IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES INC., GALDERMA LABORATORIES, L.P., and SUPERNUS PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
IMPAX LABORATORIES, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Galderma Laboratories Inc., Galderma Laboratories, L.P., and Supernus Pharmaceuticals, Inc. (collectively, "Plaintiffs"), for their Complaint against Defendant Impax Laboratories, Inc. ("Impax"), 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 Impax is a Delaware corporation having a principal place of business at 30831 Huntwood Avenue, Hayward, California, 94544.

NATURE OF THE ACTION

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

JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over Impax because, *inter alia*, it is a Delaware corporation. In addition, Impax has engaged in substantial and continuing contacts with the State. Upon information and belief, Impax researches, develops, and manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district. Upon information and belief, Impax has submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. For example, Impax 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. 91-447. *See Research Foundation of State of New York, et al. v. Impax Laboratories, Inc.*, C.A. No. 09-703 (D. Del.) at D.I. 11, Answer ¶¶ 7-9, Counterclaim ¶ 1.

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

THE PATENT-IN-SUIT

9. 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.

10. 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 ("USPTO") to Supernus as assignee. A copy of the '532 patent is attached as Exhibit A.

11. 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®.

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

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

14. 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

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

16. Upon information and belief, on or before April 12, 2011, Impax submitted ANDA No. 91-447 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FFDCA") (21 U.S.C. § 355(j)).

17. ANDA No. 91-447 seeks FDA approval for the commercial manufacture, use and sale of generic doxycycline delayed-release capsules, 40 mg, for oral administration ("the Generic Products").

18. On information and belief, prior to April 12, 2011, Impax submitted in ANDA No. 91-447 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.

19. ANDA No. 91-447 specifically seeks FDA approval to market the Generic Products prior to the expiration of the '532 patent.

20. Plaintiffs received written notice of the § 505(j)(2)(A)(vii)(IV) certification regarding the '532 patent in ANDA No. 91-447 by letter dated April 12, 2011. Impax's certification notice does not assert that its Generic Products do not infringe the claims of the '532 patent.

21. Impax's submission of ANDA No. 91-447 and associated § 505(j)(2)(A)(vii)(IV) allegations concerning the '532 patent to the FDA constituted infringement of the '532 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Impax 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).

22. Plaintiffs will be irreparably harmed by Impax's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

23. This is an exceptional case under 35 U.S.C. § 285 because Impax was aware of the existence of the '532 patent at least as of April 12, 2011.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Impax has infringed the '532 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 91-447 under § 505(j) of the Federal Food, Drug and Cosmetic Act

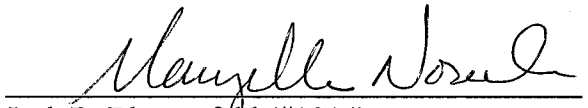
(21 U.S.C. § 355(j)) shall not be earlier than the expiration of the '532 patent, including any extensions;

C. That Impax, 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;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL, LLP



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May 26, 2011
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