

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

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

Plaintiffs,

v.

Amneal Pharmaceuticals, LLC,

Defendants.

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

AMNEAL PHARMACEUTICALS LLC'S POST-TRIAL BRIEF REGARDING
INVALIDITY OF CLAIMS 1 AND 2 OF THE '336 PATENT FOR
OBVIOUSNESS-TYPE DOUBLE PATENTING

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Claims 1 and 2 of the '336 patent are invalid for obviousness-type double patenting over claims 1 and 5 of the '130 patent. The salient facts established at trial are undisputed, and demonstrate by clear and convincing evidence that the claims of the '336 patent are patentably indistinct and obvious variants of the claims of the '130 patent.

The only real dispute over obviousness-type double patenting is purely legal. Plaintiffs contend that the '130 patent is not available as a reference against the '336 patent. The Court should reject Plaintiffs' legal argument because it is contrary to Federal Circuit guidance and seeks to countermand the very bedrock principles and public policy objectives of patent law that the doctrine of obviousness-type double patenting exists to protect.

I. BACKGROUND: THE '336 PATENT AND THE '130 PATENT

A. The '336 Patent

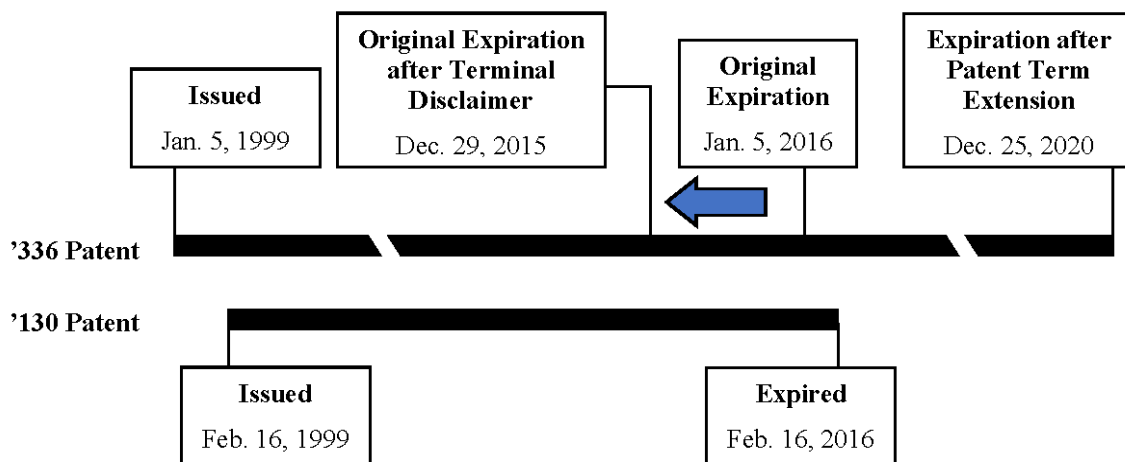
The patent subject to Amneal's obviousness-type double patenting ("ODP") challenge is U.S. Patent No. 5,856,336 ("the '336 patent"). The '336 patent contains two claims. Claim 1 claims the calcium salt of pitavastatin, and claim 2 claims a method of reducing certain lipid disorders by administering that salt. (DTX-0032 at 9130.) The '336 patent is assigned to Nissan Chemical Industries, Ltd. ("Nissan"). It issued on January 5, 1999, and its named inventors are Yoshihiro Fujikawa, Mikio Suzuki, Hiroshi Iwasaki, Mitsuaki Sakashita, and Masaki Kitahara. (*Id.* at 9114.)

The '336 patent was originally going to expire on January 5, 2016. (PTX-0170 at KN001333527, -617.) But in September 2009, Nissan applied for Patent Term Extension ("PTE") pursuant to 35 U.S.C. §156, in view of FDA regulatory review of Livalo®. (PTX-0170 at KN001333523.) The PTO granted this request in April 2013, extending the '336 patent by 1,823 days, and setting the new expiration date at January 1, 2021. (PTX-0170 at KN001333616–20.) Thereafter, in July 2013, Nissan terminally disclaimed the '336 patent over U.S. Patent No. 5,854,259. (PTX-0170 at KN001333621–22.) In its terminal disclaimer, Nissan stated that it was

refusing to disclaim any portion of its PTE. (PTX-0170 at KN001333621–22.) Accordingly, the '336 patent is not set to expire until December 25, 2020.

B. The '130 Patent

The reference patent for ODP is U.S. Patent No. 5,872,130 (“the '130 patent”). The '130 Patent has the same assignee (Nissan), and the same named inventors as the '336 patent. (DTX-0264, front page.) The '130 patent issued on February 16, 1999. (DTX-0264, front page.) The '130 patent expired on February 16, 2016, which is after the original expiration date of the '336 patent, but more than four years before the actual expiration date of the '336 patent after PTE. The lives of the '336 and '130 patents are depicted graphically below:



Claim 1 of the '130 patent claims several compounds, including the sodium salt of pitavastatin. Claim 5 claims a method of reducing certain lipid disorders by administering any of the compounds of claim 1. (*Id.* at 39:25–40:14, 40:26–31.)

II. ARGUMENT

The evidence presented at trial relating to ODP stands unrebutted. Amneal’s expert witness, Dr. Anthony Palmieri, testified that Claim 1 of the '336 patent is a patentably indistinct and obvious variant of claim 1 of the '130 patent, and that claim 2 of the '336 patent is a patentably indistinct and

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