IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
PAR PHARMACEUTICAL, INC.	)	
Defendant.	)	

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.

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

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."

10. Everolimus is a 40-*O*-substituted rapamycin.

11. Plaintiff Novartis AG is the owner of United States Letters Patent No. 5,665,772 ("the '772 patent"). The '772 patent was duly and legally issued on September 9, 1997.

12. The '772 patent claims, *inter alia*, the compound which is 40-*O*-(2-hydroxyethyl)-rapamycin and a pharmaceutical composition containing this compound. A true copy of the '772 patent is attached as Exhibit A.

13. Plaintiff Novartis AG is the owner of United States Letters Patent No. 7,297,703 ("the '703 patent"). The '703 patent was duly and legally issued on November 20, 2007.

14. The '703 patent claims, *inter alia*, a solid mixture comprising a 40-*O*-substituted rapamycin and an antioxidant present in a catalytic amount, and pharmaceutical compositions comprising such solid mixture as active ingredient, admixed with one or more pharmaceutically acceptable carriers or diluents. A true copy of the '703 patent is attached as Exhibit B.

15. Plaintiff Novartis AG is the owner of United States Letters Patent No. 7,741,338 ("the '338 patent"). The '338 patent was duly and legally issued on June 22, 2010.

16. The '338 patent claims, *inter alia*, a solid mixture comprising 40-*O*-(2-hydroxy)ethyl-rapamycin and 2,6-di-tert-butyl-methylphenol (BHT), and pharmaceutical compositions comprising this solid mixture together with one or more pharmaceutically acceptable diluents or carriers. A true copy of the '338 patent is attached as Exhibit C.

17. On information and belief, Par submitted to the FDA 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, and 7.5 mg dosage strengths) ("Par's ANDA Products") before the expiration of the '772, '703 and '338 patents.

18. On information and belief, Par made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the '772 and '703 patent claims are invalid and/or will not be infringed. Par did not allege that any of the '772 and/or '703 patent claims were unenforceable.

19. Plaintiffs received written notification of Par's ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter dated December 10, 2014 ("Notice Letter") informing Plaintiffs that Par had submitted to the FDA an ANDA under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and sale of 2.5 mg, 5 mg, and 7.5 mg everolimus tablets.

20. This action was commenced within 45 days of receipt of the Par Notice Letter.

21. By filing 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 '772, '703 and '338 patents, Par has committed an act of infringement under 35 U.S.C. § 271(e)(2).

22. On information and belief, when Par filed its ANDA, it was aware of the '772, '703 and '338 patents and that the filing of its ANDA with the request for its approval prior to the expiration of the '772, '703 and '338 patents was an act of infringement of those patents.

23. On information and belief, the commercial manufacture, use, offer for sale, sale, and/or importation of Par's ANDA Products will infringe one or more claims of the '772, '703 and '338 patents.

24. On information and belief, Par's ANDA Products, if approved, will contain 40-*O*-(2-hydroxyethyl)-rapamycin.

25. On information and belief, Par's ANDA Products, if approved, will be pharmaceutical compositions containing a therapeutically effective amount of 40-*O*-(2-hydroxyethyl)-rapamycin and a pharmaceutically acceptable carrier.

26. Par did not deny infringement of claims 1–3 and 7–10 of the '772 patent in its Notice Letter.

27. On information and belief, the commercial manufacture of Par's ANDA Products will involve direct infringement of the '772 patent. On information and belief, this will occur at Par's active behest, and with Par's intent, knowledge, and encouragement.

28. On information and belief, Par's ANDA Products, if approved, will be pharmaceutical compositions comprising an active ingredient admixed with one or more pharmaceutically acceptable carriers or diluents. On information and belief, said active ingredient will be a solid mixture comprising a 40-*O*-substituted rapamycin and an antioxidant present in a catalytic amount.

29. On information and belief, the commercial manufacture of Par's ANDA Products will involve direct infringement of the '703 patent. On information and belief, this will occur at Par's active behest, and with Par's intent, knowledge, and encouragement.

30. On information and belief, Par's ANDA Products, if approved, will comprise a solid mixture comprising 40-*O*-(2-hydroxy)ethyl-rapamycin and 2,6-di-tert-butyl-methylphenol (BHT).

31. On information and belief, Par's ANDA Products, if approved, will be pharmaceutical compositions comprising a solid mixture comprising 40-*O*-(2-hydroxy)ethyl-rapamycin and 2,6-di-tert-butyl-methylphenol (BHT) together with one or more pharmaceutically acceptable diluents or carriers.

32. On information and belief, the commercial manufacture of Par's ANDA Products will involve direct infringement of the '338 patent. On information and belief, this will occur at Par's active behest, and with Par's intent, knowledge, and encouragement.

33. Plaintiffs are 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 March 9, 2020, the expiration of the '772 patent's pediatric exclusivity, and June 6, 2020, the expiration of the '703 and '338 patents' 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 '772, '703 and '338 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

34. 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 of those products under Par's ANDA.

35. There is a substantial and immediate controversy between Plaintiffs and Par concerning the '772, '703 and '338 patents. Plaintiffs are entitled to declaratory judgment

under 28 U.S.C. §§ 2201 and 2202 that Par will infringe and/or induce infringement of one or more claims of the '772, '703 and '338 patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Par has directly infringed and/or induced infringement of one or more claims of the '772, '703 and '338 patents by filing an ANDA relating to Par's everolimus tablets (2.5 mg, 5 mg, and 7.5 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, and 7.5 mg dosage strengths), as claimed in the '772, '703 and '338 patents;

C. An order that the effective date of any approval of the ANDA relating to Par's everolimus tablets (2.5 mg, 5 mg, and 7.5 mg dosage strengths), be a date that is not earlier than the expiration of the right of exclusivity under the '772, '703 and '338 patents;

D. Declaratory judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of Par's everolimus tablets (2.5 mg, 5 mg, and 7.5 mg dosage strengths) will infringe one or more claims of the '772, '703 and '338 patents and/or that Par will induce infringement of one or more claims of the '772, '703 and '338 patents;

E. Damages from Par for the infringement and inducement of infringement of the '772, '703 and '338 patents;

F. The costs and reasonable attorney fees of Plaintiffs in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: January 23, 2015

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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