**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| KING PHARMACEUTICALS RESEARCH AND DEVELOPMENT, INC., ASTELLAS US LLC, and ASTELLAS PHARMA US, INC.<br><br>Plaintiffs,<br><br>v.<br><br>SICOR INC., SICOR PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD.<br><br>Defendants. | Civil Action No. 05-337 SLR |

**SICOR PHARMACEUTICALS, INC.'S ANSWER AND AFFIRMATIVE DEFENSES**

Defendant Sicor Pharmaceuticals, Inc. ("Sicor Pharmaceuticals") answers the correspondingly numbered paragraphs of Plaintiffs' Complaint ("the Complaint") as follows:

**JURISDICTION AND PARTIES**

1. On information and belief, Sicor Pharmaceuticals admits the allegations in paragraph 1.

2. On information and belief, Sicor Pharmaceuticals admits the allegations in paragraph 2.

3. On information and belief, Sicor Pharmaceuticals admits the allegations in paragraph 3.

4. Sicor Pharmaceuticals is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 and denies the same.

5. Paragraph 5 makes only allegations as to Teva Pharmaceutical Industries, Ltd. ("Teva Israel") and thus no response is required from Sicor Pharmaceuticals.

6. Paragraph 6 makes only allegations as to Teva Pharmaceuticals USA ("Teva USA") and Teva Israel, and thus no response is required from Sicor Pharmaceuticals.

7. Paragraph 7 makes only allegations as to Teva Israel and Teva USA, and thus no response is required from Sicor Pharmaceuticals.

8. Paragraph 8 makes only allegations as to Sicor Inc. and thus no response is required from Sicor Pharmaceuticals.

9. Paragraph 9 makes only allegations as to Sicor Inc. and thus no response is required from Sicor Pharmaceuticals.

10. To the extent that the allegations of paragraph 10 regarding "Sicor" are directed to Sicor Pharmaceuticals, it denies the same. To the extent that the allegations of paragraph 10 are directed to Sicor Inc., no response is required from Sicor Pharmaceuticals.

11. Sicor Pharmaceuticals admits that it is a Delaware corporation having its principal place of business at 19 Hughes, Irvine, California, and a wholly owned subsidiary of Sicor Inc. Sicor Pharmaceuticals denies the remaining allegations in paragraph 11.

12. To the extent that paragraph 12 makes allegations directed to Teva Israel, Teva USA, and Sicor Inc., no response is required from Sicor Pharmaceuticals. To the extent that paragraph 12 makes allegations directed to Sicor Pharmaceuticals, it admits that Sicor Pharmaceuticals is a wholly owned subsidiary of Teva Israel and denies the remaining allegations of paragraph 12.

13. To the extent that paragraph 13 makes allegations directed to Teva Israel, Teva USA, and Sicor Inc., no response is required from Sicor Pharmaceuticals. To the extent that paragraph 13 makes allegations directed to Sicor Pharmaceuticals, it denies the same.

14. To the extent paragraph 14 makes allegations directed to Teva Israel, Teva USA and Sicor Inc., or states conclusions of law, no response is required from Sicor Pharmaceuticals. To the extent that paragraph 14 makes allegations directed to Sicor Pharmaceuticals, it admits that Sicor Pharmaceuticals is a wholly owned subsidiary of Teva Israel and is incorporated in Delaware, and denies the remaining allegations of paragraph 14.

15. To the extent paragraph 15 makes allegations directed to Teva USA and Sicor Inc., or states conclusions of law, no response is required from Sicor Pharmaceuticals. To the extent that paragraph 15 makes allegations directed to Sicor Pharmaceuticals, for purposes of this case only, Sicor Pharmaceuticals admits that this Court has personal jurisdiction over it and denies the remaining allegations in paragraph 15.

16. To the extent that paragraph 16 makes allegations directed to Teva Israel, Teva USA, or Sicor Inc., no response is required from Sicor Pharmaceuticals. To the extent that paragraph 16 makes allegations directed to Sicor Pharmaceuticals, it admits that plaintiffs purport to bring this action under the United States Patent Laws, Title 35, United States Code, including 35 U.S.C. §§ 271(b), (c), and (e), and §§ 281-285, for infringement, and admits that plaintiffs purport to base jurisdiction over the subject matter pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and, for the purposes of this case only, that venue with respect to Sicor Pharmaceuticals is proper in this judicial district. Sicor Pharmaceuticals denies the remaining allegations in paragraph 16.

## BACKGROUND

17. Sicor Pharmaceuticals admits that U.S. Patent No. 5,070,877 ("the '877 patent") is entitled on its face "NOVEL METHOD OF MYOCARDIAL IMAGING," lists an issue date of December 10, 1991, and a copy is attached to the Complaint. Sicor Pharmaceuticals further admits that Medco Research, Inc. ("Medco") is listed on the face of the patent as the assignee, but lacks knowledge or information sufficient to form a belief as to the ownership status. Sicor Pharmaceuticals denies the remaining allegations in paragraph 17.

18. Sicor Pharmaceuticals is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 18 and denies the same.

19. Sicor Pharmaceuticals is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 19 and denies the same.

20. Sicor Pharmaceuticals denies the allegations in paragraph 20.

21. Paragraph 21 makes only allegations as to Teva USA and thus no response is required from Sicor Pharmaceuticals.

22. To the extent that paragraph 22 makes allegations directed to Teva USA, no response is required from Sicor Pharmaceuticals. To the extent that paragraph 22 makes allegations directed to Sicor Pharmaceuticals, it denies them.

23. To the extent that paragraph 23 makes allegations directed to Teva USA, no response is required from Sicor Pharmaceuticals. To the extent that paragraph 23 makes allegations directed to Sicor Pharmaceuticals, Sicor Pharmaceuticals admits that it mailed a notice letter dated April 16, 2005, to Astellas but denies that the allegations in paragraph 23 characterize that notice letter accurately and refers the Court to the full document, which speaks for itself. On information and belief, Sicor Pharmaceuticals admits that Astellas received the

April 16, 2005 letter on or about April 18, 2005. Sicor Pharmaceuticals denies the remaining allegations in paragraph 23.

24. Sicor Pharmaceuticals admits that it filed with the FDA an Abbreviated New Drug Application ("ANDA") No. 77-425 pursuant to 21 U.S.C. § 355(j) seeking approval from the FDA to market "Adenosine Injection, USP" as a generic version of Adenoscan® as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately. Sicor Pharmaceuticals refers the Court to the full text of ANDA No. 77-425, which speaks for itself, and denies the remaining allegations of paragraph 24.

25. Sicor Pharmaceuticals admits that its Adenosine Injection, USP package insert will have the indications and dosage instructions approved by the FDA for Adenoscan® intravenous injection. Sicor Pharmaceuticals denies the remaining allegations of paragraph 25.

26. Sicor Pharmaceuticals admits it filed an amendment to ANDA No. 77-425 which contains a certification with respect to the '877 patent pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Sicor Pharmaceuticals denies the remaining allegations in paragraph 26.

27. Sicor Pharmaceuticals admits that it filed ANDA No. 77-425 seeking approval from the FDA to market "Adenosine Injection, USP" as a generic version of Adenoscan®. Sicor Pharmaceuticals denies the remaining allegations in paragraph 27.

28. To the extent paragraph 28 makes allegations directed to Teva Israel, Teva USA, and Sicor Inc., or states conclusions of law, no response is required from Sicor Pharmaceuticals. To the extent that paragraph 28 makes allegations directed to Sicor Pharmaceuticals, it denies the same.

29. To the extent paragraph 29 makes allegations directed to Teva Israel, Teva USA, and Sicor Inc., or states conclusions of law, no response is required from Sicor Pharmaceuticals.

To the extent that paragraph 29 makes allegations directed to Sicor Pharmaceuticals, it denies the same.

**Count I: Patent Infringement**

30. Sicor Pharmaceuticals denies the allegations in paragraph 30.

31. To the extent paragraph 31 makes allegations directed to Teva Israel, Teva USA, and Sicor Inc., no response is required from Sicor Pharmaceuticals. To the extent that paragraph 31 makes allegations directed to Sicor Pharmaceuticals, it denies the same.

32. To the extent paragraph 32 makes allegations directed to Teva Israel, Teva USA, and Sicor Inc., no response is required from Sicor Pharmaceuticals. To the extent paragraph 32 makes allegations directed to Sicor Pharmaceuticals, it denies the same.

**Count II: Declaratory Judgment**

33. Sicor Pharmaceuticals repeats and incorporates herein by reference its responses to paragraphs 1-32.

34. To the extent paragraph 34 makes allegations directed to Teva Israel, Teva USA, and Sicor Inc., no response is required from Sicor Pharmaceuticals. To the extent that paragraph 34 makes allegations directed to Sicor Pharmaceuticals, it denies the same.

35. To the extent paragraph 35 makes allegations directed to Teva Israel, Teva USA, and Sicor Inc., no response is required from Sicor Pharmaceuticals. To the extent that paragraph 35 makes allegations directed to Sicor Pharmaceuticals, it denies the same.

36. To the extent paragraph 36 makes allegations directed to Teva Israel, Teva USA, and Sicor Inc., no response is required from Sicor Pharmaceuticals. To the extent that paragraph 36 makes allegations directed to Sicor Pharmaceuticals, it denies the same.

37. To the extent paragraph 37 makes allegations directed to Teva Israel, Teva USA, and Sicor Inc., no response is required from Sicor Pharmaceuticals. To the extent that paragraph 37 makes allegations directed to Sicor Pharmaceuticals, it denies the same.

38. To the extent paragraph 38 makes allegations directed to Teva Israel, Teva USA, and Sicor Inc., no response is required from Sicor Pharmaceuticals. To the extent that paragraph 38 makes allegations directed to Sicor Pharmaceuticals, it denies the same.

**Count III: Willful Patent Infringement**

39. Sicor Pharmaceuticals repeats and incorporates herein by reference its responses to paragraphs 1-38.

40. To the extent paragraph 40 makes allegations directed to Teva Israel, Teva USA, and Sicor Inc., no response is required from Sicor Pharmaceuticals. To the extent that paragraph 40 makes allegations directed to Sicor Pharmaceuticals, it denies the same.

41. To the extent paragraph 41 makes allegations directed to Teva Israel, Teva USA, and Sicor Inc., no response is required from Sicor Pharmaceuticals. To the extent that paragraph 41 makes allegations directed to Sicor Pharmaceuticals, it denies the same.

42. To the extent paragraph 42 makes allegations directed to Teva Israel, Teva USA, and Sicor Inc., no response is required from Sicor Pharmaceuticals. To the extent that paragraph 42 makes allegations directed to Sicor Pharmaceuticals, it denies the same.

Sicor Pharmaceuticals further answers that any allegations in the Complaint requiring a response from Sicor Pharmaceuticals not specifically admitted are denied. Sicor Pharmaceuticals also denies that plaintiffs are entitled to the judgment and relief prayed for in paragraphs (a)-(f) of the Complaint.

## SICOR PHARMACEUTICALS' AFFIRMATIVE DEFENSES

### First Affirmative Defense:
### (Non-Infringement)

43. The manufacture, use, offer for sale, sale or importation of Adenosine Injection, USP specified in ANDA No. 77-425 does not and will not infringe one or more claims of the '877 patent, either literally or under the doctrine of equivalents.

### Second Affirmative Defense:
### (Invalidity)

44. The claims of the '877 patent are invalid under 35 U.S.C. § 101 *et seq.*

### Third Affirmative Defense:
### (Failure to State a Claim)

45. To the extent that plaintiffs allege in Count I that Sicor Inc. has infringed or will infringe and in Count III that Sicor Inc. has willfully infringed and that this case is exceptional under 35 U.S.C. § 285, the Complaint fails to state a claim upon which relief can be granted and must be dismissed.

### Fourth Affirmative Defense:
### (Lack of Subject Matter Jurisdiction)

46. To the extent that plaintiffs demand declaratory judgment seeking to enjoin "threatened infringement" before the FDA has approved ANDA 77-425, this Court lacks jurisdiction over the subject matter.

Sicor Pharmaceuticals specifically reserves the right to assert each and every other defense which may become evident in the course of discovery, including but not limited to inequitable conduct.

WHEREFORE, defendant Sicor Pharmaceuticals prays that the Court enter judgment against plaintiffs and in favor of Sicor Pharmaceuticals, dismissing with prejudice each of the

claims asserted by plaintiffs, and that the Court award Sicor Pharmaceuticals any other relief it deems to be just and proper.

Respectfully submitted,

Dated: August 8, 2005

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## CERTIFICATE OF SERVICE

I, D. Fon Muttamara-Walker, Esquire, hereby certify that on August 8, 2005, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on August 8, 2005, I caused copies of the foregoing document to be served by hand delivery on the above listed counsel of record and on the following in the manner indicated:

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