IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANTEN PHARMACEUTICAL CO., LTD., ASAHI GLASS CO., LTD., and OAK PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
MICRO LABS LIMITED, and MICRO LABS USA INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Santen Pharmaceutical Co., Ltd. ("Santen"), Asahi Glass Co., Ltd. ("AGC"), and Oak Pharmaceuticals, Inc. ("Oak") (collectively, "Plaintiffs"), for their Complaint against Defendants Micro Labs Limited ("Micro Labs LTD") and Micro Labs USA Inc. ("Micro Labs USA") (together, "Micro Labs"), allege as follows:

NATURE OF THE CASE

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising from Micro Labs' filing of an Abbreviated New Drug Application ("ANDA") with the United Stated Food and Drug Administration ("FDA"), in which Micro Labs seeks FDA approval to manufacture and sell a generic version of Plaintiffs' ZIOPTAN® (tafluprost ophthalmic solution) 0.0015% ("ZIOPTAN®") prior to the expiration of U.S. Patent No. 5,886,035 ("the '035 Patent").

2. By letter dated April 5, 2016, Micro Labs USA notified Plaintiffs that Micro Labs LTD had filed ANDA No. 209051 ("Micro Labs ANDA"), seeking FDA approval to

manufacture and sell a generic version of Plaintiffs' ZIOPTAN® prior to the expiration of the '035 Patent.

THE PARTIES

3. Plaintiff Santen is a Japanese corporation, having a principal place of business at 9-19, Shimoshinjo 3-chome, Higashiyodogawa-ku, Osaka, Japan.

4. Plaintiff AGC is a Japanese corporation, having a principal place of business at 1-5-1, Marunouchi, Chiyoda-ku, Tokyo, Japan.

5. Plaintiff Oak is a Delaware corporation, having a principal place of business at 1925 West Field Court, Suite 300, Lake Forest IL 60045.

6. On information and belief, Defendant Micro Labs LTD is an Indian corporation, having a principal place of business at 27 Race Course Road, Bangalore 560001, India.

7. On information and belief, Defendant Micro Labs USA is a New Jersey corporation, having a principal place of business at 104 Carnegie Center, Suite 216, Princeton, NJ 08540.

8. On information and belief, Micro Labs USA is a wholly owned subsidiary of Micro Labs LTD, and is controlled and/or dominated by Micro Labs LTD.

9. On information and belief, Micro Labs LTD and Micro Labs USA are agents of each other and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

10. On information and belief, Micro Labs LTD and Micro Labs USA regularly transact business within Delaware, including but not limited to, through Micro Labs LTD's direction of the operations and management of Micro Labs USA, as well as shipping generic

drugs to Micro Labs USA from locations outside the United States for marketing, sale and distribution by Micro Labs USA within the United States generally, and Delaware specifically.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. Micro Labs LTD is subject to personal jurisdiction in this District, because, *inter alia*, it, on information and belief, regularly transacts business in this District and has engaged in systematic and continuous business contacts within the State of Delaware, and its suit-related conduct, *i.e.*, the Micro Labs ANDA seeking FDA approval to manufacture and sell a generic version of ZIOPTAN® in the United States, including in Delaware, creates a substantial connection with Delaware, and also demonstrates Micro Labs LTD's plans to direct sales of its generic drugs into Delaware. Moreover, Micro Labs LTD has consented to jurisdiction in Delaware (and has filed counterclaims) in other similar actions, in which Micro Labs LTD has been accused of infringement in connection with the filing of ANDAs seeking FDA approval to manufacture and sell generic drugs. *See, e.g., Bayer Intellectual Prop. GmbH et al. v. Aurobindo Pharma Ltd. et al.*, No. 1:15-cv-00902-SLR (D. Del.); *Alcon Research, Ltd. v. Micro Labs Ltd. et al.*, No. 1:14-cv-00014-SLR (D. Del.).

13. Micro Labs USA is subject to personal jurisdiction in this District, because, *inter alia*, it, on information and belief, regularly transacts business in this District and has engaged in systematic and continuous business contacts within the State of Delaware, and, on information and belief, it has acted in concert with Micro Labs LTD to file the Micro Labs ANDA, and will continue to act in concert to manufacture and sell a generic version of ZIOPTAN® in the United

States, including in Delaware. Micro Labs USA has also consented to jurisdiction in Delaware (and has filed counterclaims) in other similar actions, in which Micro Labs USA has been accused of infringement in connection with the filing of ANDAs by Micro Labs LTD seeking FDA approval to manufacture and sell generic drugs. *See, e.g.*, *Bayer Intellectual Prop. GmbH et al. v. Aurobindo Pharma Ltd. et al.*, No. 1:15-cv-00902-SLR (D. Del.); *Alcon Research, Ltd. v. Micro Labs Ltd. et al.*, No. 1:14-cv-00014-SLR (D. Del.).

14. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE '035 PATENT AND ZIOPTAN

15. On March 23, 1999, the United States Patent and Trademark Office ("PTO") issued the '035 Patent, entitled "Difluoroprostaglandin Derivatives and Their Use," to AGC and Santen, the co-assignees of the named inventors, Eiichi Shirasawa, Masaaki Kageyama, Tadashi Nakajima, Takashi Nakano, Nobuaki Mori, Hideshi Sasakura, Yasushi Matsumura, and Yoshitomi Morizawa. Plaintiffs Santen and AGC are the record owners of the '035 Patent, and Plaintiff Oak is a licensee in relation to the sales and marketing of tafluprost in the United States. A copy of the '035 Patent is attached hereto as Exhibit A.

16. The original expiration date of the '035 Patent was December 18, 2017.

17. On February 23, 2016, the PTO issued a Certificate Extending Patent Term Under 35 U.S.C. § 156, extending the expiration date of the '035 Patent by 5 years to December 18, 2022.

18. On February 10, 2012, FDA approved New Drug Application ("NDA") No. 202514 for ZIOPTAN®. Plaintiff Oak is the holder of NDA No. 202514 for ZIOPTAN®.

19. In the publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book"), the '035 Patent is listed as covering ZIOPTAN®.

THE MICRO LABS ANDA

20. On information and belief, Micro Labs LTD and Micro Labs USA seek to constantly expand the range of generic products sold by them.

21. On information and belief, Micro Labs LTD and Micro Labs USA collaborate in the manufacture, marketing and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to an approved ANDA) within the United States generally, and the State of Delaware specifically.

22. On information and belief, Micro Labs LTD and Micro Labs USA actively review pharmaceutical patents and seek opportunities to challenge those patents.

23. On information and belief, Micro Labs LTD and Micro Labs USA reviewed the '035 Patent and certain commercial and economic information relating to ZIOPTAN®, including estimates of the revenues generated by the sale of ZIOPTAN®, and decided to file an ANDA, seeking approval to market a generic version of ZIOPTAN®.

24. On information and belief, Micro Labs LTD and Micro Labs USA collaborated in the research, development, preparation and filing of the Micro Labs ANDA.

25. On information and belief, Micro Labs LTD submitted to FDA the Micro Labs ANDA seeking approval to engage in the commercial manufacture, use, and sale of a generic version of ZIOPTAN®, prior to the expiration of the '035 Patent.

26. Plaintiffs have received a letter dated April 5, 2016 from Micro Labs USA notifying them that the Micro Labs ANDA includes a certification under 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Micro Labs LTD's opinion, the '035 Patent is invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of the generic version of ZIOPTAN® described in the Micro Labs ANDA.

27. On information and belief, Micro Labs USA collaborated with Micro Labs LTD for the purpose of preparing and filing the Micro Labs ANDA with FDA.

28. Micro Labs LTD and Micro Labs USA were necessarily aware of the '035 Patent when the Micro Labs ANDA was filed with a Paragraph IV certification.

29. Plaintiffs commenced this action within 45 days of the date they received notice of the Micro Labs ANDA containing the Paragraph IV certification.

30. On information and belief, Micro Labs LTD and Micro Labs USA continue to collaborate in seeking FDA approval of the Micro Labs ANDA and intend to collaborate in the commercial manufacture, marketing, and sale of a generic version of ZIOPTAN® (including commercial marketing and sale in the State of Delaware) in the event that FDA approves the Micro Labs ANDA.

FIRST CLAIM FOR RELIEF
(Direct Infringement of the '035 Patent by Micro Labs LTD and Micro Labs USA)

31. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 30 hereof, as if fully set forth herein.

32. Through the conduct alleged above, Micro Labs LTD and Micro Labs USA have directly infringed, and continue to directly infringe, one or more claims of the '035 Patent.

33. By filing the Micro Labs ANDA with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of the generic version of ZIOPTAN® disclosed therein, prior to the expiration of the '035 Patent, Micro Labs LTD and Micro Labs USA have infringed the '035 Patent under 35 U.S.C. § 271(e)(2).

34. Micro Labs LTD and Micro Labs USA were aware of the existence of the '035 Patent prior to the filing of the Micro Labs ANDA, but took such action knowing that it would constitute infringement of the '035 Patent.

35. On information and belief, Micro Labs LTD and Micro Labs USA acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '035 Patent.

36. Micro Labs LTD and Micro Labs USA's conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

37. Plaintiffs will be irreparably harmed if Micro Labs LTD and Micro Labs USA are not enjoined from infringing the '035 Patent.

SECOND CLAIM FOR RELIEF
(Inducement of Infringement of the '035 Patent by Micro Labs USA)

38. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 37 hereof, as if fully set forth herein.

39. Through the conduct alleged above, Micro Labs USA has knowingly and actively induced Micro Labs LTD to infringe, and continue to infringe, one or more claims of the '035 Patent.

40. By reason of Micro Labs USA's inducement of Micro Labs LTD's direct infringement of the '035 Patent, Micro Labs USA has caused and continues to cause irreparable harm to Plaintiffs.

41. On information and belief, Micro Labs USA's inducement of Micro Labs LTD's direct infringement of the '035 Patent will continue unless enjoined by this Court.

42. Plaintiffs have no adequate remedy at law for Micro Labs USA's inducement of Micro Labs LTD's direct infringement of the '035 Patent.

43. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

WHEREFORE, Plaintiffs respectfully request the following relief:

A. An order adjudging and decreeing that Micro Labs LTD and Micro Labs USA have directly infringed the '035 Patent;

B. An order adjudging and decreeing that Micro Labs USA has induced infringement of the '035 Patent;

C. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of the Micro Labs ANDA be no earlier than December 18, 2022, the date on which the '035 Patent expires;

D. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Micro Labs LTD and Micro Labs USA, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the generic version of ZIOPTAN® described in the Micro Labs ANDA until December 18, 2022;

E. A declaration that this case is exceptional and an award of attorneys' fees under 35 U.S.C. § 285 and costs and expenses in this action;

F. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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