IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

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. § 1400(b) because Teva is a Delaware corporation.

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. 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. 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 '772 patent.

16. Plaintiffs received written notification of Teva's ANDA containing a § 355(j)(2)(A)(vii)(IV) certification by letter dated May 17, 2017 ("Notice Letter"), which alleges that claims 1-3, 7 and 10 of the '772 patent are invalid and that claims 4-6 and 8-9 of the '772 patent will not be infringed by Teva. The Teva Notice Letter does not allege that Teva's ANDA Products do not infringe claims 1-3, 7 and 10 of the '772 patent for any reason other than that those claims are invalid. The Teva Notice Letter does not include a detailed statement of the legal and factual bases for any allegation that any claim of the '772 patent is unenforceable.

17. This action was commenced within 45 days of Plaintiffs' receipt of the Teva Notice Letter.

18. 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 '772 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

19. On information and belief, when Teva filed its ANDA, it was aware of the '772 patent and that the filing of Teva's ANDA with the request for its approval prior to the expiration of the '772 patent was an act of infringement of that patent.

20. On information and belief, Teva'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 Teva's ANDA Products will directly infringe one or more claims of the '772 patent.

21. 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 March 9, 2020, the expiration of the '772 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 '772 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

22. 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.

23. There is a substantial and immediate controversy between Plaintiffs and Teva concerning the '772 patent. Plaintiffs are entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Teva will infringe one or more claims of the '772 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Teva has directly infringed one or more claims of the '772 patent 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 '772 patent;

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 '772 patent;

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 directly infringe one or more claims of the '772 patent;

E. Damages from Teva for the infringement of the '772 patent;

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 30, 2017

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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