v.

PAR PHARMACEUTICAL, INC.

Defendant.

DEFENDANT PAR PHARMACEUTICAL, INC.'S ANSWER AND COUNTERCLAIMS

Par Pharmaceutical, Inc. ("Par"), answers the Complaint of Novartis Pharmaceuticals Corporation and Novartis AG (collectively "Plaintiffs") as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

Answer: Par admits that Plaintiffs purport to bring an action for patent infringement against Par. Par denies that Plaintiffs properly state a claim 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.

Answer: Par lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint and therefore denies them.

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.

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.

Answer: Par admits the allegations in paragraph 4 of the Complaint.

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.

Answer: Par admits that Plaintiffs purport to bring this action under the patent laws of the United States of America. Par states that it does not contest this Court's subject matter jurisdiction over this action.

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.

Answer: Par states that it does not contest this Court's personal jurisdiction for purposes of this action.

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

Answer: Par states that it does not contest venue in this judicial district for purposes of this action.

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.

Answer: Par states that the FDA website lists "Novartis" as the holder of NDA No. 22-334 for AFINITOR ® (everolimus) tablets (2.5 mg, 5 mg, 7.5 mg and 10 mg dosage strengths) and lists 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) as the approval dates for that NDA. Par further states that the FDA-approved labeling for AFINITOR ® states:

> AFINITOR is a kinase inhibitor indicated for the treatment of:
>
> - postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+ BC) in combination with exemestane after failure of treatment with letrozole or anastrozole.
> - adults with progressive neuroendocrine tumors of pancreatic origin (PNET) that are unresectable, locally advanced or metastatic. AFINITOR is not indicated for the treatment of patients with functional carcinoid tumors.
> - adults with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib.
> - adults with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery. The effectiveness of AFINITOR in the treatment of renal angiomyolipoma is based on an analysis of durable objective responses in patients treated for a median of 8.3 months. Further follow-up of patients is required to determine long-term outcomes.
>
> AFINITOR and AFINITOR DISPERZ are kinase inhibitors indicated for the treatment of:
>
> - pediatric and adult patients with tuberous sclerosis complex (TSC) who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic

remaining allegations in paragraph 8 of the Complaint and therefore denies them.

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."

Answer: On information and belief, Par admits the allegations in paragraph 9 of the Complaint.

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

Answer: On information and belief, Par admits the allegations in paragraph 10 of the Complaint.

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.

Answer: Par admits that the '772 patent was issued on September 9, 1997. Par denies that the '772 patent was duly and lawfully issued. Par further states that the PTO assignment database lists Novartis AG as the assignee of the '772 patent. Par lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 11 of the Complaint and therefore denies them.

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.

("the '703 patent"). The '703 patent was duly and legally issued on November 20, 2007.

Answer: Par admits that the '703 patent was issued on November 20, 2007. Par denies that the '703 patent was duly and lawfully issued. Par further states that the face of the '703 patent lists Novartis AG as the assignee. Par lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 13 of the Complaint and therefore denies them.

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.

Answer: Par admits that what appears to be a copy of the '703 patent is attached as Exhibit B to the Complaint. Par states that the '703 patent speaks for itself. To the extent that the allegations in paragraph 14 of the Complaint vary therewith, Par denies them.

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.

Answer: Par admits that the '338 patent was issued on June 22, 2010. Par denies that the '338 patent was duly and lawfully issued. Par further states that the face of the '338 patent lists Novartis AG as the assignee. Par lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 15 of the Complaint and therefore denies them.

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.

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