IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ÉLAN PHARMACEUTICAL INTERNATIONAL LIMITED, Plaintiff, v. ABRAXIS BIOSCIENCE, INC., Defendant.	)	Civil Action No. 06-438-GMS

ANSWER TO COMPLAINT AND COUNTERCLAIMS BY DEFENDANT ABRAXIS BIOSCIENCE, INC.

DEMAND FOR JURY TRIAL

Defendant Abraxis BioScience, Inc. ("Abraxis"), by its attorneys, answers Plaintiff Élan Pharmaceutical International Limited's ("Élan") Complaint for patent infringement dated July 19, 2006 as follows:

THE PARTIES

1. Abraxis is without sufficient information to admit or deny the allegations of Paragraph 1 and on that basis denies each and every allegation in Paragraph 1 of the Complaint.

2. Abraxis admits that it is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 11777 San Vicente Boulevard, Suite 550, Los Angeles, CA 90049. Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 2 of the Complaint.

JURISDICTION AND VENUE

3. Abraxis admits that claims for infringement of a United States patent are governed by the patent laws of the United States, Title 35 of the United States Code. Abraxis admits that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) over patent infringement actions brought pursuant to the patent laws of the United States, Title 35 of the United States Code. Abraxis denies that Élan has a cause of action against Abraxis for patent infringement. Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 3 of the Complaint.

4. Abraxis admits that this Court has personal jurisdiction over Abraxis. Abraxis denies that it has committed acts of patent infringement in this or any other judicial district. Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 4 of the Complaint.

5. Abraxis denies each and every allegation of Paragraph 5 of the Complaint.

6. Abraxis admits that venue is proper in this judicial district. Abraxis denies that it has engaged in any infringing activity in this or any other judicial district. Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 6 of the Complaint.

FACTUAL BACKGROUND

7. Abraxis admits that United States Patent No. 5,399,363 ("the '363 patent") is entitled "Surface Modified Anticancer Nanoparticles". Abraxis admits that the face of the '363 patent lists Gary G. Liversidge, Elaine Liversidge, and Pramod P. Sarpotdar as inventors. Abraxis admits that the face of the '363 patent lists March 21, 1995 as the date of patent. Abraxis admits that Exhibit A to the Complaint is a document that on its face purports to be the '363 patent. Abraxis is without sufficient information to admit or deny the allegation of Paragraph 7 of the Complaint that "Élan is the owner by assignment of all right, title, and interest in and to" the '363 patent and on that basis denies that allegation. Abraxis denies that

the '363 patent was duly and legally issued. Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 7 of the Complaint.

8. Abraxis admits that United States Patent No. 5,834,025 ("the '025 patent") is entitled "Reduction Of Intravenously Administered Nanoparticulate-Formulation-Induced Adverse Physiological Reactions". Abraxis admits that the face of the '025 patent lists Lawrence de Garavilla, Elaine M. Liversidge, and Gary G. Liversidge as inventors. Abraxis admits that the face of the '025 patent lists November 10, 1998 as the date of patent. Abraxis admits that Exhibit B to the Complaint is a document that on its face purports to be the '025 patent. Abraxis is without sufficient information to admit or deny the allegation of Paragraph 8 of the Complaint that "Élan is the owner by assignment of all right, title, and interest in and to" the '025 patent and on that basis denies that allegation. Abraxis denies that the '025 patent was duly and legally issued. Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 8 of the Complaint.

9. Abraxis admits that the United States Food and Drug Administration ("FDA") approved the sale of Abraxane™ in the United States for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy, where prior therapy included an anthracycline unless clinically contraindicated. Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 9 of the Complaint.

10. Abraxis admits that Abraxane® is a particulate formulation of paclitaxel. Abraxis admits that Abraxane® is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant therapy, where prior therapy included an anthracycline unless clinically contraindicated. Abraxis is without sufficient information to admit or deny the allegation of Paragraph 10 of the Complaint that Abraxane® "is intravenously administered to patients for the treatment of

breast cancer" and on that basis denies that allegation. Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 10 of the Complaint.

11. Abraxis admits that Abraxane® is a product offered for sale or sold by Abraxis within this judicial district. Abraxis admits that it has title to doses of Abraxane® within this judicial district before delivery to purchasers within this judicial district. Abraxis denies that Abraxane® is a product manufactured by Abraxis within this judicial district. Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 11 of the Complaint.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 5,399,363

12. Abraxis incorporates by reference its answers in paragraphs 1-11 above. Abraxis further denies any implication or allegation purportedly contained in the heading immediately preceding Paragraph 12 of the Complaint.

13. Abraxis denies each and every allegation in Paragraph 13 of the Complaint.

14. Abraxis denies each and every allegation in Paragraph 14 of the Complaint.

15. Abraxis denies each and every allegation in Paragraph 15 of the Complaint.

16. Abraxis denies each and every allegation in Paragraph 16 of the Complaint.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 5,834,025

17. Abraxis incorporates by reference its answers in paragraphs 1-16 above. Abraxis further denies any implication or allegation purportedly contained in the heading immediately preceding Paragraph 17 of the Complaint.

18. Abraxis denies each and every allegation in Paragraph 18 of the Complaint.

19. Abraxis denies each and every allegation in Paragraph 19 of the Complaint.

20. Abraxis denies each and every allegation in Paragraph 20 of the Complaint.

21. Abraxis denies each and every allegation in Paragraph 21 of the Complaint.

ADDITIONAL DEFENSES

For its further and separate defenses to the allegations in the Complaint, and without assuming any burden of proof it would not otherwise bear under applicable law, Abraxis pleads as follows:

FIRST ADDITIONAL DEFENSE
('363 patent — Noninfringement)

Abraxis does not and has not infringed, either directly or indirectly, any valid claim of the '363 patent.

SECOND ADDITIONAL DEFENSE
('025 patent — Noninfringement)

Abraxis does not and has not infringed, either directly or indirectly, any valid claim of the '025 patent.

THIRD ADDITIONAL DEFENSE
('363 Patent — Invalidity)

The '363 patent is invalid and void for failure to comply with one or more of the provisions of Part II of Title 35 of the United States Code, including without limitation sections 102, 103, and/or 112.

FOURTH ADDITIONAL DEFENSE
('025 Patent — Invalidity)

The '025 patent is invalid and void for failure to comply with one or more of the provisions of Part II of Title 35 of the United States Code, including without limitation sections 102, 103, and/or 112.

FIFTH ADDITIONAL DEFENSE
(Prosecution History Estoppel)

Élan is barred by the doctrine of prosecution history estoppel from contending that any claim of the '363 or '025 patents covers any product manufactured, used, sold, or offered for sale by Abraxis.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

THE PARTIES

1. Counterclaim-Plaintiff Abraxis BioScience, Inc. ("Abraxis") is a Delaware corporation with its principal place of business at 11777 San Vicente Boulevard, Suite 550, Los Angeles, CA 90049.

2. According to the Complaint it filed in this action, Counterclaim-Defendant Élan Pharmaceutical International Limited ("Élan") is a company organized and existing under the laws of Ireland, having a business address at Monksland, Athlone, Co. Westmeath, Ireland.

3. This Court has jurisdiction of these Counterclaims for declaratory relief under the Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, under the laws of the United States concerning actions relating to patents, 28 U.S.C. § 1338(a), and under 28 U.S.C. § 1331.

4. As set forth in the Complaint and in the Answer to which these Counterclaims are appended, a justiciable controversy has arisen and exists between Counterclaim-Plaintiff and Counterclaim-Defendant concerning the validity and scope of the '363 and '025 patents and Abraxis's liability for alleged infringement thereof. Venue properly lies in this judicial district by virtue of Counterclaim-Defendant having filed its Complaint therein.

COUNT I: NONINFRINGEMENT OF THE '363 AND '025 PATENTS

5. Abraxis incorporates the allegations of paragraphs 1-4 as if fully set forth herein.

6. Élan has alleged and claimed that it owns all right title and interest in, and has standing to sue for infringement of, the '363 and '025 patents.

7. Élan has alleged and claimed that Abraxis infringes the '363 and '025 patents.

8. Abraxis has not and does not infringe, either directly or indirectly, any valid claim of the '363 and '025 patents.

9. A declaration of the parties' respective rights is proper and appropriate.

COUNT II: INVALIDITY OF THE '363 AND '025 PATENTS

10. Abraxis incorporates the allegations of paragraphs 1-9 as if fully set forth herein.

11. Élan has alleged and claimed that the '363 and '025 patents were duly and legally issued.

12. On information and belief, one or more claims of the '363 and '025 patents are invalid and void for failure to comply with one or more of the provisions of Part II of Title 35 of the United States Code, including without limitation sections 102, 103, and/or 112.

13. A declaration of the parties' respective rights is proper and appropriate.

PRAYER FOR RELIEF

WHEREFORE, Abraxis asks this Court to enter judgment against Élan and in Abraxis's favor on all claims in the Complaint, dismissing the Complaint with prejudice, and further:

A. that the Court declare United States Patent No. 5,399,363 to be invalid, void and/or not infringed by Abraxis;

B. that the Court declare United States Patent No. 5,834,025 to be invalid, void and/or not infringed by Abraxis;

C. that the Court declare this to be an exceptional case under 35 U.S.C. § 285 and award Abraxis its costs and reasonable attorneys' fees; and

D. that the Court award Abraxis such other relief as it may deem appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b) and Local Rule 38.1, Abraxis hereby demands a jury trial for all issues in this case that are properly subject to a jury trial.

Dated: August 22, 2006

YOUNG CONAWAY STARGATT & TAYLOR, LLP

By: /s/ *Josy W. Ingersoll*

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ABRAXIS BIOSCIENCE, INC.

CERTIFICATE OF SERVICE

I, Josy W. Ingersoll, Esquire, hereby certify that on August 22, 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 August 22, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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