IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. PAR PHARMACEUTICAL, INC. Defendant.	C.A. No. 1:15-cv-00475-RGA

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novartis Pharmaceuticals Corporation and Novartis AG (hereinafter "Plaintiffs"), for their Complaint against defendant Par Pharmaceutical, Inc. allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Plaintiff Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

4. On information and belief, defendant Par Pharmaceutical, Inc. ("Par") is a corporation organized and existing under the laws of the State of Delaware, and having designated its registered agent as The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. Upon information and belief, defendant Par has its primary place of business at One Ram Ridge Road, Spring Valley, New York 10977. Upon information and belief, defendant Par develops, manufactures, markets and distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. On information and belief, Par is in the business of developing, manufacturing, marketing, and selling pharmaceutical drug products, including generic drug products. On information and belief, Par directly or through its affiliates and agents markets and sells drug products throughout the United States and in this judicial district, is incorporated in Delaware, has a registered agent for service in Delaware, and has purposely availed itself of the rights and benefits of Delaware law and this Court. This Court has personal jurisdiction over Par by virtue of, *inter alia*, these above-mentioned facts.

7. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF – PATENT INFRINGEMENT

8. Plaintiff NPC holds approved New Drug Application ("NDA") No. 22-334 for AFINITOR® (everolimus) tablets for oral administration (2.5 mg, 5 mg, 7.5 mg and 10

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

mg dosage strengths), which contain the active ingredient everolimus. AFINITOR® tablets were approved by the United States Food and Drug Administration ("FDA") on March 30, 2009 (5 mg and 10 mg dosage strengths), July 9, 2010 (2.5 mg dosage strength), and March 30, 2012 (7.5 mg dosage strength). AFINITOR® tablets are indicated for the treatment of: postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer in combination with exemestane after failure of treatment with letrozole or anastrozole; adults with progressive neuroendocrine tumors of pancreatic origin that are unresectable, locally advanced or metastatic; adults with advanced renal cell carcinoma after failure of treatment with sunitinib or sorafenib; adults with renal angiomyolipoma and tuberous sclerosis complex, not requiring immediate surgery; and pediatric and adult patients with tuberous sclerosis complex who have subependymal giant cell astrocytoma that requires therapeutic intervention but cannot be curatively resected. AFINITOR® (everolimus) tablets for oral administration (2.5 mg, 5 mg, 7.5 mg and 10 mg dosage strengths) are sold in the United States by Plaintiff NPC.

9. Everolimus is known chemically as (1R,9S,12S,15R,16E,18R,19R,21R,23S,24E,26E,28E,30S,32S,35R)-1,18-dihydroxy-12-{(1R)-2-[(1S,3R,4R)-4-(2-hydroxyethoxy)-3-methoxycyclohexyl]-1-methylethyl}-19,30-dimethoxy-15,17,21,23,29,35-hexamethyl-11,36-dioxa-4-aza-tricyclo[30.3.1.$0^{4,9}$]hexatriaconta-16,24,26,28-tetraene-2,3,10,14,20-pentaone and also as 40-*O*-(2-hydroxyethyl)-rapamycin. The chemical name "(1R,9S,12S,15R,16E,18R,19R,21R,23S,24E,26E,28E,30S,32S,35R)-1,18-dihydroxy-12-{(1R)-2-[(1S,3R,4R)-4-(2-hydroxyethoxy)-3-methoxycyclohexyl]-1-methylethyl}-19,30-dimethoxy-15,17,21,23,29,35-hexamethyl-11,36-dioxa-4-aza-tricyclo[30.3.1.$0^{4,9}$]hexatriaconta-16,24,26,28-tetraene-2,3,10,14,20-pentaone" is equivalent to "40-*O*-(2-hydroxyethyl)-rapamycin."

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

10. Plaintiff Novartis AG is the owner of United States Letters Patent No. 9,006,224 ("the '224 Patent"). The '224 Patent was duly and legally issued on April 14, 2015.

11. The '224 Patent claims, *inter alia*, a method for treating pancreatic neuroendocrine tumors, comprising administering to a human subject in need thereof a therapeutically effective amount of 40-*O*-(2-hydroxyethyl)-rapamycin as a monotherapy and wherein the tumors are advanced tumors after failure of cytotoxic chemotherapy. A true copy of the '224 Patent is attached as Exhibit A.

12. Plaintiffs notified Par of the issuance of the '224 Patent on April 14, 2015, the day the patent issued.

13. On information and belief, Par has submitted to the FDA and maintained an abbreviated new drug application ("ANDA") under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, and sale of everolimus tablets (2.5 mg, 5 mg, 7.5 mg, and 10 mg dosage strengths) (the "ANDA Products") before the expiration of the '224 Patent.

14. On information and belief, Par has amended its ANDA to include a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '224 Patent.

15. Plaintiffs received written notification of the amendment to Par's ANDA to include the § 505(j)(2)(A)(vii)(IV) certification by a letter dated June 12, 2015 ("Notice Letter").

16. This action was commenced prior to the expiration of the 45-day period from receipt of the Par Notice Letter.

17. By filing, amending and maintaining its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

Par's ANDA Products before the expiration of the '224 Patent, Par has committed an act of infringement under 35 U.S.C. § 271(e)(2).

18. On information and belief, when Par amended and/or maintained its ANDA, it was aware of the '224 Patent and that the filing, amending and/or maintaining of its ANDA with the request for its approval prior to the expiration of the '224 Patent was an act of infringement of that patent.

19. On information and belief, the commercial manufacture, offer for sale, sale or use of Par's ANDA Products will infringe one or more claims of the '224 Patent.

20. On information and belief, Par's ANDA Products, if approved, will be administered for treating pancreatic neuroendocrine tumors to a human subject in need thereof in a therapeutically effective amount as a monotherapy and wherein the tumors are advanced tumors after failure of cytotoxic chemotherapy, which administration will constitute direct infringement of the '224 Patent. On information and belief, if its ANDA Products are approved, Par will actively induce, encourage, and abet this infringement with knowledge of the '224 Patent and that its acts will induce infringement of the '224 Patent.

21. On information and belief, Par's ANDA Products, if approved, will contain instructions for administering 40-*O*-(2-hydroxyethyl)-rapamycin for treating pancreatic neuroendocrine tumors to a human subject in need thereof in a therapeutically effective amount as a monotherapy and wherein the tumors are advanced tumors after failure of cytotoxic chemotherapy.

22. On information and belief, if its ANDA is approved, Par will actively induce, encourage, and abet infringement of the '224 Patent, and will do so with knowledge of the '224 Patent and with knowledge that its acts will induce infringement of the '224 Patent.

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

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.