

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., and PURDUE)
PHARMACEUTICALS L.P.,)
)
Plaintiffs,)
v.)
) C.A. No. _____
KASHIV PHARMA, LLC,)
)
Defendant.)

COMPLAINT

Plaintiffs, Purdue Pharma L.P. and Purdue Pharmaceuticals L.P. (collectively, “Purdue” or “Plaintiffs”), for their Complaint against Defendant Kashiv Pharma, LLC (“Kashiv”), aver as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, for infringement of United States Patent Nos. 9,763,933 (the “Mannion ’933 patent”)¹; 9,770,416 (the “’416 patent”); and 9,775,808 (the “’808 patent”) (collectively, “the patents-in-suit”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 203235 as amended, submitted, upon information and belief, by Amneal Pharmaceuticals, LLC (“Amneal’s Amended ANDA”) to the United States Food and Drug Administration (“FDA”). Plaintiffs seek judgment that Kashiv has infringed the Mannion ’933, ’416 and ’808 patents. The Mannion ’933, ’416 and ’808 patents are listed in the FDA

¹ The Mannion ’933 patent is different from U.S. Patent No. 9,073,933, which is one of the patents-in-suit asserted against Amneal Pharmaceuticals, LLC, in related action C.A. No. 15-1152-RGA, and which has been referred to as the “’933 patent.” To avoid confusion, Plaintiffs refer to U.S. Patent No. 9,073,933 as the Kupper ’933 patent.

Approved Drug Products With Therapeutic Equivalence Evaluations (“Orange Book”) as covering Purdue’s OxyContin® (oxycodone hydrochloride) (“OxyContin®”), an extended-release pain medication. Kashiv alleges to have filed Amneal’s Amended ANDA and, if so, Kashiv has infringed the patents-in-suit under 35 U.S.C. § 271(e)(2)(A). Amneal’s Amended ANDA seeks approval to market a generic version of Purdue’s OxyContin®, which is the subject of approved NDA No. 022272, in the 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg dosage strengths (“Amneal’s Amended ANDA Products”).

2. On September 17, 2015, Purdue filed a related complaint against Amneal, C.A. No. 15-831-RGA, for patent infringement of U.S. Patent Nos. 9,060,976 (the “’976 patent”) and 9,034,376 (the “’376 patent”). The previous action was filed in connection with Amneal’s ANDA No. 203235, which contained a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the ’976 patent, listed in the Orange Book as covering OxyContin®, is “unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the drug product for which ANDA No. 203235 has been submitted by Amneal.”

3. On December 15, 2015, Purdue filed a related complaint against Amneal, C.A. No. 15-1152-RGA, for patent infringement of U.S. Patent Nos. 7,674,799 (the “’799 patent”); 7,674,800 (the “’800 patent”); 7,683,072 (the “’072 patent”); 8,114,383 (the “’383 patent”); 8,309,060 (the “’060 patent”); 8,337,888 (the “’888 patent”); 8,808,741 (the “’741 patent”); 8,894,987 (the “’987 patent”); 8,894,988 (the “’988 patent”); 9,060,976 (the “’976 patent”); 9,034,376 (the “’376 patent”); and 9,073,933 (the “Kupper ’933 patent”). The previous action was filed in connection with Amneal’s Amended ANDA, which contained a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that, *inter alia*, the

'799, '800, '072, '383, '060, '888, '741, '987, '988, '976, and Kupper '933 patents, listed in the Orange Book as covering OxyContin®, are “unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the drug product for which ANDA No. 203235 has been submitted by Amneal.”

4. On March 1, 2017, Purdue filed a related complaint against Amneal, C.A. No. 17-210-RGA, for patent infringement of United States Patent Nos. 9,492,392 (the “’392 patent”); 9,492,393 (the “’393 patent”); and 9,522,919 (the “’919 patent”). The previous action was filed in connection with Amneal’s Amended ANDA, which contained a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the ’392, ’393, and ’919 patents, listed in the Orange Book as covering OxyContin®, are “unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the drug product for which ANDA No. 203235 has been submitted by Amneal.”

5. On October 10, 2017, Purdue filed a related complaint against Amneal, C.A. No. 17-1421-RGA, for patent infringement of United States Patent Nos. 9,763,886 (the “’886 patent”), the Mannion ’933 patent, and 9,675,610 (the “’610 patent”). The previous action was filed in connection with Amneal’s Amended ANDA, which contained a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the ’610 patent, listed in the Orange Book as covering OxyContin®,² is “unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the drug product for which ANDA No. 203235 has been submitted by Amneal.”

² The Mannion ’933 patent is also listed in the Orange Book as covering OxyContin®, but no “Paragraph IV” certification had been received as of the filing of the lawsuit.

6. Purdue has also filed, concurrently with the filing of the present Complaint, a related complaint against Amneal for patent infringement of the '416 and '808 patents ("the Concurrent Amneal Action"). The Concurrent Amneal Action is identical to the present Complaint, except that in the Concurrent Amneal Action, (a) Amneal is the sole-named Defendant and (b) there are no allegations of infringement with respect to the Mannion '933 patent, which are included in the related C.A. No. 17-1421. On information and belief, Amneal (not Kashiv) is the owner of Amneal's Amended ANDA. Plaintiffs are filing the present Complaint out of an abundance of caution should Kashiv demonstrate that it, in fact, is the owner of Amneal's Amended ANDA.

THE PARTIES

7. Plaintiff Purdue Pharma L.P. ("Purdue Pharma") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. Purdue Pharma is an owner of the '416 and '808 patents. Purdue Pharma is also the holder of approved NDA No. 022272 for OxyContin®, indicated for pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Purdue Pharma sells OxyContin® in the United States.

8. Plaintiff Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, NC 27893. Purdue Pharmaceuticals is an owner of the '416 and '808 patents.

9. On information and belief, Kashiv is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 995 US 202/206, Bridgewater, NJ 08807.

SUBJECT MATTER JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, including 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b) because Kashiv resides in this judicial district and because Kashiv has committed acts of infringement in this judicial district.

PERSONAL JURISDICTION

13. This Court has personal jurisdiction over Kashiv by virtue of, *inter alia*, the fact that Kashiv is a Delaware limited liability company, Kashiv's systematic and continuous contacts with Delaware, and Kashiv's contacts with Delaware in connection with its alleged submission of Amneal's Amended ANDA, as set forth below.

14. On information and belief, Kashiv is registered to conduct business within the State of Delaware and maintains as a registered agent Paracorp Inc., 2140 S Dupont Hwy, Camden, Delaware 19934.

15. On information and belief, Kashiv is in the business of preparing generic pharmaceuticals that it or its agents distribute in the State of Delaware and throughout the United States.

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.