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Lupin Limited and Defendant Lupin Pharmaceuticals, Inc.*

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

SENJU PHARMACEUTICAL CO., LTD.,	:	
BAUSCH & LOMB, INC. and BAUSCH &	:	Civil Action No.: 14-00667 (JBS)(KMW)
LOMB PHARMA HOLDINGS CORP.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	
	:	
LUPIN LIMITED and LUPIN	:	
PHARMACEUTICALS, INC.,	:	
	:	
Defendants.	:	

**LUPIN LIMITED’S AND LUPIN PHARMACEUTICALS, INC.’S
ANSWER, DEFENSES, AND COUNTERCLAIMS
TO COMPLAINT FOR PATENT INFRINGEMENT**

Defendants Lupin Limited (“Lupin Ltd.”) and Lupin Pharmaceuticals, Inc. (“LPI”) (together, “Lupin” or “Defendants”), through their undersigned counsel, hereby submit the following answer and defenses in response to the complaint of Senju Pharmaceutical Co., Ltd., Bausch & Lomb, Inc., and Bausch & Lomb Pharma Holdings Corp. (together, “Plaintiffs”), and Lupin Ltd. hereby submits the following counterclaims. The numbered paragraphs below correspond to the numbered paragraphs in the complaint. To the extent not specifically admitted herein, the allegations of the complaint are denied.

THE PARTIES¹

1. Lupin is without information sufficient to form a belief as to the allegations of this paragraph, and therefore denies them.

2. Upon information and belief, Lupin admits that Bausch & Lomb, Inc. is the holder of approved New Drug Application (“NDA”) No. 203168. Lupin is without information sufficient to form a belief as to the remaining allegations of this paragraph, and therefore denies them.

3. Lupin is without information sufficient to form a belief as to the allegations of this paragraph, and therefore denies them.

4. Lupin admits that Lupin Ltd. is a corporation organized and existing under the laws of India, having a place of business at C/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051. The allegations of this paragraph are otherwise denied.

5. Lupin admits that LPI is a corporation organized and existing under the laws of Virginia, having a place of business at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202. Lupin further admits that LPI is a wholly-owned subsidiary of Lupin Ltd. The allegations of this paragraph are otherwise denied. By way of further response, Lupin denies that LPI is a proper defendant in this action.

NATURE OF THE ACTION

6. Lupin admits that this is an action for alleged infringement of U.S. Patent No. 8,129,431 (the “431 patent”). Lupin further admits that Lupin Ltd. filed an Abbreviated New Drug Application (“ANDA”) seeking U.S. Food and Drug Administration (“FDA”) approval to market Bromfenac Ophthalmic Solution 0.07%. The allegations of this paragraph are otherwise denied.

¹ Lupin has included the headings set forth in the complaint merely for convenience. By so doing, Lupin is not admitting any express or implied statements set forth in those headings.

JURISDICTION AND VENUE

7. Lupin admits that this Court has subject matter jurisdiction over claims against Lupin Ltd. under 35 U.S.C. § 271(e)(2) set forth in the complaint. The allegations of this paragraph are otherwise denied.

8. Lupin admits that Lupin Ltd. manufactures pharmaceutical products. Lupin does not contest personal jurisdiction as to Lupin Ltd. in this judicial district for the limited purpose of this action only. The allegations of this paragraph are otherwise denied.

9. Lupin admits that LPI sells and distributes pharmaceutical products, including pharmaceutical products manufactured by Lupin Ltd. Lupin does not contest personal jurisdiction as to LPI in this judicial district for the limited purpose of this action only. The allegations of this paragraph are otherwise denied.

10. Lupin does not contest venue in this judicial district for the limited purpose of this action only. The allegations of this paragraph are otherwise denied.

COUNT FOR PATENT INFRINGEMENT

11. Upon information and belief, Lupin admits that the U.S. Patent and Trademark Office (“PTO”) issued the ’431 patent on or about March 6, 2012. Lupin further admits that Senju Pharmaceutical Co., Ltd. is listed as the assignee on the face of the ’431 patent. Lupin admits that Exhibit A to the complaint purports to be a copy of the ’431 patent. The second sentence of this paragraph states legal conclusions to which no response is required, and in any event, the claims of the ’431 patent speak for themselves. Lupin is without information sufficient to form a belief as to the remaining allegations of this paragraph, and therefore denies them.

12. Upon information and belief, admitted.

13. Upon information and belief, admitted.

14. Admitted.

15. Lupin admits that Lupin Ltd.'s ANDA No. 206027 seeks FDA approval to market in the United States Bromfenac Ophthalmic Solution 0.07%. The allegations of this paragraph are otherwise denied.

16. Lupin admits that, by letter dated December 19, 2013, Lupin Ltd. provided a Notification of Certification of Invalidity, Unenforceability, and/or Noninfringement for U.S. Patent No. 8,129,431 to Bausch & Lomb, Inc. for ANDA No. 206027 ("Lupin Ltd.'s notice letter") under Sections 505(j)(2)(B)(ii) and (iv) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 355(j)(2)(B)(ii) and (iv), and 21 C.F.R. § 314.95. Lupin is without information sufficient to form a belief as to the remaining allegations of this paragraph, and therefore denies them.

17. Lupin admits that Lupin Ltd.'s notice letter states that Lupin Ltd. has submitted ANDA No. 206027 to FDA to obtain FDA approval to market Bromfenac Ophthalmic Solution 0.07%. The allegations of this paragraph are otherwise denied.

18. Lupin admits that Lupin Ltd.'s ANDA No. 206027 seeks FDA approval for Bromfenac Ophthalmic Solution 0.07%. The allegations of this paragraph are otherwise denied.

19. Denied.

20. Denied.

21. Denied.

22. Lupin admits that LPI is designated as Lupin Ltd.'s U.S. agent in Lupin Ltd.'s ANDA No. 206027. The allegations of this paragraph are otherwise denied.

PRAYER FOR RELIEF

23. Lupin denies that Plaintiffs are entitled to the judgment and relief requested in the complaint.

DEFENSES

Lupin, without any admission as to burden of proof and without prejudice to the denials set forth in its answer, alleges the following defenses to the allegations in the complaint. Lupin reserves the right to supplement this answer, including the right to assert additional defenses, as more information is learned through discovery.

First Defense (Lack of Subject Matter Jurisdiction as to LPI)

24. The claims in the complaint against LPI should be dismissed for lack of subject matter jurisdiction because LPI did not submit ANDA No. 206027 to FDA.

Second Defense (LPI Not Proper Defendant)

25. LPI is not a proper defendant in this action.

Third Defense (Failure to State a Claim)

26. The complaint fails to state a claim upon which relief can be granted.

Fourth Defense (Invalidity of the '431 Patent)

27. The claims of the '431 patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C. § 100 *et seq.*, including but not limited to §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting.

Fifth Defense (Non-infringement of the '431 Patent)

28. Lupin has not infringed, either directly or indirectly, any valid and enforceable claim of the '431 patent, either literally or under the doctrine of equivalents, and Lupin's manufacture, sale, use, offer for sale, and/or importation of the drug product that is the subject of ANDA No. 206027 would not infringe, either directly or indirectly, any valid and enforceable claim of the '431 patent, either literally or under the doctrine of equivalents.

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