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Attorneys for Plaintiffs
SENJU PHARMACEUTICAL CO., LTD.
BAUSCH & LOMB INCORPORATED, and
BAUSCH & LOMB PHARMA HOLDINGS CORP.

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

SENJU PHARMACEUTICAL CO., LTD.,)	
BAUSCH & LOMB INCORPORATED and)	
BAUSCH & LOMB PHARMA HOLDINGS)	
CORP.)	
)	
Plaintiffs,)	
)	
v.)	
)	
INNOPHARMA LICENSING, INC.,)	Civil Action No.:
INNOPHARMA LICENSING, LLC,)	
INNOPHARMA, INC., INNOPHARMA,)	
LLC, MYLAN PHARMACEUTICALS, INC.,)	
and MYLAN INC.)	
)	
)	
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, “InnoPharma”), and Mylan Pharmaceuticals, Inc. and Mylan Inc. (collectively, “Mylan”) (InnoPharma and Mylan collectively as “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, Piscataway, 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, Piscataway, 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, Piscataway, 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, Piscataway, New Jersey 08854.

8. Upon information and belief, defendant Mylan Pharmaceuticals, Inc. is a company organized and existing under the laws of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharmaceuticals, Inc. is a wholly-owned subsidiary of Mylan Inc. Upon information and belief, Mylan Pharmaceuticals, Inc. is registered to do business in New Jersey and has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey, as its registered agent for the receipt of service of process.

9. Upon information and belief, defendant Mylan Inc. is a company organized and existing under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Upon information and belief, Mylan Inc. is registered to do business in New Jersey and has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey, as its registered agent for the receipt of service of process.

NATURE OF THE ACTION

10. This is an action for infringement of United States Patent No. 9,144,609 (“the ’609 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

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

12. 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, marketing, importing and selling pharmaceutical drug 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, Piscataway, New Jersey 08854, and has thereby purposefully and systematically conducted and continues to conduct business in this judicial district.

13. 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, Piscataway, New Jersey 08854, and has thereby purposefully and systematically conducted and continues to conduct business in this judicial district.

14. 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.

15. 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.

16. Upon information and belief, this court has jurisdiction over Mylan Pharmaceuticals, Inc. Upon information and belief, Mylan Pharmaceuticals, 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, Mylan Pharmaceuticals, Inc. purposefully has conducted and continues to conduct business in this judicial district. Mylan Pharmaceuticals, Inc. is also one of the listed real parties in interest for *Inter Partes* Reviews (“IPR”) 2015-00902 and IPR 2015-00903, filed by InnoPharma and Mylan collectively on March 19, 2015, and IPR 2016-00089, IPR 2016-00090 and IPR 2015-00091, filed by InnoPharma and Mylan collectively on November 2, 2015.

17. Upon information and belief, this court has jurisdiction over Mylan Inc. Upon information and belief, Mylan 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, Mylan Inc. purposefully has conducted and continues to conduct business in this judicial district. Mylan Inc. is also one of the listed real parties in interest for IPR 2015-00902 IPR 2015-00903, filed by Innopharma and Mylan collectively on March 19, 2015, and IPR 2016-00089, IPR 2016-00090 and IPR 2015-00091, filed by InnoPharma and Mylan collectively on November 2, 2015.

18. 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

19. The U.S. Patent and Trademark Office (“PTO”) issued the ’609 patent on September 29, 2015. The ’609 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the ’609 patent and have the right to sue for infringement thereof. Senju is the assignee of the ’609 patent. A copy of the ’609 patent is attached hereto as Exhibit A.

20. 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 ’609 patent is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”).

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

DEFENDANTS' INFRINGING ANDA SUBMISSION

22. 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).

23. 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[®].

24. Plaintiffs received letters from InnoPharma Licensing, Inc. dated January 25, 2016, purporting to be a Notice of Certification for ANDA No. 206326 ("Defendants' 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).

25. Defendants' 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[®].

26. 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[®].

27. 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., InnoPharma, LLC, Mylan Pharmaceuticals, Inc. and Mylan Inc.

COUNT I AGAINST INNOPHARMA

Infringement of the '609 patent under § 271(e)(2)

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

29. Under 35 U.S.C. § 271(e)(2), InnoPharma has infringed at least one claim of the '609 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 '609 patent.

30. Upon information and belief, InnoPharma Licensing, Inc.'s generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '609 patent.

31. Upon information and belief, InnoPharma 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 '609 patent.

COUNT II AGAINST INNOPHARMA

Declaratory Judgment of Infringement of the '609 Patent

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

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

34. 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.

35. InnoPharma 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 '609 patent, including InnoPharma Licensing, Inc.'s filing of ANDA No. 206326.

36. 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 '609 patent.

37. 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 '609 patent.

COUNT I AGAINST MYLAN

Infringement of the '609 patent under § 271(e)(2)

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

39. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '609 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 '609 patent.

40. Upon information and belief, InnoPharma Licensing, Inc.'s generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '609 patent.

41. Upon information and belief, Mylan 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 '609 patent.

COUNT II AGAINST MYLAN

Declaratory Judgment of Infringement of the '609 Patent

42. Paragraphs 1-41 are incorporated herein as set forth above.

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

44. 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.

45. Mylan 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 '609 patent, including InnoPharma Licensing, Inc.'s filing of ANDA No. 206326.

46. 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 '609 patent.

47. 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 '609 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), InnoPharma has infringed at least one claim of the '609 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 '609 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Myaln has infringed at least one claim of the '609 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 '609 patent;

3. 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 '609 patent, or such later date as the Court may determine;

4. enjoin InnoPharma 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 '609 patent, or such later date as the Court may determine;

5. enjoin Mylan 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 '609 patent, or such later date as the Court may determine;

6. enjoin InnoPharma and all persons acting in concert with InnoPharma from seeking, obtaining or maintaining approval of Lupin's ANDA No. 206326 until expiration of the '609 patent;

7. enjoin Myaln and all persons acting in concert with Mylan from seeking, obtaining or maintaining approval of Lupin's ANDA No. 206326 until expiration of the '609 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 Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: March 10, 2016

Respectfully submitted,

s/ Melissa A. Chuderewicz

Melissa A. Chuderewicz

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