IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT FOR PATENT INFRINGEMENT

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

having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, defendant Mylan directly or indirectly 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. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and/or 28 U.S.C. § 1400(b).

6. This Court has jurisdiction over Mylan, because, *inter alia*, on information and belief, Mylan is registered to do business in Delaware as a foreign corporation, with filing number 4809319. Mylan has a designated agent in Delaware for the receipt of service of process as The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. Mylan holds a Pharmacy Wholesale License from the State of Delaware under License No. A4-0001719. Mylan holds a Distributor/Manufacturer License for Controlled Substances from the State of Delaware under License No. DM-0007571. Mylan directly or indirectly is in the business of developing, manufacturing, marketing, importing, offering to sell and selling pharmaceutical drug products, including generic drug products, throughout the United States, including this judicial district. Delaware would be a destination of Mylan's ANDA Products upon approval and marketing of Mylan's ANDA Products involved in this action. Mylan's filing of its ANDA involved in this action constitutes a formal act that reliably indicates its plans to engage in marketing of the accused infringing ANDA products in Delaware.

This act is sufficient to confer specific jurisdiction over Mylan in Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016).

7. On information and belief, Mylan has purposely availed itself of the rights and benefits of this Court without objecting on the basis of lack of personal jurisdiction when sued in this Court and through the assertions of counterclaims in suits against it brought in this Court.

8. On information and belief, Mylan has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Mylan regularly and continuously transacts business within the State of Delaware, including by selling pharmaceutical products in Delaware, either on its own or through its affiliates. Upon information and belief, Mylan derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

9. This Court has personal jurisdiction over Mylan by virtue of, *inter alia*, these above-mentioned facts.

10. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Mylan.

11. 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

12. 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 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.

13. 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."

14. 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.

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

16. 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.

17. 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 B.

18. 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.

19. The '010 patent claims, *inter alia*, a method for inhibiting growth of solid tumors of the breast in a subject having a solid breast tumor, said method consisting of administering to said subject a therapeutically effective amount of 40-O-(2-hydroxyethyl)-rapamycin (everolimus) concomitantly or sequentially with exemestane. A true copy of the '010 patent is attached as Exhibit C.

20. On information and belief, Mylan 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, offer for sale and sale of everolimus tablets in 2.5 mg, 5 mg, 7.5 mg, and 10 mg dosage strengths (the "ANDA Products") before the expiration of the '772, '962 and '010 patents.

21. Plaintiffs received written notification of Mylan's ANDA containing a § 355(j)(2)(A)(vii)(IV) certification by letter dated April 23, 2019 ("Notice Letter"), which alleged that claims 1-3 and 7-10 of the '772 patent are invalid and claims 4-6 and 8-9 of the '772 patent will not be infringed by Mylan, claims 1-6 of the '962 patent are invalid and will not be infringed by Mylan, and claims 1-11 of the '010 patent are invalid and will not be infringed by Mylan. Mylan did not allege non-infringement of claims 1-3, 7, and 10 of the '772 patent. Mylan also did not allege that any of the claims of the '772, '962 and '010 patents were unenforceable.

22. This action was commenced within 45 days of Novartis's receipt of the Mylan 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 Mylan's ANDA Products before the expiration of the '772, '962 and '010 patents, Mylan has committed an act of infringement under 35 U.S.C. § 271(e)(2).

24. On information and belief, when Mylan filed its ANDA, it was aware of the '772, '962 and '010 patents and that the filing of its ANDA with the request for its approval prior to the expiration of the '772, '962 and '010 patents was an act of infringement of those patents.

25. 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 Mylan's ANDA Products will infringe one or more claims of the '772, '962 and '010 patents.

26. On information and belief, Mylan'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 Mylan's ANDA Products will directly infringe the '772 patent.

27. Mylan did not deny infringement of claims 1-3, 7, and 10 of the '772 patent in its Notice Letter.

28. On information and belief, Mylan'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 Mylan's ANDA Products are approved, physicians and/or patients following said instructions will directly infringe the '962 patent. On information and belief, if Mylan's ANDA Products are approved, Mylan will actively encourage, recommend, or promote this infringement with knowledge of the '962 patent, and that its acts will induce infringement of the '962 patent.

29. On information and belief, if Mylan's ANDA Products are approved, Mylan will commercially manufacture, offer for sale and/or sell 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 Mylan'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 Mylan's

ANDA Products are approved, physicians and/or patients following the instructions in Mylan's ANDA Products will directly infringe the '962 patent. On information and belief, if Mylan's ANDA Products are approved, Mylan 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.

30. On information and belief, Mylan's ANDA Products, if approved, will contain instructions for administering a therapeutically effective amount of everolimus concomitantly or sequentially with exemestane for inhibiting growth of solid tumors of the breast in a subject having a solid breast tumor, which administration will constitute direct infringement of the '010 patent. On information and belief, if Mylan's ANDA Products are approved, physicians and/or patients following said instructions will directly infringe the '010 patent. On information and belief, if Mylan's ANDA Products are approved, Mylan will actively encourage, recommend, or promote this infringement with knowledge of the '010 patent, and that its acts will induce infringement of the '010 patent.

31. On information and belief, if Mylan's ANDA Products are approved, Mylan will commercially manufacture, offer for sale and/or sell those products, which will be specifically labeled for use in a method for inhibiting growth of solid tumors of the breast in a subject having a solid breast tumor, said method consisting of administering to said subject a therapeutically effective amount of everolimus concomitantly or sequentially with exemestane. On information and belief, if Mylan's ANDA Products are approved, those products will constitute a material part of a method for inhibiting growth of solid tumors of the breast in a subject having a solid breast tumor, said method consisting of administering to said subject a

therapeutically effective amount of everolimus concomitantly or sequentially with exemestane. On information and belief, if Mylan's ANDA Products are approved, physicians and/or patients following the instructions in Mylan's ANDA Products will directly infringe the '010 patent. On information and belief, if Mylan's ANDA Products are approved, Mylan 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.

32. 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 Mylan's ANDA Products be a date that is no earlier than March 9, 2020, the expiration of the '772 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 Mylan's ANDA Products and any act committed by Mylan with respect to the subject matter claimed in the '772, '962, and '010 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

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

34. There is a substantial and immediate controversy between Plaintiffs and Mylan concerning the '772, '962 and '010 patents. Plaintiffs are entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Mylan will infringe, induce infringement of and/or contributorily infringe one or more claims of the '772, '962 and '010 patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Mylan has directly infringed, induced infringement of and/or contributorily infringed one or more claims of the '772, '962 and '010 patents by filing an ANDA relating to Mylan's everolimus tablets in 2.5 mg, 5 mg, 7.5 mg, and 10 mg dosage strengths;

B. A permanent injunction restraining and enjoining Mylan 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 Mylan's everolimus tablets in 2.5 mg, 5 mg, 7.5 mg, and 10 mg dosage strengths, as claimed in the '772, '962 and '010 patents;

C. An order that the effective date of any approval of the ANDA relating to Mylan's everolimus tablets in 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 '772, '962 and '010 patents;

D. Declaratory judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's everolimus tablets in 2.5 mg, 5 mg, 7.5 mg, and 10 mg dosage strengths will directly infringe, induce infringement of and/or contributorily infringe one or more claims of the '772, '962 and '010 patents;

E. Damages from Mylan for the infringement, inducement of infringement and contributory infringement of the '772, '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: June 5, 2019

MCCARTER & ENGLISH, LLP

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