

**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 PROPOSED FINDINGS OF FACT AND  
CONCLUSIONS OF LAW REGARDING INVALIDITY OF CLAIMS 1 AND 2 OF THE  
'336 PATENT FOR OBVIOUSNESS-TYPE DOUBLE PATENTING**

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## I. INTRODUCTION

1. Amneal contends that Claims 1 and 2 of U.S. Patent No. 5,856,336 (“the ’336 patent”) are invalid over claims 2 and 5, respectively, of U.S. Patent No. 5,872,130 (“the ’130 patent”) under the doctrine of Obviousness-Type Double Patenting (“ODP”).

2. The facts relating to this defense and the scientific conclusions based on those facts are largely undisputed. Amneal’s expert witness, Dr. Anthony Palmieri, testified that Claim 1 of the ’336 patent is an obvious variant of claim 1 of the ’130 patent, and that claim 2 of the ’336 patent is an obvious variant of claim 5 of the ’130 patent. Plaintiffs did not present any evidence to refute those facts or conclusions. Plaintiffs did present certain evidence relating to secondary considerations of non-obviousness, which is addressed below in section II.D.

3. Plaintiffs contend that as a matter of law, the ’130 patent is not a proper ODP reference against the ’336 patent. The Court’s findings of fact are set forth first below, followed by the Court’s conclusions on the disputed issue of law.

## II. PROPOSED FINDINGS OF FACT REGARDING ODP

### A. The ’336 Patent

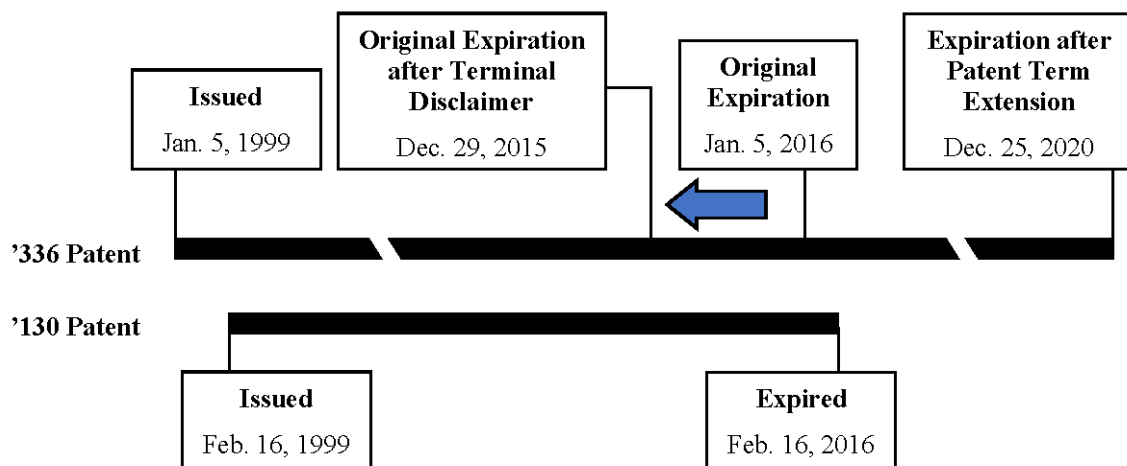
4. The ’336 patent is assigned to Nissan Chemical Industries, Ltd. (“Nissan”), and issued on January 5, 1999. (DTX-0032 at 9114.) The named inventors are Yoshihiro Fujikawa, Mikio Suzuki, Hiroshi Iwasaki, Mitsuaki Sakashita, and Masaki Kitahara. (*Id.*)

5. The ’336 patent originally was going to expire on December 29, 2015, but Nissan requested and obtained 1,823 days of Patent Term Extension (“PTE”) pursuant to 35 U.S.C. §156, in view of FDA regulatory review of Livalo®. Nissan terminally disclaimed the ’336 patent over U.S. Patent No. 5,854,259. (PTX-0170 at KN001333621.) Thus, the ’336 patent does not expire until December 25, 2020.

6. The '336 patent contains two claims, and both are asserted against Amneal. Claim 1 claims the calcium salt of pitavastatin; claim 2 claims a method of reducing certain lipid disorders by administering the calcium salt of pitavastatin. (DTX-0032 at 9130.)

### B. The '130 Patent

7. The '130 Patent is also assigned to Nissan, and has 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 several months after the original expiration date of the '336 patent, but over four years before the actual expiration date of the '336 patent after patent term extension. These dates can be represented on a timeline as follows:



8. 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.)

### C. Comparison of the '336 patent claims and the '130 patent claims<sup>1</sup>

9. Below, the '336 patent claims are set forth beside claims 1 and 5 of the '130 patent.

<sup>1</sup> There are no claim construction disputes relating to the '336 or '130 patents.

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