IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES INC., GALDERMA LABORATORIES, L.P., and SUPERNUS PHARMACEUTICALS, INC., Plaintiffs, vs. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Defendants.	Civil Action No. _____

COMPLAINT

Plaintiffs Galderma Laboratories Inc., Galderma Laboratories, L.P., and Supernus Pharmaceuticals, Inc. (collectively, "Plaintiffs"), for their Complaint against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc., hereby allege as follows:

PARTIES

1. Plaintiff Galderma Laboratories Inc. (hereinafter, "GLI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177.

2. Plaintiff Galderma Laboratories, L.P. (hereinafter, "GLLP") is a privately held partnership registered in the state of Texas, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177.

3. Plaintiff Supernus Pharmaceuticals, Inc. (hereinafter, "Supernus") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1550 East Gude Drive, Rockville, Maryland 20850.

4. Upon information and belief, Defendant Lupin Limited (hereinafter, "Lupin Ltd.") is an Indian corporation having a principal place of business at Laxmi Towers "B" Wing, 5th floor, Banda Kurla Complex, Mumbai 400 051, India.

5. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. (hereinafter, "Lupin Pharma") is a Virginia corporation and a wholly-owned subsidiary and agent of Defendant Lupin Ltd., having a principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202.

NATURE OF THE ACTION

6. This is a civil action for infringement of United States Patent No. 7,749,532 B2 ("the '532 patent"). (Exhibit A.) This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Defendant Lupin Ltd. by virtue of, *inter alia*, its having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State. Upon information and belief, Defendant Lupin Ltd. researches, develops, and manufactures numerous generic drugs for sale

and use throughout the United States, including in this judicial district. Upon information and belief, Defendant Lupin Ltd., itself or through its wholly-owned subsidiary and agent Defendant Lupin Pharma, distributes numerous generic drugs for sale and use throughout the United States, including this judicial district. Upon information and belief, Lupin Ltd. has submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. For example, Lupin Ltd. submitted to jurisdiction and filed counterclaims in an action in this Court against Plaintiffs GLI and GLLP concerning the same Abbreviated New Drug Application ("ANDA") at issue here, ANDA No. 91-277. *See Research Foundation of State of New York, et al. v. Lupin Ltd., et al.*, C.A. No. 09-483-HB (D. Del.) at D.I. 11, Answer ¶ 9, Counterclaim ¶¶ 8-9.

9. This Court has personal jurisdiction over Defendant Lupin Pharma by virtue of, *inter alia*, its having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State. Upon information and belief, Defendant Lupin Pharma distributes numerous generic drugs for sale and use throughout the United States, including this judicial district. Upon information and belief, Lupin Pharma has submitted to the jurisdiction of this Court in other civil actions initiated in this jurisdiction. For example, Lupin Pharma submitted to jurisdiction in an action in this Court against Plaintiffs GLI and GLLP concerning the same ANDA at issue here, ANDA No. 91-277. *See Research Foundation of State of New York, et al. v. Lupin Ltd., et al.*, C.A. No. 09-483-HB (D. Del.) at D.I. 11, Answer ¶ 10.

10. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

11. GLLP holds New Drug Application ("NDA") No. 50-805 on Oracea® brand doxycycline capsules, and is the exclusive distributor of Oracea® in the United States.

12. On July 6, 2010, the '532 patent, titled "Once Daily Formulations of Tetracyclines," was duly and legally issued by the United States Patent and Trademark Office to Supernus as assignee. A copy of the '532 patent is attached as Exhibit A.

13. The '532 patent is listed in the U.S. Food and Drug Administration's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Oracea®.

14. Supernus is the current assignee of the '532 patent.

15. GLI is the exclusive licensee of the '532 patent.

16. Plaintiffs GLI and GLLP have the right to sue and recover for any infringement of the '532 patent.

ACTS GIVING RISE TO THIS ACTION

CLAIM – INFRINGEMENT OF THE '532 PATENT

17. Plaintiffs restate all of the preceding paragraphs as if fully set forth herein.

18. Upon information and belief, Lupin Ltd., through its subsidiary and agent Lupin Pharma, submitted ANDA No. 91-277 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FFDCA") (21 U.S.C. § 355(j)).

19. ANDA No. 91-277 seeks FDA approval for the commercial manufacture, use and sale of generic doxycycline delayed-release capsules, 40mg, for oral administration ("the Generic Products").

20. On information and belief, prior to November 9, 2010, Lupin Ltd. submitted in ANDA No. 91-277 a certification pursuant to § 505(j)(2)(A)(vii)(IV) that the claims of the '532 patent are invalid and/or not infringed by the commercial manufacture, use or sale of the Generic Products.

21. ANDA No. 91-277 specifically seeks FDA approval to market the Generic Products prior to the expiration of the '532 patent.

22. Plaintiffs received written notice of the § 505(j)(2)(A)(vii)(IV) certification regarding the '532 patent in ANDA No. 91-277 by letter dated November 9, 2010.

23. Lupin Ltd.'s submission of ANDA No. 91-277 and associated § 505(j)(2)(A)(vii)(IV) allegations concerning the '532 patent, through its agent Lupin Pharma, constituted infringement under 35 U.S.C. § 271(e)(2)(A). Moreover, if Lupin Ltd. commercially manufactures, uses, offers to sell, sells, or imports any of the Generic Products, or induces or contributes to any such conduct, it would further infringe the '532 patent under 35 U.S.C. § 271(a), (b) and/or (c).

24. Lupin Pharma is jointly and severally liable for any infringement of the '532 patent. Upon information and belief, Lupin Pharma participated in, contributed to, aided, abetted and/or induced Lupin Ltd.'s submission of ANDA No. 91-277 and its § 505(j)(2)(A)(vii)(IV) allegations regarding the '532 patent to the FDA.

25. Lupin Pharma's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 91-227 and its § 505(j)(2)(A)(vii)(IV) allegations regarding the '532 patent to the FDA constitutes infringement under 35 U.S.C. § 271(e)(2)(A). Moreover, if Lupin Pharma commercially manufactures, uses, offers to sell, sells, or imports any of the Generic Products, or induces or contributes to any such conduct, it would further infringe the '532 patent under 35 U.S.C. § 271(a), (b) and/or (c).

26. Plaintiffs will be irreparably harmed by Lupin Ltd.'s and Lupin Pharma's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

27. This is an exceptional case under 35 U.S.C. § 285 because Lupin Ltd. and Lupin Pharma were aware of the existence of the '532 patent at least as of November 9, 2010.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Lupin Ltd. has infringed the '532 patent;

B. That Lupin Pharma has infringed the '532 patent;

C. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 91-277 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration of the '532 patent, including any extensions;

D. That Lupin Ltd., its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently

enjoined from commercially manufacturing, using, offering to sell, selling or importing any Generic Products, prior to the expiration of the '532 patent, including any extensions;

E. That Lupin Pharma, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling or importing any Generic Products, prior to the expiration of the '532 patent, including any extensions;

F. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

G. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (# 1014)
Maryellen Noreika (# 3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Gerald J. Flattmann, Jr.
Christine Willgoos
PAUL, HASTINGS, JANOFSKY & WALKER LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000

December 17, 2010