

# EXHIBIT 2

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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

Kowa Company, Ltd., et al.,

Plaintiffs,

v.

Amneal Pharmaceuticals, LLC

Defendant.

14-CV-2758 (PAC)

**FINDINGS OF FACT AND**  
**CONCLUSIONS OF LAW**

HONORABLE PAUL A. CROTTY, United States District Judge:

This is a Hatch-Waxman patent infringement litigation initiated by Plaintiffs Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd. (collectively, "Plaintiffs"), manufacturers of the cholesterol-lowering drug Livalo<sup>®</sup>, against defendant Amneal Pharmaceuticals, LLC ("Amneal"), a generic drug manufacturer. Plaintiffs allege that Amneal's proposed Abbreviated New Drug Application ("ANDA") product would infringe U.S. Patent No. 5,856,336 ("the '336 patent"). Amneal concedes infringement of claims 1 and 2 of the '336 patent, but contends that the patent is invalid on the grounds of obviousness-type double patenting over claims 1 and 5 of U.S. Patent No. 5,872,130 ("the '130 patent").<sup>1</sup>

After considering the parties' arguments, memoranda of law, and proposed findings of fact and conclusions of law, and evaluating the evidence produced at trial, including the

<sup>1</sup> Plaintiffs commenced this litigation against eight defendants, each of which was a generic drug manufacturer, and asserted infringement of the '336 patent in six of the actions. By the time the Court held a ten-day bench trial from January 17 through January 30, 2017, with closing arguments held on February 3, 2017, only four of the eight defendants remained. One defendant settled mid-trial; another settled post-trial. Now, only Amneal still challenges the '336 patent. Both Amneal and Apotex challenge the validity of the '993 patent, but Amneal concedes infringement.

documentary record and witness testimony, the Court determines that Amneal has failed to satisfy its burden of proof of demonstrating invalidity for three reasons.

First, since the '336 patent was issued and originally expired earlier than the '130 patent, there can be no double patenting. The span of the '336 patent was extended by a Hatch-Waxman Patent Term Extension, which provides patent-holding manufacturers extended protection. This protection is an integral part of the legislation which allows generic drug manufacturers expedited access to the market. But the extension of the '336 patent term has nothing to do with, and is not invalidated by, the obviousness-type double patenting doctrine.

Second, even if the '130 patent were available as an obviousness-type double patenting reference, Amneal has failed to meet its burden of establishing by clear and convincing evidence that the '336 patent claims are obvious in view of the '130 patent claims. A person of ordinary skill in the art at the time would not have had a reasonable expectation of success in modifying the pitavastatin sodium in the '130 patent by substituting calcium for sodium and preparing the pitvastatin calcium salt claimed by the '336 patent, nor would it have been obvious to do so.

Third, assuming *arguendo* that Amneal had satisfied its burden of demonstrating obviousness-type double patenting, the objective secondary considerations evidence of non-obviousness presented by Plaintiffs would rebut Amneal's prima facie case.

The '336 patent is valid.

## FINDINGS OF FACT

### I. THE PARTIES

1. Plaintiff Kowa Company, Ltd. (“KCL”) is a Japanese corporation with its corporate headquarters and principal place of business in Aichi, Japan.<sup>2</sup> (Compl. ¶ 2, ECF 2).<sup>3</sup> Plaintiff Kowa Pharmaceuticals America, Inc. (“KPA”) is a wholly-owned subsidiary of KCL organized under the laws of Delaware, with its corporate headquarters and principal place of business in Montgomery, Alabama. (*Id.*). Plaintiff Nissan Chemical Industries, Ltd. (“NCI”) is a Japanese corporation with its corporate headquarters and principal place of business in Tokyo, Japan. (*Id.* ¶ 3). Plaintiffs are manufacturers, researchers, developers, and marketers of the cholesterol-lowering drug Livalo<sup>®</sup>. (*Id.* ¶ 4).

2. Defendant Amneal is incorporated in Delaware, with a place of business in Bridgewater, New Jersey. (*Id.* ¶ 5; Answer ¶ 5, ECF 17). Amneal filed an ANDA with the Food and Drug Administration (“FDA”) under 21 U.S.C. § 355(j), seeking approval to market 1 mg, 2 mg, and 4 mg tablets comprising pitavastatin calcium. (Compl. ¶ 20; Answer ¶ 20). The ANDA filing contains a paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) respecting the ’336 patent. (Answer ¶ 21).

### II. THE ’336 PATENT

3. The ’336 patent is assigned to NCI. (Compl. ¶ 13). KCL is NCI’s licensee for the ’336 patent, and KPA holds a license from KCL for the ’336 patent. (*Id.*).

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<sup>2</sup> The Court has made its findings or conclusions based upon its own review of the evidence and the law, even though it may utilize the parties’ submissions. To the extent that any finding of fact may be considered a conclusion of law, or vice versa, each should be considered as such.

<sup>3</sup> All ECF citations in these Findings of Fact and Conclusions of Law refer to the electronic docket of the Amneal action, 14-CV-2758.

4. Plaintiffs assert that Amneal's proposed ANDA product would infringe the '336 patent. (Tr. at 14; 25; 1785–86). Amneal does not dispute that its proposed ANDA product would infringe claims 1 and 2 of the '336 patent, but contends that such claims are invalid for obviousness-type double patenting over claims 1 and 5 of the '130 patent. (Tr. at 14; 16; 25; 44–46; 353; 1775–76).

5. Plaintiffs maintain that the '130 patent may not be used as a reference to invalidate the '336 patent, and that Amneal has otherwise failed to meet its burden of proof of establishing invalidity. (Tr. at 17–18; 1785–91).

**A. The '336 Patent Claims**

6. The '336 patent, "Quinoline Type Mevalonolactones," consists of two claims: claim 1 describes the chemical compound of the calcium salt of pitavastatin; claim 2 describes a method of reducing certain lipid disorders through administration of an effective amount of the compound of formula A as defined in claim 1. (PTX-142).

7. The '336 patent covers Livalo<sup>®</sup>. (PTX-0170 at KN001333523–615).

**B. The '130 Patent Claims**

8. Claim 1 of the '130 patent describes several chemical compounds, including the sodium salt of pitavastatin. (PTX-290). Claim 5 describes a method of reducing certain lipid disorders through administration of an effective amount of the compound of formula A as defined in claim 1. (PTX-290).

**C. Prosecution History of the '336 and '130 Patents**

9. The '336 and '130 patents arose from the same U.S. patent application, filed on August 19, 1988, which claimed priority to a Japanese application filed on August 20, 1987. (PTX-142; PTX-290).

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