IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC,	)	
Plaintiffs,	)	
v.	)	Civil Action No. _____
MSP SINGAPORE COMPANY, LLC,	)	
Defendant.	)	

COMPLAINT

Pfizer Inc., Pfizer Ireland Pharmaceuticals, and Warner-Lambert Company LLC, formerly Warner-Lambert Company (collectively, "Pfizer"), by their attorneys, for their Complaint against MSP Singapore Company, LLC ("MSP Singapore") allege as follows:

1. This is an action by Pfizer against Defendant for infringement of U.S. Patent No. 5,969,156 and its Reexamination Certificate (collectively "the '156 patent"). A copy of the '156 patent with the '156 Reexamination Certificate is attached hereto as Exhibit A.

PATENTS IN SUIT

2. On October 19, 1999, the United States Patent and Trademark Office (the "USPTO") issued the '156 patent, entitled "Crystalline [R-(R*,R*)]-2-(4-Fluorophenyl)-ß,δ-Dihydroxy-5-(1-Methylethyl)-3-Phenyl-4-[(Phenylamino)Carbonyl]-1H-Pyrrole-1-Heptanoic Acid Hemicalcium Salt (Atorvastatin)", on an application filed by Christopher Briggs, *et al.*, and assigned to Warner-Lambert Company. On September 26, 2006, the USPTO issued an Ex Parte Reexamination Certificate for the '156 patent.

PARTIES, JURISDICTION AND VENUE

3. Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and has a place of business at 235 East 42nd Street, New York, New York 10017.

4. Warner-Lambert Company is a corporation formerly organized under the laws of the State of Delaware with offices for service of process at 235 East 42nd Street, New York, New York 10017. Warner-Lambert Company has been the owner of record of the '156 patent since its issuance.

5. Warner-Lambert Company became a wholly-owned subsidiary of Pfizer Inc. effective June 19, 2000.

6. Warner-Lambert Company was converted into a Delaware limited liability company and changed its name to Warner-Lambert Company LLC on December 31, 2002. Warner-Lambert Company LLC has offices located at 235 East 42nd Street, New York, New York 10017.

7. Pfizer Ireland Pharmaceuticals is an Irish unlimited liability company having its registered office at Operations Support Group, Ringaskiddy, Co. Cork. Pfizer Ireland Pharmaceuticals is an indirect wholly-owned subsidiary of Pfizer Inc.

8. Pfizer Ireland Pharmaceuticals is the exclusive licensee of the '156 patent.

9. Pfizer has all the right, title, and interest in the '156 patent and the right to sue for infringement thereof.

10. Pfizer holds an approved New Drug Application for atorvastatin calcium formulations, including 10 mg, 20 mg, 40 mg, and 80 mg dosage strengths, which it sells under the registered name Lipitor®.

11. The ‘156 patent is identified pursuant to 21 U.S.C. § 355(b)(1) and (j)(7) by the United States Food and Drug Administration (“FDA”) as covering Pfizer’s Lipitor® product.

12. On information and belief, Defendant MSP Singapore is a company operating and existing under the laws of the State of Delaware with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

13. On information and belief, MSP Singapore participated in the preparation and/or filing of NDA No. 200-153 (“MSP Singapore NDA”).

14. This action arises under the Patent Laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction over this action pursuant to the provisions of Title 28, United States Code, Sections 1331 and 1338.

15. Personal jurisdiction over MSP Singapore is proper because MSP Singapore is incorporated in Delaware and has purposely availed itself of the privilege of doing business in this State. Further, MSP Singapore maintains continuous and systematic contacts with the State of Delaware so as to reasonably allow jurisdiction to be exercised over it.

16. Venue is proper in this District pursuant to the provisions of Title 28, United States Code, Sections 1391(c) and (d), and 1400(b).

17. On information and belief, MSP Singapore filed with the FDA, in Rockville, Maryland, New Drug Application (“NDA”) No. 200-153 under 21 U.S.C. § 355(b)(2) to obtain FDA approval for the commercial manufacture, use, importation, offer for sale, and sale in the United States of ezetimibe-atorvastatin calcium tablets in 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg dosage strengths.

18. By letter dated July 6, 2011 (the “NDA Notice Letter”), MSP Singapore notified Pfizer that it had filed NDA No. 200-153 seeking approval to market ezetimibe-atorvastatin

calcium tablets in 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg dosage strengths, and that Defendant was providing information to Pfizer pursuant to 21 U.S.C. § 355(b)(3) and 21 C.F.R. § 314.52. A copy of the NDA Notice Letter is attached hereto as Exhibit B.

FIRST CLAIM FOR RELIEF:
INFRINGEMENT OF THE '156 PATENT

19. The allegations of paragraphs 1-18 above are repeated and realleged as if set forth fully herein.

20. The expiration date for the '156 patent is July 8, 2016.

21. Patents associated with Lipitor®, including the '156 patent, have been granted a further period of pediatric exclusivity under section 505a of the Food, Drug and Cosmetic Act [21 U.S.C. § 355a].

22. The pediatric exclusivity period associated with the '156 patent will expire January 8, 2017.

23. The NDA Notice Letter notified Pfizer that MSP Singapore, by filing NDA No. 200-153, seeks approval from the FDA to engage in the commercial manufacture, use, and sale of products containing the 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg strengths of ezetimibe-atorvastatin calcium prior to the expiration of the '156 patent.

24. The NDA Notice Letter addressed the '156 patent and asserted that the patent was not infringed by Defendant's proposed NDA No. 200-153 ezetimibe-atorvastatin calcium product.

25. The NDA Notice Letter did not provide an explanation of any grounds supporting a contention that any claim of the '156 patent is invalid, as would be required by 21 C.F.R. § 314.52(c)(6)(ii) if Defendant contended that any of the claims were invalid.

26. Defendant has infringed the '156 patent under 35 U.S.C. § 271(e)(2)(A) by filing its NDA No. 200-153 seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a product containing ezetimibe-atorvastatin calcium prior to the expiration of the '156 patent.

27. Pfizer will be irreparably harmed if Defendant's NDA No. 200-153 is approved prior to the expiration date of the '156 patent.

28. Pfizer will be irreparably harmed if Defendant is not enjoined from infringing the '156 patent.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment providing that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Defendant's NDA No. 200-153 be no earlier than January 8, 2017, the date of expiration of the '156 Patent, including the period of exclusivity granted to Lipitor® under section 505a of the Food, Drug and Cosmetic Act;

B. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendant, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with it or any of them, from making, using, selling, offering to sell, or importing the atorvastatin calcium product described in Defendant's NDA No. 200-153 until January 8, 2017, the expiration date of the '156 patent including the period of exclusivity granted to Lipitor® under section 505a of the Food, Drug and Cosmetic Act;

C. Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

D. Costs and expenses in this action; and

E. Such further and other relief as this Court may deem just and proper.

RESPECTFULLY SUBMITTED,

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