IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| GALDERMA LABORATORIES INC.; GALDERMA LABORATORIES, L.P.; and SUPERNUS PHARMACEUTICALS, INC., | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. _____ |
| AMNEAL PHARMACEUTICALS, LLC and AMNEAL PHARMACEUTICALS CO. (I) PVT. LTD., | ) | |
| Defendants. | ) | |

**COMPLAINT**

Plaintiffs Galderma Laboratories Inc.; Galderma Laboratories, L.P.; and Supernus Pharmaceuticals, Inc. (collectively, "Plaintiffs"), for their Complaint against Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals Co. (I) Pvt. Ltd., 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 Amneal Pharmaceuticals, LLC (hereinafter, "Amneal Pharma") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 85 Adams Avenue, Hauppauge, NY 11788.

5. Upon information and belief, Defendant Amneal Pharmaceuticals Co. (I) Pvt. Ltd. (hereinafter, "Amneal India") is an Indian corporation and a wholly-owned subsidiary and agent of Defendant Amneal Pharma, having a principal place of business at 882/1-871, Village: Rajoda, Near Hotel Kankavati, Taluka: Bavla, District: Ahmedabad-382220, Gujarat, India.

## NATURE OF THE ACTION

6. This is a civil action for infringement of United States Patents Nos. 7,749,532 ("the '532 patent"); 7,232,572 ("the '572 patent"); and 7,211,267 ("the '267 patent"). (Exhibits A-C.) 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 Amneal Pharma because, *inter alia*, it is a Delaware corporation. In addition, Amneal has engaged in substantial and continuing contacts with the State. Upon information and belief, Amneal Pharma researches, develops, manufactures and distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

9. This Court has personal jurisdiction over Amneal India 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, Amneal India manufactures numerous generic drugs, which in partnership and agency with its parent corporation, Amneal Pharma, are offered for sale, sold and used throughout the United States, including in this judicial district.

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

## THE PATENTS-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 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 (hereinafter, "FDA") *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 licensee of the '532 patent.

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

17. On June 19, 2007, the '572 patent, entitled "Methods of Treating Rosacea" was duly and legally issued to CollaGenex Pharmaceuticals, Inc. as assignee. A copy of the '572 patent is attached as Exhibit B.

18. The '572 patent is listed in the Orange Book for Oracea®.

19. GLI is the current assignee of the '572 patent.

20. Plaintiffs GLI and GLLP have the right to sue and recover for any infringement of the '572 patent.

21. On May 1, 2007, the '267 patent, entitled "Methods of Treating Acne" was duly and legally issued to CollaGenex Pharmaceuticals, Inc. as assignee. A copy of the '267 patent is attached as Exhibit C.

22. The '267 patent is listed in the Orange Book for Oracea®.

23. GLI is the current assignee of the '267 patent.

24. Plaintiffs GLI and GLLP have the right to sue and recover for any infringement of the '267 patent.

## ACTS GIVING RISE TO THIS ACTION

### Count I – Infringement of the '532 Patent

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

26. Upon information and belief, Amneal Pharma submitted ANDA No. 203-278 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FFDCA") (21 U.S.C. § 355(j)).

27. Upon information and belief, ANDA No. 203-278 seeks FDA approval for the commercial manufacture, use and sale of generic doxycycline delayed-release capsules, 40 mg, for oral administration ("the Generic Products").

28. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Amneal Pharma alleged in ANDA No. 203-278 that claims of the '532 patent are invalid and/or will not be infringed by the commercial manufacture, use or sale of the Generic Products.

29. Upon information and belief, ANDA No. 203-278 specifically seeks FDA approval to market the Generic Products prior to the expiration of the '532 patent.

30. Plaintiffs received written notice of the § 505(j)(2)(A)(vii)(IV) allegations regarding the '532 patent in ANDA No. 203-278 by letter dated September 27, 2011 ("Notice of Paragraph IV Certification").

31. Upon information and belief, Amneal Pharma's submission of ANDA No. 203-278 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations concerning the '532 patent, constitutes infringement under 35 U.S.C. § 271(e)(2)(A). Moreover, if Amneal 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).

32. Amneal India is jointly and severally liable for any infringement of the '532 patent. This is so because, upon information and belief, Amneal India participated in, contributed to, aided and abetted and/or induced the submission of ANDA No. 203-278 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA. Additionally, upon information and belief, Amneal India will, without authority, import the Generic Products into the United States for subsequent commercial sale by Amneal Pharma under ANDA No. 203-278.

33. Amneal India's participation in, contributing to, aiding, abetting and/or inducement of the submission of ANDA No. 203-278 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 Amneal India imports any of the Generic Products into the United States, 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).

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

**Count II – Infringement of the '572 Patent**

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

36. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Amneal Pharma alleged in ANDA No. 203-278 that claims of the '572 patent are invalid and/or will not be infringed by the commercial manufacture, use or sale of the Generic Products.

37. Upon information and belief, ANDA No. 203-278 specifically seeks FDA approval to market the Generic Products prior to the expiration of the '572 patent.

38. Upon information and belief, Amneal Pharma's submission of ANDA No. 203-278 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations concerning the '572 patent, constitutes infringement under 35 U.S.C. § 271(e)(2)(A). Moreover, if Amneal 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 '572 patent under 35 U.S.C. § 271(a), (b) and/or (c).

39. Amneal India is jointly and severally liable for any infringement of the '572 patent. This is so because, upon information and belief, Amneal India participated in,

contributed to, aided and abetted and/or induced the submission of ANDA No. 203-278 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA. Additionally, upon information and belief, Amneal India will, without authority, import the Generic Products into the United States for subsequent commercial sale by Amneal Pharma under ANDA No. 203-278.

40. Amneal India's participation in, contributing to, aiding, abetting and/or inducement of the submission of ANDA No. 203-278 and its § 505(j)(2)(A)(vii)(IV) allegations regarding the '572 patent to the FDA constitutes infringement under 35 U.S.C. § 271(e)(2)(A). Moreover, if Amneal India imports any of the Generic Products into the United States, or induces or contributes to any such conduct, it would further infringe the '572 patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

**Count III – Infringement of the '267 Patent**

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

43. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Amneal Pharma alleged in ANDA No. 203-278 that claims of the '267 patent are invalid and/or will not be infringed by the commercial manufacture, use or sale of the Generic Products.

44. Upon information and belief, ANDA No. 203-278 specifically seeks FDA approval to market the Generic Products prior to the expiration of the '267 patent.

45. Upon information and belief, Amneal Pharma's submission of ANDA No. 203-278 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations concerning the '267

**Prayer for Relief**

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Amneal Pharma has infringed the '532, '572, and '267 patents;

B. That Amneal India has infringed the '532, '572, and '267 patents;

C. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 203-278 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration dates of the '532, '572, and '267 patents, including any extensions;

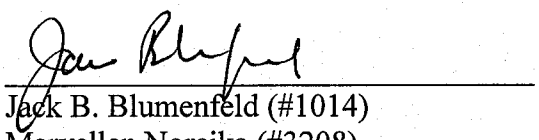
D. That Amneal Pharma, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling or importing any Generic Products, prior to the expiration of the '532, '572, and '267 patents, including any extensions;

E. That Amneal India, 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, '572, and '267 patents, 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



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