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)

[PROPOSED] FINAL JUDGMENT

This matter having come on for trial on the merits before the undersigned Hon. Paul A. Crotty (without a jury), and having been tried to conclusion between January 17, 2017 and January 30, 2017, with closing arguments held on February 3, 2017, and upon all of the prior pleadings and proceedings herein, and upon and in accordance with the Court's Findings of Fact and Conclusions of Law dated April 11, 2017 and September 19, 2017, it is hereby ORDERED, ADJUDGED and DECREED as follows:

1. Defendant Amneal Pharmaceuticals, LLC ("Amneal") has failed to meet its burden of proving that U.S. Patent No. 5,856,336 ("the '336 patent") is invalid. The '336 patent is valid. All affirmative defenses and counterclaims asserted by Amneal with respect to the '336 patent are hereby dismissed on the merits and with prejudice.

2. Amneal admitted infringement of claims 1 and 2 of the '336 patent in this action. Amneal infringed claims 1 and 2 of the '336 patent by filing Abbreviated New Drug Application ("ANDA") No. 20-5961 with the Food and Drug Administration ("FDA") including a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355). Amneal would further infringe claims 1 and 2 of the '336 patent by making, using, offering to sell, or selling within the United States or by importing into the United States pitavastatin calcium tablets as described in ANDA No. 20-5961.

3. Amneal has failed to meet its burden of proving that U.S. Patent No. 8,557,993 ("the '993 patent") is invalid. The '993 patent is valid. All affirmative defenses and counterclaims asserted by Amneal with respect to the '993 patent are hereby dismissed on the merits and with prejudice.

4. Amneal admitted infringement of claims 1, 22, 23, 24, and 25 of the '993 patent in this action. Amneal infringed claims 1, 22, 23, 24, and 25 of the '993 patent by filing ANDA

No. 20-5961 with the FDA including a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355). Amneal would further infringe claims 1, 22, 23, 24, and 25 of the '993 patent by making, using, offering to sell, or selling within the United States or by importing into the United States pitavastatin calcium tablets as described in ANDA No. 20-5961.

5. Amneal, its officers, agents and employees, and all persons acting (directly or indirectly) in privity or concert with them, are permanently enjoined pursuant to 35 U.S.C. § 271(e)(4)(B) from making, using, offering to sell or selling within the United States and from importing into the United States the pitavastatin calcium product as described in ANDA No. 20-5961 until after February 2, 2024, the expiration of the '993 patent, as that date may be extended pursuant to law.

6. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Amneal's ANDA No. 20-5961, or amendments thereof, shall be a date which is not earlier than February 2, 2024, after the expiration date of the '993 patent, as that date may be extended pursuant to law.

7. Defendants Apotex, Inc. and Apotex Corp. (collectively, "Apotex") have failed to meet their burden of proving that U.S. Patent No. 8,557,993 is invalid. The '993 patent is valid. All affirmative defenses and counterclaims asserted by Apotex with respect to the '993 patent are hereby dismissed on the merits and with prejudice.

8. Apotex infringed the '993 patent by filing Abbreviated New Drug Application ("ANDA") No. 20-6068 with the Food and Drug Administration ("FDA") including a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355). Apotex would further infringe claims 1, 22, 23, 24, and 25 of the '993 patent by

making, using, offering to sell, or selling within the United States or by importing into the United States pitavastatin calcium tablets as described in ANDA No. 20-6068.

9. Apotex, its officers, agents and employees, and all persons acting (directly or indirectly) in privity or concert with them, are permanently enjoined pursuant to 35 U.S.C. § 271(e)(4)(B) from making, using, offering to sell or selling within the United States and from importing into the United States the pitavastatin calcium product as described in ANDA No. 20-6068 until after February 2, 2024, the expiration of the '993 patent, as that date may be extended pursuant to law.

10. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Apotex's ANDA No. 20-6068, or amendments thereof, shall be a date which is not earlier than February 2, 2024, after the expiration date of the '993 patent, as that date may be extended pursuant to law.

11. Plaintiffs Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd. (collectively "Plaintiffs") have requested that the Court award their reasonable attorney fees pursuant to 35 U.S.C. § 285. Plaintiffs may file a motion requesting such additional relief within 21 days of the date hereof, with a briefing schedule to be set by the Court.

Dated: New York, New York
October 10, 2017

SO ORDERED

PAUL A. CROTTY
United States District Judge