IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

MEDIMMUNE ONCOLOGY, INC. One MedImmune Way Gaithersburg, Maryland 20878 Montgomery County Plaintiff, v. SUN PHARMACEUTICAL INDUSTRIES LIMITED, Acme Plaza, Andheri Kurla Road, Andheri (East) Mumbai, 400 059, India Defendant.	)	Civil Action No. _____

COMPLAINT

Plaintiff MedImmune Oncology, Inc. ("MedImmune Oncology"), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by defendant Sun Pharmaceutical Industries Limited ("Sun") of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") in Maryland seeking approval to manufacture and sell a generic version of MedImmune Oncology's drug product ETHYOL® prior to the expiration of various U.S. Patents.

JURISDICTION AND VENUE

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

3. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

PARTIES

4. Plaintiff MedImmune Oncology is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 1 MedImmune Way, Gaithersburg, Maryland 20878.

5. Upon information and belief, defendant Sun is a corporation or other entity organized and existing under the laws of India, having its principal place of business at Acme Plaza, Andheri Kurla Road, Andheri (East) Mumbai, 400 059, India. Upon information and belief, Sun neither resides nor has a place of business anywhere within the United States of America.

6. Sun is required under applicable laws to designate an agent who resides or maintains a place of business within the United States of America with respect to each application filed with the FDA seeking to market a new drug, including any abbreviated new drug application.

7. Upon information and belief, Sun has chosen to appoint as it agent, pursuant to 21 C.F.R. §§ 314.94(a)(1) and 314.50(a)(5), an organization that resides in, regularly transacts business in, and is subject to the jurisdiction of the Courts of Maryland, namely A.A.C. Consulting Group, Inc., 7361 Calhoun Place, Suite 500, Rockville, MD 20855 ("A.A.C.").

8. Upon information and belief, Sun has regularly retained and appointed one or more agents acting within the State of Maryland for the purpose of filing and/or seeking approval of various filings with the FDA, including one or more ANDAs and one or more Drug Master Files.

9. Sun has purposely availed itself of the rights and privileges of the state of Maryland by appointing A.A.C. as its agent in Maryland to act on its behalf.

BACKGROUND

10. United States Patent No. 5,424,471 ("the '471 patent"), entitled "CRYSTALLINE AMIFOSTINE COMPOSITIONS AND METHODS OF THE PREPARATION AND USE OF SAME," was duly and legally issued on June 13, 1995 to U.S. Bioscience, Inc., as assignee of Paul E. Kennedy, Roger A. Rajewski and John M. Baldoni. The '471 patent will expire on July 31, 2012. A copy of the '471 patent is attached to this Complaint as Exhibit A.

11. United States Patent No. 5,591,731 ("the '731 patent"), entitled "CRYSTALLINE AMIFOSTINE COMPOSITIONS," was duly and legally issued on January 7, 1997 to U.S. Bioscience, Inc. as assignee of Paul E. Kennedy, Roger A. Rajewski and John M. Baldoni. The '731 patent will expire on July 31, 2012. A copy of the '731 patent is attached to this Complaint as Exhibit B.

12. United States Patent No. 5,994,409 ("the '409 patent"), entitled "METHODS FOR TREATMENT OF NEURO—AND NEPHRO—DISORDERS AND THERAPEUTIC TOXICITIES USING AMINOTHIOL COMPOUNDS," was duly and legally issued on November 30, 1999 to co-owners U.S. Bioscience, Inc. as assignee of Martin Stogniew and Edward H. Kaplan, and the Arizona Board of Regents on behalf of the University of Arizona ("Arizona") as assignee of David S. Alberts. The '409 patent will expire on December 8, 2017. A copy of the '409 patent is attached to this Complaint as Exhibit C.

13. Plaintiff MedImmune Oncology is the successor in interest to U.S. Bioscience, Inc., and MedImmune Oncology owns the '471 patent and the '731 patent and co-owns the '409 patent. MedImmune Oncology has been granted an exclusive license from Arizona under the '409 patent and holds all substantial rights in the '409 patent. Plaintiff will be substantially and irreparably damaged by infringement of the '471 patent, the '731 patent and the '409 patent.

14. Plaintiff MedImmune Oncology sells one or more drug products containing sterile crystalline amifostine trihydrate under the trade name ETHYOL® in the United States pursuant to an approved New Drug Application (No. 20-221) held by MedImmune Oncology. Such drug products, and approved uses of such drug products, are claimed by the '471 patent, the '731 patent and the '409 patent.

15. By a letter dated June 29, 2004 (the "Notice Letter"), defendant Sun notified MedImmune Oncology that Sun had submitted an ANDA, No. 77-126, to the FDA. The purpose of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, and sale of a drug product containing crystalline amifostine trihydrate in an injectable form prior to the expiration of the '471 patent, the '731 patent and the '409 patent.

16. The Notice Letter was sent by facsimile and mail to MedImmune Oncology's offices in Gaithersburg, Maryland.

17. Upon information and belief, the drug product that is the subject of ANDA No. 77-126 contains sterile crystalline amifostine trihydrate. Such drug product and its use are covered by one or more claims of the '471 patent, the '731 patent and the '409 patent.

18. Upon information and belief, Sun has appointed A.A.C. as its agent, pursuant to 21 C.F.R. §§ 314.94(a)(1) and 314.50(a)(5), in connection with ANDA No. 77-126.

19. In the Notice Letter, defendant notified MedImmune Oncology that as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '471 patent, the '731 patent and the '409 patent.

20. This action is being brought before the expiration of forty-five days from the date of receipt of Sun's June 29, 2004 letter, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

21. Upon information and belief, Sun has filed its ANDA because it seeks to enter the

market that the ETHYOL® product has created due to its benefits and advantages.

COUNT I

22. Paragraphs 1 to 21 are incorporated herein by reference as if fully set forth.

23. Defendant Sun has filed its ANDA in order to obtain approval under the FDCA to engage in the commercial manufacture, use, or sale of a drug product which is claimed in the '471 patent before the expiration of that patent. Such filing is an act of infringement of the '471 patent under 35 U.S.C. § 271(e)(2)(A).

24. The commercial manufacture, use, importation into the United States, sale or offering for sale of Sun's crystalline amifostine trihydrate injectable drug product will infringe the '471 patent under 35 U.S.C. § 271(a).

25. Unless Sun is enjoined from infringing the '471 patent, MedImmune Oncology will suffer irreparable injury. MedImmune Oncology has no adequate remedy at law.

26. When Sun filed its ANDA seeking approval to manufacture and sell an injectable form of crystalline amifostine trihydrate, it was aware of the existence of the '471 patent and that the filing of the ANDA constituted an act of infringement of that patent. Sun acted without a reasonable basis for believing that it would not be liable for infringement of the '471 patent. Sun's infringement of the '471 patent was willful and deliberate.

COUNT II

27. Paragraphs 1 to 21 are incorporated herein by reference as if fully set forth.

28. Defendant Sun has filed its ANDA in order to obtain approval under the FDCA to engage in the commercial manufacture, use, or sale of a drug product which is claimed in the '731 patent before the expiration of that patent. Such filing is an act of infringement of the '731 patent under 35

U.S.C. § 271(e)(2)(A).

29. The commercial manufacture, use, importation into the United States, sale or offering for sale of Sun's crystalline amifostine trihydrate injectable drug product will infringe the '731 patent under 35 U.S.C. § 271(a).

30. Unless Sun is enjoined from infringing the '731 patent, MedImmune Oncology will suffer irreparable injury. MedImmune Oncology has no adequate remedy at law.

31. When Sun filed its ANDA seeking approval to manufacture and sell an injectable form of crystalline amifostine trihydrate, it was aware of the existence of the '731 patent and that the filing of the ANDA constituted an act of infringement of that patent. Sun acted without a reasonable basis for believing that it would not be liable for infringement of the '731 patent. Sun's infringement of the '731 patent was willful and deliberate.

COUNT III

32. Paragraphs 1 to 21 are incorporated herein by reference as if fully set forth.

33. Defendant Sun has filed its ANDA in order to obtain approval under the FDCA to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '409 patent before the expiration of that patent. Such filing is an act of infringement of the '409 patent under 35 U.S.C. § 271(e)(2)(A).

34. The use of Sun's crystalline amifostine trihydrate injectable drug product will infringe the '409 patent under 35 U.S.C. § 271(a), and the sale or offering for sale of Sun's crystalline amifostine trihydrate injectable drug product will induce and/or contribute to infringement of the '409 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

35. Unless Sun is enjoined from infringing, inducing infringement and contributing to

infringement of the '409 patent, plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

36. When Sun filed its ANDA seeking approval to manufacture and sell an injectable form of crystalline amifostine trihydrate, it was aware of the existence of the '409 patent and that the filing of the ANDA constituted an act of infringement of that patent. Sun acted without a reasonable basis for believing that it would not be liable for infringement of the '409 patent. Sun's infringement of the '409 patent was willful and deliberate.

WHEREFORE, plaintiff requests the following relief:

(a) A judgment providing that the effective date of any FDA approval for defendant Sun to commercially make, use, import into the United States, sell or offer for sale sterile crystalline amifostine trihydrate or any drug product containing sterile crystalline amifostine be not earlier than the latest of the expiration dates of United States Patent No. 5,424,471; United States Patent No. 5,591,731; and United States Patent No. 5,994,409;

(b) A preliminary and permanent injunction restraining or enjoining defendant Sun, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, importation into the United States, sale, or offer for sale of sterile crystalline amifostine trihydrate or any drug product containing sterile crystalline amifostine for the full terms of United States Patents Nos. 5,424,471; 5,591,731; and 5,994,409;

(c) A declaration that the commercial manufacture, use, importation into the United States, sale or offering for sale of Sun's crystalline amifostine trihydrate drug product will infringe United States Patent No. 5,424,471; United States Patent No. 5,591,731; and United States Patent No. 5,994,409;

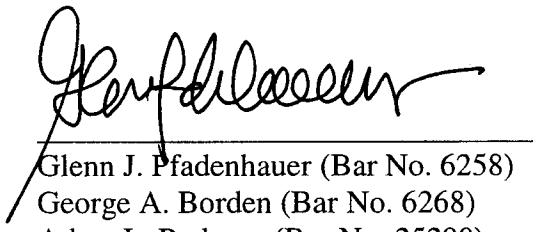
(d) A declaration that the commercial manufacture, use, importation into the United States, sale or offering for sale of Sun's crystalline amifostine trihydrate drug product will induce and/or contribute to infringement of United States Patent No. 5,994,409;

(e) A judgment providing that Sun's infringement of United States Patents Nos. 5,424,471; 5,591,731; and 5,994,409 was willful and deliberate;

(f) A determination that this is an exceptional case pursuant to 35 U.S.C. § 285 and an award of plaintiff's reasonable attorney's fees and costs; and

(g) Such further and other relief as this Court may deem just and proper.

Respectfully submitted,



Dated: August 10, 2004

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