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

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| NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG,<br><br>Plaintiffs,<br><br>v.<br><br>BRECKENRIDGE PHARMACEUTICAL, INC.,<br><br>Defendant. | ) | C.A. No. _____ |

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Novartis Pharmaceuticals Corporation and Novartis AG (hereinafter "Plaintiffs"), for their Complaint against defendant Breckenridge 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 Breckenridge Pharmaceutical, Inc. ("Breckenridge") is a corporation organized and existing under the laws of the State of Florida,

having a place of business at 6111 Broken Sound Parkway, NW, Suite 170, Boca Raton, Florida 33487. Upon information and belief, defendant Breckenridge manufactures 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, Breckenridge is in the business of manufacturing, marketing, and selling pharmaceutical drug products, including generic drug products. On information and belief, Breckenridge directly or through its affiliates and agents markets and sells drug products throughout the United States and in this judicial district, and has purposely availed itself of the rights and benefits of Delaware law and this Court. This Court has personal jurisdiction over Breckenridge for this reason and the additional reasons set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

7. This Court has personal jurisdiction over Breckenridge because, as explained further below, Breckenridge has taken the costly, significant step of applying, through an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA"), for approval under the Hatch-Waxman Act to engage in future infringing activities, including the marketing and sale of the accused infringing everolimus tablets, 10 mg dosage strength described herein, that will be purposefully directed at Delaware. Breckenridge's ANDA filing constitutes a formal act that reliably indicates its plans to engage in marketing of the accused infringing product in Delaware. This act is sufficient to confer specific jurisdiction over Breckenridge in Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, 817 F.3d 755 (Fed. Cir. 2016).

8. This Court has personal jurisdiction over Breckenridge because Breckenridge has affirmatively availed itself of the jurisdiction of this Court by filing a lawsuit and counterclaims in this district, and has previously been sued in this district and has not challenged personal jurisdiction. *See, e.g.*, *Pamlab, LLC, et al. v. Acella Pharmaceuticals, LLC*, 1:12-cv-01403 (D. Del.) (plaintiff); *Pfizer Inc., et al. v. Breckenridge Pharmaceutical, Inc., et al.*, 1:12-cv-00810 (consolidated with 1:12-cv-00808) (D. Del.) (defendant and counterclaimant); *Par Pharmaceutical, Inc., et al. v. Breckenridge Pharmaceutical, Inc.*, 1:13-cv-01114 (D. Del.) (defendant and counterclaimant); *UCB, Inc., et al. v. Breckenridge Pharmaceutical, Inc., et al.*, 1:13-cv-01211 (D. Del.) (defendant and counterclaimant); *Cephalon, Inc. v. Breckenridge Pharmaceutical, Inc., et al.*, 1:14-cv-00671 (D. Del.) (defendant and counterclaimant); *Cephalon, Inc., et al. v. Breckenridge Pharmaceutical, Inc., et al.*, 1:11-cv-01070 (D. Del.) (defendant); and *Novartis Pharmaceuticals Corporation v. Breckenridge Pharmaceutical, Inc.*, 1:14-cv-01043 (D. Del.) (defendant and counterclaimant).

9. This Court has personal jurisdiction over Breckenridge by virtue of, *inter alia*, the fact that Breckenridge has availed itself of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware.

10. 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**

11. 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 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 progressive, well-differentiated, non-functional, neuroendocrine tumors of gastrointestinal or lung origin with unresectable, locally advanced or metastatic disease; 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.

12. 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."

13. 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.

14. The '772 patent claims, *inter alia*, the compound everolimus and a pharmaceutical composition containing a therapeutically effective amount everolimus and a pharmaceutically acceptable carrier. A true copy of the '772 patent is attached as Exhibit A.

15. Plaintiff NPC is the owner of United States Letters Patent No. 8,410,131 ("the '131 patent"). The '131 patent was duly and legally issued on April 2, 2013.

16. The '131 patent claims, *inter alia*, a method for inhibiting growth of solid excretory system tumors in a subject, said method consisting of administering to said subject a therapeutically effective amount of everolimus. A true copy of the '131 patent is attached as Exhibit B.

17. Plaintiff NPC is the owner of United States Letters Patent No. 8,778,962 ("the '962 patent"). The '962 patent was duly and legally issued on July 15, 2014.

18. The '962 patent claims, *inter alia*, a method for inhibiting growth of non-malignant solid tumors of the brain in a subject, said method consisting of administering to said subject a therapeutically effective amount of everolimus. A true copy of the '962 patent is attached as Exhibit C.

19. On information and belief, Breckenridge 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, 10 mg dosage strength ("Breckenridge's ANDA Product") before the expiration of the '772, '131 and '962 patents.

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