IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KING PHARMACEUTICALS RESEARCH AND DEVELOPMENT, INC., ASTELLAS US LLC, and ASTELLAS PHARMA US, INC. Plaintiffs, v. SICOR INC., SICOR PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD. Defendants.	CIVIL ACTION NO.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, King Pharmaceuticals Research and Development, Inc., Astellas US LLC, and Astellas Pharma US, Inc. (hereinafter collectively "Plaintiffs"), bring this action for patent infringement against SICOR, Inc., SICOR Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. (hereinafter collectively "Defendants"). This action concerns a patent relating to the use of adenosine, a prescription drug, as an adjunct to thallium-201 myocardial perfusion scintigraphy, used, *inter alia*, in the diagnosis of coronary artery disease in patients unable to exercise adequately.

JURISDICTION AND PARTIES

1. Plaintiff King Pharmaceuticals Research and Development, Inc. (hereinafter "King"), is a Delaware corporation having an office and principal place of business at 7001 Weston Parkway, Suite 300, Cary, NC 27513.

2. Plaintiff Astellas US LLC (hereinafter "Astellas US") is a limited liability corporation organized under the laws of Delaware having an office and principal place of business at Three Parkway North, Deerfield, IL 60015-2548.

3. Plaintiff Astellas Pharma US, Inc. (hereinafter "Astellas Pharma") is a corporation organized under the laws of Delaware having an office and principal place of business at Three Parkway North, Deerfield, IL 60015-2548.

4. Astellas US and Astellas Pharma (collectively hereinafter "Astellas") are engaged in the business of research, development, and sale of pharmaceutical products throughout the United States.

5. Upon information and belief, Teva Pharmaceutical Industries, Ltd. (hereinafter "Teva Industries") is an Israeli corporation and maintains an office at 5 Basel St., Patach, Tikva 49131 Israel.

6. Upon information and belief, Teva Pharmaceuticals USA (hereinafter "Teva USA") is a Delaware corporation and maintains an office at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454-1090, and is a wholly owned subsidiary of Teva Industries.

7. Upon information and belief, Teva Industries markets generic pharmaceuticals throughout the United States through its wholly owned and directly controlled subsidiary Teva USA.

8. Upon information and belief, SICOR Inc. (hereinafter "Sicor Inc.") is a Delaware corporation having a principal place of business at 19 Hughes, Irvine, California 92618 and is another wholly owned and directly controlled subsidiary of Teva Industries.

9. Upon information and belief, Teva Industries acquired Sicor Inc. in January 2004 and since then has endeavored to completely integrate Sicor Inc.'s businesses into the operations of Teva Industries.

10. Upon information and belief, Sicor's managers are in no way separate from the managers of Teva Industries and are Teva people in every respect.

11. Upon information and belief, SICOR Pharmaceuticals, Inc. (hereinafter "Sicor Pharma") is a Delaware corporation having its principal place of business at 19 Hughes, Irvine, California 92618. Upon information and belief, Sicor Pharma is a wholly owned subsidiary of Sicor Inc., but is under the complete and direct control of Teva Industries by virtue of that company's ownership and control of Sicor Inc.

12. Upon information and belief, Teva Industries owns 100% of the ownership and voting interest in Teva USA, Sicor Inc., and Sicor Pharma.

13. Upon information and belief, Teva Industries, through Teva USA, uses Sicor Inc. and Sicor Pharma to carry out its business of importing or manufacturing, formulating, filling, labeling, and packaging finished dosage forms of injectable generic pharmaceutical products for distribution throughout the United States and in this district.

14. Personal jurisdiction over Teva Industries is proper because it maintains such minimum contacts with the State of Delaware as would cause it to reasonably expect to be haled into Court in Delaware. Among other things, upon information and belief, Teva Industries places goods into the stream of commerce for distribution in Delaware and throughout the United States by its wholly owned and controlled subsidiaries, Teva USA, Sicor Inc., and Sicor Pharma, which are incorporated in Delaware.

15. Personal jurisdiction over Teva USA, Sicor Inc., and Sicor Pharma is proper because those corporations have purposely availed themselves of the privilege of doing business in the state by incorporating in Delaware, and they maintain such continuous and systematic contacts with the state as to reasonably allow jurisdiction to be exercised over them.

16. This action for patent infringement arises under the United States Patent Laws, Title 35, United States Code, including 35 U.S.C. §§ 271(b), (c), and (e), and §§ 281-285. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this judicial district under one or more of 28 U.S.C. §§ 1391(b), (c), and (d), and § 1400(b).

BACKGROUND

17. On December 10, 1991, the United States Patent and Trademark Office duly and legally issued United States Patent No. 5,070,877 ("the '877 patent") to Medco Research, Inc. (hereinafter "Medco") for a NOVEL METHOD OF MYOCARDIAL IMAGING. A copy of the '877 patent is attached hereto as Exhibit A.

18. Subsequently, the assets of Medco were acquired by King. King is the assignee of the '877 patent by virtue of documents duly recorded at the United States Patent and Trademark Office.

19. Astellas is the exclusive licensee, with right to bring suit, of certain rights in the '877 patent and, pursuant to those rights, sells Adenoscan®, an adenosine-based product approved by the United States Food and Drug Administration ("FDA") for use as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately.

20. The use of Adenoscan® in accordance with its FDA-approved labeling is covered by one or more of the claims of the '877 patent.

21. In a letter dated April 7, 2005, Teva USA requested information from Astellas on process patents relating to the manufacture of a pharmaceutical product containing adenosine and advised Astellas, referring to Adenoscan®, that Teva USA contemplated selling a finished dosage pharmaceutical product containing adenosine in the United States.

22. Teva USA's April 7, 2005, letter requested that Astellas send its response to Karen Loberg at 11 Hughes, Irvine, CA 92618. Upon information and belief, this is an address used by Sicor Pharma and Sicor Inc.

23. On April 18, 2005, less than two weeks after receiving Teva USA's letter concerning its "contemplated" plan to sell a finished dosage adenosine product in the United States, Astellas received a letter from Sicor Pharma, dated April 16, 2005, notifying Astellas that Sicor Pharma had sought approval from the FDA to begin selling Adenosine Injection, USP as a generic substitute for Adenoscan® prior to the expiration of the '877 patent and alleging that the '877 patent claims were invalid, unenforceable, or not infringed.

24. Upon information and belief, Sicor Pharma has filed with the FDA, in Rockville, Maryland, an Abbreviated New Drug Application ("ANDA") No. 77-425 for "Adenosine Injection, USP" under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of adenosine as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately.

25. Upon information and belief, Sicor Pharma's Adenosine Injection, USP Package Insert will have the same indications and dosage instructions as those contained in the FDA-approved Adenoscan® intravenous injection product package insert so that use of Sicor Pharma's Adenosine Injection, USP according to its approved labeling will result in infringement of one or more claims of the '877 patent.

26. Upon information and belief, Sicor Pharma has filed an amendment to ANDA 77-425 containing a purported certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

27. Upon information and belief, Sicor Pharma intends to engage in the commercial manufacture, use, advertising, importation, offer for sale, and sale of Sicor Pharma's Adenosine Injection, USP, with its associated instructions for use and labeling, promptly upon receiving FDA approval to do so.

28. Upon information and belief, Teva Industries, Teva USA, and Sicor Inc. have acted in concert, actively encouraging, and inducing Sicor Pharma in filing ANDA No. 77-425 for "Adenosine Injection, USP" and in preparing to sell, in the United States, a finished dosage pharmaceutical product that will contain adenosine and carry associated labeling pursuant to that ANDA.

29. Upon further information and belief, Teva Industries, Teva USA, and Sicor Inc. will continue to actively aid, abet, encourage, and induce Sicor Pharma to sell Adenosine Injection, USP, with its associated labeling under ANDA No. 77-425, if the ANDA is approved by the FDA.

COUNT I

PATENT INFRINGEMENT

30. Under 35 U.S.C. § 271(e)(2)(A), Sicor Pharma infringed one or more claims of the '877 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '877 patent, of Adenosine Injection, USP labeled for use as an adjunct to thallium-201

myocardial perfusion scintigraphy, a product the use or sale of which would contribute to or induce the direct infringement of one or more claims of the '877 patent by ultimate purchasers.

31. Upon information and belief, Teva Industries, Teva USA, and Sicor Inc. have also induced or contributed to and will induce or contribute to infringement of one or more claims of the '877 patent by acting in concert and actively aiding, abetting, encouraging, and inducing Sicor Pharma (1) to file ANDA No. 77-425 for "Adenosine Injection, USP", (2) to prepare to sell such an Adenosine Injection product pursuant to that ANDA, and (3) upon FDA approval, to sell such an Adenosine Injection product together with instructions and labeling which will result in direct infringement of one or more claims of the '877 patent by ultimate purchasers.

32. Plaintiffs will be substantially and irreparably damaged and harmed if Defendants' infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

COUNT II

DECLARATORY JUDGMENT

33. Paragraphs 1-32 are incorporated herein by reference.

34. Upon information and belief, Defendants have acted in concert and made substantial preparations for Sicor Pharma to sell Adenosine Injection, USP labeled for the same indications and the same dosage and method of use as the Adenoscan® product sold by Astellas.

35. Upon further information and belief, Defendants further intend that Sicor Pharma will commence sales of such Adenosine Injection, USP immediately upon receiving approval from the FDA.

36. The manufacture, importation, sale, and offer for sale of Adenosine Injection, USP so labeled, once approved by the FDA, will induce and contribute to infringement of one or more claims of the '877 patent.

37. Defendants' actions in actively aiding, abetting, encouraging, and inducing sales of such Adenosine Injection, USP threaten to and will induce and/or contribute to infringement of one or more claims of the '877 patent.

38. Plaintiffs will be substantially and irreparably damaged and harmed if Defendants' threatened infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

COUNT III

WILLFUL PATENT INFRINGEMENT

39. Paragraphs 1-38 are incorporated herein by reference.

40. Defendants have proceeded with their unlawful activities despite knowledge of the '877 patent under 35 U.S.C. § 284.

41. On information and belief, Defendants' infringement has been willful.

42. This is an exceptional case warranting imposition of attorney fees against Defendants under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment against Defendants as follows:

(a) finding that Defendants have infringed one or more claims of the '877 patent by filing the aforesaid ANDA relating to Sicor Pharma's Adenosine Injection, USP;

(b) prohibiting any approval by the FDA of Defendants' aforesaid ANDA for Adenosine Injection, USP on any effective date prior to the date of expiration of the '877 patent, or such later date as the Court may determine;

(c) declaring that Defendants will infringe one or more claims of the '877 patent if Sicor Pharma's aforesaid ANDA relating to Adenosine Injection, USP is approved and the approved product is sold and used in the United States;

(d) enjoining Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them or any of them, from the commercial manufacture, use, or sale of an Adenosine Injection, USP product labeled for use in myocardial perfusion imaging until the expiration of the '877 patent, or such later date as the Court may determine;

(e) finding that this is an exceptional case and granting Plaintiffs reasonable attorney fees pursuant to 35 U.S.C. § 285; and

(f) awarding Plaintiffs any further and additional relief as this Court deems just and proper.

Dated:May 26, 2005

Richard K. Herrmann (I.D. #405)
Mary B. Matterer (I.D. #2696)
Morris, James, Hitchens & Williams LLP
222 Delaware Avenue, 10th Floor
Wilmington, DE 19801
302.888.6800
rherrmann@morrisjames.com
mmatterer@morrisjames.com

Of counsel:
Charles E. Lipsey
Finnegan, Henderson, Farabow,
Garrett & Dunner, LLP.
Two Freedom Square
11955 Freedom Drive
Reston, VA 20190-5675
(571) 203-2700

Susan H. Griffen
David P. Frazier
Finnegan, Henderson, Farabow,
Garrett & Dunner, LLP
901 New York Avenue, N.W.
Washington, DC 20001-4413
(202) 408-4000

Attorneys for Plaintiffs
Astellas US LLC and
Astellas Pharma US, Inc.

Paul E. Crawford (I.D. #493)
Patricia Smink Rogowski (I.D. #2632)
Connolly Bove Lodge & Hutz LLP
1007 N. Orange Street
P.O.Box 2207
Wilmington, DE 19899-2207
302.658.9141
pcrawford@cblh.com
progowski@cblh.com

Of counsel:
F. Dominic Cerrito
Daniel L. Malone
Gasper J. LaRosa
Jones Day
222 East 41 Street
New York, NY 10017
(212) 326-3413

Attorney for Plaintiff
King Pharmaceuticals Research
and Development, Inc.