

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

BAUSCH & LOMB INCORPORATED,)
BAUSCH & LOMB PHARMA HOLDINGS)
CORP., MITSUBISHI TANABE PHARMA)
CORP., and UBE INDUSTRIES, LTD.,)
) Civil Action No.:
Plaintiffs,)
)
v.)
)
SANDOZ INC. and SANDOZ)
INTERNATIONAL GMBH,)

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch & Lomb Incorporated, Bausch & Lomb Pharma Holdings Corp., Mitsubishi Tanabe Pharma Corp., and Ube Industries, Ltd. (collectively “Plaintiffs”) by way of Complaint against Defendants Sandoz Inc. (“Sandoz”) and Sandoz International GmbH (“Sandoz International”) (collectively, “Defendants”) allege as follows:

THE PARTIES

1. 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 (“NDA”) No. 022288, which covers Bepreve[®].

2. 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.

3. Plaintiff Mitsubishi Tanabe Pharma Corp. (“Mitsubishi Tanabe”) is a corporation organized and existing under the laws of Japan, with a principal place of business at 2-6-18, Kitahama, Chuo-ku, Osaka 541-8505, Japan.

4. Plaintiff Ube Industries, Ltd. (“Ube”) is a corporation organized and existing under the laws of Japan, with a principal place of business at 1978-96, Kogushi, Ube, Yamaguchi 755-8633, Japan.

5. Upon information and belief, defendant Sandoz is a corporation organized and existing under the laws of Colorado, with a principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540. Upon information and belief, defendant Sandoz is a wholly-owned subsidiary of defendant Sandoz International.

6. Upon information and belief, defendant Sandoz International is a corporation organized and existing under the laws of Germany, with a principal place of business at Industriestrasse 25, 83607 Holzkirchen, Germany.

NATURE OF THE ACTION

7. This is an action for infringement of United States Patent No. 6,780,877 (“the ’877 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 Sandoz’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 bepotastine besilate 1.5%, solution/drops; ophthalmic (“Sandoz’s generic bepotastine besilate ophthalmic solution”).

JURISDICTION AND VENUE

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

9. Upon information and belief, this Court has jurisdiction over Sandoz. Upon information and belief, Sandoz is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sandoz 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 Sandoz's generic bepotastine besilate ophthalmic solution. Upon information and belief, Sandoz purposefully has conducted and continues to conduct business in this judicial district.

10. Upon information and belief, this Court has jurisdiction over Sandoz International. Upon information and belief, Sandoz International directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Sandoz Inc., throughout the United States and in this judicial district, and this judicial district is a likely destination for Sandoz's generic bepotastine besilate ophthalmic solution. Upon information and belief, Sandoz International purposefully has conducted and continues to conduct business in this judicial district.

11. 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

12. The U.S. Patent and Trademark Office ("PTO") issued the '877 patent on August 24, 2004. The '877 patent claims, *inter alia*, bepotastine besilate and a pharmaceutical composition including it. Plaintiffs holds all substantial rights in the '877 patent and have the right to sue for infringement thereof. Mitsubishi Tanabe and Ube are the assignees of the '877 patent. A copy of the '877 patent is attached hereto as Exhibit A.

13. B+L is the holder of NDA No. 022288 for Bepreve[®], which the FDA approved on September 8, 2009. In conjunction with NDA No. 022288, the '877 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

14. Bepotastine besilate ophthalmic solution is sold in the United States under the trademark Bepreve[®].

15. Upon information and belief, Sandoz filed with the FDA ANDA No. 206080, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

16. Upon information and belief, Sandoz's ANDA No. 206080 seeks FDA approval to sell in the United States Sandoz's generic bepotastine besilate ophthalmic solution, intended to be a generic version of Bepreve[®].

17. B+L received a letter from Sandoz dated January 17, 2014, purporting to be a Notice of Certification for ANDA No. 206080 ("Sandoz'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. Sandoz's notice letter alleges that Sandoz has submitted to the FDA ANDA No. 206080 seeking FDA approval to sell generic bepotastine besilate ophthalmic solution, intended to be a generic version of Bepreve[®].

19. Upon information and belief, ANDA No. 206080 seeks approval of Sandoz's generic bepotastine besilate ophthalmic solution that is the same, or substantially the same, as Bepreve[®].

20. Under 35 U.S.C. § 271(e)(2), Sandoz has infringed at least one claim of the '877 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206080 seeking approval for the commercial marketing of Sandoz's generic bepotastine besilate ophthalmic solution before the expiration date of the '877 patent.

21. Upon information and belief, Sandoz's generic bepotastine besilate ophthalmic solution will, if approved and marketed, infringe at least one claim of the '877 patent.

22. Upon information and belief, Sandoz will, through the manufacture, use import, offer for sale and/or sale of Sandoz's generic bepotastine besilate ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '877 patent.

23. Upon information and belief, Sandoz's actions relating to ANDA No. 206080 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Sandoz International.

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), Sandoz has infringed at least one claim of the '877 patent through Sandoz's submission of ANDA No. 206080 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Sandoz's generic bepotastine besilate ophthalmic solution before the expiration of the '877 patent;

2. order that the effective date of any approval by the FDA of Sandoz's generic bepotastine besilate ophthalmic solution be a date that is not earlier than the expiration of the '877 patent, or such later date as the Court may determine;

3. enjoin Sandoz from the commercial manufacture, use, import, offer for sale and/or sale of Sandoz's generic bepotastine besilate ophthalmic solution until expiration of the '877 patent, or such later date as the Court may determine;

4. enjoin Sandoz and all persons acting in concert with Sandoz from seeking, obtaining or maintaining approval of Sandoz's ANDA No. 206080 until expiration of the '877 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;
6. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: March 2, 2014

Respectfully submitted,

s/John F. Brenner
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