IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELAN PHARMA INTERNATIONAL LIMITED, Plaintiff, v. ABRAXIS BIOSCIENCE, INC., Defendant.	)	C.A. No. 06-438-GMS

JOINT STATUS REPORT

Pursuant to Federal Rule of Civil Procedure 16, Delaware Local Rule 16.2, and this Court's Notice of Scheduling Conference dated October 24, 2006, Plaintiff Elan Pharma International Limited ("Elan") and Defendant Abraxis BioScience, Inc. ("Abraxis") (collectively, "the Parties") submit this Joint Status Report by and through their undersigned counsel. Counsel for the Parties participated in a telephone conference pursuant to the Notice of Scheduling Conference.

Counsel for Abraxis offered to meet and confer pursuant to Federal Rule of Civil Procedure 26(f) on or before the filing of this Joint Status Report but was informed by counsel for Elan that such a conference could not take place until later this week due to the unavailability of Elan's lead trial counsel.

1. Jurisdiction and Service

The Parties agree that this Court has subject matter jurisdiction over Plaintiff's claims pursuant to 35 U.S.C. §§ 1331 and 1338(a), and Defendant's counterclaims pursuant to the

Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) and 2202. The Parties further agree that the Court has personal jurisdiction over each of the Parties. No party remains to be served.

2. Substance of the Action

A. **Elan's Statement**

Abraxis admits that their product, Abraxane®, is a product offered for sale or sold by Abraxis within this judicial district for the treatment of breast cancer. Abraxis further admits that it has title to doses of Abraxane® within this judicial district before delivery to purchasers within this judicial district. Plaintiff alleges that by making, using, selling, and/or offering for sale Abraxane® for intravenous administration to patients in need thereof, Abraxis infringes the claims of Elan's U.S. Patent Nos. 5,399,363 and 5,834,025 (collectively the "Elan Patents-In-Suit"). Plaintiff further alleges that Abraxis's infringement is willful and deliberate, and that Plaintiff will be substantially and irreparably harmed by Abraxis's willful infringement.

B. **Abraxis's Statement**

Elan alleges infringement of the Elan Patents-In-Suit by Abraxis's product Abraxane®, which incorporates a revolutionary invention by Abraxis for administering substantially water-insoluble drugs to patients -- albumin-bound nanoparticle technology. Last year, the United States Food and Drug Administration approved Abraxane for treatment of certain breast cancer patients. The drug in Abraxane is paclitaxel. Paclitaxel was previously used to treat breast cancer but was limited in its use by the difficulties associated with intravenously administering this water-insoluble drug. Abraxis developed a solution to those problems: administer nanoparticles of the drug in its amorphous form that are coated with the natural blood protein albumin. This novel formulation for delivering paclitaxel results in greater efficacy and lesser side-effects as compared to prior paclitaxel formulations.

Elan does not market nanoparticulate pharmaceutical formulations. Nor does Elan market any paclitaxel product. Instead, Elan has developed a licensing program for what Elan calls its "NanoCrystal® Technology."

Elan has accused Abraxane of infringing two Elan patents. One patent ("the '363 patent") requires, among other things, particles of a drug that is in crystalline form. The other patent is drawn to methods of administering nanoparticulate drug compositions without eliciting hemodynamic effects ("the '025 patent") and requires, among other things, particles of a drug that is in crystalline form, liposomes or "colloidal polymeric material," administration with antihistamine, and/or administration at an infusion rate of less than 10 mg/ml.

Abraxane differs in many respects from the claims of the Elan Patents-In-Suit. For example, Abraxane differs from all the claims of the '363 patent and most of the claims of the '025 patent because the paclitaxel in Abraxane is in its amorphous form, not the claimed crystalline form. Abraxane also differs from the claims of the '025 patent because, for example, Abraxane does not include liposomes or a "colloidal polymeric material" and because Abraxis does not encourage administration of Abraxane with antihistamine or at an infusion rate of less than 10 mg/ml.

Abraxis denies Elan's allegations of infringement and willfulness. Abraxis also denies Elan's allegations with respect to damages and irreparable harm. Abraxis alleges that the Elan Patents-In-Suit are invalid for failure to comply with one or more of the conditions of patentability set forth in Part II of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103 and 112. Abraxis also asserts the affirmative defense of prosecution history estoppel. Abraxis counterclaims for a declaratory judgment that Abraxis has not directly infringed, contributorily infringed, or induced infringement of any claim of the Elan

Patents-In-Suit. Abraxis also seeks a declaratory judgment that the Elan Patents-In-Suit are invalid. Abraxis seeks recovery of its attorneys' fees and costs, as permitted under 35 U.S.C. § 285 or otherwise.

3. Identification of Issues

The principal factual and legal issues genuinely in dispute include the following:

a. the construction of the terms of the claims of the Elan Patents-In-Suit;

b. the validity of the claims of the Elan Patents-In-Suit;

c. whether Abraxis infringes any valid claim of the Elan Patents-In-Suit;

d. if Abraxis is found to infringe any valid claim, whether that infringement has been willful and deliberate;

e. if Abraxis is found to infringe any valid claim, Elan contends it is entitled to an accurate accounting of all gains, profits, and advantages derived by Abraxis's infringement of the '363 and '025 patents;

f. if Abraxis is found to infringe any valid claim, the amount of damages under 35 U.S.C. § 284, including, if willfulness is found, whether there will be an increase in such damages of up to three times;

g. if Abraxis is found to infringe any valid claim, whether the entry of an injunction and/or other relief is warranted;

h. whether Abraxis is entitled to other relief; and

i. whether this case is exceptional within the meaning of 35 U.S.C. § 285, permitting the award of attorneys' fees for the prevailing party.

4. Narrowing of Issues

A. **Elan's Statement**

Elan believes that once fact and expert discovery is commenced, the Parties may be better able to narrow issues by eliminating claims and/or defenses prior to trial by way of stipulation or dispositive motions. Elan has at the present time identified no dispositive or partially dispositive issues for decision on motion.

B. **Abraxis's Statement**

All of the claims of the Elan '363 Patent-In-Suit and most of the claims of the '025 Patent-In-Suit require a "crystalline" drug. As explained in the Elan Patents-In-Suit, "[t]he crystalline phase differs from an amorphous, i.e., non-crystalline phase." ('363 Patent, column 2, lines 29-30; *see also* '025 Patent, column 7, lines 29-31.) The drug in Abraxane® is amorphous, not crystalline. This difference is public knowledge. Abraxis requests leave to file an early noninfringement summary judgment motion based on this fundamental difference.

5. Relief

A. **Elan's Statement**

Plaintiff Elan requests damages amounting to a reasonable royalty and/or lost profits for Abraxis's alleged infringement of the Elan Patents-In-Suit, in addition to a temporary and/or permanent injunction. Elan also requests treble or enhanced damages due to Abraxis's alleged willful and deliberate infringement of the Elan Patents-In-Suit. Elan has also requested it be awarded its reasonable attorneys' fees, costs, and expenses incurred in this action.

B. **Abraxis's Statement**

Abraxis requests that Elan be denied any relief in connection with its Complaint, and that judgment on the Complaint be entered in favor of Abraxis. Abraxis also asks that Abraxis be

declared not to have infringed or willfully infringed either of the Elan Patents-In-Suit, and that the Elan Patents-In-Suit be declared invalid. Abraxis requests that it be awarded its attorneys' fees and costs under 35 U.S.C. § 285 or otherwise.

6. Amendment of Pleadings

Apart from the stipulated amendment of the caption to correctly name Plaintiff, the Parties have not sought leave to amend the pleadings to date. If any further amendments are necessary, the Parties agree to seek leave to amend on or before **March 30, 2007 (Elan) or September 14, 2007 (Abraxis)**.

7. Joinder of Parties

At this time, no other Parties have been joined. The Parties, however, respectfully seek to reserve the right to file motions to join Parties on or before **January 15, 2007 (both Parties)**.

8. Discovery

The Parties anticipate that discovery in this action may include, but will not be limited to, the following topics:

a. composition and method of administering the accused product and the protocols used in the accused methods;

b. research, development, sales, distribution, and use of the accused product and methods of administration;

c. Elan alleges the right to discovery of Abraxis's construction of the claims of the Elan Patents-In-Suit;

d. financials related to the sales of the accused product and methods of administration within the scope of the Elan Patents-In-Suit;

e. marketing related to the offering for sale of the accused product and methods of

administration within the scope of the Elan Patents-In-Suit;

f. Elan's basis for filing suit against Abraxis based on alleged infringement of the Elan Patents-In-Suit.

g. validity of the Elan Patents-In-Suit;

h. Elan's licensing activities with respect to the Elan Patents-In-Suit, whether independently or as part of Elan's NanoCrystal technology;

i. Elan's research and development with respect to the Elan Patents-In-Suit;

j. Elan's knowledge of the prior art; and

k. Elan's communications with Abraxis and knowledge of Abraxis's activities.

The Parties will commence discovery in time for fact discovery to be completed on or before **July 30, 2007 (Elan) or December 21, 2007 (Abraxis)** and for expert discovery to be completed on or before **November 30, 2007 (Elan) or April 4, 2008 (Abraxis).**

The Parties believe that discovery in this matter will proceed in a less costly, less time-consuming, and more efficient manner if reasonable limits are placed at the outset on certain forms of discovery. Absent later agreement between the Parties or Order of this Court, each Party should be limited to:

- 100 requests for admission, with the understanding that this limit shall not apply to requests for admission as to authenticity of documents or business record status;
- 50 interrogatories, including subparts as provided by Delaware Local Rule 26.1; and
- depositions of ten (10) fact witnesses

    1. Elan contends that these ten fact witnesses (whether of a party or a non-party) should (1) *exclude* Rule 30(b)(6) deponents and (2) be limited to 140 hours on the record (with no limit for Rule 30(b)(6) depositions).

2. Abraxis contends that these ten fact depositions (whether of a party or of a non-party) should (1) *include* Rule 30(b)(6) deponents (with each party deposed counting as one witness) and (2) be limited to 70 hours on the record (including any Rule 30(b)(6) depositions), consistent with Federal Rule of Civil Procedure 30(d)(2) and 30(a)(2)(A).

The Parties further believe that, should the need arise later in the case to modify any of the above limits, the Parties will work together to reach any reasonable accommodation that is available.

9. Estimated Trial Length

The Parties estimate that the trial will take 10-11 full court days. The Parties are not contemplating bifurcation at this time. The Parties will employ their best efforts to reduce the length of the trial by stipulations, use of summaries, and other expedited means of presenting evidence.

10. Jury Trial

The Parties have requested a jury trial on all issues so triable in accordance with Federal Rule of Civil Procedure 38(b) and Delaware Local Rule 38.1.

11. Settlement

There have been no settlement discussions as of the date this Joint Status Report was executed. The prospects for settlement are unknown. Abraxis believes that referral to the Magistrate for mediation is appropriate. Elan will consider referral to the Magistrate for mediation.

12. Other Matters

Counsel for the Parties propose the following additional scheduling terms which are alternatively set forth in Appendix A.

A. Initial Disclosures pursuant to Federal Rule of Civil Procedure 26(a) will be provided on or before **November 16, 2006 (both Parties).**

B. Abraxis shall inform Elan whether Abraxis intends to rely on advice of counsel in response to Elan's allegation of willful infringement and shall produce to Elan the advice on which Abraxis intends to rely no later than **March 16, 2007 (Elan) or August 10, 2007 (Abraxis).**

C. The Parties shall file a final joint claim chart which shall include citations to intrinsic evidence on or before **April 16, 2007 (Elan) or June 1, 2007 (Abraxis).** The Parties will exchange opening claim construction briefs on or before **May 7, 2007 (Elan) or June 22, 2007 (Abraxis).** Depositions of any declarants submitting declarations in support of a party's claim construction brief shall be deposed on or before **May 21, 2007 (Elan) or July 13, 2007 (Abraxis).** Answering claim construction briefs must be filed on or before **June 18, 2007 (Elan) or August 3, 2007 (Abraxis).**

D. The Parties will serve opening expert reports on issues for which that party bears the burden of proof on or before **September 14, 2007 (Elan) or February 7, 2008 (Abraxis)** and responsive expert reports will be served **October 15, 2007 (Elan) or March 7, 2008 (Abraxis).**

E. The Parties will submit any letter briefs seeking permission to file any summary judgment motions on or before **December 14, 2007 (Elan) or May 2, 2008 (Abraxis),** answering letter briefs will be filed within five (5) days thereafter, and reply letter briefs will be

filed within three (3) days thereafter.

F. Should the Court permit the filing of summary judgment motions, an opening brief and declarations, if any, in support of such motions shall be served and filed within thirty (30) days after the Court permits such motions, an answering brief and declarations shall be filed within fifteen (15) days after service of the opening brief, and reply brief shall be filed within fifteen (15) days after service of the answering brief.

G. Thirty (30) days before a joint pretrial order is due, each Party will forward a draft of a pretrial order to the other Party.

H. Opening briefs on all motions *in limine* shall be filed on or before six (6) weeks prior to the Pretrial Conference. All answering briefs on all motions *in limine* shall be filed within fourteen (14) days from filing of the opening briefs. All reply briefs on all motions *in limine* shall be filed within seven (7) days from filing of the answering briefs.

I. The Parties have agreed that a stipulated protective order is necessary due to the confidential, technical and business information that will be exchanged in this action. The Parties will present a joint draft to the Court for its consideration. The Parties will employ their best efforts to reach an agreement on the terms of the protective order by **November 30, 2006**. Prior to entry of a protective order, any documents or information deemed confidential by the other Party may only be disclosed to members and employees of the firm of the outside counsel of record in this action.

13. Statement Regarding Conference.

The Parties certify that they have conferred about each of the above matters set forth in this report.

ASHBY & GEDDES

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Dated: October 30, 2006
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Appendix A

DEADLINE	ELAN PROPOSAL	ABRAXIS PROPOSAL
Rule 26(a)(1) Disclosures	November 16, 2006	November 16, 2006
Filing of Proposed Protective Order	November 30, 2006	November 30, 2006
Joinder of Parties	January 15, 2007	January 15, 2007
Production of Advice of Counsel Relied Upon for Non-Willfulness	March 16, 2007	August 10, 2007
Filing of Motion for Leave to Amend Pleadings	March 30, 2007	September 14, 2007
Filing of Joint Claim Chart	April 16, 2007	June 1, 2007
Opening *Markman* Briefs	May 7, 2007	June 22, 2007
Depositions of any Claim Construction Declarants	May 21, 2007	July 13, 2007
Rebuttal *Markman* Briefs	June 18, 2007	August 3, 2007
Fact Discovery Cutoff	July 30, 2007	December 21, 2007
Opening Expert Reports	September 14, 2007	February 7, 2008
Rebuttal Expert Reports	October 15, 2007	March 7, 2008
Expert Discovery Cutoff	November 30, 2007	April 4, 2008
Letter Brief Seeking to file summary judgment motion	December 14, 2007	May 2, 2008
Last day for filing permitted summary judgment motions	To be determined (TBD)	30 days after court order permitting the filing
Last day for filing oppositions to summary judgment motions	TBD	15 days after filing of summary judgment motion
Last day for filing replies to summary judgment motions	TBD	15 days after filing of opposition to summary judgment motion
Last day to file motions in limine	6 weeks before pretrial conference	6 weeks before pretrial conference
Parties exchange draft pretrial orders	30 days before joint pretrial order due	30 days before joint pretrial order due
Pretrial Order	TBD	TBD
Pretrial Conference	TBD	TBD
Trial	TBD	Late 2008