

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

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

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 One Health Plaza, 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”) and then amending its ANDA, for approval under the Hatch-Waxman Act to engage in future infringing activities, including the marketing and sale of the accused infringing everolimus tablets, 2.5 mg, 5 mg and 7.5 mg dosage strengths described herein, that will be purposefully directed at Delaware. Breckenridge’s filing of an amendment to its ANDA

No. 205426 constitutes a formal act that reliably indicates its plans to engage in marketing of the accused infringing products in Delaware. This act is sufficient to confer specific jurisdiction over Breckenridge in Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharms. 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 Pharms., LLC*, 1:12-cv-01403 (D. Del.) (plaintiff); *Pfizer Inc., et al. v. Breckenridge Pharm., Inc., et al.*, 1:12-cv-00810 (consolidated with 1:12-cv-00808) (D. Del.) (defendant and counterclaimant); *Par Pharm., Inc., et al. v. Breckenridge Pharm., Inc.*, 1:13-cv-01114 (D. Del.) (defendant and counterclaimant); *UCB, Inc., et al. v. Breckenridge Pharm., Inc., et al.*, 1:13-cv-01211 (consolidated with 1:13-cv-01206) (D. Del.) (defendant and counterclaimant); *Cephalon, Inc. v. Breckenridge Pharm., Inc., et al.*, 1:14-cv-00671 (consolidated with 1:13-cv-02046) (D. Del.) (defendant and counterclaimant); *Cephalon, Inc., et al. v. Breckenridge Pharm., Inc., et al.*, 1:11-cv-01070 (D. Del.) (defendant); and *Novartis Pharms. Corp. et al. v. Breckenridge Pharm., Inc.*, 1:14-cv-01043 (D. Del.) (defendant and counterclaimant).

9. This Court has personal jurisdiction over Breckenridge because Breckenridge has affirmatively availed itself of the jurisdiction of this Court by consenting to jurisdiction and asserting counterclaims in this Court in a related case with Novartis involving the same Breckenridge ANDA Products as accused of infringement here in a different 10 mg

dosage strength, and involving the same patents as involved in this case. *See* 1:16-cv-00431-RGA, Document 8, filed September 6, 2016, which is still pending.

10. 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.

11. On or about March 23, 2017, by and through its attorneys, Breckenridge stated that it would not contest jurisdiction in the District of Delaware for the purposes of this infringement action concerning its amended ANDA for everolimus tablets, 2.5 mg, 5 mg and 7.5 mg dosage strengths.

12. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b). On March 27, 2017, by and through its attorneys, Breckenridge stated that it would not contest venue in the District of Delaware for the purposes of this infringement action concerning its amended ANDA for everolimus tablets, 2.5 mg, 5 mg and 7.5 mg dosage strengths.

CLAIM FOR RELIEF – PATENT INFRINGEMENT

13. 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[®] (everolimus) 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 July 29, 2011 (7.5 mg dosage strength). AFINITOR[®] (everolimus) 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.

14. 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.”

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

21. On information and belief, Breckenridge submitted to the FDA an amendment to its abbreviated new drug application ("ANDA") No. 205426 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 ("Breckenridge's ANDA Products") before the expiration of the '772, '131 and '962 patents.

22. On information and belief, Breckenridge made and included in its amended 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, '131 and '962 patents claim are invalid and/or will not be infringed. On information and belief, Breckenridge has not provided a detailed statement of the legal and factual bases for any allegation that any claim of the '772, '131 or '962 patents is unenforceable.

23. Plaintiffs received written notification of Breckenridge's amended ANDA and its accompanying 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certification by a letter dated March 1, 2017 ("Notice Letter").

24. This action was commenced within 45 days of receipt of the Breckenridge Notice Letter.

25. By filing its amended ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Breckenridge's ANDA Products before the expiration of the '772, '131 and '962 patents, Breckenridge has committed an act of infringement under 35 U.S.C. § 271(e)(2).

26. On information and belief, when Breckenridge filed its amended ANDA, it was aware of the '772, '131 and '962 patents and that the filing of its amended ANDA with the request for its approval prior to the expiration of the '772, '131 and '962 patents was an act of infringement of those patents.

27. On information and belief, the commercial manufacture, use, offer for sale, sale, and/or importation of Breckenridge's ANDA Products will infringe, induce infringement of and/or contributorily infringe one or more claims of the '772, '131 and '962 patents.

28. On August 26, 2016, Novartis and Breckenridge filed a stipulation in Civil Action No. 14-1043, pursuant to which Breckenridge stipulated, *inter alia*, that its everolimus tablet 10 mg dosage strength, the same Breckenridge ANDA Products as accused of infringement here in a different 10 mg dosage strength, infringes at least claims 1, 7 and 10 of the '772 patent. *See* 1:14-cv-1043-RGA, Document 152.

29. On information and belief, Breckenridge's ANDA Products, if approved, will contain everolimus and be a pharmaceutical composition containing a therapeutically effective amount of everolimus and a pharmaceutically acceptable carrier. On information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Breckenridge's ANDA Products will directly infringe the '772 patent.

30. On information and belief, Breckenridge's ANDA Products, if approved, will contain instructions for administering a therapeutically effective amount of everolimus to inhibit growth of solid excretory system tumors in a subject, which administration will constitute direct infringement of the '131 patent. On information and belief, if Breckenridge's ANDA Products are approved, Breckenridge will actively induce, encourage, and abet this infringement with knowledge of the '131 patent, and that its acts will induce infringement of the '131 patent.

31. On information and belief, if Breckenridge's ANDA Products are approved, Breckenridge will commercially manufacture, offer for sale, sell, and/or import those products, which will be specifically labeled for use in 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. On information and belief, if Breckenridge's ANDA Products are approved, those products will constitute a material part of a method for

inhibiting growth of solid excretory system tumors, said method consisting of administering to said subject a therapeutically effective amount of everolimus. On information and belief, if Breckenridge's ANDA Products are approved, Breckenridge will contributorily infringe the '131 patent with knowledge of the '131 patent, and that its ANDA Products are especially made or especially adapted for use in infringing the '131 patent and are not suitable for a substantial noninfringing use.

32. On information and belief, Breckenridge's ANDA Products, if approved, will contain instructions for administering a therapeutically effective amount of everolimus to inhibit growth of non-malignant solid tumors of the brain in a subject, which administration will constitute direct infringement of the '962 patent. On information and belief, if Breckenridge's ANDA Products are approved, Breckenridge will actively induce, encourage, and abet this infringement with knowledge of the '962 patent, and that its acts will induce infringement of the '962 patent.

33. On information and belief, if Breckenridge's ANDA Products are approved, Breckenridge will commercially manufacture, offer for sale, sell, and/or import those products, which will be specifically labeled for use in 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. On information and belief, if Breckenridge's ANDA Products are approved, those products will constitute a material part of 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. On information and belief, if Breckenridge's ANDA Products are approved,

Breckenridge will contributorily infringe the '962 patent, and will do so with knowledge of the '962 patent, and that its ANDA Products are especially made or especially adapted for use in infringing the '962 patent and are not suitable for a substantial noninfringing use.

34. 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 Breckenridge's ANDA Products be a date that is no earlier than March 9, 2020, the expiration of the '772 patent's pediatric exclusivity, May 1, 2026, the expiration date of the '131 patent's pediatric exclusivity, and August 18, 2022, the expiration date of the '962 patent's pediatric exclusivity, and an award of damages for any commercial sale or use of Breckenridge's ANDA Products and any act committed by Breckenridge with respect to the subject matter claimed in the '772, '131 and '962 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

35. On information and belief, Breckenridge has taken and continues to take active steps towards the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Products, including seeking approval of those products under Breckenridge's ANDA.

36. There is a substantial and immediate controversy between Plaintiffs and Breckenridge concerning the '772, '131 and '962 patents. Plaintiffs are entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Breckenridge will infringe, induce infringement and/or contributorily infringe of one or more claims of the '772, '131 and '962 patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Breckenridge has directly infringed, induced infringement of and/or contributorily infringed one or more claims of the '772, '131 and '962 patents by filing an amended ANDA for Breckenridge's everolimus tablets, 2.5 mg, 5 mg and 7.5 mg dosage strengths;

B. A permanent injunction restraining and enjoining Breckenridge 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 Breckenridge's everolimus tablets, 2.5 mg, 5 mg and 7.5 mg dosage strengths, as claimed in the '772, '131 and '962 patents;

C. An order that the effective date of any approval of the ANDA for Breckenridge'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, '131 and '962 patents;

D. Declaratory judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of Breckenridge's everolimus tablets, 2.5 mg, 5 mg and 7.5 mg dosage strengths, will infringe, induce infringement of and/or contributorily infringe one or more claims of the '772, '131 and '962 patents;

E. Damages from Breckenridge for the infringement, inducement of infringement and/or contributory infringement of the '772, '131 and '962 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: April 13, 2017

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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