UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Kowa Company, Ltd., et al., Plaintiffs, v. Amneal Pharmaceuticals, LLC Defendant.	Civil Action No. 14-CV-2758 (PAC)
Kowa Company, Ltd., et al., Plaintiffs, v. Apotex, Inc., et al., Defendants.	Civil Action No. 14-CV-7934 (PAC)

PLAINTIFFS' PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

I. THE '336 PATENT

1. Plaintiffs assert that Amneal's ANDA product would infringe the '336 Patent. (Trial Tr. at 1785-86.)

2. Amneal has stipulated that its proposed ANDA product comprises (3R,5S)-7-(2-cyclopropyl-4-(4-fluorophenyl)quinolin-3-yl]-3,5-dihydroxy-6(E)-heptenoic acid hemicalcium salt, also known as pitavastatin calcium, and that the commercial manufacture, use, importation, sale and/or offer for sale within the United States of its ANDA Product would infringe claims 1 and 2 of the '336 patent, provided that such claims are not found to be invalid. (Tr. at 353.)

3. Amneal's sole remaining defense regarding the '336 Patent is its assertion that claims 1 and 2 of the '336 Patent should be held invalid on grounds of obviousness-type double patenting. Claims 1 and 5 of the '130 Patent are the only basis for Amneal's obviousness-type double-patenting defense. (Tr. at 1775-76.)

4. Plaintiffs maintain that the '130 patent cannot be used as a reference to invalidate the '336 patent, and that Amneal has otherwise failed to meet its burden of proof on the merits. (Tr. at 1785-91.)

A. Prosecution History of the '336 and '130 Patents

5. The '130 and '336 patents are related; they arose from a patent application filed in the USPTO on August 19, 1988, which claimed priority to an earlier application filed in Japan on August 20, 1987. (PTX-142; PTX 290.)

6. The claims in both the '130 and '336 patents were examined on two occasions by the same examiners, Examiners Laura Stockton and Johann Richter, and on both occasions the claims were found to be in condition for allowance. (PTX-0170 at KN001333506, KN00133513 (re the '336 Patent application); PTX-0131 at KN000838907, KN000838919 (re the '130 Patent application).)

7. Examiner Stockton deemed the claims of each application to be "in condition for allowance" on the same date, September 24, 1998. (PTX-0170 at KN001333506, KN00133513 (re the '336 Patent application); PTX-0131 at KN000838907, KN000838919 (re the '130 Patent application).)

8. The USPTO mailed a "Notice of Allowability" on September 30, 1998, in each of those patent applications. (PTX-0170 at KN00133515 (regarding the '336 Patent application); PTX-0131 at KN000838922 (regarding the '130 Patent application).)

9. NCI paid the issue fees on both applications on the same day, October 15, 1998. (PTX-0170 at KN00133522 (regarding the '336 patent application); PTX-0131 at KN000838930 (regarding the '130 patent application).)

10. The '336 patent issued on January 5, 1999. (PTX-142).

11. The '130 patent issued on February 16, 1999. (PTX-290.)

12. The original expiration date of the '336 patent was January 5, 2016. (PTX-142.)

13. The original expiration date of the '130 patent was February 16, 2016. (PTX 290.)

14. The original term of the '336 patent was later shortened by a few days when Nissan filed a terminal disclaimer making it coterminous with another patent owned by NCI, U.S. Patent No. 5,854,259 (the "'259 Patent"). (PTX-170 at KN001333621-22.)

15. As a result of the terminal disclaimer, and but for a Hatch Waxman patent term extension, the expiration date of the '336 patent would have been December 29, 2015. (See PTX-170 at KN001333621-22.)

B. The Hatch Waxman Act Patent Term Extension of the '336 Patent

16. Plaintiffs sought regulatory approval from the U.S. Food and Drug Administration ("FDA") for Livalo® (pitavastatin calcium), which is covered by the '336 patent. (PTX-0170 at KN001333523-615).

17. The FDA's regulatory review period began in June 2000 and went on for more than nine years. (PTX-0170 at KN001333530-44.)

18. After the '336 patent issued, and after the FDA approved Livalo®, Plaintiffs selected the '336 patent for a Hatch Waxman Act patent term extension under 35 U.S.C. § 156, and applied for an extension based on the regulatory review period for Livalo®. (*Id.* at KN001333523-615).

19. On April 29, 2013, the USPTO granted that application and extended the term of the '336 patent for a period of 1,823 days. (PTX-170 at KN00133619-20.)

20. As extended by § 156, the '336 patent term (as shortened based on the disclaimer to the '259 patent term) will expire on December 25, 2020. (PTX-170 at KN00133619-20.)[1]

[1] The '259 patent expiration date was December 29, 2015 (7 days before the original expiration date of the '336 patent and 49 days before the original expiration date of the '130 patent, namely February 16, 2016). The patent term extension originally extended the '336 patent term to January 1, 2021 (1823 days after the '336 patent's original expiration date (January 5, 2016)). After the terminal disclaimer was filed with regard to the '259 patent, the Patent Office correspondingly shortened the extended patent term of the '336 Patent such that it runs 1823 days from December 29, 2015, and thus expires on December 25, 2020 rather than January 1, 2021.

CONCLUSIONS OF LAW

II. THE PRESUMPTION OF VALIDITY & THE BURDEN OF PROOF

21. By express Congressional declaration, patents are to be presumed valid. Each patent claim is independently presumed valid, even if other claims within the same patent are held invalid. 35 U.S.C. § 282.

III. CLAIMS 1 AND 2 OF THE '336 PATENT ARE NOT INVALID UNDER THE DOCTRINE OF OBVIOUSNESS-TYPE DOUBLE PATENTING[2]

22. Amneal, as the party challenging the validity of the '336 patent, must prove invalidity by clear and convincing evidence. *See, e.g., Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340, 1362 (Fed. Cir. 2009) (affirming district court's grant of JMOL of no obviousness-type double patenting where "the identified differences between the asserted claims … and [the allegedly invalidating claims] renders the claims patentably distinct.").

A. The Doctrine of Obviousness-Type Double Patenting

23. The double patenting doctrine was judicially created in the 1800s. *See Suffolk Co. v. Haden*, 70 U.S. 315; 3 Wall. 315, 319 (1866); *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 197 (1894).

24. The doctrine arose based on the rationale that because 35 U.S.C. § 101 states that an inventor may obtain "a patent" for an invention, the statute permits only one patent to be obtained for a single invention. *E.g.*, Abbvie Inc. v. Mathilda & Terrence Kennedy Inst. of Rheumatology Trust, 764 F.3d 1366, 1372 (Fed. Cir. 2014)..

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[2] Obviousness-type double patenting was never properly placed at issue in this litigation, as Amneal did not raise it as an affirmative defense, nor move the Court for leave to add it. In any event, Amneal has failed to prove that the '336 Patent is invalid.

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