

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH HOLDINGS CORPORATION and
WYETH-AYERST LEDERLE LLC,

Plaintiffs,

V.

SANDOZ INC.,

Defendant.

Civil Action No. _____

COMPLAINT

Plaintiffs Wyeth Holdings Corporation and Wyeth-Ayerst Lederle LLC, for their
Complaint herein, aver as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code.

JURISDICTION AND VENUE

2. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

3. This court has personal jurisdiction over the defendant Sandoz Inc. (“Sandoz”) because, *inter alia*, Sandoz has purposefully availed itself of the rights and benefits of Delaware law. Upon information and belief, Sandoz has continuous and systematic business contacts with the State of Delaware. Among other things, Sandoz is registered with the Delaware Board of Pharmacy as a “Distributor/Manufacturer CSR” and “Pharmacy-Wholesale.”

Additionally, Sandoz has agreed that it will not oppose jurisdiction in this Judicial District for this action.

4. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PARTIES

5. Plaintiff Wyeth Holdings Corporation is corporation organized and existing under the laws of the State of Maine, having its principal place of business at 5 Giralda Farms, Madison, NJ 07940. Wyeth Holdings Corporation is the owner of the patent-in-suit identified in paragraph 8 below.

6. Plaintiff Wyeth-Ayerst Lederle LLC is a limited liability company of Puerto Rico, having its principal place of business at 65th Infantry Avenue, Kilometer 9.7, Carolina, Puerto Rico 00987. Wyeth-Ayerst Lederle LLC is the exclusive licensee of the patent-in-suit identified in paragraph 8 below.

7. Upon information and belief, defendant Sandoz is a corporation organized and existing under the laws of Colorado, having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540, and does business in the state of Delaware.

THE PATENT-IN-SUIT

8. Wyeth Holdings Corporation is the lawful owner of all right, title, and interest in and to the following United States patent, including all right to sue and to recover for past infringement thereof, which patent is listed in the U.S. Food and Drug Administration (“FDA”) “Orange Book” (*Approved Products With Therapeutic Equivalence Evaluation*) as covering the antibacterial medication TYGACIL®:

United States Patent No. RE40,183, entitled “7-SUBSTITUTED-9-SUBSTITUTED AMINO-6-DEMETHYL-6-DEOXYTETRACYCLINES” (“the ‘183 reissue patent”), a copy of which is attached hereto as Exhibit A, which was duly and legally issued March 25, 2008, naming Joseph J. Halavka, Phaik-Eng Sum, Yakov Gluzman, Ving J. Lee and Adma A. Ross as the inventors.

9. Wyeth-Ayerst Lederle LLC is the exclusive licensee of the patent-in-suit. It markets and sells TYGACIL[®] in the United States.

**SANDOZ’S ANDA FOR TIGECYCLINE
INJECTABLE IV, 50 mg/vial**

10. Upon information and belief, Sandoz submitted Abbreviated New Drug Application (“ANDA”) No. 91-620 to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), in order to obtain approval to engage in the commercial manufacture, use, or sale of Tigecycline Injectable IV 50mg/vial, a generic version of TYGACIL[®], before the expiration date of the ‘183 reissue patent.

11. Upon information and belief, Sandoz’s generic tigecycline (a) is bioequivalent to TYGACIL[®], (b) has the same active ingredient and method of use as TYGACIL[®], (c) has the same route of administration, dosage form, and strength as TYGACIL[®], and (d) has the same, or substantially the same, proposed labeling as TYGACIL[®].

12. In a letter dated October 30, 2009 addressed to Wyeth Holdings Corporation and third-party Wyeth Pharmaceuticals Inc., Sandoz sent a “Notice of Certification Under 21 U.S.C. § 355(j)(2)(B) (§ 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95” (“Notice Letter”). The Notice Letter does not provide any valid basis for concluding that the ‘183 reissue patent is invalid and/or not infringed. Wyeth Holdings Corporation received the Notice Letter on November 2, 2009.

13. Upon information and belief, Sandoz's submission of ANDA No. 91-620 was an act of infringement of one or more claims of the '183 reissue patent under the United States Patent Laws, 35 U.S.C. § 271(e)(2)(A).

14. Upon information and belief, Sandoz's generic tigecycline is the subject of one or more claims of the '183 reissue patent.

15. Upon information and belief, Sandoz's manufacture, use, sale, and/or offer for sale of generic tigecycline will infringe, contribute to the infringement of, and induce infringement of one or more claims of the '183 reissue patent. Upon information and belief, at the time it committed the infringing activities set forth above, Sandoz was aware of the existence of the patent-in-suit, and had the specific intent to induce its direct infringement by health care professionals and patients.

16. Upon information and belief, Sandoz has been aware of the existence of the '183 reissue patent, but nevertheless has infringed one or more claims of the patent-in-suit in disregard of Plaintiffs' lawful rights under this patent, thus rendering this case "exceptional," as that term is set forth in 35 U.S.C. § 285.

17. The acts of infringement by Sandoz set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law and will continue unless enjoined by this Court.

RELIEF

WHEREFORE, Wyeth Holdings Corporation and Wyeth-Ayerst Lederle LLC pray for judgment against Sandoz as follows:

A. Adjudging that Sandoz has infringed the '183 reissue patent, and that the sale, offer for sale, and/or manufacture by the defendant of generic tigecycline, would infringe, induce infringement of, and/or contribute to infringement of the '183 reissue patent;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Sandoz's ANDA No. 91-620, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date which is not earlier than the last date of expiration of the '183 reissue patent plus any additional periods of exclusivity;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, Sandoz, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors or assigns, from any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any drug product that infringes the '183 reissue patent;

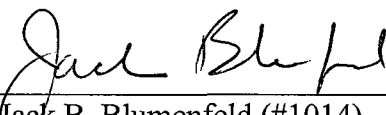
D. Declaring this an exceptional case and awarding Wyeth Holdings Corporation and Wyeth-Ayerst Lederle LLC their attorney fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding Wyeth Holdings Corporation and Wyeth-Ayerst Lederle LLC such other and further relief as this Court may deem just and proper.

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