistakon") is a Florida limited liability company, having a principal place of business at 7500 Centurion Parkway, Jacksonville, Florida, 32256.

3. On information and belief, Wilshire Pharmaceuticals, Inc. ("Wilshire") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at Six Concourse Parkway, Suite 1800, Atlanta, Georgia, 30328.

4. On information and belief, Wilshire is in the business of developing, marketing and selling generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. Wilshire is subject to personal jurisdiction in this District because it is a corporation organized and existing under the laws of the State of Delaware.

7. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 28 U.S.C. § 1400(b).

ALLERGAN'S NDA AND ASSERTED PATENT

8. Vistakon filed New Drug Application ("NDA") No. 022134, pursuant to which the U.S. Food and Drug Administration ("FDA") granted approval for alcaftadine ophthalmic solution 0.25% for the prevention of itching associated with allergic conjunctivitis. Vistakon has assigned all right, title, and interest to NDA No. 022134 to Allergan. Alcaftadine ophthalmic solution 0.25% is sold by Allergan under the trade name Lastacaft®.

9. Vistakon is the assignee of U.S. Patent No. 8,664,215 (the "'215 patent"). A copy of the '215 patent is attached as Exhibit A. The '215 patent discloses and claims methods of treating and preventing clinical symptoms of ocular allergy (including ocular itching) comprising the administration once daily of an ophthalmic solution comprising alcaftadine, its pharmaceutically acceptable salts, or mixtures thereof. Allergan is the exclusive licensee of the '215 patent.

10. Pursuant to 21 U.S.C. §355(b)(1), Allergan has submitted information concerning the '215 patent to the FDA in connection with NDA No. 022134, identifying it as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." The '215 patent has been listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering Lastacaft®.

WILSHIRE'S ANDA AND NOTICE LETTER

11. By letter ("Wilshire Notice Letter") dated October 20, 2014, and received by Allergan and Vistakon (hereinafter collectively "Plaintiffs") on October 21, 2014, Wilshire gave notice that it had submitted Abbreviated New Drug Application ("ANDA") No. 207213 to the FDA under 21 U.S.C. §355(j) seeking approval to manufacture, use or sell alcaftadine ophthalmic solution 0.25% (the "Wilshire Generic Product"), prior to the expiration of the '215 patent.

12. The Wilshire Notice Letter informed Plaintiffs that Wilshire's ANDA contained a "Paragraph IV Certification" alleging that the claims of the '215 patent are invalid.

13. The Wilshire Notice Letter does not deny that the Wilshire Generic Product will infringe the '215 patent, and did not include an offer of confidential access to Wilshire's ANDA No. 207213.

14. On information and belief, Wilshire intends to manufacture, import, use, sell, or offer to sell the Wilshire Generic Product for uses that would infringe the claims of the '215 patent.

15. This action is being filed within 45 days of Plaintiffs' receipt of Wilshire's Notice Letter.

COUNT I – INFRINGEMENT OF '215 PATENT

16. Plaintiffs reallege, as if fully set forth herein, the averments contained in paragraphs 1-15.

17. Wilshire submitted ANDA No. 207213 to the FDA under 21 U.S.C. §355(j) to obtain approval to engage in the commercial manufacture, use, or sale of the Wilshire Generic Product prior to the expiration of the '215 patent. By submitting this application, Wilshire has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

18. On information and belief, Wilshire was aware of the existence of the '215 patent and was aware that the filing of its ANDA and certification with respect to the '215 patent constituted an act of infringement of that patent.

19. On information and belief, the commercial manufacture, use, or sale of the Wilshire Generic Product prior to the expiration of the '215 patent will directly infringe the '215 patent under 35 U.S.C. §271(a), will actively induce infringement of the '215 patent under 35 U.S.C. §271(b), and will constitute contributory infringement of the '215 patent under 35 U.S.C. §271(c).

20. Plaintiffs will be substantially and irreparably harmed if Wilshire's infringement of the '215 patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

21. Plaintiffs are entitled to the relief provided by 35 U.S.C. §271(e)(4), including an order of this Court that the effective date of the approval of Wilshire's ANDA be a

date that is not earlier the expiration date of the '215 patent, or the date of any later expiration of exclusivity to which Plaintiffs are or become entitled.

22. This case is an exceptional one, and Plaintiffs are entitled to an award of reasonable attorney fees under 35 U.S.C. §§271(e)(4) and 285.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF '215 PATENT

23. Plaintiffs reallege, as if fully set forth herein, the averments contained in paragraphs 1-22.

24. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202.

25. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of right by this Court.

26. On information and belief, Wilshire has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import the Wilshire Generic Product.

27. Wilshire's Notice Letter indicates a refusal to change the course of its actions directed to obtaining FDA approval for and commercially marketing the Wilshire Generic Product prior to the expiration of the '215 patent.

28. Wilshire's Notice Letter does not deny that the Wilshire Generic Product will infringe the '215 patent, or assert that the '215 patent is unenforceable.

29. On information and belief, in its ANDA No. 207213, Wilshire has represented to the FDA that the Wilshire Generic Product is pharmaceutically and therapeutically equivalent to Allergan's Lastacaft® product.

30. On information and belief, the commercial manufacture, use, or sale of the Wilshire Generic Product prior to the expiration of the '215 patent will directly infringe the '215 patent under 35 U.S.C. §271(a), will actively induce infringement of the '215 patent under 35 U.S.C. §271(b), and will constitute contributory infringement of the '215 patent under 35 U.S.C. §271(c).

31. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, and/or sale of the Wilshire Generic Product will infringe the '215 patent.

PRAYER FOR RELIEF

32. Plaintiffs request that:

a. Judgment be entered that Wilshire has infringed the '215 patent under 35 U.S.C. §271(e)(2)(A) by submitting ANDA No. 207213;

b. Judgment be entered that the commercial manufacture, use, offer for sale, and/or sale of Wilshire's Generic Product in the United States, and/or the importation of the Wilshire Generic Product into the United States, will infringe the '215 patent under 35 U.S.C. §§271(a), (b), and/or (c).

c. A permanent injunction be issued, pursuant to 35 U.S.C. §271(e)(4)(B), restraining and enjoining Wilshire, its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Wilshire Generic Product prior to the expiration date of the '215 patent, or the date of any later expiration of exclusivity to which Plaintiffs are or become entitled.

d. An order be issued pursuant to 35 U.S.C. §271(e)(4)(A) that the effective date of any approval of ANDA No. 207213 be a date which is not earlier than the later of the expiration date of the '215 patent, or the date of any later expiration of exclusivity to which Plaintiffs are or become entitled; and

e. Judgment be entered that this is an exceptional case, and that Plaintiffs are entitled to its reasonable attorney fees pursuant to 35 U.S.C. §§271(e)(4) and 285;

f. The Court grant such other and further relief as it may deem just and proper under the circumstances.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld
Jack B. Blumenfeld (#1014)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
dfahnestock@mnat.com

Attorneys for Plaintiff Allergan, Inc.

ASHBY & GEDDES

/s/ Steven J. Balick
Steven J. Balick (#2114)
Lauren E. Maguire (#4261)
Andrew C. Mayo (#5207)
500 Delaware Avenue – 8th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888
sbalick@ashby-geddes.com
lmaguire@ashby-geddes.com
amayo@ashby-geddes.com

Attorneys for Plaintiff Vistakon Pharm., LLC

OF COUNSEL:

Debra D. Condino
Donald P. Bunnin
ALLERGAN, INC.
2525 Dupont Drive
Irvine, CA 92612
(714) 246-4500

Attorneys for Plaintiff Allergan, Inc.

Gregory L. Diskant
Kathleen M. Crotty
PATTERSON, BELKNAP, WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036

Attorneys for Plaintiff Vistakon Pharm., LLC

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