

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

)	
)	
NOVARTIS PHARMACEUTICALS)	
CORPORATION,)	
)	
Plaintiff,)	
)	C.A. No. _____
v.)	
)	
PAR PHARMACEUTICAL, INC.)	
)	
)	
Defendant.)	
)	
)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Novartis Pharmaceuticals Corporation (hereinafter “Plaintiff”), for its 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. 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

4. 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.

5. 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.

6. 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

7. 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 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.

8. 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-dioxo-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-dioxo-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.”

9. Plaintiff NPC is the owner of United States Letters Patent No. 8,436,010 (“the ’010 patent”). The ’010 patent was duly and legally issued on May 7, 2013.

10. The ’010 patent claims, *inter alia*, a method for inhibiting growth of solid tumors of the breast in a patient having a solid breast tumor, said method consisting of

administering to said subject a therapeutically effective amount of 40-*O*-(2-hydroxyethyl)-rapamycin concomitantly or sequentially with exemestane. A true copy of the '010 patent is attached as Exhibit A.

11. 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 '010 patent.

12. On information and belief, Par amended its ANDA to seek approval to market its ANDA Products for the indication of 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.

13. On information and belief, Par amended its ANDA to include a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '010 patent.

14. Plaintiff received written notification of the amendment to Par's ANDA to include the § 505(j)(2)(A)(vii)(IV) certification by a letter dated October 1, 2015 (“Notice Letter”), which alleged that claims 1-11 of the '010 patent are invalid. Par did not allege non-infringement of any of the claims of the '010 patent. Par did not allege that any of the claims of the '010 patent are unenforceable.

15. This action was commenced within 45 days of receipt of the Par's Notice Letter.

16. 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

Par's ANDA Products before the expiration of the '010 patent, Par has committed an act of infringement under 35 U.S.C. § 271(e)(2).

17. 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 '010 patent.

18. On information and belief, Par's ANDA Products, if approved, will be administered for inhibiting growth of solid tumors of the breast in a patient having a solid breast tumor in a therapeutically effective amount concomitantly or sequentially with exemestane, which administration will constitute direct infringement of the '010 patent.

19. On information and belief, Par's ANDA Products, if approved, will contain instructions for administering 40-*O*-(2-hydroxyethyl)-rapamycin for inhibiting growth of solid tumors of the breast in a patient having a solid breast tumor in a therapeutically effective amount concomitantly or sequentially with exemestane.

20. Par did not deny infringement of any claims of the '010 patent in its Notice Letter.

21. On information and belief, if its ANDA is approved, Par will actively induce, encourage, and abet infringement of the '010 patent, and will do so with knowledge of the '010 patent and with knowledge that its acts will induce infringement of the '010 patent.

22. On information and belief, if its ANDA is approved, Par will commercially manufacture, offer for sale, and sell its ANDA Products for use in a method for inhibiting growth of solid tumors of the breast in a patient having a solid breast tumor, said method consisting of administering to said subject a therapeutically effective amount of 40-*O*-(2-hydroxyethyl)-rapamycin concomitantly or sequentially with exemestane.

23. On information and belief, if its ANDA is approved, Par's ANDA Products will be specifically labeled for administering 40-O-(2-hydroxyethyl)-rapamycin for inhibiting growth of solid tumors of the breast in a patient having a solid breast tumor in a therapeutically effective amount concomitantly or sequentially with exemestane.

24. On information and belief, there are no substantial noninfringing uses of Par's ANDA Products.

25. On information and belief, if approved, Par's ANDA Products will constitute a material part of a method for inhibiting growth of solid tumors of the breast in a patient having a solid breast tumor, said method consisting of administering to said subject a therapeutically effective amount of 40-O-(2-hydroxyethyl)-rapamycin concomitantly or sequentially with exemestane.

26. On information and belief, if its ANDA is approved, Par will contributorily infringe the '010 patent, and will do so with knowledge of the '010 patent and that its ANDA Products are especially made or especially adapted for use in infringing the '010 patent.

27. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the ANDA relating to Par's ANDA Products be a date that is no earlier than August 22, 2022, the expiration of the '010 patent's pediatric exclusivity, and an award of damages for any commercial sale or use of Par's ANDA Products and any act committed by Par with respect to the subject matter claimed in the '010 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

28. On information and belief, Par has taken and continues to take active steps towards the commercial manufacture, use, offer for sale, sale, and/or importation of Par's ANDA

Products, including seeking approval to market those products under Par's ANDA prior to the expiration of the '010 patent.

29. There is a substantial and immediate controversy between Plaintiff and Par concerning the '010 patent. Plaintiff is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Par will induce infringement of and/or contributorily infringe one or more claims of the '010 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. Judgment that Par has directly infringed one or more claims of the '010 patent by filing, amending or maintaining an ANDA relating to Par's everolimus tablets (2.5 mg, 5 mg, 7.5 mg, and 10 mg dosage strengths);

B. A permanent injunction restraining and enjoining Par and its officers, agents, attorneys, and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Par's everolimus tablets (2.5 mg, 5 mg, 7.5 mg, and 10 mg dosage strengths), as claimed in the '010 patent;

C. An order that the effective date of any approval of the ANDA relating to Par's everolimus tablets (2.5 mg, 5 mg, 7.5 mg, and 10 mg dosage strengths), be a date that is not earlier than the expiration of the right of exclusivity under the '010 patent;

D. Declaratory judgment that Par will induce infringement of and/or contributorily infringe one or more claims of the '010 patent by commercially manufacturing, use, offering for sale and/or selling its everolimus tablets (2.5 mg, 5 mg, 7.5 mg, and 10 mg dosage strengths);

- E. Damages from Par for the infringement and/or inducement of infringement and/or contributory infringement of the '010 patent;
- F. The costs and reasonable attorney fees of Plaintiff in this action; and
- G. Such other and further relief as the Court may deem just and proper.

Dated: November 13, 2015

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

Michael P. Kelly (#2295)

Daniel M. Silver (#4758)

Benjamin A. Smyth (#5528)

Renaissance Centre

405 N. King Street, 8th Floor

Wilmington, Delaware 19801

(302) 984-6300

mkelly@mccarter.com

dsilver@mccarter.com

bsmyth@mccarter.com

Attorneys for Plaintiff

Of Counsel:

Nicholas N. Kallas

Christopher E. Loh

Charlotte Jacobsen

Christina Schwarz

FITZPATRICK, CELLA, HARPER & SCINTO

1290 Avenue of the Americas

New York, New York 10104-3800

(212) 218-2100

nkallas@fchs.com

cloh@fchs.com

cjacobsen@fchs.com

cschwarz@fchs.com