

271(c), and 281-283. Amneal denies the remaining allegations of Paragraph 1. Amneal will not contest subject matter or personal jurisdiction for purposes of this action only.

PARTIES

2. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2, and therefore denies them.

3. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3, and therefore denies them.

4. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 4, and therefore denies them.

5. Admitted.

6. Admitted in part and denied in part. Amneal admits only that it is registered as a Pharmacy Establishment in the State of New York and has facilities located in Hauppauge and Brookhaven, New York. Amneal denies the remaining allegations of Paragraph 6.

7. Admitted in part and denied in part. Amneal admits only that it is registered as a Foreign Limited Liability Company in New York. Amneal denies the remaining allegations of Paragraph 7.

THE NEW DRUG APPLICATION

8. Admitted.

9. Admitted.

10. Admitted.

11. Admitted.

THE PATENTS IN SUIT

12. Admitted in part and denied in part. Amneal admits that the ‘336 patent is entitled, “Quinoline Type Mevalonolactones,” and that the named inventors are Yoshihiro Fujikawa, Mikio Suzuki, Hiroshi Iwasaki, Mitsuaki Sakashita, and Masaki Kitahara. Amneal further admits that the ‘336 patent issued on January 5, 1999 and that a purported copy of the ‘336 patent is attached to Plaintiffs’ complaint as Exhibit A. Amneal states that the claims of the patent speak for themselves, subject to construction by the Court. Amneal is without knowledge or information sufficient to form a belief as to the remaining allegations of Paragraph 12, and therefore denies those allegations.

13. Admitted in part and denied in part. Amneal admits that the ‘336 patent will expire on December 25, 2020. Amneal is without knowledge sufficient to form a belief as to the remaining allegations of Paragraph 13, and therefore denies those allegations.

14. Admitted in part and denied in part. Amneal admits that the ‘993 patent is entitled “Crystalline Forms of Pitavastatin Calcium,” and that the named inventors are Paul Adriaan Van Der Schaaf, Fritz Blatter, Martin Szelagiewicz, and Kai-Uwe Schoening. Amneal also admits that the ‘993 patent issued on October 15, 2013. Amneal states that the claims of the ‘993 patent speak for themselves, subject to construction by the Court. Amneal is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 14, and therefore denies those allegations.

15. Admitted in part and denied in part. Amneal admits that the ‘993 patent expires on February 2, 2024. Amneal is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 15, and therefore denies those allegations.

16. Amneal admits that KPA sells a pitavastatin drug product in the United States under the trade name Livalo[®]. Amneal is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 16, and therefore denies those allegations.

17. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 17, and therefore denies those allegations.

18. Denied.

COUNT I

INFRINGEMENT OF THE '336 PATENT UNDER 35 U.S.C. S 271(e)(2)(a)

19. Amneal repeats its responses to Paragraphs 1 through 18 above, which are explicitly incorporated by reference.

20. Admitted.

21. Admitted in part and denied in part. Amneal admits that the Amneal ANDA contains a paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) respecting the '336 patent. Amneal denies the remaining allegations of Paragraph 21.

22. Admitted in part and denied in part. Amneal admits that the Amneal ANDA contains a paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) respecting the '336 patent. Amneal denies the remaining allegations of Paragraph 22.

23. Admitted in part and denied in part. Amneal admits that it notified Plaintiffs by letter dated March 5, 2014 that Amneal had submitted the Amneal ANDA containing a Paragraph IV certification respecting the '336 patent. Amneal is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 23, and therefore denies those allegations.

24. Amneal states that its March 5, 2014 Notice Letter speaks for itself and respectfully refers the Court to that letter for its contents.

25. Denied.

26. Denied.

27. Amneal states that its proposed labeling material is a part of its ANDA and that such material speaks for itself. Amneal respectfully refers the Court to that material for its contents.

28. Denied.

COUNT II

INFRINGEMENT OF THE METHOD CLAIM OF THE '336 PATENT UNDER 35 U.S.C. § 271(b)

29. Amneal repeats its responses to Paragraph 1-28 above which are explicitly incorporated by reference.

30. Denied.

31. Amneal states that its proposed labeling material are a part of its ANDA and that such material speaks for itself. Amneal respectfully refers the Court to that material for its contents.

32. Admitted in part and denied in part. Amneal states that it is aware of the label indications for Livalo®, which include the use of pitavastatin as an adjunct therapy to diet to treat primary hyperlipidemia and mixed dyslipidemia. Amneal denies the remaining allegations in Paragraph 32.

33. Denied.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.