IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. BRECKENRIDGE PHARMACEUTICAL, INC., 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 corporationorganized 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, is incorporated in Florida, has its principal place of business in this judicial district, and haspurposely availed itself of the rights and benefits of Florida law and this Court. This Court has personal jurisdiction over Breckenridge for this reason andthe 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 by virtue of,*inter alia*, the above-mentioned facts.

8. 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

9. Plaintiff NPC holds approved New Drug Application ("NDA") No. 21-560 for ZORTRESS® (everolimus) tablets (0.25 mg, 0.5 mg, and 0.75 mg dosage strengths),

which contain the active ingredient everolimus. ZORTRESS®tablets were approved by the United States Food and Drug Administration ("FDA") on April 20, 2010. ZORTRESS® tablets are indicated for the prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant, and for the prophylaxis of allograft rejection in adult patients receiving a liver transplant. ZORTRESS® tablets (0.25 mg, 0.5 mg, and 0.75 mg dosage strengths) are sold in the United States by Plaintiff NPC.

10. 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 as40-*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."

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, a pharmaceutical composition containing this compound, and methods of inducing an immunosuppressant effect and preventing allograft rejection using 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. 6,004,973 ("the '973 patent"). The '973 patent was duly and legally issued on December 21, 1999.

14. The '973 patent claims, *inter alia*, pharmaceutical compositionscomprising: a solid dispersion in the form of a co-precipitate, said solid dispersion comprising 40-*O*-(2-hydroxy)ethyl rapamycin and a carrier medium,and a method of treating organ allo-transplant rejection using said pharmaceutical compositions. A true copy of the '973 patent is attached as Exhibit B.

15. Plaintiff Novartis AG is the owner of United States Letters Patent No. 6,239,124 ("the '124 patent"). The '124 patent was duly and legally issued on May 29, 2001.

16. The '124 patent claims, *inter alia*, methods of treating or preventing a transplant rejection andmethods of treating or preventing chronic rejection of a kidney transplant in a subject at risk for such rejection, comprising co-administering synergisticallyeffective amounts of cyclosporin A and 40-*O*-(2-hydroxyethyl)-rapamycin. A true copy of the '124 patent is attached as Exhibit C.

17. Plaintiff Novartis AG is the owner of United States Letters Patent No. 6,455,518 ("the '518 patent"). The '518 patent was duly and legally issued on September 24, 2002.

18. The '518 patent claims,*inter alia*, methods of treating or preventing a transplant rejection andmethods of treating or preventing chronic rejection of a kidney transplant in a subject at risk for such rejection, comprising co-administering synergistically effective amounts of an IL-2 transcription inhibitor and 40-*O*-(2-hydroxyethyl)-rapamycin. A true copy of the '518 patent is attached as Exhibit D.

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, 0.25 mg, 0.5 mg, and 0.75 mg dosage strengths ("Breckenridge's ANDA Products") before the expiration of the '772, '973, '124, and '518 patents.

20. On information and belief, Breckenridge 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, '973, '124, and '518 patent claims are invalid and/or will not be infringed. Breckenridge did not allege that any of the '772, '973, '124, and/or '518 patent claims were unenforceable.

21. Plaintiffs received written notification of Breckenridge's ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter dated July 1, 2014 ("Notice Letter").

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

23. 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 Breckenridge's ANDA Products before the expiration of the '772, '973, '124, and '518 patents, Breckenridge has committed an act of infringement under 35 U.S.C. § 271(e)(2).

24. On information and belief, when Breckenridge filed its ANDA, it was aware of the '772, '973, '124, and '518 patents and that the filing of its ANDA with the request for its approval prior to the expiration of the '772, '973, '124, and '518 patents was an act of infringement of those patents.

25. On information and belief, the commercial manufacture, use, offer for sale, sale, and/or importation of Breckenridge's ANDA Products will infringe and/or induce infringement of one or more claims of the '772, '973, '124, and '518 patents.

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

27. On information and belief, Breckenridge'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.

28. On information and belief, Breckenridge's ANDA Products, if approved, will contain instructions for administeringan immunosuppressant effective amount of 40-*O*-(2-hydroxyethyl)-rapamycin to a subject in need of immunosuppression, which will induce an immunosuppressant effect in said subject.

29. On information and belief, Breckenridge's ANDA Products, if approved, will contain instructions for administering an amount of 40-*O*-(2-hydroxyethyl)-rapamycin effective to prevent allograft rejection to a subject in need of such treatment,which will prevent allograft rejection in said subject.

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

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

32. On information and belief, Breckenridge's ANDA Products, if approved, will be administered to induce an immunosuppressant effect in a subject in need of immunosuppression, which administration will constitute direct infringement of the '772 patent. On information and belief, Breckenridge will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the rights under the '772 patent.

33. On information and belief, Breckenridge's ANDA Products, if approved, will be administered to prevent allograft rejection in a subject in need of such treatment, which administration will constitute direct infringement of the '772 patent. On information and belief, Breckenridge will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the rights under the '772 patent.

34. On information and belief, Breckenridge's ANDA Products, if approved, will be pharmaceutical compositions comprising a solid dispersion in the form of a co-precipitate. On information and belief, said solid dispersion will comprise 40-*O*-(2-hydroxyethyl)-rapamycin and a carrier medium. On information and belief, said carrier medium will containhydroxypropylmethylcellulose (a water-soluble polymer). On information and belief, said pharmaceutical composition will be free of surfactants. On information and belief, said pharmaceutical composition will containan antioxidant.

35. On information and belief, Breckenridge's ANDA Products, if approved, will contain instructions for orally administering an effective amount ofa pharmaceutical composition, in the form of a co-precipitate comprising 40-*O*-(2-hydroxyethyl)-rapamycin and a carrier medium,to a subject at risk for organ allo-transplant rejection, which will treatsuch rejection.

36. Breckenridge did not deny infringement of claims 1–10 and 13–15 of the '973 patent in its Notice Letter.

37. On information and belief, the commercial manufacture of Breckenridge's ANDA Products will involve direct infringement of the '973 patent. On information and belief, this will occur at Breckenridge's active behest, and with Breckenridge's intent, knowledge, and encouragement.

38. On information and belief, Breckenridge's ANDA Products, if approved, will be orally administered to treat organ allo-transplant rejection, which administration will constitute direct infringement of the '973 patent. On information and belief, Breckenridge will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the rights under the '973 patent.

39. On information and belief, Breckenridge's ANDA products, if approved, will contain instructions for co-administering synergistically effective amounts of cyclosporin A and 40-*O*-(2-hydroxyethyl)-rapamycin toa subject at risk for transplant rejection or chronic rejection of a kidney transplant, which will treat orprevent such rejection.

40. Breckenridge did not deny infringement of claims 7–8 and 11–13 of the '124 patent in its Notice Letter.

41. On information and belief, Breckenridge's ANDA Products, if approved, will be co-administered with cyclosporin A in synergistically effective amounts to a subjectfor the treatment orprevention of a transplant rejection and chronic rejection of a kidney transplant in particular in a subject at risk for such rejection, which co-administration will constitute direct infringement of the '124 patent.On information and belief, this will occur at Breckenridge's active behest, and with Breckenridge's intent, knowledge, and encouragement. On information

and belief, Breckenridge will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the rights under the '124 patent.

42. Breckenridge did not deny infringement of claims 7–8 and 11–13 of the '518 patent in its Notice Letter.

43. On information and belief, Breckenridge's ANDA Products, if approved, will be co-administered with cyclosporin A (an IL-2 transcription inhibitor) in synergistically effective amounts to a subjectfor the treatment or prevention ofa transplant rejection andfor the treatment orprevention of chronic rejection of a kidney transplant, in a subject at risk for such rejection, which co-administration will constitute direct infringement of the '518 patent. On information and belief, this will occur at Breckenridge's active behest, and with Breckenridge's intent, knowledge, and encouragement. On information and belief, Breckenridge will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the rights under the '518 patent.

44. 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, 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, '973, '124, and '518 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

45. 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

Breckenridge's ANDA Products, including seeking approval of those products under Breckenridge's ANDA.

46. There is a substantial and immediate controversy between Plaintiffs and Breckenridge concerning the '772, '973, '124, and '518 patents. Plaintiffs are entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Breckenridge will infringe and/or induce infringement of one or more claims of the '772, '973, '124, and '518 patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Breckenridge has directly infringed and/or induced infringement of one or more claims of the '772, '973, '124, and '518 patents by filing an ANDA relating to Breckenridge's everolimus tablets, 0.25 mg, 0.5 mg, and 0.75 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, 0.25 mg, 0.5 mg, and 0.75 mg dosage strengths, as claimed in the '772, '973, '124, and '518 patents;

C. An order that the effective date of any approval of the ANDA relating to Breckenridge's everolimus tablets, 0.25 mg, 0.5 mg, and 0.75 mg dosage strengths, be a date that is not earlier than the expiration of the right of exclusivity under the '772, '973, '124, and '518 patents;

D. Declaratory judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of Breckenridge's everolimus tablets, 0.25 mg, 0.5 mg, and 0.75 mg dosage strengths, will infringe one or more claims of the '772, '973, '124, and '518 patents

and/or that Breckenridge will induce infringement of one or more claims of the '772, '973, '124, and '518 patents;

E. Damages from Breckenridge for the infringement and inducement of infringement of the '772, '973, '124, and '518 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: August 15, 2014

LUCA R. BRONZI, P.A.

/s/ Luca R. Bronzi
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