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October 3, 2014

VIA ECF

Hon. Paul A. Crotty
United States District Judge
United States Courthouse
500 Pearl Street, Room 735
New York, NY 10007

Re: *Kowa Company, Ltd., et al. v Aurobindo Pharma Limited , et al., and related cases*, 14-cv-2497-PAC, 14-cv-2647-PAC, 14-cv-2758, 14-cv-2759, 14-cv-27-60-PAC, and 14-cv-5575-PAC.

Dear Judge Crotty,

We represent plaintiffs Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd. ("Plaintiffs") in this matter. We write on behalf of all parties, and respectfully submit this joint letter pursuant to Your Honor's Individual Practice Rule 6G, addressing the following:

1. The names, addresses (including firm names), e-mail addresses, telephone, and fax numbers of trial counsel.

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[1] We believe that Amneal is in agreement with this submission but have not yet received final confirmation.

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2. A brief description of the case, including the factual and legal bases for the claim(s) and defense(s).

Kowa Pharmaceuticals America, Inc. ("KPA") sells pharmaceutical products containing the active ingredient pitavastatin calcium under the trade name Livalo® in the United States pursuant to the United States Food and Drug Administration's ("FDA") approval of New Drug Application No. 22-363 ("pitavastatin NDA"). Kowa Company, Ltd., ("KCL") represents it is the holder of the pitavastatin NDA. Nissan Chemical Industries, Ltd. ("NCI") represents it has been and still is the owner through assignment of United States Patent No. 5,856,336 ("the '336 patent"). KCL and KPA represent that they are licensed under the '336 patent. KCL and NCI represent that they have been and still are the owners through assignment of United States Patent No. 6,465,477 ("the '477 patent"). KPA represents it is licensed under the '477 patent. NCI

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represents it has been and still is the owner through assignment of United States Patent No. 8,557,993 ("the '993 patent"). KCL and KPA represent they are licensed under the '993 patent. The '336 patent, '477 patent, and '993 patent (collectively the "patents-in-suit") are listed in the Orange Book for pitavastatin calcium.

These are Hatch-Waxman cases (35 U.S.C. § 271(e)) involving the submission of various separately owned and developed Abbreviated New Drug Applications ("ANDA") with the FDA under 21 U.S.C. § 355(j). Various defendants in these civil actions filed these ANDAs, which seek approval to market drug products comprising pitavastatin calcium. Various of the defendants in these civil actions also served Plaintiffs with a "Paragraph IV" notice letter pursuant to 21 U.S.C. § 355(j)(2)(B), contending that one or more of the patents-in-suit are invalid and/or will not be infringed by the individual defendants' sale of their pitavastatin drug products. In response, Plaintiffs have filed these patent infringement suits seeking relief against each defendant for, inter alia, infringement under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), inducing infringement under 35 U.S.C. § 271(b), and/or contributory infringement under 35 U.S.C. § 271(c).

3. A brief statement by plaintiff as to the basis of subject-matter jurisdiction and a brief statement by each other party as to the presence or absence of subject-matter jurisdiction. Such statements shall include citations to all statutes relied on and relevant facts as to citizenship and jurisdictional amount.

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