IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT FOR PATENT INFRINGEMENT

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

a place of business at 1809 Wilson Road, Columbus, Ohio 43228. Upon information and belief, defendant Roxane 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, Roxane is in the business of developing, manufacturing, marketing, and selling pharmaceutical drug products, including generic drug products. On information and belief, Roxane 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 Roxane 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).

8. Roxane has agreed not to contest personal jurisdiction or venue in this Court for the purposes of this action.

CLAIM FOR RELIEF – PATENT INFRINGEMENT

9. 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.

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 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."

11. Plaintiff Novartis AG is the owner of United States Letters Patent No. 9,006,224 ("the '224 Patent"). The '224 Patent was duly and legally issued on April 14, 2015.

12. The '224 Patent claims, *inter alia*, a method for treating pancreatic neuroendocrine tumors, comprising administering to a human subject in need thereof a

therapeutically effective amount of 40-*O*-(2-hydroxyethyl)-rapamycin as a monotherapy and wherein the tumors are advanced tumors after failure of cytotoxic chemotherapy. A true copy of the '224 Patent is attached as Exhibit A.

13. 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.

14. 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 40-*O*-(2-hydroxyethyl)-rapamycin. A true copy of the '131 Patent is attached as Exhibit B.

15. On information and belief, Roxane 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, 7.5 mg, and 10 mg dosage strengths) (the "ANDA Products") before the expiration of the '224 and '131 Patents.

16. On information and belief, on or about April 27, 2015, Roxane amended its ANDA to seek approval to market its ANDA Products for the indication of treatment of advance renal cell carcinoma (RCC), after failure of treatment with sunitinib or sorafenib.

17. On information and belief, Roxane seeks to market its ANDA Products for the indication of treatment of adult patients with progressive neuroendocrine tumors of pancreatic origins (PNET) with unresectable, locally advanced or metastatic disease.

18. Plaintiffs notified Roxane of the issuance of the '224 Patent on April 14, 2015, the day the patent issued.

19. On information and belief, on or about April 27, 2015, Roxane amended its ANDA to include a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '224 and '131 Patents.

20. Plaintiffs received written notification of the amendment to Roxane's ANDA to include the § 505(j)(2)(A)(vii)(IV) certification by a letter dated April 27, 2015 ("Notice Letter"), which alleged that claims 1-3 of the '224 Patent are invalid, and that claims 1-3 and 5-9 of the '131 Patent are invalid and claim 4 of the '131 Patent will not be infringed by Roxane. Roxane did not allege non-infringement of any of the claims of the '224 Patent or claims 1-3 and 5-9 of the '131 Patent. Roxane did not allege that any of the claims of the '224 or '131 Patents were unenforceable.

21. This action was commenced within 45 days of receipt of the Roxane Notice Letter.

22. By filing and/or amending 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 Roxane's ANDA Products before the expiration of the '224 and '131 Patents, Roxane has committed an act of infringement under 35 U.S.C. § 271(e)(2).

23. On information and belief, when Roxane filed and/or amended its ANDA, it was aware of the '224 and '131 Patents and that the filing and/or amending of its ANDA with the request for its approval prior to the expiration of the '224 and '131 Patents was an act of infringement of those patents.

24. On information and belief, the commercial manufacture, offer for sale, sale or use of Roxane's ANDA Products will infringe one or more claims of the '224 and '131 Patents.

25. On information and belief, Roxane's ANDA Products, if approved, will be administered for treating pancreatic neuroendocrine tumors to a human subject in need thereof in a therapeutically effective amount as a monotherapy and wherein the tumors are advanced tumors after failure of cytotoxic chemotherapy, which administration will constitute direct infringement of the '224 Patent. On information and belief, if its ANDA Products are approved, Roxanne will actively induce, encourage, and abet this infringement with knowledge of the '224 Patent and that its acts will induce infringement of the '224 Patent.

26. On information and belief, if Roxane's ANDA is approved and following expiration of Plaintiffs' orphan drug exclusivity for the treatment of progressive neuroendocrine tumors of pancreatic origin (PNET) in patients with unresectable, locally advanced or metastatic disease, Roxane's ANDA Products will contain instructions for administering 40-*O*-(2-hydroxyethyl)-rapamycin for treating pancreatic neuroendocrine tumors to a human subject in need thereof in a therapeutically effective amount as a monotherapy and wherein the tumors are advanced tumors after failure of cytotoxic chemotherapy.

27. Roxane did not deny infringement of any of claims 1-3 of the '224 Patent in its Notice Letter.

28. On information and belief, if its ANDA Products are approved, Roxane will actively induce, encourage, and abet infringement of the '224 Patent, and will do so with knowledge of the '224 Patent and with knowledge that its acts will induce infringement of the '224 Patent.

29. On information and belief, Roxane's ANDA Products, if approved, will be administered for inhibiting growth of solid excretory system tumors in a subject in a therapeutically effective amount, which administration will constitute direct infringement of the

'131 Patent. On information and belief, if its ANDA Products are approved, Roxane 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.

30. On information and belief, Roxane's ANDA Products, if approved, will contain instructions for administering 40-*O*-(2-hydroxyethyl)-rapamycin for inhibiting growth of solid excretory system tumors in a subject in a therapeutically effective amount.

31. Roxane did not deny infringement of claims 1-3 and 5-9 of the '131 Patent in its Notice Letter.

32. On information and belief, if its ANDA Products are approved, Roxane will actively induce, encourage, and abet infringement of the '131 Patent, and will do so with knowledge of the '131 Patent and with knowledge that its acts will induce infringement of the '131 Patent.

33. On information and belief, if Roxane's ANDA is approved and following expiration of Plaintiffs' orphan drug exclusivity for the treatment of progressive neuroendocrine tumors of pancreatic origin (PNET) in patients with unresectable, locally advanced or metastatic disease, Roxane will commercially manufacture, offer for sale, and sell its ANDA Products for use in a method for treating pancreatic neuroendocrine tumors, comprising administering to a human subject in need thereof a therapeutically effective amount of 40-*O*-(2-hydroxyethyl)-rapamycin as a monotherapy and wherein the tumors are advanced tumors after failure of cytotoxic chemotherapy.

34. On information and belief, if Roxane's ANDA is approved and following expiration of Plaintiffs' orphan drug exclusivity for the treatment of progressive neuroendocrine tumors of pancreatic origin (PNET) in patients with unresectable, locally advanced or metastatic

disease, Roxane's ANDA Products will be specifically labeled for administering 40-*O*-(2-hydroxyethyl)-rapamycin for treating pancreatic neuroendocrine tumors to a human subject in need thereof in a therapeutically effective amount as a monotherapy and wherein the tumors are advanced tumors after failure of cytotoxic chemotherapy.

35. On information and belief, if Roxanne's ANDA is approved and following expiration of Plaintiffs' orphan drug exclusivity for the treatment of progressive neuroendocrine tumors of pancreatic origin (PNET) in patients with unresectable, locally advanced or metastatic disease, Roxane's ANDA Products will constitute a material part of a method for treating pancreatic neuroendocrine tumors, comprising administering to a human subject in need thereof a therapeutically effective amount of 40-*O*-(2-hydroxyethyl)-rapamycin as a monotherapy and wherein the tumors are advanced tumors after failure of cytotoxic chemotherapy.

36. On information and belief, if its ANDA is approved, Roxane will commercially manufacture, offer for sale, and sell its ANDA Products 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 40-*O*-(2-hydroxyethyl)-rapamycin.

37. On information and belief, if its ANDA is approved, Roxane's ANDA Products will be specifically labeled for administering 40-*O*-(2-hydroxyethyl)-rapamycin for inhibiting growth of solid excretory system tumors in a subject in a therapeutically effective amount.

38. On information and belief, if its ANDA is approved, Roxane's ANDA Products will constitute a material part of 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 40-*O*-(2-hydroxyethyl)-rapamycin.

39. On information and belief, there are no substantial uses of Roxane's ANDA Products that do not infringe the '224 and/or '131 Patents.

40. On information and belief, if its ANDA is approved, Roxane will contributorily infringe the '224 and '131 Patents, and will do so with knowledge of the '224 and '131 Patents and that its ANDA Products are especially made or especially adapted for use in infringing the '224 and '131 Patents.

41. 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 Roxane's ANDA Products be a date that is no earlier than July 1, 2028, the expiration of the '224 Patent, and November 22, 2025, the expiration of the '131 Patent's pediatric exclusivity, and an award of damages for any commercial sale or use of Roxane's ANDA Products and any act committed by Roxane with respect to the subject matter claimed in the '224 and '131 Patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

42. On information and belief, Roxane has taken and continues to take active steps towards the commercial manufacture, use, offer for sale, sale, and/or importation of Roxane's ANDA Products, including seeking approval to market those products under Roxane's ANDA prior to the expiration of the '224 and '131 Patents.

43. There is a substantial and immediate controversy between Plaintiffs and Roxane concerning the '224 and '131 Patents. Plaintiffs are entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Roxane will induce infringement of and/or contributorily infringe one or more claims of the '224 and '131 Patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Roxane has directly infringed one or more claims of the '224 and '131 Patents by filing and/or amending its ANDA relating to Roxane's everolimus tablets (2.5 mg, 5 mg, 7.5 mg, and 10 mg dosage strengths);

B. A permanent injunction restraining and enjoining Roxane 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 Roxane's everolimus tablets (2.5 mg, 5 mg, 7.5 mg, and 10 mg dosage strengths), as claimed in the '224 and '131 Patents;

C. An order that the effective date of any approval of the ANDA relating to Roxane's everolimus tablets (2.5 mg, 5 mg, 7.5 mg, and 10 mg dosage strengths), be a date that is not earlier than the expiration of the right of exclusivity under the '224 and '131 Patents;

D. Declaratory judgment that Roxane will induce infringement of and/or contributorily infringe one or more claims of the '224 and '131 Patents by commercially manufacturing, offering for sale and/or selling its everolimus tablets (2.5 mg, 5 mg, 7.5 mg, and 10 mg dosage strengths);

E. Damages from Roxane for the infringement and/or inducement of infringement and/or contributory infringement of the '224 and '131 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: June 10, 2015

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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