

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON PHARMACEUTICALS LTD. and)	
ALCON RESEARCH, LTD.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. _____
)	
IMPRIMIS PHARMACEUTICALS, INC.,)	
)	
Defendant.)	

COMPLAINT

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

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 Imprimis Pharmaceuticals, Inc.’s (“Imprimis”) manufacture and sale of ophthalmic drug products containing moxifloxacin hydrochloride, which infringes two Alcon U.S. patents.

PARTIES

2. Plaintiff Alcon Pharmaceuticals Ltd. is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Rue Louis d’Affry 6, Case Postale, 1701 Fribourg, Switzerland.

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

4. Upon information and belief, defendant Imprimis is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 12264 El Camino Real, Suite 350, San Diego, California 92130.

JURISDICTION AND VENUE

5. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1391 and 1400(b).

6. This Court has personal jurisdiction over Imprimis because Imprimis has availed itself of the legal protections of the State of Delaware by, among other things, incorporating in Delaware. By incorporating in Delaware, Imprimis is “at home” in Delaware for purposes of personal jurisdiction. In addition, upon information and belief, Imprimis manufactures, markets and/or sells drug products throughout the United States and within the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiffs’ claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

7. Venue is proper in this District because Imprimis resides in this District and because Imprimis is subject to personal jurisdiction in this District.

COUNT I-INFRINGEMENT OF THE '830 PATENT

8. Alcon incorporates each of the preceding paragraphs 1-7 as if fully set forth herein.

9. United States Patent No. 6,716,830 (“the ’830 patent”), titled “Ophthalmic Antibiotic Compositions Containing Moxifloxacin” (Exhibit A hereto), was duly and legally issued on April 6, 2004 to Alcon, Inc., as assignee of Gerald Cagle, Robert L. Abshire, David W. Stroman, and John M. Yanni.

10. Alcon, Inc.'s interest in the '830 patent has been subsequently assigned to Alcon Pharmaceuticals Ltd. Alcon Pharmaceuticals Ltd. owns the '830 patent and has been and will be substantially and irreparably damaged by infringement of the '830 patent.

11. Alcon Research, Ltd. has been granted an exclusive license under the '830 patent. Alcon Research, Ltd. has been and will be substantially and irreparably damaged by infringement of the '830 patent.

12. The '830 patent claims, *inter alia*, topical ophthalmic pharmaceutical compositions comprising moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration of 0.1 to 1.0 wt. % of moxifloxacin and a pharmaceutically acceptable vehicle therefor. The '830 patent also claims such compositions that further comprise a glucocorticoid, or a prostaglandin H synthetase inhibitor.

13. Alcon manufactures and sells VIGAMOX® ophthalmic solution, an antibiotic eye drop containing moxifloxacin hydrochloride. VIGAMOX® is covered by the '830 patent. Since its launch in 2003, doctors have prescribed VIGAMOX® more than 30 million times, and VIGAMOX® has established and maintained strong branded market share in the ophthalmic anti-infective drug category. VIGAMOX® is indicated for treatment of bacterial conjunctivitis, and is also prescribed by physicians for use in conjunction with cataract, LASIK, and other ocular surgeries.

14. Upon information and belief, Imprimis manufactures, markets, offers for sale, and sells topical ophthalmic pharmaceutical compositions comprising moxifloxacin hydrochloride in a concentration of 0.1 to 1.0 wt %, and a pharmaceutically acceptable vehicle therefor ("Imprimis's moxifloxacin ophthalmic products"), including Imprimis's Pred-Moxi, Pred-Moxi-Ketor, Pred-Moxi-Nepaf, and Tri-Moxi products. Ex. C.

15. Upon information and belief, Imprimis's Pred-Moxi, Pred-Moxi-Ketor, and Pred-Moxi-Nepaf products further contain prednisolone, a glucocorticoid compound.

16. Upon information and belief, Imprimis's Pred-Moxi-Ketor product further contains ketorolac, a prostaglandin H synthetase inhibitor.

17. Upon information and belief, Imprimis's Pred-Moxi-Nepaf product further contains nepafenac, a prostaglandin H synthetase inhibitor.

18. Upon information and belief, Imprimis's Tri-Moxi product further contains triamcinolone, a glucocorticoid compound.

19. Imprimis's marketing literature states that Imprimis's Pred-Moxi, Pred-Moxi-Ketor, Pred-Moxi-Nepafenac, and Tri-Moxi products are each "topical eye drop formulations." Ex. C.

20. According to a June 7, 2016 Imprimis investor presentation, Imprimis's goal is to "disrupt[]" the ">\$1B[illion] Eye Drop Market," specifically targeting Alcon's sales of VIGAMOX®. Ex. D at 11-12. According to that same presentation, Imprimis intends to undercut the cost of certain treatment regimens utilizing VIGAMOX® by up to 92%, and claims to have captured more than "10% market share related to pre[-] and post[-]operative eye drops for cataract surgery." *Id.* at 13.

21. Imprimis's moxifloxacin ophthalmic compositions are covered by one or more claims of the '830 patent.

22. Upon information and belief, Imprimis has knowledge of the claims of the '830 patent. Upon information and belief, Imprimis has cited the '830 patent in submissions to the United States Patent and Trademark Office in conjunction with the prosecution of Imprimis's own patent applications. Upon information and belief, Imprimis has notice of this Court's

October 19, 2009, opinion affirming the validity of claim 1 of the '830 patent, which covers Imprimis's moxifloxacin ophthalmic products. Notwithstanding this knowledge, Imprimis has continued to manufacture, offer for sale, sell, and distribute its moxifloxacin ophthalmic compositions during the term of the '830 patent, and intends to continue doing so. Accordingly, Imprimis has willfully, wantonly, and deliberately engaged in acts of infringement of the '830 patent.

23. The manufacture, use, sale, offer for sale, or importation of Imprimis's moxifloxacin ophthalmic compositions infringes one or more claims of the '830 patent.

24. The foregoing actions by Imprimis constitute and/or will constitute infringement, and active inducement of infringement, of the '830 patent.

25. Upon information and belief, Imprimis has acted with full knowledge of the '830 patent and without a reasonable basis for believing that it would not be liable for infringement of the '830 patent and/or active inducement of infringement of the '830 patent.

26. As a result of Imprimis's wrongful acts, Alcon has suffered irreparable injury. Unless Imprimis is enjoined from infringing and inducing infringement of the '830 patent, Alcon will suffer additional irreparable injury. Alcon has no adequate remedy at law.

27. Imprimis's infringement has damaged Alcon, which is entitled to recover from Imprimis the damages resulting from Imprimis's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

28. Imprimis's willful, wanton, and deliberate infringement of the '830 patent justifies an award to Alcon of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

COUNT II-INFRINGEMENT OF THE '070 PATENT

29. Alcon incorporates each of the preceding paragraphs 1-28 as if fully set forth herein.

30. United States Patent No. 7,671,070 (“the ’070 patent”), titled “Method of Treating Ophthalmic Infections with Moxifloxacin Compositions” (Exhibit B hereto), was duly and legally issued on March 2, 2010 to Alcon, Inc., as assignee of Gerald Cagle, Robert L. Abshire, David W. Stroman, and John M. Yanni.

31. Alcon, Inc.’s interest in the ’070 patent has been subsequently assigned to Alcon Pharmaceuticals Ltd. Alcon Pharmaceuticals Ltd. owns the ’070 patent and has been and will be substantially and irreparably damaged by infringement of the ’070 patent.

32. Alcon Research, Ltd. has been granted an exclusive license under the ’070 patent. Alcon Research, Ltd. has been and will be substantially and irreparably damaged by infringement of the ’070 patent.

33. The ’070 patent claims, *inter alia*, a method of treating ophthalmic infections, which comprises topically applying to the eye a therapeutically effective amount of a pharmaceutical composition comprising moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration of 0.1 to 1.0 wt. % of moxifloxacin and a pharmaceutically acceptable vehicle therefor. The ’070 patent also claims such methods of treatment with compositions that further comprise a glucocorticoid, or a prostaglandin H synthetase inhibitor.

34. The approved use of VIGAMOX® is covered by one or more claims of the ’070 patent.

35. Upon information and belief, Imprimis manufactures, markets, offers for sale, and sells topical ophthalmic pharmaceutical compositions comprising moxifloxacin

hydrochloride in a concentration of 0.1 to 1.0 wt %, and a pharmaceutically acceptable vehicle therefor (“Imprimis’s moxifloxacin ophthalmic products”), including Imprimis’s Pred-Moxi, Pred-Moxi-Ketor, Pred-Moxi-Nepaf, and Tri-Moxi products. Ex. C.

36. Upon information and belief, Imprimis’s Pred-Moxi, Pred-Moxi-Ketor, and Pred-Moxi-Nepaf products further contain prednisolone, a glucocorticoid compound.

37. Upon information and belief, Imprimis’s Pred-Moxi-Ketor product further contains ketorolac, a prostaglandin H synthetase inhibitor.

38. Upon information and belief, Imprimis’s Pred-Moxi-Nepaf product further contains nepafenac, a prostaglandin H synthetase inhibitor.

39. Upon information and belief, Imprimis’s Tri-Moxi product further contains triamcinolone, a glucocorticoid compound.

40. Imprimis’s marketing literature states that Imprimis’s Pred-Moxi, Pred-Moxi-Ketor, Pred-Moxi-Nepafenac, and Tri-Moxi products are each “topical eye drop formulations.” Ex. C.

41. Upon information and belief, patients have used, and will continue to use, Imprimis’s moxifloxacin ophthalmic products to practice the methods claimed by the ’070 patent.

42. Upon information and belief, Imprimis instructs patients to treat ophthalmic infections by topically applying Imprimis’s moxifloxacin ophthalmic products to the eye. For example, Imprimis’s Order Form for Pred-Moxi, Pred-Moxi-Ketor, and Pred-Moxi-Nepaf instructs patients to “[i]nstill” those products “into the affected eye(s)” as further directed by the prescribing physician. Ex. E. Imprimis further provides patient instruction sheets on which the prescriber is to detail the schedule and duration of treatment with its products. *E.g.*

Ex. F. In addition, Imprimis's marketing materials state that Imprimis's moxifloxacin ophthalmic products are "[c]ombination topical eye drops for patients following LASIK, PRK, cataract, and other ocular surgeries," and encourage patients and doctors to "[p]lace an order today." Ex. G.

43. Upon information and belief, the use of the Imprimis's moxifloxacin ophthalmic products as directed by Imprimis would infringe one or more claims of the '070 patent.

44. Upon information and belief, Imprimis has actively induced infringement of the '070 patent, and intends to continue actively inducing infringement of the '070 patent.

45. Upon information and belief, Imprimis knows that its moxifloxacin ophthalmic products are especially made or adapted for use in infringing the '070 patent, are not a staple article or commodity of commerce, and that Imprimis's moxifloxacin ophthalmic products, along with Imprimis's instructions, are not suitable for substantial noninfringing use. Upon information and belief, Imprimis has contributed, and will continue to contribute, to infringement of the '070 patent.

46. Upon information and belief, Imprimis has knowledge of the claims of the '070 patent. Notwithstanding this knowledge, Imprimis has continued to manufacture, offer for sale, sell, and distribute its moxifloxacin ophthalmic compositions, along with instructions for their use, during the term of the '070 patent, and intends to continue doing so. Accordingly, Imprimis has willfully, wantonly, and deliberately engaged in acts of infringement of the '070 patent.

47. The foregoing actions by Imprimis constitute and/or will constitute active inducement of infringement of the '070 patent, and contribution to the infringement by others of the '070 patent.

48. Upon information and belief, Imprimis has acted with full knowledge of the '070 patent and without a reasonable basis for believing that it would not be liable for active inducement of infringement of the '070 patent, and/or contributing to the infringement by others of the '070 patent.

49. As a result of Imprimis's wrongful acts, Alcon has suffered irreparable injury. Unless Imprimis is enjoined from inducing infringement and contributing to the infringement of, the '070 patent, Alcon will suffer additional irreparable injury. Alcon has no adequate remedy at law.

50. Imprimis's infringement has damaged Alcon, which is entitled to recover from Imprimis the damages resulting from Imprimis's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

51. Imprimis's willful, wanton, and deliberate infringement of the '070 patent justifies an award to Alcon of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that United States Patent Nos. 6,716,830 and 7,671,070 are valid and enforceable, and have been infringed by Imprimis;

(b) A preliminary and permanent injunction against any infringement, or inducement of infringement, by Imprimis of United States Patent No. 6,716,830, through the commercial manufacture, use, sale, offer for sale, or importation into the United States of

Imprimis's moxifloxacin ophthalmic products, or any other drug product that is covered by that patent;

(c) A preliminary and permanent injunction against any inducement of infringement, or contribution to infringement, by Imprimis of United States Patent No. 7,671,070, through the commercial manufacture, use, sale, offer for sale, or importation into the United States of Imprimis's moxifloxacin ophthalmic products, or any other drug product whose use is covered by that patent;

(d) An award of damages pursuant to 35 U.S.C. § 284;

(e) A declaration that Imprimis's infringement was willful and deliberate, and an increase to the award of damages of three times the amount found or assessed by the Court, in accordance with 35 U.S.C. § 284;

(f) An award for an accounting of damages from Imprimis's infringement;

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

(h) Costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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