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

SANTEN PHARMACEUTICAL CO. LTD., AGC INC., AND OAK PHARMACEUTICALS, INC., Plaintiffs, v. MICRO LABS LIMITED AND MICRO LABS USA INC., Defendants.	:	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL RULE 11.2**

Plaintiffs Santen Pharmaceutical Co., Ltd. ("Santen"), AGC Inc. ("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. 9,999,593 ("the '593 Patent" or "patent-in-suit").

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®.

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, Ken Towers, Bengaluru, Karnataka, 560001, India.

7. On information and belief, Defendant Micro Labs USA is a New Jersey corporation, having a principal place of business at 106 Allen Road, Suite 102, Basking Ridge, NJ, 07920.

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 New Jersey, 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 New Jersey 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*, on information and belief, it regularly transacts business in this District and has engaged in systematic and continuous business contacts within the State of New Jersey, 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 New Jersey, creates a substantial connection with New Jersey, and also demonstrates Micro Labs LTD's plans to direct sales of its generic drugs into New Jersey. Moreover, Micro Labs LTD has consented to jurisdiction in New Jersey (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., AstraZeneca AB et al. v. Micro Labs USA, Inc. et al.*, No. 15-07921-FLW-DEA (D.N.J.); *Bausch & Lomb Inc. et al. v. Micro Labs USA , Inc. et al.*, No. 15-03113-NLH-JS (D.N.J.).

13. Micro Labs USA is subject to personal jurisdiction in this District, because, *inter alia*, on information and belief, it is a New Jersey corporation with a principal place of business in New Jersey.

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

THE '593 PATENT AND ZIOPTAN

15. On June 19, 2018, the United States Patent and Trademark Office ("PTO") issued the '593 Patent, entitled "Method and Composition for Treating Ocular Hypertension and Glaucoma," to Santen and Asahi Glass Co., Ltd. (now AGC Inc.), the co-assignees of the named inventors, Timo Reunamaki, Pertti Pellinen, Olli Oksala, and Kari Lehmussaari. Plaintiffs Santen and AGC are the record owners of the '593 Patent, and Plaintiff Oak is a licensee in relation to the sales and marketing of tafluprost in the United States. A copy of the '593 Patent is attached hereto as Exhibit A.

16. 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®.

17. In the publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book"), the '593 Patent is listed as covering ZIOPTAN®.

THE MICRO LABS ANDA

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

19. 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 New Jersey specifically.

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

21. On information and belief, Micro Labs LTD and Micro Labs USA reviewed the Orange Book-listed patent for ZIOPTAN® at the time, *i.e.*, U.S. Patent No. 5,886,035 ("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®.

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

23. 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®.

24. Plaintiffs received a letter dated April 5, 2016 from Micro Labs USA notifying Plaintiffs that the Micro Labs ANDA had been filed and that the Micro Labs ANDA included 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.

25. On May 13, 2016, Plaintiffs filed suit in the District of Delaware against Defendants for the infringement of the '035 Patent, based upon, *inter alia*, Defendants' written notification of their filing of the Micro Labs ANDA. *See Santen Pharmaceutical Co., Ltd. et al. v. Micro Labs Ltd. et al.*, No. 16-00353 (GMS) (D. Del.) ("the '035 Patent Suit"). The '035 Patent Suit is currently stayed pending issuance of the Final Written Decision in an *inter partes* review proceeding brought by Defendants with respect to the '035 Patent. *Id*. (D.I. 85); *Micro Labs Ltd. et al. v. Santen Pharmaceutical Co., Ltd. et al.*, IPR2017-01434.

26. On June 19, 2018, the PTO issued the '593 Patent. On or about July 31, 2018, the '593 Patent was listed in the Orange Book for ZIOPTAN®.

27. 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 New Jersey) in the event that FDA approves the Micro Labs ANDA.

FIRST CLAIM FOR RELIEF
(Direct Infringement of the '593 Patent by Micro Labs LTD and Micro Labs USA)

28. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 27 hereof, as if fully set forth herein.

29. 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 ’593 Patent.

30. By filing the Micro Labs ANDA and 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 ’593 Patent, Micro Labs LTD and Micro Labs USA have infringed the ’593 Patent under 35 U.S.C. § 271(e)(2).

31. Micro Labs LTD and Micro Labs USA continue to seek approval of the Micro Labs ANDA despite being aware of the ’593 Patent and knowing that such action would constitute infringement of the ’593 Patent.

32. 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 ’593 Patent.

33. Micro Labs LTD and Micro Labs USA’s conduct renders this case “exceptional” as described in 35 U.S.C. § 285.

34. Plaintiffs will be irreparably harmed if Micro Labs LTD and Micro Labs USA are not enjoined from infringing the ’593 Patent.

SECOND CLAIM FOR RELIEF
(Inducement of Infringement of the ’593 Patent by Micro Labs USA)

35. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 34 hereof, as if fully set forth herein.

36. 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 ’593 Patent.

37. By reason of Micro Labs USA's inducement of Micro Labs LTD's direct infringement of the '593 Patent, Micro Labs USA has caused and continues to cause irreparable harm to Plaintiffs.

38. On information and belief, Micro Labs USA's inducement of Micro Labs LTD's direct infringement of the '593 Patent will continue unless enjoined by this Court.

39. Plaintiffs have no adequate remedy at law for Micro Labs USA's inducement of Micro Labs LTD's direct infringement of the '593 Patent.

40. 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 '593 Patent;

B. An order adjudging and decreeing that Micro Labs USA has induced infringement of the '593 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 the expiration date of the patent-in-suit, including any extensions and/or exclusivities;

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 the expiration date of the patent-in-suit, including any extensions and/or exclusivities;

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.

Respectfully submitted,

Dated: August 1, 2018

By: *s/ John E. Flaherty*

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CERTIFICATION PURSUANT TO LOCAL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the ANDA at issue in the above-captioned proceeding and a different Orange Book-listed patent for ZIOPTAN® are the subject of the following action in the District of Delaware: *Santen Pharmaceutical Co., Ltd., Asahi Glass Co., Ltd., and Oak Pharmaceuticals, Inc. v. Micro Labs Limited and Micro Labs USA, Inc.*, No. 16-353-GMS (D. Del.). I further certify that the aforementioned different Orange Book-listed patent for ZIOPTAN® is the subject of the following *inter partes* review proceeding before the Patent Trial and Appeal Board: *Micro Labs Limited and Micro Labs USA Inc. v. Santen Pharmaceutical Co., Ltd. and Asahi Glass Co., Ltd.*, IPR2017-01434.

Respectfully submitted,

Dated: August 1, 2018

By: *s/ John E. Flaherty*

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