IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

C.A. No. 1:17-CV-54

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, on information and belief, Mylan is a company organized and existing under the laws of West Virginia and has a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

7. This Court also has jurisdiction over Mylan, because, *inter alia*, this action arises from actions of Mylan directed toward West Virginia and because Mylan has purposefully availed itself of the rights and benefits of West Virginia law by engaging in systematic and continuous contacts with West Virginia. Mylan regularly and continuously transacts business within the State of West Virginia, including by selling pharmaceutical products in West Virginia, either on its own or through its affiliates. Upon information and belief, Mylan derives substantial revenue from the sale of those products in West Virginia and has availed itself of the privilege of conducting business within the State of West Virginia.

8. This Court also has jurisdiction over Mylan because Mylan has availed itself of the legal protections of the State of West Virginia by, among other things, selecting the State of West Virginia as its place of incorporation and by consenting to jurisdiction and/or

asserting counterclaims in prior cases filed in this district under the Hatch-Waxman Act. *See, e.g.*, *Novartis Pharms. Corp. et al. v. Mylan Pharms., Inc. et al.*, No. 1:14-cv-00111-IMK (N.D. W. Va. Dec. 4, 2014); *Teva Pharms. USA, Inc. et al. v. Mylan Pharms., Inc. et al.*, No. 1:14-cv-00167-IMK (N.D. W. Va. Nov. 26, 2014); *Acorda Therapeutics, Inc. et al. v. Mylan Pharms., Inc. et al.*, No. 1:14-cv-00139-IMK (N.D. W. Va. Jan. 12, 2015); *Pfizer Inc. et al. v. Mylan Inc. et al.*, No. 1:15-cv-00004-IMK (N.D. W. Va. Feb. 13, 2015); *Noven Pharms., Inc. et al. v. Mylan Techs., Inc. et al.*, No. 1:15-cv-00069-IMK-MJA (N.D. W. Va. May 4, 2015).

9. Mylan's counsel in this matter, Perkins Coie LLP, having conferred with Plaintiffs' counsel in this matter, Fitzpatrick, Cella, Harper & Scinto, agrees that, for this matter, jurisdiction and venue are proper over Mylan in West Virginia.

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.

CLAIM FOR RELIEF – PATENT INFRINGEMENT

11. Plaintiff NPC holds approved New Drug Application ("NDA") No. 203985 for AFINITOR Disperz® (everolimus tablets for oral suspension) 2 mg, 3 mg and 5 mg dosage strengths, which contain the active ingredient everolimus. AFINITOR Disperz® (everolimus tablets for oral suspension) was approved by the United States Food and Drug Administration ("FDA") on August 29, 2012 (2 mg, 3 mg and 5 mg). AFINITOR Disperz® (everolimus tablets for oral suspension) is indicated for the treatment of pediatric and adult patients with tuberous sclerosis complex who have subependymal giant cell astrocytoma that requires therapeutic intervention but cannot be curatively resected. AFINITOR Disperz® (everolimus tablets for oral suspension) 2 mg, 3 mg, and 5 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. 5,665,772 ("the '772 patent"). The '772 patent was duly and legally issued on September 9, 1997.

14. 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.

15. 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.

16. 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.

17. Plaintiff Novartis AG is the owner of United States Letters Patent No. 8,617,598 ("the '598 patent"). The '598 patent was duly and legally issued on December 31, 2013.

18. The '598 patent claims, *inter alia*, certain pharmaceutical compositions in the form of a dispersible tablet comprising a solid dispersion of everolimus, a disintegrant and colloidal silicon dioxide. A true copy of the '598 patent is attached as Exhibit C.

19. 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 for oral suspension in 2 mg, 3 mg and 5 mg dosage strengths (the "ANDA Products") before the expiration of the '772, '962 and '598 patents.

20. Plaintiffs received written notification of Mylan's ANDA containing a § 355(j)(2)(A)(vii)(IV) certification by letter dated February 24, 2017 ("Notice Letter"), which alleged that claims 1-3 and 7-10 of the '772 patent are invalid and claims 4-6 of the '772 patent will not be infringed by Mylan, claims 1-6 of the '962 patent are invalid, and claims 1-6 of the '598 will not be infringed by Mylan. Mylan did not allege non-infringement of claims 1-3 and 7-10 of the '772 patent or claims 1-6 of the '962 patent. Mylan also did not allege that any of the claims of the '772, '962 and '598 patents were unenforceable.

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

22. 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 '598 patents, Mylan has committed an act of infringement under 35 U.S.C. § 271(e)(2).

23. On information and belief, when Mylan filed its ANDA, it was aware of the '772, '962 and '598 patents and that the filing of its ANDA with the request for its approval prior to the expiration of the '772, '962 and '598 patents was an act of infringement of those patents.

24. 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 '598 patents.

25. 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.

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

27. 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, Mylan 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.

28. 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, 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.

29. Mylan did not deny infringement of claims 1-6 of the '962 patent in its Notice Letter.

30. On information and belief, Mylan's ANDA Products, if approved, will contain a pharmaceutical composition in the form of a solid dispersion comprising everolimus, a disintegrant and colloidal silicon dioxide. On information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's ANDA Products will directly infringe the '598 patent.

31. 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 March 27, 2023, the expiration of the '598 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, '598, and '962 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

32. 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.

33. There is a substantial and immediate controversy between Plaintiffs and Mylan concerning the '772, '962 and '598 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 '598 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 '598 patents by filing an ANDA relating to Mylan's everolimus tablets for oral suspension in 2 mg, 3 mg and 5 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 for oral suspension in 2 mg, 3 mg and 5 mg dosage strengths, as claimed in the '772, '962 and '598 patents;

C. An order that the effective date of any approval of the ANDA relating to Mylan's everolimus tablets for oral suspension in 2 mg, 3 mg and 5 mg dosage strengths be a date that is not earlier than the expiration of the right of exclusivity under the '772, '962 and '598 patents;

D. Declaratory judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's everolimus tablets for oral suspension in 2 mg, 3 mg and 5 mg dosage strengths will directly infringe, induce infringement of and/or contributorily infringe one or more claims of the '772, '962 and '598 patents;

E. Damages from Mylan for the infringement, inducement of infringement and contributory infringement of the '772, '962 and '598 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 10, 2017

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