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**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

Kowa Company, Ltd.,  
Kowa Pharmaceuticals America, Inc., and  
Nissan Chemical Industries, Ltd.,

Plaintiffs,

v.

Amneal Pharmaceuticals, LLC,

Defendant.

Civil Action No. 14-cv-2758 (PAC)

**ANSWER TO COUNTERCLAIM**

Plaintiffs, Kowa Company, Ltd. (“KCL”), Kowa Pharmaceuticals America, Inc. (“KPA”) (collectively, “Kowa”), and Nissan Chemical Industries, Ltd. (“NCI”) (collectively, “Counterdefendants”) by their undersigned counsel, answer the counterclaim of defendant Amneal Pharmaceuticals, LLC (“Amneal” or “Counterplaintiff”), as follows:

1. Paragraph 1 states a conclusion of law rather than an allegation of fact to which a response is required. Counterdefendants admit, insofar as a response is required, that Counterplaintiff's counterclaim purports to arise under the patent laws of the United States and purports to be for declaratory judgment.

2. Paragraph 2 states a conclusion of law rather than an allegation of fact to which a response is required. Counterdefendants admit, insofar as a response is required, that Counterplaintiff's counterclaim purports to arise out of the same transactions and occurrences that are the subject of the claims asserted in the Complaint in the above-captioned action.

3. Paragraph 3 states a conclusion of law rather than an allegation of fact to which a response is required. Counterdefendants admit, insofar as a response is required, that Counterplaintiff's counterclaim purports to arise under the patent laws of the United States and purports to be for declaratory judgment.

4. Paragraph 4 states a conclusion of law rather than an allegation of fact to which a response is required. Counterdefendants admit, insofar as a response is required, that venue is proper in this district under 28 U.S.C. §§ 1391(b) and (c).

5. Counterdefendants admit, on information and belief, the allegations contained in paragraph 5.

6. Denied as phrased. Admitted that Counterdefendant KCL is a Japanese corporation having its corporate headquarters and principal place of business in Aichi, Japan.

7. Denied as phrased. Admitted that Counterdefendant KPA is a wholly owned U.S. subsidiary of KCL, and that KPA has its principal place of business and corporate headquarters in Montgomery, Alabama.

8. Admitted that Counterdefendant NCI is a Japanese corporation having its principal place of business in Tokyo, Japan.

11.<sup>1</sup> Admitted.

12. Admitted.

15.<sup>2</sup> Paragraph 15 states a conclusion of law rather than allegations of fact to which a response is required. Counterdefendants admit, insofar as a response is required, that Counterplaintiff has purported to establish an actual controversy with respect to the noninfringement and/or invalidity of U.S. Patent Nos. 5,856,336 (“the ‘336 patent”) and 8,557,993 (“the ‘993 patent”) (collectively, “the patents-in-suit”).

16. Counterdefendants admit, on information and belief, the allegations contained in paragraph 16.

17. The allegations contained in paragraph 17 contain characterizations of a document which speaks for itself, and Counterdefendants deny the allegations contained in paragraph 17 to the extent incomplete or inconsistent with the Complaint. Further answering, Counterdefendants admit that Amneal’s act of submitting ANDA No. 20-5961 infringed the patents-in-suit.

18. Admitted that Counterplaintiff denies that it infringes any valid and enforceable claim of the patents-in-suit.

19. Paragraph 19 states a conclusion of law rather than allegations of fact to which a response is required. Counterdefendants admit, insofar as a response is required, that Counterplaintiff has purported to establish an actual controversy between itself and Counterdefendants with respect to whether it infringes any valid and enforceable claim of the patents-in-suit.

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<sup>1</sup> Counterplaintiff’s counterclaim does not contain a paragraph 9 or a paragraph 10.

<sup>2</sup> Counterplaintiff’s counterclaim does not contain a paragraph 13 or a paragraph 14.

20. In response to paragraph 20, Counterdefendants lack information sufficient to form a belief as to Counterplaintiff's beliefs, and therefore deny the allegations contained in paragraph 20.

21. In response to paragraph 21, Counterdefendants deny the allegations contained therein.

**First Counterclaim- Noninfringement of the '336 and '993 Patents**

22. In response to paragraph 22, Counterdefendants repeat and incorporate herein by reference their responses to paragraphs 1 through 21 above.

23. In response to paragraph 23, Counterdefendants deny the allegations contained therein.

**Second Counterclaim- Invalidity of the '336 and '993 Patents**

24. In response to paragraph 24, Counterdefendants repeat and incorporate herein by reference their responses to paragraphs 1 through 23 above.

25. In response to paragraph 25, Counterdefendants deny the allegations contained therein.

**WHEREFORE**, Plaintiffs and Counterdefendants Kowa and NCI respectfully request that the Court enter judgment against Defendant and Counterplaintiff Amneal Pharmaceuticals, LLC as follows:

- (a) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that making, using, selling, offering to sell and/or importing Amneal's pitavastatin drug product for which it seeks FDA approval or any drug product containing pitavastatin will infringe at least one claim of one or more of the patents-in-suit;

- (b) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that the making, using, offering for sale, selling and/or importing of Amneal's pitavastatin drug product or any drug product containing pitavastatin, will induce the infringement at least one claim of one or more of the patents-in-suit;
- (c) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that the making, using, offering for sale, selling and/or importing of Amneal's pitavastatin drug product or any drug product containing pitavastatin, will contribute to the infringement of at least one claim of one or more of the patents-in-suit;
- (d) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. and an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for Amneal to commercially make, use, sell, offer to sell or import its pitavastatin drug product or any drug product containing pitavastatin be no earlier than the date following the expiration date of the last to expire of the patents-in-suit (as extended, if applicable);
- (e) a permanent injunction restraining and enjoining against any infringement by defendant, its officers, agents, attorneys, employees, successors or assigns, or those acting in privity or concert with them, of the patents-in-suit, through the commercial manufacture, use, sale, offer for sale or importation into the United States of Amneal's pitavastatin drug product or any drug product containing pitavastatin, and/or any inducement of or contribution to the same;
- (f) That Counterplaintiff take nothing by its First Counterclaim and Second Counterclaim against Counterdefendants, and that its First Counterclaim and Second Counterclaim be dismissed with prejudice;

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