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Attorneys for Defendants Amneal Pharmaceuticals, LLC

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

KOWA COMPANY, LTD., KOWA PHARMACEUTICALS AMERICA, INC. and NISSAN CHEMICAL INDUSTRIES. LTD.,)))	Civil Action No. 14-cv-2758 (PAC)
Plaintiffs, v.)	Electronically Filed
AMNEAL PHARMACEUTICALS, LLC))	
Defendant.	<u> </u>	

ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS OF DEFENDANT AMNEAL PHARMACEUTICALS, LLC

Defendant-Counterclaim Plaintiff Amneal Pharmaceuticals, LLC ("Amneal") by its attorneys, hereby responds to the Complaint of Plaintiffs-Counterclaim Defendants Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc. and Nissan Chemical Industries, Ltd ("Plaintiffs") as follows:

JURISDICTION AND VENUE

1. Admitted in part and denied in part. Amneal admits that this is an action by Plaintiffs against Amneal alleging patent infringement under 35 U.S.C. §§ 271(e) (2), 271(b),



271(c), and 281-283. Amneal denies the remaining allegations of Paragraph 1. Amneal will not contest subject matter or personal jurisdiction for purposes of this action only.

PARTIES

- 2. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2, and therefore denies them.
- 3. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3, and therefore denies them.
- 4. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 4, and therefore denies them.
 - 5. Admitted.
- 6. Admitted in part and denied in part. Amneal admits only that it is registered as a Pharmacy Establishment in the State of New York and has facilities located in Hauppauge and Brookhaven, New York. Amneal denies the remaining allegations of Paragraph 6.
- 7. Admitted in part and denied in part. Amneal admits only that it is registered as a Foreign Limited Liability Company in New York. Amneal denies the remaining allegations of Paragraph 7.

THE NEW DRUG APPLICATION

- 8. Admitted.
- 9. Admitted.
- 10. Admitted.
- 11. Admitted.



THE PATENTS IN SUIT

- 12. Admitted in part and denied in part. Amneal admits that the '336 patent is entitled, "Quinoline Type Mevalonolactones," and that the named inventors are Yoshihiro Fujikawa, Mikio Suzuki, Hiroshi Iwasaki, Mitsuaki Sakashita, and Masaki Kitahara. Amneal further admits that the '336 patent issued on January 5, 199 and that a purported copy of the '336 patent is attached to Plaintiffs' complaint as Exhibit A. Amneal states that the claims of the patent speak for themselves, subject to construction by the Court. Amneal is without knowledge or information sufficient to form a belief as to the remaining allegations of Paragraph 12, and therefore denies those allegations.
- 13. Admitted in part and denied in part. Amneal admits that the '336 patent will expire on December 25, 2020. Amneal is without knowledge sufficient to form a belief as to the remaining allegations of Paragraph 13, and therefore denies those allegations.
- 14. Admitted in part and denied in part. Amneal admits that the '993 patent is entitled "Crystalline Forms of Pitavastatin Calcium," and that the named inventors are Paul Adriaan Van Der Schaaf, Fritz Blatter, Martin Szelagiewicz, and Kai-Uwe Schoening. Amneal also admits that the '993 patent issued on October 15, 2013. Amneal states that the claims of the '993 patent speaks for themselves, subject to construction by the Court. Amneal is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 14, and therefore denies those allegations.
- 15. Admitted in part and denied in part. Amneal admits that the '993 patent expires on February 2, 2024. Amneal is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 15, and therefore denies those allegations.



- 16. Amneal admits that KPA sells a pitavastatin drug product in the United States under the trade name Livalo [®]. Amneal is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 16, and therefore denies those allegations.
- 17. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 17, and therefore denies those allegations.
 - 18. Denied.

COUNT I

INFRINGEMENT OF THE '336 PATENT UNDER 35 U.S.C. S 271(e)(2)(a)

- 19. Amneal repeats its responses to Paragraphs 1 through 18 above, which are explicitly incorporated by reference.
 - 20. Admitted.
- 21. Admitted in part and denied in part. Amneal admits that the Amneal ANDA contains a paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) respecting the '336 patent. Amneal denies the remaining allegations of Paragraph 21.
- 22. Admitted in part and denied in part. Amneal admits that the Amneal ANDA contains a paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) respecting the '336 patent. Amneal denies the remaining allegations of Paragraph 22.
- 23. Admitted in part and denied in part. Amneal admits that it notified Plaintiffs by letter dated March 5, 2014 that Amneal had submitted the Amneal ANDA containing a Paragraph IV certification respecting the '336 patent. Amneal is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 23, and therefore denies those allegations.



- 24. Amneal states that its March 5, 2014 Notice Letter speaks for itself and respectfully refers the Court to that letter for its contents.
 - 25. Denied.
 - 26. Denied.
- 27. Amneal states that its proposed labeling material is a part of its ANDA and that such material speaks for itself. Amneal respectfully refers the Court to that material for its contents.
 - 28. Denied.

COUNT II

INFRINGEMENT OF THE METHOD CLAIM OF THE '336 PATENT UNDER 35 U.S.C. § 271(b)

- 29. Amneal repeats its responses to Paragraph 1-28 above which are explicitly incorporated by reference.
 - 30. Denied.
- 31. Amneal states that its proposed labeling material are a part of its ANDA and that such material speaks for itself. Amneal respectfully refers the Court to that material for its contents.
- 32. Admitted in part and denied in part. Amneal states that it is aware of the label indications for Livalo®, which include the use of pitavastatin as an adjunct therapy to diet to treat primary hyperlipidemia and mixed dyslipidemia. Amneal denies the remaining allegations in Paragraph 32.
 - 33. Denied.



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