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. and SICOR PHARMACEUTICALS, INC.,<br><br>Defendants. | Civil Action No. 05-337 SLR |

**DEFENDANT SICOR'S MOTION FOR LEAVE TO AMEND ITS ANSWER**

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John W. Shaw (No. 3362)
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Dated: March 30, 2006

## I. INTRODUCTION

Defendants Sicor Inc. and Sicor Pharmaceuticals, Inc. (collectively "Sicor") submit this memorandum in support of their motion for leave to amend their respective August 8, 2005 Answers pursuant to Rule 15(a), Fed. R. Civ. P. Sicor's proposed amended Answers are attached hereto as Exhibits A and B in the form required by Local Rule 15.1.

Sicor seeks to amend its first affirmative defense of non-infringement in the answers filed by Sicor Inc. and Sicor Pharmaceuticals, Inc., and its response to paragraph 30 in the answer filed by Sicor Pharmaceuticals, Inc. Sicor's non-infringement defense was previously asserted with respect to "one or more claims" of U.S. Patent No. 5,070,877 ("the '877 patent") in response to the Complaint filed by plaintiffs King Pharmaceuticals Research and Development ("King") and Astellas US LLC and Astellas Pharma US, Inc. ("Astellas"). In its amended Answers, Sicor has clarified that its non-infringement defense is asserted with respect to "any asserted valid and enforceable claim" of the '877 patent, which responds more directly to the claims that plaintiffs identified its October 28, 2005 Preliminary Infringement Contentions to be asserted in this action.

For this reason, and for the additional reasons stated below, Sicor's motion to amend its Answer should be granted.

## II. BACKGROUND

On May 26, 2005, plaintiffs filed their Complaint for patent infringement in this action. On August 8, 2005, Sicor Inc. and Sicor Pharmaceuticals, Inc. individually answered plaintiffs' Complaint. On October 12, 2005, the Court issued its Scheduling Order, which directed that, *inter alia*, all motions to amend the pleadings shall be filed on or before March 30, 2006.

Plaintiffs' Complaint did not identify the claims of the '877 patent that were allegedly infringed by Sicor's filing of its Abbreviated New Drug Application ("ANDA"). In fact, the claims to be asserted against Sicor were not identified until five months later, in Plaintiffs' Preliminary Infringement Contentions. Based upon the claims identified in plaintiffs' contentions, Sicor now seeks to clarify its previously asserted answer and affirmative defense of non-infringement, and should be given leave to do so.

## III. SICOR SHOULD BE GIVEN LEAVE TO AMEND ITS ANSWERS

### A. Legal Standard

Rule 15(a), Fed. R. Civ. P., embodies the liberal pleading policy of the Federal Rules of Civil Procedures and is founded in a policy favoring decisions on the merits, rather than technicalities. *See Centerforce Tech., Inc. v. Austin Logistics Inc.*, No. 99-243 MMS, 2000 U.S. Dist. LEXIS 6924 at *8-*9 (D. Del. Mar. 10, 2000). Specifically, Rule 15(a) declares that "leave to amend shall be freely given when justice so requires," and the United States Supreme Court has emphasized that "this mandate is to be heeded." *Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Ondeo Nalco Co. v. Eka Chemicals, Inc.*, No. 01-537 SLR, 2002 U.S. Dist. LEXIS 26195, at *5 (D. Del. Aug. 10, 2002).

"[T]he clearest cases for leave to amend are correction of an insufficient claim or defense and amplification of previously alleged claims or defenses." *See France Telecom S.A. v. Novell, Inc.*, No. 02-437 GMS, 2002 U.S. Dist. LEXIS 19967, at *3 (D. Del. Oct. 17, 2002); *see also Symbol Tech., Inc. v. Proxim Inc.*, No. 01-801 SLR, 2003 U.S. Dist. LEXIS 6686, at *3 (D. Del. Apr. 17, 2003) "If the underlying facts or circumstances relied upon by a [party] may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits."). Although a trial court has the discretion to grant or deny leave to amend, leave to amend should

be freely granted in accordance with Rule 15(a) unless there is an apparent or declared reason for denial. *See Trueposition, Inc. v. Allen Telecom, Inc.*, No. 01-823 GMS, 2002 U.S. Dist. LEXIS 12848, at *3 (D. Del. July 16, 2002)(internal citations omitted). Reasons deemed by the District of Delaware to be "sufficient" for denial include undue delay, bad faith or dilatory motive on the part of the movant, undue prejudice to the opposing party, and futility of the amendment. *See id.*; *see also Symbol Tech., Inc.*, 2003 U.S. Dist. LEXIS at *3.

**B. Sicor's Motion to Amend its Answer Should Be Granted**

Sicor seeks to clarify a defense that has previously been asserted against plaintiffs, which this District has held to be the "clearest case" for granting a motion for leave to amend a pleading. Moreover, none of the reasons deemed "sufficient" to deny a motion for leave to amend are present here, so there is no basis upon which Sicor's motion should be denied.

First, Sicor's motion to amend its Answers is timely. In accordance with the Court's Scheduling Order in this case, Sicor has moved to amend its Answers by the March 30, 2006 deadline to amend pleadings.

Second, Sicor's motion to amend its Answers will not prejudice the plaintiffs in any way.[1] Sicor asserted the affirmative defense of non-infringement in each of its August 8, 2005 Answers, and its proposed amendment here serves only to clarify that Sicor does not and will not infringe any "asserted valid and enforceable" claim of the '877 patent.

Third, Sicor's motion to amend its Answers is not in bad faith or a result of any dilatory motive on behalf of Sicor. At the time Sicor's Answers were filed, plaintiffs had not yet identified which claims of the '877 patent would be asserted to be infringed, and did not do so

[1] "Prejudice for the purpose of Rule 15(a) does not concern potential prejudice resulting from the nature of claims sought to be added; it concerns only the prejudice resulting from the fact of adding new claims at a later date." *See Centerforce Tech.. Inc.*, 2000 U.S. Dist. LEXIS at *19.

until the filing of its Preliminary Invalidity Contentions – nearly three months later. Moreover, Sicor's proposed amendment to its non-infringement defense will not require any dates set forth in the Court's October 12, 2005 Scheduling Order to be postponed, nor will it delay the date that has already been set by the Court for trial. *See, e.g.*, *Centerforce Tech. Inc.*, 2000 U.S. Dist. LEXIS at *22-24.

Finally, Sicor's motion to amend its Answers is not futile. Sicor seeks to modify its non-infringement defense to be asserted with respect to "any asserted valid and enforceable claim" of the '877 patent, which responds more directly to the claims that plaintiffs identified its Preliminary Infringement Contentions. In its Answers, Sicor reserved the right to assert each and every defense that became evident during the course of discovery, and its entitled to do so now.

## IV. CONCLUSION

In view of the foregoing, defendant Sicor respectfully requests that the Court grant its motion for leave to amend its Answers.

Respectfully submitted,

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*Attorneys for Defendants Sicor Inc. and Sicor Pharmaceuticals, Inc.*

Of Counsel:
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GOODWIN PROCTER LLP
599 Lexington Avenue
New York, NY 10022
(212) 813-8800

Dated: March 30, 2006

**CERTIFICATE OF SERVICE**

I, Monté T. Squire, Esquire, hereby certify that on March 30, 2006, 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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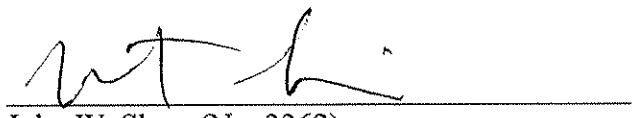
I further certify that on March 30, 2006, I caused copies of the foregoing document to be served by hand delivery on the above listed counsel of record and on the following in the manner indicated:

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# Exhibit A

[Proposed] Amended Answer

**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.<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 |

**[PROPOSED] AMENDED ANSWER AND AFFIRMATIVE DEFENSES OF SICOR INC.**

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

**JURISDICTION AND PARTIES**

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

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

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

4. Sicor Inc. 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 Inc.

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

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

8. Sicor Inc. admits that it is a Delaware corporation having its principal place of business at 19 Hughes, Irvine, California and is a wholly owed subsidiary of Teva Israel. Sicor Inc. denies the remaining allegations in paragraph 8.

9. To the extent that Paragraph 9 makes allegations directed to Teva Israel, no response is required from Sicor Inc. To the extent that the allegations is paragraph 9 are directed to Sicor Inc., Sicor Inc. admits that it was acquired by Teva Israel in or about January 2004.

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

11. To the extent that paragraph 11 makes allegations directed to Sicor Pharmaceuticals, Inc. ("Sicor Pharmaceuticals"), no response is required from Sicor Inc. Sicor Inc. admits that Sicor Pharmaceuticals is a wholly owned subsidiary of Sicor Inc. and denies the remaining allegations of paragraph 11.

12. To the extent that paragraph 12 makes allegations directed to Teva Israel, Teva USA, and Sicor Pharmaceuticals, no response is required from Sicor Inc. To the extent that paragraph 12 makes allegations directed to Sicor Inc., it admits that Sicor Inc. 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 Pharmaceuticals, no response is required from Sicor Inc. To the extent that paragraph 13 makes allegations directed to Sicor Inc., it denies the same.

14. To the extent paragraph 14 makes allegations directed to Teva Israel, Teva USA, and Sicor Pharmaceuticals, or states conclusions of law, no response is required from Sicor Inc. To the extent that paragraph 14 makes allegations directed to Sicor Inc., it admits that Sicor Inc. is a wholly owned subsidiary of Teva Israel 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 Pharmaceuticals, or states conclusions of law, no response is required from Sicor Inc. To the extent that paragraph 15 makes allegations directed to Sicor Inc., for purposes of this case only, Sicor Inc. 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 Pharmaceuticals, no response is required from Sicor Inc. To the extent that paragraph 16 makes allegations directed to Sicor Inc., 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 Inc. is proper in this judicial district. Sicor Inc. denies the remaining allegations in paragraph 16.

**BACKGROUND**

17. Sicor Inc. 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 Inc. 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 Inc. denies the remaining allegations of paragraph 17.

18. Sicor Inc. 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 Inc. 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 Inc. denies the allegations in paragraph 20.

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

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

23. Paragraph 23 makes only allegations as to Teva USA and Sicor Pharmaceuticals, and thus no response is required from Sicor Inc.

24. Paragraph 24 makes only allegations as to Sicor Pharmaceuticals, and thus no response is required from Sicor Inc.

25. Paragraph 25 makes only allegations as to Sicor Pharmaceuticals, and thus no response is required from Sicor Inc.

26. Paragraph 26 makes only allegations as to Sicor Pharmaceuticals, and thus no response is required from Sicor Inc.

27. Paragraph 27 makes only allegations as to Sicor Pharmaceuticals, and thus no response is required from Sicor Inc.

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

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

**Count I: Patent Infringement**

30. Paragraph 30 makes only allegations as to Sicor Pharmaceuticals, and thus no response is required from Sicor Inc.

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

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

**Count II: Declaratory Judgment**

33. Sicor Inc. 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 Pharmaceuticals, no response is required from Sicor Inc. To the extent that paragraph 34 makes allegations directed to Sicor Inc., Sicor Inc. denies the same.

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

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

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

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

**Count III: Willful Patent Infringement**

39. Sicor Inc. 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 Pharmaceuticals, no response is required from Sicor Inc. To the extent that paragraph 40 makes allegations directed to Sicor Inc., Sicor Inc. denies the same.

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

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

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

**SICOR INC.'S 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 any asserted valid and enforceable claim 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 that Sicor Inc. has infringed or will infringe in Count I and that Sicor Inc. has willfully infringed and that this case is exceptional under 35 U.S.C. § 285 in Count III, 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 Inc. 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 Inc. prays that the Court enter judgment against plaintiffs and in favor of Sicor Inc., dismissing with prejudice each of the claims asserted by plaintiffs, and that the Court award Sicor Inc. any other relief it deems to be just and proper.

Respectfully submitted,

Dated: April ___, 2006

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D. Fon Muttamara-Walker (No. 4646)
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Attorneys for Defendants

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

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9. To the extent that Paragraph 9 makes allegations directed to Teva Israel, no response is required from Sicor Inc. To the extent that the allegations is paragraph 9 are directed to Sicor Inc., Sicor Inc. admits that it was acquired by Teva Israel in or about January 2004.

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

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

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

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18. Sicor Inc. 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 Inc. 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 Inc. denies the allegations in paragraph 20.

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

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

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24. Paragraph 24 makes only allegations as to Sicor Pharmaceuticals, and thus no response is required from Sicor Inc.

25. Paragraph 25 makes only allegations as to Sicor Pharmaceuticals, and thus no response is required from Sicor Inc.

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27. Paragraph 27 makes only allegations as to Sicor Pharmaceuticals, and thus no response is required from Sicor Inc.

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

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

**Count I: Patent Infringement**

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**Count II: Declaratory Judgment**

33. Sicor Inc. 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 Pharmaceuticals, no response is required from Sicor Inc. To the extent that paragraph 34 makes allegations directed to Sicor Inc., Sicor Inc. denies the same.

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

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

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

**Count III: Willful Patent Infringement**

39. Sicor Inc. 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 Pharmaceuticals, no response is required from Sicor Inc. To the extent that paragraph 40 makes allegations directed to Sicor Inc., Sicor Inc. denies the same.

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

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

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

**SICOR INC.'S 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 any asserted valid and enforceable claim 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 that Sicor Inc. has infringed or will infringe in Count I and that Sicor Inc. has willfully infringed and that this case is exceptional under 35 U.S.C. § 285 in Count III, 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 Inc. 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 Inc. prays that the Court enter judgment against plaintiffs and in favor of Sicor Inc., dismissing with prejudice each of the claims asserted by plaintiffs, and that the Court award Sicor Inc. any other relief it deems to be just and proper.

Respectfully submitted,

Dated: April ___, 2006

John W. Shaw (No. 3362)
Josy W. Ingersoll (No. 1088)
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Attorneys for Defendants

# Exhibit A

Redlined Version of [Proposed] Amended Answer

**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.<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 |

**[PROPOSED] AMENDED ANSWER AND AFFIRMATIVE DEFENSES OF SICOR INC.**

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

**JURISDICTION AND PARTIES**

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

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

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

4. Sicor Inc. 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 Inc.

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

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

8. Sicor Inc. admits that it is a Delaware corporation having its principal place of business at 19 Hughes, Irvine, California and is a wholly owed subsidiary of Teva Israel. Sicor Inc. denies the remaining allegations in paragraph 8.

9. To the extent that Paragraph 9 makes allegations directed to Teva Israel, no response is required from Sicor Inc. To the extent that the allegations is paragraph 9 are directed to Sicor Inc., Sicor Inc. admits that it was acquired by Teva Israel in or about January 2004.

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

11. To the extent that paragraph 11 makes allegations directed to Sicor Pharmaceuticals, Inc. ("Sicor Pharmaceuticals"), no response is required from Sicor Inc. Sicor Inc. admits that Sicor Pharmaceuticals is a wholly owned subsidiary of Sicor Inc. and denies the remaining allegations of paragraph 11.

12. To the extent that paragraph 12 makes allegations directed to Teva Israel, Teva USA, and Sicor Pharmaceuticals, no response is required from Sicor Inc. To the extent that paragraph 12 makes allegations directed to Sicor Inc., it admits that Sicor Inc. 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 Pharmaceuticals, no response is required from Sicor Inc. To the extent that paragraph 13 makes allegations directed to Sicor Inc., it denies the same.

14. To the extent paragraph 14 makes allegations directed to Teva Israel, Teva USA, and Sicor Pharmaceuticals, or states conclusions of law, no response is required from Sicor Inc. To the extent that paragraph 14 makes allegations directed to Sicor Inc., it admits that Sicor Inc. is a wholly owned subsidiary of Teva Israel 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 Pharmaceuticals, or states conclusions of law, no response is required from Sicor Inc. To the extent that paragraph 15 makes allegations directed to Sicor Inc., for purposes of this case only, Sicor Inc. 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 Pharmaceuticals, no response is required from Sicor Inc. To the extent that paragraph 16 makes allegations directed to Sicor Inc., 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 Inc. is proper in this judicial district. Sicor Inc. denies the remaining allegations in paragraph 16.

**BACKGROUND**

17. Sicor Inc. 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 Inc. 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 Inc. denies the remaining allegations of paragraph 17.

18. Sicor Inc. 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 Inc. 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 Inc. denies the allegations in paragraph 20.

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

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

23. Paragraph 23 makes only allegations as to Teva USA and Sicor Pharmaceuticals, and thus no response is required from Sicor Inc.

24. Paragraph 24 makes only allegations as to Sicor Pharmaceuticals, and thus no response is required from Sicor Inc.

25. Paragraph 25 makes only allegations as to Sicor Pharmaceuticals, and thus no response is required from Sicor Inc.

26. Paragraph 26 makes only allegations as to Sicor Pharmaceuticals, and thus no response is required from Sicor Inc.

27. Paragraph 27 makes only allegations as to Sicor Pharmaceuticals, and thus no response is required from Sicor Inc.

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

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

**Count I: Patent Infringement**

30. Paragraph 30 makes only allegations as to Sicor Pharmaceuticals, and thus no response is required from Sicor Inc.

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

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

**Count II: Declaratory Judgment**

33. Sicor Inc. 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 Pharmaceuticals, no response is required from Sicor Inc. To the extent that paragraph 34 makes allegations directed to Sicor Inc., Sicor Inc. denies the same.

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

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

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

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

**Count III: Willful Patent Infringement**

39. Sicor Inc. 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 Pharmaceuticals, no response is required from Sicor Inc. To the extent that paragraph 40 makes allegations directed to Sicor Inc., Sicor Inc. denies the same.

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

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

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

**SICOR INC.'S 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] any asserted valid and enforceable claim 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 that Sicor Inc. has infringed or will infringe in Count I and that Sicor Inc. has willfully infringed and that this case is exceptional under 35 U.S.C. § 285 in Count III, 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 Inc. 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 Inc. prays that the Court enter judgment against plaintiffs and in favor of Sicor Inc., dismissing with prejudice each of the claims asserted by plaintiffs, and that the Court award Sicor Inc. any other relief it deems to be just and proper.

Respectfully submitted,

Dated: April __, 2006

John W. Shaw (No. 3362)
Josy W. Ingersoll (No. 1088)
D. Fon Muttamara-Walker (No. 4646)
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Attorneys for Defendants

# Exhibit B

[Proposed] Amended Answer

**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.<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 |

**[PROPOSED]AMENDED ANSWER AND AFFIRMATIVE DEFENSES OF SICOR PHARMACEUTICALS INC.**

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 that it infringes any asserted valid and enforceable claim of the '877 patent. Sicor Pharmaceuticals further denies the remaining allegations of 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 any asserted valid and enforceable claim 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: April ___, 2006

_____

John W. Shaw (No. 3362)
Josy W. Ingersoll (No. 1088)
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Attorneys for Defendants

**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.<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 |

**[PROPOSED]AMENDED ANSWER AND AFFIRMATIVE DEFENSES OF SICOR PHARMACEUTICALS INC.**

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 that it infringes any asserted valid and enforceable claim of the '877 patent. Sicor Pharmaceuticals further denies the remaining allegations of 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 any asserted valid and enforceable claim 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: April ___, 2006

_____

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Attorneys for Defendants

# Exhibit B

Redlined Version of [Proposed] Amended Answer

**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.<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 |

**[PROPOSED] AMENDED ANSWER AND AFFIRMATIVE DEFENSES OF SICOR PHARMACEUTICALS, INC.**

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] that it infringes any asserted valid and enforceable claim of the '877 patent. Sicor Pharmaceuticals further denies the remaining allegations of 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] any asserted valid and enforceable claim 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: April __, 2006

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