IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., WYETH LLC. and WYETH PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SANDOZ INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs, Pfizer Inc., Wyeth LLC, and Wyeth Pharmaceuticals Inc. (collectively "Pfizer"), for their Complaint against Defendant, Sandoz Inc. ("Sandoz"), allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 5,362,718 ("the '718 Patent"). Pfizer institutes this action to enforce its patent rights covering Torisel® (Temsirolimus) Injection dosage form 25 mg/mL, 1.8 mL vial, that is approved in the United States by the U.S. Food and Drug Agency ("FDA") for the treatment of advanced renal cell carcinoma. This action relates to Abbreviated New Drug Application ("ANDA") Nos. 203-140 and 203-216 filed by Sandoz with the FDA for approval to market generic copies of Pfizer's Torisel® pharmaceutical products that are sold in the United States.

PARTIES

2. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 235 East 42nd Street, New York, New York 10017.

3. Plaintiff Wyeth LLC is a company organized and existing under the laws of the State of Delaware with its principal place of business at Five Giralda Farms, Madison, NJ 07940.

4. Plaintiff Wyeth Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 500 Arcola Road, Collegeville, PA 19426.

5. Upon information and belief, Defendant Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado with its principal place of business at 605 Carnegie Center, Suite 400, Princeton, NJ 08540.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, generally, and 35 U.S.C. § 271(e)(2) specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Sandoz by virtue of the fact that, *inter alia*, Sandoz has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Pfizer, which manufactures numerous drugs for sale and use throughout the United States, including this judicial district.

8. This Court also has personal jurisdiction over Sandoz by virtue of Sandoz's systematic and continuous contact with Delaware. Upon information and belief, Sandoz regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or

consumed in Delaware. Accordingly, Sandoz has purposefully availed itself of the privilege of conducting business in the State of Delaware so as to reasonably allow jurisdiction to be exercised over it.

9. On information and belief, Sandoz Inc. is in the business of formulating, manufacturing, and commercializing pharmaceutical products.

10. On information and belief, by virtue of, *inter alia*, Sandoz's sales-related activities in Delaware, including, but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of Delaware, this Court has personal jurisdiction over Sandoz.

11. On information and belief, Sandoz is licensed to distribute pharmaceuticals in the state of Delaware and is in the business of making and selling generic pharmaceutical products for sale throughout the United States, including Delaware. On further information and belief, Sandoz is registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer" and "Pharmacy-Wholesale" of drug products. *See* https://dpronline.delaware.gov/mylicense%20weblookup/SearchResults.aspx.

12. On information and belief, Sandoz has previously availed itself of this jurisdiction for the purpose of litigating its patent suits. *See, e.g., Sandoz Inc. v Pfizer Inc.*, C.A. No. 09-2457 (D. Del.). On further information and belief, Sandoz has previously been sued in this district and has not challenged personal jurisdiction. *See, e.g., Aventis Pharma S.A. v. Sandoz Inc.*, C.A. No. 11-043 (D. Del.). Sandoz has also submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Specifically, Sandoz consented to jurisdiction and filed counterclaims in, *inter alia*, *Genzyme Corp. v. Sandoz Inc.*, C.A. No. 10-429 (D. Del.); *Cephalon Inc. v. Sandoz Inc.*, C.A. No. 10-123 (D. Del.);

Allergan Inc. v. Sandoz Inc., C.A. 10-024 (D. Del.); *Daiichi Sankyo Co., LTD. v. Sandoz Inc.*, C.A. No. 09-898 (D. Del.); *Bone Care Int'l LLC v. Sandoz Inc.*, C.A. No. 09-524 (D. Del.); *Pfizer Inc. v. Sandoz Inc.*, C.A. No. 09-310 (D. Del.); *Abbott Labs. v. Sandoz Inc.*, C.A. No. 09-215 (D. Del.); *Medicis Pharms. Corp. v. Mylan Inc. et al.*, C.A. No. 09-033 (D. Del.); *Wyeth v. Sandoz Inc.*, C.A. No. 08-317 (D. Del.); and *AstraZeneca Pharms. LP v. Sandoz Inc.*, C.A. No. 07-807 (D. Del).

13. On information and belief, by virtue of, *inter alia*, Sandoz's filing of ANDA Nos. 203-140 and 203-216, and the associated systematic and continuous activities within the state of Delaware, including but not limited to the development of generic drug products for sale to residents of Delaware, this Court has general and specific personal jurisdiction over Sandoz. These activities satisfy due process and confer personal jurisdiction over Sandoz consistent with the Delaware Long Arm Statute.

14. On information and belief, Sandoz caused tortious injury in Delaware to Pfizer by filing ANDA Nos. 203-140 and 203-216, further supporting specific and/or general jurisdiction over Sandoz.

15. Sandoz has consented to jurisdiction in this Court for the purposes of this case.

16. Venue is proper in this district under 28 U.S.C. §§ 1391(b), (c), and (d) and/or 1400(b).

BACKGROUND

U.S. Patent 5,362,718

17. On November 8, 1994, the United States and Patent and Trademark Office ("USPTO") issued U.S. Patent No. 5,362,718 (the "'718 patent") entitled, "Rapamycin Hydroxyesters." A true and correct copy of the '718 patent is attached hereto as Exhibit A.

18. The '718 patent claims rapamycin hydroxyesters, pharmaceutical compositions thereof, and methods of treatment using such compositions.

19. The '718 patent covers Pfizer's product Torisel®, which contains temsirolimus, a rapamycin hydroxyester, and is indicated for the treatment of advanced renal cell carcinoma.

20. The '718 patent is assigned to Wyeth LLC, which is a wholly owned subsidiary of Pfizer Inc.

21. A patent term extension ("PTE") application was filed under 35 U.S.C. § 156 on July 24, 2007 for the '718 patent requesting an extension of 1,764 days.

22. On January 7, 2008, the USPTO forwarded the PTE application to the FDA with a letter indicating that the '718 patent would not be eligible for PTE because the approval of Torisel® did not comply with 35 U.S.C. § 156(a)(5)(A), *i.e.*, Torisel® was an ester of a previously approved compound.

23. On November 4, 2010, Pfizer Inc. sent a letter asking that the PTE be granted based on a May 2010 Federal Circuit decision, *Photocure ASA v. Kappos*, 603 F.3d 1372 (Fed. Cir. 2010), where the Court held that an ester of a previously approved human drug product could support term extension even in light of a previous approval of a product containing

the same "active moiety." In other words, "product," as used in § 156(a), means the product that is present in the drug for which federal approval was obtained, thus an ester of a previously approved drug substance formulated as a salt may still be eligible for a PTE.

24. The '718 will expire on February 15, 2019, if the patent term extension is granted. If the patent term extension is not granted, then the '718 patent will expire on April 18, 2014.

Torisel®

25. Wyeth Pharmaceuticals Inc. (a wholly owned subsidiary of Pfizer Inc.) is the holder of approved New Drug Application ("NDA") No. 22-088 for Torisel® (Temsirolimus) Injection, 25 mg/mL, 1.8 mL vial, for the treatment of advanced renal cell carcinoma.

26. Torisel® is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") as having New Chemical Exclusivity until May 30, 2012 and Orphan Drug Exclusivity until May 30, 2014.

27. On information and belief, Sandoz filed with the FDA ANDA Nos. 203-140 and 203-216 under 21 U.S.C. § 355(j), seeking approval to market Temsirolimus Injection, dosage form 25 mg/mL, 1.8 mL vial ("Sandoz's Temsirolimus Injection"), which are generic copies of Pfizer's Torisel® (Temsirolimus) Injection, 25 mg/mL, 1.8 mL vial.

28. By two letters dated November 3, 2011, Sandoz notified Pfizer that it had filed ANDA Nos. 203-140 and 203-216, seeking approval to market Sandoz's Temsirolimus Injection, and that it was providing information to Pfizer pursuant to 21 U.S.C. § 355(j)(2)(B)(i) and (ii). Pfizer received the letters on or about November 3, 2011.

CLAIM FOR INFRINGEMENT

Infringement of U.S. Patent No. 5,362,718

29. Pfizer incorporates by reference paragraphs 1-28 of this Complaint as if fully set forth herein.

30. Sandoz has infringed the '718 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting ANDA Nos. 203-140 and 203-216, by which Sandoz seeks FDA approval to engage in the commercial manufacture, use, or sale of Sandoz's Temsirolimus Injection for the treatment of advanced renal cell carcinoma prior to the expiration of the '718 patent.

31. If Sandoz commercially manufactures, uses, offers to sell, or sells the Sandoz product within the United States, or imports Sandoz's Temsirolimus Injection into the United States, for the treatment of advanced renal cell carcinoma, or induces or contributes to any such conduct during the term of the '718 patent, it would further infringe the '718 patent under 35 U.S.C. § 271(a), (b), and/or (c).

32. On information and belief, Sandoz's Temsirolimus Injection, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '718 patent either literally or under the doctrine of equivalents.

33. On information and belief, the use of Sandoz's Temsirolimus Injection constitutes a material part of at least one of the claims of the '718 patent; Sandoz knows that its Temsirolimus Injection is especially made or adapted for use in infringing at least one of the claims of the '718 patent, either literally or under the doctrine of equivalents; and its

Temsirolimus Injection is not a staple article of commerce or commodities of commerce suitable for substantial noninfringing use.

34. On information and belief, the offering to sell, sale, and/or importation of Sandoz's Temsirolimus Injection would contributorily infringe at least one of the claims of the '718 patent, either literally or under the doctrine of equivalents.

35. On information and belief, Sandoz had knowledge of the '718 patent and, by its promotional activities and package insert for Sandoz's Temsirolimus Injection, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '718 patent, either literally or under the doctrine of equivalents.

36. On information and belief, the offering to sell, sale, and/or importation of Sandoz's Temsirolimus Injection would actively induce infringement of at least one of the claims of the '718 patent, either literally or under the doctrine of equivalents.

37. Pfizer will be irreparably harmed if Sandoz's infringement is not enjoined. Pfizer does not have an adequate remedy at law.

38. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Pfizer's reasonable attorney fees.

RELIEF SOUGHT

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor as follows:

A) That pursuant to 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed the '718 patent;

B) That judgment be entered that the manufacture, use, sale or offer to sell within the United States, or importation into the United States, of the Sandoz product described in ANDA Nos. 203-140 and 203-216 for the treatment of advanced renal cell carcinoma, will infringe the '718 patent;

C) That the effective date of any FDA approval of the Sandoz product for the treatment of advanced renal cell carcinoma not be earlier than the expiration of the '718 patent, including extensions;

D) That Sandoz, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale or selling the Sandoz product described in ANDA Nos. 203-140 and 203-216 for the treatment of advanced renal cell carcinoma, and any other product that infringes or induces or contributes to the infringement of the '718 patent, prior to the expiration of the '718 patent, including any extensions;

E) That Pfizer be awarded monetary relief if Sandoz commercially uses, offers to sell, or sells its proposed generic version of Torisel® for the treatment of advanced renal cell carcinoma, or any other product that infringes or induces or contributes to the infringement of the '718 patent, within the United States prior to the expiration of that patent, including any extensions, and that any such monetary relief be awarded to Pfizer with prejudgment interest;

F) That judgment be entered that this is an exceptional case under 35 U.S.C. § 285;

G) That pursuant to 35 U.S.C. § 285, Pfizer recover its reasonable attorney fees incurred in connection with this action;

H) For an assessment of costs and expenses against Sandoz; and

I) For such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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