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.	)	
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. and Lupin Pharmaceuticals, Inc. (collectively "Lupin") 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 No. 8,129,431 ("the '431 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 Ltd.'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, Ltd. Upon information and belief, Lupin Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Lupin Ltd. 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 Ltd. 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 Ltd., 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).

COUNT FOR PATENT INFRINGEMENT

11. 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 holds 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.

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

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

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

15. Upon information and belief, Lupin Ltd.'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®.

16. Bausch & Lomb received a letter from Lupin Ltd. dated December 19, 2013, 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).

17. Lupin's notice letter alleges that Lupin Ltd. 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®.

18. 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®.

19. Under 35 U.S.C. § 271(e)(2), Lupin Ltd. has infringed at least one claim of the '431 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 '431 patent.

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

21. Upon information and belief, Lupin Ltd. 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 '431 patent.

22. Upon information and belief, Lupin Ltd.'s actions relating to ANDA No. 206027 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.

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 '431 patent through Lupin Ltd.'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 '431 patent;

2. 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 '431 patent, or such later date as the Court may determine;

3. enjoin Lupin from the commercial manufacture, use, import, offer for sale and/or sale of Lupin's generic bromfenac ophthalmic solution until expiration of the '431 patent, or such later date as the Court may determine;

4. enjoin Lupin and all persons acting in concert with Lupin from seeking, obtaining or maintaining approval of Lupin Ltd.'s ANDA No. 206027 until expiration of the '431 patent;

5. 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;

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