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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.)	
)	Civil Action No.:
Plaintiffs,)	
)	
v.)	
)	
LUPIN, LTD. and LUPIN)	
PHARMACEUTICALS, 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 Lupin, Ltd. (“Lupin”) and Lupin Pharmaceuticals, Inc. (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 Lupin, Ltd. is a corporation organized and existing under the laws of India, having a corporate headquarters at C/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051.

5. Upon information and belief, defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Virginia, having a principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202. Upon information and belief, Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of Lupin, Ltd.

NATURE OF THE ACTION

6. This is an action for infringement of United States Patent Nos. 8,871,813 (“the ’813 patent”) and 8,927,606 (“the ’606 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 Lupin’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% (“Lupin’s generic bromfenac ophthalmic solution”).

JURISDICTION AND VENUE

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

8. Upon information and belief, this Court has jurisdiction over Lupin. Upon information and belief, Lupin is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Lupin directly 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 Lupin’s generic bromfenac ophthalmic solution. Upon information and belief, Lupin purposefully has conducted and continues to conduct business in this judicial district.

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

10. 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

11. 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 A.

12. The U.S. Patent and Trademark Office ("PTO") issued the '606 patent on January 6, 2015. The '606 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the '606 patent and have the right to sue for infringement thereof. Senju is the assignee of the '606 patent. A copy of the '606 patent is attached hereto as Exhibit B.

13. 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 '290 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

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

LUPIN'S INFRINGING ANDA SUBMISSION

15. Upon information and belief, Lupin filed with the FDA ANDA No. 206027, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

16. Upon information and belief, Lupin's ANDA No. 206027 seeks FDA approval to sell in the United States Lupin's generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa[®].

17. Bausch & Lomb received a letter from Lupin dated December 17, 2014, purporting to be a Notice of Certification for ANDA No. 206027 ("Lupin'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).

18. Lupin's notice letter alleges that Lupin has submitted to the FDA ANDA No. 206027 seeking FDA approval to sell generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa[®].

19. Upon information and belief, ANDA No. 206027 seeks approval of Lupin's generic bromfenac ophthalmic solution that is the same, or substantially the same, as Prolensa[®].

20. Upon information and belief, Lupin's actions relating to ANDA No. 207584 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Lupin Pharmaceuticals, Inc.

COUNT I

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

21. Paragraphs 1-20 are incorporated herein as set forth above.

22. Under 35 U.S.C. § 271(e)(2), Lupin has infringed at least one claim of the '813 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206027 seeking approval for the commercial marketing of Lupin's generic bromfenac ophthalmic solution before the expiration date of the '813 patent.

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

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

COUNT II

Declaratory Judgment of Infringement of the '813 Patent

25. Paragraphs 1-24 are incorporated herein as set forth above.

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

27. 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.

28. Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Lupin's generic bromfenac ophthalmic solution before the expiration date of the '813 patent, including Lupin's filing of ANDA No. 206027.

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

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

COUNT III

Infringement of the '606 patent under § 271(e)(2)

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

32. Under 35 U.S.C. § 271(e)(2), Lupin has infringed at least one claim of the '606 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206027 seeking approval for the commercial marketing of Lupin's generic bromfenac ophthalmic solution before the expiration date of the '606 patent.

33. Upon information and belief, Lupin's generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '606 patent.

34. Upon information and belief, Lupin will, through the manufacture, use import, offer for sale and/or sale of Lupin's generic bromfenac ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '606 patent.

COUNT IV

Declaratory Judgment of Infringement of the '606 Patent

35. Paragraphs 1-34 are incorporated herein as set forth above.

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

37. 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.

38. Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Lupin's generic bromfenac ophthalmic solution before the expiration date of the '606 patent, including Lupin's filing of ANDA No. 206027.

39. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's generic bromfenac ophthalmic solution will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '606 patent.

40. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '606 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), Lupin has infringed at least one claim of the '813 patent through Lupin's submission of ANDA No. 206027 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Lupin's generic bromfenac ophthalmic solution before the expiration of the '813 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Lupin has infringed at least one claim of the '606 patent through Lupin's submission of ANDA No. 206027 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Lupin's generic bromfenac ophthalmic solution before the expiration of the '606 patent;

3. order that the effective date of any approval by the FDA of Lupin's generic bromfenac ophthalmic solution be a date that is not earlier than the expiration of the '813 patent and the '606 patent, or such later date as the Court may determine;

4. enjoin Defendants from the commercial manufacture, use, import, offer for sale and/or sale of Lupin's generic bromfenac ophthalmic solution until expiration of the '813 patent and the '606 patent, or such later date as the Court may determine;

5. enjoin Defendants and all persons acting in concert with Defendants from seeking, obtaining or maintaining approval of Lupin's ANDA No. 206027 until expiration of the '813 patent and the '606 patent;

6. 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; and

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

Dated: January 16, 2015

Respectfully submitted,

s/ Melissa A. Chuderewicz

Melissa A. Chuderewicz

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