

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

SENJU PHARMACEUTICAL CO., LTD.,)	
BAUSCH & LOMB, INC. and BAUSCH &)	
LOMB PHARMA HOLDINGS CORP.)	
)	
Plaintiffs,)	Civil Action No.:
)	
v.)	
)	
INNOPHARMA LICENSING, INC.,)	
INNOPHARMA LICENSING, LLC,)	
INNOPHARMA, INC., AND)	
INNOPHARMA, LLC,)	
)	
Defendants.)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Senju Pharmaceutical Co., Ltd., Bausch & Lomb Incorporated and Bausch & Lomb Pharma Holdings Corp. (collectively “Plaintiffs”) by way of Complaint against Defendants Innopharma Licensing, Inc., InnoPharma Licensing, LLC, InnoPharma, Inc., and InnoPharma, LLC (collectively, “Defendants”) allege as follows:

THE PARTIES

1. Plaintiff Senju Pharmaceutical Co., Ltd. (“Senju”) is a corporation organized and existing under the laws of Japan, with a principal place of business at 2-5-8, Hirano-machi, Chuo-ku, Osaka 541-0046, Japan.
2. Plaintiff Bausch & Lomb Incorporated (“B+L”) is a corporation organized and existing under the laws of New York, with a place of business at 1400 North Goodman St.,

Rochester, New York 14609. B+L is the registered holder of approved New Drug Application No. 203168, which covers Prolensa[®].

3. Plaintiff Bausch & Lomb Pharma Holdings Corp. (“B+L Pharma Holdings”) is a corporation organized and existing under the laws of Delaware, with a place of business at 700 Route 202/206, Bridgewater, New Jersey 08807. B+L Pharma Holdings is a wholly-owned subsidiary of B+L.

4. Upon information and belief, defendant Innopharma Licensing, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10 Knightsbridge Road, Picastaway, New Jersey 08854.

5. Upon information and belief, defendant InnoPharma Licensing, LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 10 Knightsbridge Road, Picastaway, New Jersey 08854.

6. Upon information and belief, defendant InnoPharma Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10 Knightsbridge Road, Picastaway, New Jersey 08854.

7. Upon information and belief, defendant InnoPharma, LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 10 Knightsbridge Road, Picastaway, New Jersey 08854.

NATURE OF THE ACTION

8. This is an action for infringement of United States Patent Nos. 8,129,431 (“the ’431 patent”), 8,669,290 (“the ’290 patent”), 8,754,131 (“the ’131 patent”), and 8,871,813 (“the 813 patent”) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Innopharma Licensing, Inc.’s filing of an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal

Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market generic Bromfenac Ophthalmic Solution 0.07% (“Innopharma Licensing, Inc.’s generic bromfenac ophthalmic solution”).

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

10. Upon information and belief, this Court has jurisdiction over Innopharma Licensing, Inc. Upon information and belief, Innopharma Licensing, Inc. is in the business of licensing, manufacturing, distributing and selling pharmaceutical products, including generic drug products. Upon information and belief, Innopharma Licensing, Inc. directly licenses, manufactures, markets and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Innopharma Licensing, Inc.’s generic bromfenac ophthalmic solution. Upon information and belief, Innopharma Licensing, Inc. operates as a patent owner or lessor for InnoPharma, Inc., whose principal place of business is, on information and belief, at 10 Knightsbridge Road, Picastaway, New Jersey 08854, and has thereby purposefully and systematically conducted and continues to conduct business in this judicial district.

11. Upon information and belief, this Court has jurisdiction over InnoPharma Licensing, LLC. Upon information and belief, InnoPharma Licensing, LLC is in the business of licensing, manufacturing, distributing and selling pharmaceutical products, including generic drug products. Upon information and belief, InnoPharma Licensing, LLC directly licenses, manufactures, markets and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for InnoPharma Licensing, LLC’s generic bromfenac ophthalmic solution. Upon information and belief, InnoPharma Licensing, LLC operates as a patent owner or lessor for InnoPharma, LLC, whose principal place of

business is, on information and belief, at 10 Knightsbridge Road, Picastaway, New Jersey 08854, and has thereby purposefully and systematically conducted and continues to conduct business in this judicial district.

12. Upon information and belief, this court has jurisdiction over InnoPharma, Inc. Upon information and belief, InnoPharma, Inc. directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Innopharma Licensing, Inc. and InnoPharma Licensing, LLC, throughout the United States and in this judicial district. Upon information and belief, InnoPharma, Inc. purposefully has conducted and continues to conduct business in this judicial district.

13. Upon information and belief, this court has jurisdiction over InnoPharma, LLC. Upon information and belief, InnoPharma, LLC directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Innopharma Licensing, Inc. and InnoPharma Licensing, LLC, throughout the United States and in this judicial district. Upon information and belief, InnoPharma, LLC purposefully has conducted and continues to conduct business in this judicial district.

14. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

THE PATENTS IN SUIT

15. The U.S. Patent and Trademark Office (“PTO”) issued the ’431 patent on March 6, 2012. The ’431 patent claims, inter alia, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the ’431 patent and have the right to sue for infringement thereof. Senju is the assignee of the ’431 patent. A copy of the ’431 patent is attached hereto as Exhibit A.

16. The U.S. Patent and Trademark Office (“PTO”) issued the ’290 patent on March 11, 2014. The ’290 patent claims, inter alia, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the ’290 patent and have the right to sue for infringement thereof. Senju is the assignee of the ’290 patent. A copy of the ’290 patent is attached hereto as Exhibit B.

17. The U.S. Patent and Trademark Office (“PTO”) issued the ’131 patent on June 17, 2014. The ’131 patent claims, inter alia, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the ’131 patent and have the right to sue for infringement thereof. Senju is the assignee of the ’131 patent. A copy of the ’131 patent is attached hereto as Exhibit C.

18. The U.S. Patent and Trademark Office (“PTO”) issued the ’813 patent on October 28, 2014. The ’813 patent claims, inter alia, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the ’813 patent and have the right to sue for infringement thereof. Senju is the assignee of the ’813 patent. A copy of the ’813 patent is attached hereto as Exhibit D.

19. B+L is the holder of New Drug Application (“NDA”) No. 203168 for Prolensa[®], which the FDA approved on April 5, 2013. In conjunction with NDA No. 203168, the ’431, the ’290, the ’131, and the ’813 patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”).¹

20. Bromfenac Ophthalmic Solution 0.07% is sold in the United States under the trademark Prolensa[®].

¹ Due to an error by the FDA, the information in the Orange Book for the ’813 patent incorrectly identifies the patent’s expiration date as January 16, 2016. Plaintiffs are in the process of notifying the FDA of this error and requesting that the FDA correct it.

INNOPHARMA LICENSING, INC.'S INFRINGING ANDA SUBMISSION

21. Upon information and belief, Innopharma Licensing, Inc. filed with the FDA ANDA No. 206326, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

22. Upon information and belief, Innopharma Licensing, Inc.'s ANDA No. 206326 seeks FDA approval to sell in the United States Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa[®].

23. Bausch & Lomb received a letter from Innopharma Licensing, Inc. dated September 19, 2014, purporting to be a Notice of Certification for ANDA No. 206326 ("Innopharma Licensing, Inc.'s notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 § C.F.R. 314.95(c).

24. Innopharma Licensing, Inc.'s notice letter alleges that Innopharma Licensing, Inc. has submitted to the FDA ANDA No. 206326 seeking FDA approval to sell generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa[®].

25. Upon information and belief, ANDA No. 206326 seeks approval of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution that is the same, or substantially the same, as Prolensa[®].

26. Upon information and belief, Innopharma Licensing, Inc.'s actions relating to ANDA No. 206326 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of InnoPharma Licensing, LLC, InnoPharma, Inc., and InnoPharma, LLC.

COUNT I

Infringement of the '431 Patent under § 271(e)(2)

27. Paragraphs 1-26 are incorporated herein as set forth above.

28. Under 35 U.S.C. § 271(e)(2), Innopharma Licensing, Inc. has infringed at least one claim of the '431 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206326 seeking approval for the commercial marketing of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution before the expiration date of the '431 patent.

29. Upon information and belief, Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '431 patent.

30. Upon information and belief, Innopharma Licensing, Inc. will, through the manufacture, use import, offer for sale and/or sale of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '431 patent.

COUNT II

Declaratory Judgment of Infringement of the '431 Patent

31. Paragraphs 1-30 are incorporated herein as set forth above.

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

33. 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 this actual case or controversy requires a declaration of rights by this Court.

34. Innopharma Licensing, Inc. has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution before the expiration date of the '431 patent, including Innopharma Licensing, Inc.'s filing of ANDA No. 206326.

35. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '431 patent.

36. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '431 patent.

COUNT III

Infringement of the '290 patent under § 271(e)(2)

37. Paragraphs 1-36 are incorporated herein as set forth above.

38. Under 35 U.S.C. § 271(e)(2), Innopharma Licensing, Inc. has infringed at least one claim of the '290 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206326 seeking approval for the commercial marketing of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution before the expiration date of the '290 patent.

39. Upon information and belief, Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '290 patent.

40. Upon information and belief, Innopharma Licensing, Inc. will, through the manufacture, use import, offer for sale and/or sale of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '290 patent.

COUNT IV

Declaratory Judgment of Infringement of the '290 Patent

41. Paragraphs 1-40 are incorporated herein as set forth above.
42. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
43. 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 this actual case or controversy requires a declaration of rights by this Court.
44. Innopharma Licensing, Inc. has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution before the expiration date of the '290 patent, including Innopharma Licensing, Inc.'s filing of ANDA No. 206326.
45. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '290 patent.
46. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '290 patent.

COUNT V

Infringement of the '131 patent under § 271(e)(2)

47. Paragraphs 1-46 are incorporated herein as set forth above.
48. Under 35 U.S.C. § 271(e)(2), Innopharma Licensing, Inc. has infringed at least one claim of the '131 patent by submitting, or causing to be submitted to the FDA, ANDA No.

206326 seeking approval for the commercial marketing of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution before the expiration date of the '131 patent.

49. Upon information and belief, Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '131 patent.

50. Upon information and belief, Innopharma Licensing, Inc. will, through the manufacture, use import, offer for sale and/or sale of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '131 patent.

COUNT VI

Declaratory Judgment of Infringement of the '131 Patent

51. Paragraphs 1-50 are incorporated herein as set forth above.

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

53. 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 this actual case or controversy requires a declaration of rights by this Court.

54. Innopharma Licensing, Inc. has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution before the expiration date of the '131 patent, including Innopharma Licensing, Inc.'s filing of ANDA No. 206326.

55. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution

will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '131 patent.

56. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '131 patent.

COUNT VII

Infringement of the '813 patent under § 271(e)(2)

57. Paragraphs 1-56 are incorporated herein as set forth above.

58. Under 35 U.S.C. § 271(e)(2), Innopharma Licensing, Inc. has infringed at least one claim of the '131 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206326 seeking approval for the commercial marketing of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution before the expiration date of the '813 patent.

59. Upon information and belief, Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '813 patent.

60. Upon information and belief, Innopharma Licensing, Inc. will, through the manufacture, use import, offer for sale and/or sale of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '813 patent.

COUNT VI

Declaratory Judgment of Infringement of the '813 Patent

61. Paragraphs 1-60 are incorporated herein as set forth above.

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

63. 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 this actual case or controversy requires a declaration of rights by this Court.

64. Innopharma Licensing, Inc. has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution before the expiration date of the '813 patent, including Innopharma Licensing, Inc.'s filing of ANDA No. 206326.

65. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '813 patent.

66. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '813 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Defendants on the patent infringement claim set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), has infringed at least one claim of the '431 patent through Innopharma Licensing, Inc.'s submission of ANDA No. 206326 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution before the expiration of the '431 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), has infringed at least one claim of the '290 patent through Innopharma Licensing, Inc.'s submission of ANDA No. 206326 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution before the expiration of the '290 patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), has infringed at least one claim of the '131 patent through Innopharma Licensing, Inc.'s submission of ANDA No. 206326 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution before the expiration of the '131 patent;

4. enter judgment that, under 35 U.S.C. § 271(e)(2), has infringed at least one claim of the '813 patent through Innopharma Licensing, Inc.'s submission of ANDA No. 206326 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution before the expiration of the '813 patent;

5. order that the effective date of any approval by the FDA of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution be a date that is not earlier than the

expiration of the '431 patent, the '290 patent, the '131 patent, and the '813 patent, or such later date as the Court may determine;

6. enjoin Defendants from the commercial manufacture, use, import, offer for sale and/or sale of Innopharma Licensing, Inc.'s generic bromfenac ophthalmic solution until expiration of the '431 patent, the '290 patent, the '131 patent, and the '813 patent, or such later date as the Court may determine;

7. enjoin Defendants and all persons acting in concert with Defendants from seeking, obtaining or maintaining approval of Innopharma Licensing, Inc.'s ANDA No. 206326 until expiration of the '431 patent, the '290 patent, the '131 patent, and the '813 patent;

8. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses and disbursements in this action, including reasonable attorneys fees;

9. award Plaintiff such further and additional relief as this Court deems just and proper.

Dated: November 3, 2014

Respectfully submitted,

s/ Melissa A. Chuderewicz
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