

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

MEDIMMUNE, LLC)
One MedImmune Way)
Gaithersburg, Maryland 20878)
Montgomery County,)
)
Plaintiff,)
)
v.) Civil Action No. _____)
)
SUN PHARMACEUTICAL INDUSTRIES)
LIMITED,)
Acme Plaza, Andheri Kurla Road,)
Andheri (East) Mumbai, 400 059, India,)
)
and)
)
CARACO PHARMACEUTICAL)
LABORATORIES LTD.)
1150 Elijah McCoy Drive)
Detroit, MI 48202,)
)
Defendants.)
_____)

COMPLAINT

Plaintiff MedImmune, LLC (“MedImmune”), 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, arising out of the manufacture, use, importation into, offer for sale and/or sale within the United States by defendants Sun Pharmaceutical Industries Limited (“Sun”) and Caraco Pharmaceutical Laboratories, Ltd. (“Caraco”) of a generic version of MedImmune’s ETHYOL[®], product, prior to the expiration of MedImmune’s patents.

2. This action is related to *MedImmune Oncology, Inc. v. Sun Pharmaceuticals Industries Ltd.*, 1:04-cv-02612-MJG, which is pending in this District and involves the same patents.

JURISDICTION AND VENUE

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

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

PARTIES

5. Plaintiff MedImmune, LLC is a limited liability company organized and existing under the laws of the state of Delaware, having its principal place of business at 1 MedImmune Way, Gaithersburg, Maryland 20878.

6. 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.

7. Sun is engaged in the business of developing, manufacturing, marketing, distributing and selling generic and private-label pharmaceuticals throughout the world, including in the United States. Upon information and belief, Sun causes its pharmaceuticals, including a generic version of ETHYOL[®], to be marketed and/or distributed and/or sold in the state of Maryland, thus purposely availing itself of the rights and privileges of the state of Maryland.

8. Sun has consented to jurisdiction in this District in the pending action, *MedImmune Oncology, Inc. v. Sun Pharmaceuticals Industries Ltd.*, 1:04-cv-02612-MJG.

9. Upon information and belief, Defendant Caraco is a corporation or other entity organized and existing under the laws of Michigan, having its principal place of business at 1150 Elijah

McCoy Drive, Detroit, MI 48202.

10. Caraco is engaged in the business of developing, manufacturing, marketing and distributing generic and private-label pharmaceuticals to the nation's largest wholesalers, distributors, warehousing and non-warehousing chain drugstores and managed care providers, throughout the United States. Upon information and belief, Caraco, working in concert with, at the behest of, and with the encouragement of Sun, offers to sell, sells and distributes these pharmaceuticals, including a generic version of ETHYOL[®], in the state of Maryland, thus purposely availing itself of the rights and privileges of the state of Maryland.

BACKGROUND

11. 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.

12. 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.

13. MedImmune is the successor in interest to U.S. Bioscience, Inc. and now owns the '471 patent and the '731 patent and holds all patent rights, including the rights to sue for past, present, and future infringement damages, based on the asserted patents.

14. Plaintiff MedImmune sells amifostine drug products, including under the trade

name ETHYOL[®], in the United States pursuant to an approved New Drug Application (No. 20-221) held by MedImmune. Such drug products are covered by claims of the '471 patent and the '731 patent.

15. A generic copy of MedImmune's ETHYOL[®] product is currently being sold in the United States as "Amifostine for Injection USP" under NDC numbers NDC 62756-581-40 and NDC 62756-581-42 (hereinafter the "Sun/Caraco Amifostine Product").

16. The Sun/Caraco Amifostine Product is labeled "Manufactured by: Sun Pharmaceutical Industries Ltd." and "Distributed by: Caraco Pharmaceutical Laboratories, Ltd."

17. Upon information and belief, on or about March 31, 2008, Sun began, and is currently, commercially manufacturing, using, importing into, offering for sale in, and/or selling in the United States the Sun/Caraco Amifostine Product pursuant to authorization granted to Sun by the U.S. Food and Drug Administration to engage in such activities.

18. Upon information and belief, on or about March 31, 2008, Caraco began, and is currently, using, importing into, offering for sale in, and/or selling in the United States the Sun/Caraco Amifostine Product pursuant to the authorization granted to Sun by the U.S. Food and Drug Administration to engage in such activities.

19. The foregoing activities by Caraco have been undertaken and are continuing pursuant to the encouragement, direction and express authorization by Sun.

20. Plaintiff MedImmune has been, is, and will continue to be substantially and irreparably damaged by infringement of the '471 patent and the '731 patent based on the manufacture, use, importation into, offer for sale, and/or sale in the United States of the Sun/Caraco Amifostine Product.

COUNT I

21. Paragraphs 1 to 20 are incorporated herein by reference as if fully set forth.

22. The following count pleads infringement of the '471 patent by the manufacture, use, importation, offer for sale, and/or sale of the Sun/Caraco Amifostine Product. MedImmune acknowledges that the Court in the related case referenced above has ruled that the Sun/Caraco Amifostine Product does not infringe the '471 patent. MedImmune disagrees with this ruling and intends to appeal it upon final judgment in the related case. Accordingly, MedImmune has pled infringement of this patent below for the purpose of preserving the issue for appeal and maintaining this claim should the Court's ruling in the related case be reversed.

23. The commercial manufacture, use, importation into, sale and/or offering for sale in the United States of the Sun/Caraco Amifostine Product has infringed and will continue to infringe the '471 patent under 35 U.S.C. § 271(a).

24. Furthermore, Sun's inducement of Caraco's commercial use, importation into, sale and/or offering for sale in the United States of the Sun/Caraco Amifostine Product has infringed and will continue to infringe the '471 patent under 35 U.S.C. § 271(b).

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

COUNT II

26. Paragraphs 1 to 25 are incorporated herein by reference as if fully set forth.

27. The commercial manufacture, use, importation into, sale and/or offering for sale in the United States of the Sun/Caraco Amifostine Product has infringed and will continue to infringe the '731 patent under 35 U.S.C. § 271(a).

28. Furthermore, Sun's inducement of Caraco's commercial use, importation into, sale and/or offering for sale in the United States of the Sun/Caraco Amifostine Product has infringed and will continue to infringe the '731 patent under 35 U.S.C. § 271(b).

29. Unless Sun and Caraco are enjoined from infringing the '731 patent, MedImmune will suffer irreparable injury. MedImmune has no adequate remedy at law.

30. When Sun and Caraco began manufacturing, using, importing into, offering for sale, and/or selling in the United States the Sun/Caraco Amifostine Product, and/or inducing Caraco's infringement, they were aware of the existence of the '731 patent and that the manufacture, use, importation into, offer for sale, and/or sale in the United States of the Sun/Caraco Amifostine Product constituted acts of infringement of the '731 patent. Sun and Caraco acted without a reasonable basis for believing that each would not be liable for infringement of the '731 patent. Sun's and Caraco's infringement of the '731 patent were willful and deliberate.

WHEREFORE, plaintiff requests the following relief:

(a) A permanent injunction restraining or enjoining defendants Sun and Caraco, their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, importation into, sale, or offer for sale in the United States of the Sun/Caraco Amifostine Product, and in the case of Sun from inducing such acts by Caraco, prior to the expiration dates of the '471 patent and the '731 patent;

(c) A declaration that the commercial manufacture, use, importation into, sale and/or offering for sale in the United States of the Sun/Caraco Amifostine Product, and in the case of Sun, its inducement of such acts by Caraco, has infringed and will continue to infringe the '471 patent and the '731 patent;

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