IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novartis Pharmaceuticals Corporation and Novartis AG (hereinafter "Plaintiffs"), for their Complaint against defendant Teva Pharmaceuticals USA, 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 Teva Pharmaceuticals USA, Inc. ("Teva") is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

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. This Court has personal jurisdiction over Teva because, on information and belief, Teva is a corporation organized under the laws of the State of Delaware, has a registered agent to accept service in Delaware as Corporate Creations Network, Inc., 3411 Silverside Road, Tatnall Building, Suite 104, Wilmington, Delaware 19810, and is registered to do business in Delaware under file number 2053734. On information and belief, pursuant to Del. Code Ann. Tit. 24, § 2540, Teva is registered to distribute generic pharmaceutical products in Delaware. On information and belief, Teva holds "Distributor/Manufacturer CSR" (License Nos. DM-0006546 and DM-0007115) and "Pharmacy-Wholesale" (License Nos. A4-0001447 and A4-0001468) licenses from the Delaware Board of Pharmacy.

7. This Court has personal jurisdiction over Teva because, on information and belief, Teva develops, manufactures, markets and distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district

8. This Court has personal jurisdiction over Teva because, on information and belief, Teva has previously availed itself to the rights and privileges of this forum through previous litigation, including but not limited to *Teva Pharms. USA, Inc., et al. v. Mylan Pharms. Inc. et al.*, C.A. No. 1:17-cv-00249-GMS (D. Del. 2017); *Teva Pharms. USA Inc. et al. v. Dr. Reddy's Labs., Ltd. et al.*, C.A. No. 1:16-cv-01267-GMS (D. Del. 2016); and *Teva Pharms. USA, Inc. et al. v. Biocon Ltd. et al.*, C.A. No. 1:16-cv-00278-GMS (D. Del. 2016).

9. This Court has personal jurisdiction over Teva because, as explained further below, Teva 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, 2.5 mg, 5 mg, 7.5 mg and 10 mg dosage strengths described herein, that will be purposefully directed at Delaware. Teva's filing of its ANDA 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 Teva in 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® (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 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.

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. 9,006,224 ("the '224 patent"). The '224 patent was duly and legally issued on April 14, 2015.

14. 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 everolimus 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.

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. Plaintiff NPC is the owner of United States Letters Patent No. 8,436,010 ("the '010 patent"). The '010 patent was duly and legally issued on May 7, 2013.

20. The '010 patent claims, *inter alia*, a method for inhibiting growth of solid tumors of the breast in a patient having a solid breast tumor, said method consisting of

administering to said subject a therapeutically effective amount of everolimus concomitantly or sequentially with exemestane. A true copy of the '010 patent is attached as Exhibit D.

21. On information and belief, Teva submitted to the FDA an ANDA under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, offer for sale, or sale in the United States and/or importation into the United States of generic everolimus tablets (2.5 mg, 5 mg, 7.5 mg, and 10 mg dosage strengths) (the "ANDA Products") before the expiration of the '224, '131, '962, and '010 patents.

22. On information and belief, Teva seeks approval to market its ANDA Products for the indication of treatment of adults with advanced renal cell carcinoma (RCC), after failure of treatment with sunitinib or sorafenib.

23. On information and belief, Teva seeks approval to market its ANDA Products for the indication of treatment of adults with renal angiomyolipoma and tuberous sclerosis complex, not requiring immediate surgery

24. On information and belief, Teva seeks approval to market its ANDA Products for the indication of treatment of adults with progressive neuroendocrine tumors of pancreatic origin (PNET) that are unresectable, locally advanced or metastatic.

25. On information and belief, Teva seeks approval to market its ANDA Products for the indication of the treatment of patients with tuberous sclerosis complex who have subependymal giant cell astrocytoma that requires therapeutic intervention but cannot be curatively resected.

26. On information and belief, Teva seeks approval to market its ANDA Products for the indication of 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.

27. On information and belief, Teva's ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '224, '131, '962 and '010 patents.

28. Plaintiff NPC received written notification of Teva's ANDA to include the § 355(j)(2)(A)(vii)(IV) certification by a letter dated February 21, 2017 ("Notice Letter"), which alleged that claims 1-3 of the '224 patent are invalid, claims 1-9 of the '131 patent are invalid and claim 4 of the '131 patent will not be infringed by Teva, claims 1-6 of the '962 patent are invalid, and claims 1-11 of the '010 patent are invalid and claims 10 and 11 of the '010 patent will not be infringed by Teva. Teva did not allege noninfringement of any other claims of the '224, '131, '962 or '010 patents. Teva did not allege that any of the claims of the '224, '131, '962 or '010 patents were unenforceable.

29. This action was commenced within 45 days of NPC's receipt of the Teva Notice Letter.

30. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale or sale in the United States and/or importation into the United States of Teva's ANDA Products before the expiration of the '224, '131, '962 and '010 patents, Teva has committed an act of infringement under 35 U.S.C. § 271(e)(2).

31. On information and belief, when Teva filed its ANDA, it was aware of the '224, '131, '962, and '010 patents and that the filing of its ANDA with the request for its approval prior to the expiration of the '224, '131, '962, and '010 patents was an act of infringement of those patents.

32. On information and belief, the commercial manufacture, use, offer for sale, or sale in the United States and/or importation into the United States of Teva's ANDA Products will infringe one or more claims of the '224, '131, '962, and '010 patents.

33. On information and belief, Teva'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, Teva 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.

34. On information and belief, Teva's ANDA Products, if approved, will contain instructions for administering everolimus for treating pancreatic neuroendocrine tumors in a human subject in a therapeutically effective amount.

35. On information and belief, Teva's ANDA Products, if approved, will contain instructions for administering everolimus for treating pancreatic neuroendocrine tumors in a human subject in a therapeutically effective amount as a monotherapy and wherein the tumors are advanced tumors.

36. On information and belief, Teva's ANDA Products, if approved, will contain instructions for administering everolimus 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.

37. Teva did not deny infringement of any of the claims 1–3 of the '224 patent in its Notice Letter.

38. On information and belief, Teva'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, Teva 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

39. On information and belief, Teva's ANDA Products, if approved, will contain instructions for administering everolimus for inhibiting growth of solid excretory system tumors in a subject in a therapeutically effective amount.

40. On information and belief, if its ANDA is approved, Teva's ANDA Products will be specifically labeled for administering everolimus for inhibiting growth of solid excretory system tumors in a subject in a therapeutically effective amount.

41. On information and belief, if Teva's ANDA Products are approved, Teva 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 in a therapeutically effective amount.

42. On information and belief, if Teva's ANDA Products are approved, those products will constitute a material part of a method for inhibiting growth of solid excretory system tumors in a subject in a therapeutically effective amount and will not be suitable for a substantial noninfringing use.

43. On information and belief, if its ANDA is approved, Teva will contributorily infringe the '131 patent, and will do so 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.

44. Teva did not deny infringement of claims 1–3 and 5–9 of the '131 patent in its Notice Letter.

45. On information and belief, Teva's ANDA Products, will be administered for inhibiting growth of non-malignant solid tumors of the brain in a subject in a therapeutically effective amount, which administration will constitute direct infringement of the '962 patent. On information and belief, if Teva's ANDA Products are approved, Teva 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.

46. On information and belief, Teva's ANDA Products, if approved, will contain instructions for administering everolimus for inhibiting growth of non-malignant solid tumors of the brain in a subject in a therapeutically effective amount.

47. On information and belief, if Teva's ANDA is approved, Teva's ANDA Products will contain instructions for administering everolimus for treating non-malignant solid tumors of the brain to a human subject in need thereof in a therapeutically effective amount.

48. On information and belief, if its ANDA is approved, Teva's ANDA Products will be specifically labeled for administering everolimus for inhibiting growth of non-malignant solid tumors of the brain in a subject in a therapeutically effective amount.

49. On information and belief, if Teva's ANDA Products are approved, Teva 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.

50. On information and belief, if Teva'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 and will not be suitable for a substantial noninfringing use.

51. On information and belief, if Teva's ANDA Products are approved, Teva 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.

52. Teva did not deny infringement of claims 1–6 of the '962 patent in its Notice Letter.

53. On information and belief, Teva's ANDA Products, if approved, will be administered for inhibiting growth of solid tumors of the breast in a patient having a solid breast tumor in a therapeutically effective amount concomitantly or sequentially with exemestane, which administration will constitute direct infringement of the '010 patent. On information and belief, if its ANDA is approved, Teva will actively induce, encourage, and abet infringement of the '010 patent, and will do so with knowledge of the '010 patent and with knowledge that its acts will induce infringement of the '010 patent.

54. On information and belief, Teva's ANDA Products, if approved, will contain instructions for administering everolimus for inhibiting growth of solid tumors of the

breast in a patient having a solid breast tumor in a therapeutically effective amount concomitantly or sequentially with exemestane.

55. On information and belief, if its ANDA is approved, Teva's ANDA Products will be specifically labeled for administering everolimus for inhibiting growth of solid tumors of the breast in a patient having a solid breast tumor in a therapeutically effective amount concomitantly or sequentially with exemestane.

56. On information and belief, if its ANDA is approved, Teva will commercially manufacture, offer for sale, sell and/or import its ANDA Products for use in a method for inhibiting growth of solid tumors of the breast in a patient having a solid breast tumor, said method consisting of administering to said subject a therapeutically effective amount of everolimus concomitantly or sequentially with exemestane.

57. On information and belief, if approved, Teva's ANDA Products will constitute a material part of a method for inhibiting growth of solid tumors of the breast in a patient having a solid breast tumor, said method consisting of administering to said subject a therapeutically effective amount of everolimus concomitantly or sequentially with exemestane and will not be suitable for a substantial noninfringing use.

58. On information and belief, if Teva's ANDA Products are approved, Teva will contributorily infringe the '010 patent, and will do so with knowledge of the '010 patent, and that its ANDA Products are especially made or especially adapted for use in infringing the '010 patent and are not suitable for a substantial noninfringing use.

59. Teva did not deny infringement of claims 1-9 of the '010 patent in its Notice Letter.

60. 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 Teva's ANDA Products be a date that is no earlier than July 1, 2028, the expiration of the '224 patent, May 1, 2026, the expiration of the '131 patent's pediatric exclusivity, August 18, 2022, the expiration date of the '962 patent's pediatric exclusivity, and August 22, 2022, the expiration of the '010 patent's pediatric exclusivity, and an award of damages for any commercial sale or use of Teva's ANDA Products and any act committed by Teva with respect to the subject matter claimed in the '224, '131, '962 and '010 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

61. On information and belief, Teva has taken and continues to take active steps towards the commercial manufacture, use, offer for sale, or sale in the United States, and/or importation into the United States of Teva's ANDA Products, including seeking approval of those products under Teva's ANDA.

62. There is a substantial and immediate controversy between Plaintiffs and Teva concerning the '224, '131, '962 and '010 patents. Plaintiffs are entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Teva will induce infringement of one or more claims of the '224, '131, '962 and '010 patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Teva has directly infringed, induced infringement of and/or contributorily infringed one or more claims of the '224, '131, '962 and '010 patents by filing an ANDA relating to Teva's everolimus tablets (2.5 mg, 5 mg, 7.5 mg, and 10 mg dosage strengths);

B. A permanent injunction restraining and enjoining Teva 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 in the United States, or importation into the United States, of Teva's everolimus tablets (2.5 mg, 5 mg, 7.5 mg, and 10 mg dosage strengths), as claimed in the '224, '131, '962 and '010 patents;

C. An order that the effective date of any approval of the ANDA relating to Teva'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, '131, '962 and '010 patents;

D. Declaratory judgment that the commercial manufacture, use, offer for sale, and sale in the United States, and/or importation into the United States of Teva's everolimus tablets (2.5 mg, 5 mg, 7.5 mg, and 10 mg dosage strengths) will induce infringement of and/or contributorily infringe one or more claims of the '224, '131, '962 and '010 patents;

E. Damages from Teva for the infringement, inducement of infringement and/or contributory infringement of the '224, '131, '962 and '010 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 7, 2017

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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