IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

PLAINTIFF ELAN PHARMA INTERNATIONAL LIMITED'S
MOTION TO MODIFY THE SCHEDULING ORDER

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Dated: July 2, 2007
182002.1

PLAINTIFF ELAN PHARMA INTERNATIONAL LIMITED'S MOTION TO MODIFY THE SCHEDULING ORDER

Plaintiff Elan Pharma International Limited ("Elan") hereby respectfully requests a modification of the scheduling order to extend fact discovery in light of Abraxis's recent—and still incomplete—production of a significant volume of documents that go to the heart of Elan's infringement contentions. The requested extension will affect only discovery deadlines and will not affect the trial date in this matter.

I. Factual Background

Fact discovery in this matter is currently scheduled to end on July 30, 2007. *See* D.I. 20 at 2. Adhering to this discovery deadline will cause extreme and unfair prejudice to Elan because Abraxis has yet to produce portions of hundreds of laboratory notebooks that were designated as responsive by Elan following a time-consuming and expensive review. These notebooks contain evidence directly relevant to Abraxis's infringement of the '363 Patent. Until these notebooks pages are in hand, Elan will be unable to effectively examine deposition witnesses, including the authors of the notebooks.

Additionally, although the Court ordered Abraxis to make the details of its manufacturing processes for the accused product available on May 23, Abraxis has only complied with the Court's Order as of June 19, and in a manner that hamstrings Elan's ability to prepare for depositions and that substantially increases the time necessary for review. Abraxis has posted its manufacturing documents on a secure website, limited the number of Elan's attorneys who may access the site, prohibited Elan from taking notes or printing the hosted information, and precluded Elan's experts from accessing the site. Abraxis has further complicated the process by objecting to Elan's expert having any access at all to the manufacturing documents, without sufficient explanation or reason. Moreover, Abraxis has yet

to agree to a procedure by which Elan may obtain hard copies of manufacturing documents for use during deposition examination of Abraxis's witnesses, and, in the absence of such an agreement, would purport to deny Elan any cross-examination use of the information at all.

Finally, Abraxis has only recently produced more than one-quarter million pages of responsive documents. This constitutes over half of Abraxis's production to date. Although Elan is reviewing these documents as quickly as possible, even with its best efforts, it cannot substantively analyze these documents, identify the witnesses to be deposed and specific topics to be addressed, prepare sufficiently for such depositions, and avoid the need for continued depositions of the same witnesses at a later date.

A. Elan has not received responsive portions of approximately 700 Abraxis laboratory notebooks 20 business days before the discovery deadline.

On June 13-15—less than 30 business days before the discovery deadline and for the first time—Abraxis offered Elan the opportunity to inspect more than 700 laboratory notebooks potentially responsive to requests propounded on November 10, 2006.[1] Elan dispatched five attorneys to two separate locations where they reviewed (but were not permitted to make copies of or even to take notes on) the laboratory notebooks. Elan's attorneys designated a substantial number of pages from these laboratory notebooks for production. On June 22—less than 24 business days before the current discovery deadline—Abraxis offered approximately 40 additional laboratory notebooks for Elan's inspection during a Rule 30(b)(6) deposition regarding Abraxis's document collection efforts.

As of the date of the filing of this motion—20 business days before the current fact discovery deadline—Abraxis has yet to produce the designated laboratory notebooks to Elan.

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Because Elan's attorneys were prohibited from taking any notes during their inspection of Abraxis's laboratory notebooks, Elan must undertake a second review when the notebooks are finally produced in order to identify witnesses to be deposed and specific topics to be addressed. It is self-evident that preparation for effective cross-examination of witnesses regarding technical work undertaken by Abraxis's scientists and technicians will be a meaningless exercise if Elan's counsel are not afforded access to this material and adequate time to evaluate it.

B. Abraxis did not provide Elan with access to the full details of the manufacturing processes for Abraxane® until less than 30 days before the fact discovery deadline.

On June 19—less than 30 business days before the current discovery deadline and almost one month after the Court ordered it to do so—Abraxis for the first time provided Elan with access to details of the full manufacturing processes for Abraxane®. Under the restrictive terms Abraxis unilaterally mandated, only a limited number of Elan's outside counsel have access to these documents; the documents are only available through a secure Internet site; and the documents cannot be printed. Consequently, attorneys with multiple responsibilities in this litigation must undertake document review and analysis on top of their other duties. Moreover, Abraxis has imposed severe restrictions on access to the manufacturing documents by Elan's experts, and has objected to granting any access whatsoever to an expert Elan believes is highly qualified to review and understand the documents. Elan requires time for its experts to review and analyze this information prior to depositions. Based on Abraxis's position that its manufacturing processes require unprecedented protection, Elan anticipates that reaching an agreement concerning experts who will be granted access to this material will be a grueling and time-consuming process, and one that may eventually require Court intervention.

C. On June 22, 2007, Abraxis testified that it had asked only 39 employees (in a company of approximately 2000 employees) to search for responsive documents.

On June 22, 2007, Elan conducted a Rule 30(b)(6) deposition of Abraxis concerning "[t]he identities of all individuals asked to search for documents responsive to Elan's First and Second Set of Requests for Production of Documents." *See* D.I. 138 at 4.

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Indeed, Abraxis previously provided written assurances that certain individuals did not have laboratory notebooks with entries related to Abraxane®. *See* E.

Evans June 12, 2007 email to L. Chiarini, attached as Ex. B. Elan's review of Abraxis's notebooks, however, reveals that notebooks from at least six of these individuals contain responsive information. *See* P. Fehlner June 27 letter to E. Evans, attached as Ex. C. Elan's past experience, coupled with Abraxis's testimony, suggests that there are a substantial number of additional documents responsive to Elan's discovery requests that have yet to be gathered and processed by Abraxis's counsel. Once these documents are produced to Elan, additional time will of course be required for review prior to identifying individuals to be deposed and topics to be addressed.

D. Abraxis did not produce more than half its responsive documents until less than 30 business days before the fact discovery deadline.

On June 14, 2007—less than 30 business days before the currently-scheduled fact discovery deadline—Abraxis produced 262,582 pages of documents, many of which were responsive to Elan's Requests for Production propounded on November 10, 2006 and March 1, 2007.[2] This long-overdue production stemmed at least in part from the Court's May 23 oral Order compelling Abraxis to produce certain categories of documents responsive to Elan's requests. *See generally* D.I. 128. Abraxis's June 14 production constitutes well over 50% of its total production to date. Elan is reviewing this production as rapidly as possible, but given the current fact discovery schedule, does not believe that, even with these best efforts, it will be feasible to complete substantive review and analysis of the produced documents, identify witnesses to be deposed and specific topics to be addressed, give adequate notice of deposition to

[2] In correspondence dated March 9, 2007 and March 12, 2007, the parties reached accord on the search terms to be applied to electronic data, with the exception of documents related to manufacturing. *See* D.I. 125 at 4. On June 27, 2007, Elan produced 65,514 pages of documents, the majority of which were electronically generated. This essentially completes Elan's production, although Elan will continue to seek and produce responsive, non-privileged material and to respond to any further legitimate discovery requests from Abraxis pursuant to Fed. R. Civ. P. 26.

these identified witnesses, prepare sufficiently for such depositions, and avoid the need for continued or repeated depositions of the same witnesses at a later date.

II. Argument and Authorities

A. The Court has discretion to modify the Scheduling Order.

A scheduling order can be modified upon a showing of good cause, and with the court's permission. Fed. R. Civ. P. 16(b); *see Eichorn v. AT&T Corp.*, 484 F.3d 644, 650 (3d Cir. 2007). Here, there is ample cause for the Court to modify the scheduling order to extend the discovery period.

B. Elan will be extremely and unfairly prejudiced if the current discovery deadline is allowed to stand.

The information contained in Abraxis's laboratory notebooks bears directly on an issue in this case that Abraxis has characterized as dispositive—i.e., whether the paclitaxel in Abraxane® is crystalline as opposed to amorphous. *See* D.I. 128, May 23, 2007 Discovery Telecon. Tr. 54:10-55;4; *see also id.* at 58:12-19; 59:14-60:3. *See also* D.I. 148, Elan's Answering Claim Construction Brief at 1.

Without effective access to the majority of Abraxis's notebooks, Elan has for months been, and continues to this day to be, hampered in its ability to determine who should be deposed in this matter. With only ten (10) depositions allotted to each party, Elan is hesitant to notice the depositions of individuals with relevant, but not critical, information, because it may discover that there are scientists and technicians whose depositions may have been more relevant to Elan's case-in-chief. Moreover, Elan has been precluded from propounding any discovery requests based on the contents of the notebooks due to their late production.

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. Without in-depth expert review

of Abraxis's manufacturing documents, Elan is unable to lay the foundation for depositions of fact witnesses with knowledge of Abraxane®'s manufacturing processes and of potentially infringing intermediates.

C. Elan has been diligent in its efforts to meet the scheduled discovery deadline.

Elan does not make its request to modify the Scheduling Order lightly or without having pursued alternate means of resolving discovery concerns. At the initial Scheduling Conference in this matter, Elan sought to avoid the more leisurely discovery schedule advocated by Abraxis. In doing so, Elan assumed—wrongly as it turns out—that Abraxis would be appropriately responsive to Elan's discovery requests. Abraxis, however, has been masterful at delay. Indeed, Abraxis has not produced a single document of substance without protracted wrangling and needless expenditure of time.

Elan has been diligent in its efforts to meet the current discovery deadline. Elan has responded to Abraxis's discovery requests by searching every known location for responsive documents, and continues to discharge its obligations by producing any inadvertently overlooked documents.[3] Elan has also been diligent in seeking to obtain responsive documents from Abraxis, including asking the Court for relief from Abraxis's intransigence on three separate occasions. *See generally* D.I. 47, 89, 128.

The parties have exchanged correspondence on the scheduling issues raised herein, and have met and conferred as well. Abraxis strenuously objects to this motion. Yet, Abraxis clearly will not be prejudiced by an extension of the discovery period. The parties have only recently exchanged electronic data, and an extension will provide Abraxis with additional time to review Elan's electronic data as well.

[3] As a result, in addition to the electronic discovery, Elan has recently produced documents overlooked in earlier searches.

Elan does not request movement of the trial date. Rather, Elan simply requests that fact discovery be extended to September 30, 2007, that the exchange of opening expert reports be extended to October 15, 2007, that the exchange of answering expert reports be extended to November 15, 2007, and that the deadline for the close of expert discovery be extended to December 15. Elan proposes that all other deadlines in the current Scheduling Order remain in place.

III. Conclusion

For the reasons articulated herein, Elan respectfully requests that the Court extend the fact discovery deadline to September 30, 2007, the exchange of opening expert reports to October 15, 2007, the exchange of answering expert reports to November 15, 2007, and the deadline for expert discovery to December 15.

ASHBY & GEDDES

/s/ Steven J. Balick

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Dated: July 2, 2007
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IN THE UNITED STATES DISTRICT COURT
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Plaintiff,	)	
v.	)	C.A. No. 06-438-GMS
ABRAXIS BIOSCIENCE, INC.,	)	
Defendant.	)	

ORDER

This _____ day of _____, 2007, plaintiff having moved to modify the scheduling order, and the Court having concluded that good grounds exist for the requested relief; now therefore,

IT IS HEREBY ORDERED that plaintiff's motion is granted, and that the scheduling order (D.I. 20) is amended as follows but otherwise shall remain unchanged:

Close of fact discovery	September 30, 2007
Exchange of opening expert reports	October 15, 2007
Exchange of answering expert reports	November 15, 2007
Close of expert discovery	December 15, 2007

_____
Chief Judge

CERTIFICATION PURSUANT TO LOCAL RULE 7.1.1.

I hereby certify that counsel have discussed the subject matter of the attached motion, but that an agreement could not be reached.

/s/ Steven J. Balick

Steven J. Balick

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FOR THE DISTRICT OF DELAWARE

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

AFFIDAVIT OF LINDA M. GLOVER

I, Linda M. Glover, hereby declare as follows:

1. I am an attorney for Plaintiff Elan Pharma International Limited ("Elan") in the above-styled case. I am authorized to make this Affidavit. I am knowledgeable about the information discussed in this Affidavit, and the statements made herein are true and correct and within my personal knowledge.

2. Pursuant to Civil Local Rule 16.4, I have sent a copy of Plaintiff's Motion to Modify the Scheduling Order to Gregory M. Bokar, Vice President of IP/Litigation for Elan. He is in agreement with the contents of this motion and the filing thereof.

I declare under penalty of perjury subject to 28 U.S.C. § 1746 that the foregoing is true and correct.

Executed this 2nd day of July, 2007 at Houston, Texas.

Linda M. Glover

EXHIBIT A

REDACTED

EXHIBIT B

June 12, 2007

Writer's Direct Contact
650.813.5625
EEvans@mofo.com

By Electronic Mail

Lisa A. Chiarini
Baker Botts L.L.P.
30 Rockefeller Plaza
New York, NY 10112

Re: *Elan Pharma Int'l Ltd. v. Abraxis BioScience, Inc.*

Dear Lisa:

Thank you for your letter and email of yesterday. As you know, Abraxis maintains its position that it has already produced all relevant laboratory notebooks to Elan regarding Abraxane. Nonetheless, in the spirit of compromise, Abraxis has agreed to Elan's request that Abraxis make its Abraxane-related laboratory notebooks available for inspection. As we have discussed, Abraxis will make the laboratory notebooks available for inspection in Los Angeles and Chicago from June 13 to June 18, 2007.

For all laboratory notebooks, Abraxis confirms that the Elan's counsel may create a log during its inspection which will be limited to: (1) the laboratory notebook number; (2) the author; (3) the relevant page numbers that Elan requests that Abraxis produce; and (4) a subject matter category (limited to analytical testing, clinical testing, and manufacturing). Elan will provide Abraxis with a copy of any log created during its inspection.

Abraxis also confirms that the laboratory notebooks to be made available for inspection at both the Chicago and Los Angeles facilities will include laboratory notebooks that have already been produced to Elan and those that have not. Abraxis roughly estimates that there will be approximately 200 to 300 laboratory notebooks at each location.

As we stated during the meet and confer earlier today, the notebooks that will be made available for inspection in Morrison & Foerster's Los Angeles offices do not contain Abraxis's confidential manufacturing details information. Abraxis hereby designates these laboratory notebooks RESTRICTED CONFIDENTIAL, and the relevant provisions of the existing Protective Order in this case shall govern Elan's review of those notebooks.

The laboratory notebooks that will be made available for inspection in Chicago may contain secret manufacturing details and that inspection will be governed by the Interim Protective Order. Thus, as we have discussed, the Chicago inspection will only go forward on Wednesday if Judge Sleet enters the Interim Order today.

Note that while a separate breakout room for Elan attorneys will be available in our L.A. offices, the only convenient hotel facilities in Chicago we have been able to reserve do not include a breakout room. We have reserved a conference room for Wednesday through Monday at the following hotel:

Renaissance Chicago O'Hare Suites Hotel
8500 West Bryn Mawr Avenue
Chicago, Illinois 60631 USA
Phone: 1-773-380-9600
Fax: 1-773-380-9601
Sales: 1-773-329-2816
Sales fax: 1-773-399-6511

The cost for the room is $350 per day (excluding tax and any incidental charges), which we shall be billing to Elan and consider to be Elan's responsibility to pay, along with copying costs. Please let me know tomorrow if Elan has an alternative location in mind that is similarly situated.

Please note that Abraxis disagrees with the statement in your email that "Elan's agreement to the Interim Protective Order is not intended to waive, nor does it waive, Elan's right to review Secret Abraxane Manufacturing Information pursuant to the current Stipulated Protective Order and/or controlling federal case law." The Court already ruled during the last discovery hearing that the disclosure of Abraxis's manufacturing information was entitled to additional protections that the parties were to negotiate. Elan's review of Abraxis's laboratory notebooks in Chicago shall therefore be governed by the Interim Protective Order. In addition, please confirm that Elan's reservation of rights in the first paragraph of your e-mail was merely intended to reserve the right to request fewer restrictions than those in the Interim Order, and was not intended as statement that Elan would disregard the Interim Order. In other words, please confirm that Elan will abide by the terms of the Interim Order once entered, unless and until it is vacated by the Court.

As we explained during the meet and confer yesterday morning, Abraxis believes that there are approximately 30 additional employees in its Chicago facilities, not previously identified in Elan's various notebook requests, who may have authored laboratory notebooks regarding Abraxane. Even though Elan did not specifically request these individuals' notebooks, Abraxis nonetheless offered to make their notebooks available for inspection in Chicago. Elan said it wanted to review them.

Conversely, we also let you know yesterday morning that Abraxis believes that a number of the individuals listed in Elan's requests have no laboratory notebooks regarding Abraxane. You asked for that list and indicated you would not want to review these notebooks. The following is a list of such individuals:

Nino Alapishivili
Maureen Connell
Tom Epers
Nicholas Everett
Kevin Ferreri
Michelle Fonda
Ingrid Gennity
Honga Han
Jane Li
Anthony Moskwa
Laxman Nallan
Kenney Nealy
Bob Phal
David Russell
Ziowen Sun
Kevin Westlake
Tiebebe Woldermarian
Rujin Wu
Seema Zaidi
Zhongyan Zhu

Please confirm in writing today that Elan does not wish to inspect the laboratory notebooks of the foregoing individuals. Abraxis is still willing to provide them for inspection if you let us know today, so that we have adequate time to collect these notebooks.

If you have any questions, please feel free to contact us.

Sincerely,

s/Emily A. Evans

Emily A. Evans

EXHIBIT C

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June 27, 2007

BY ELECTRONIC MAIL

Dr. Emily A. Evans
Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, CA 94304-1018

Re: *Elan Pharma Int'l Ltd. v. Abraxis BioScience, Inc.*

Dear Emily:

This letter responds to your June 12th letter to Lisa Chiarini about Elan's inspection of Abraxis's laboratory notebooks. In that letter you stated, "Abraxis believes that a number of the individuals listed in Elan's requests have no laboratory notebooks regarding Abraxane." Your belief appears mistaken, at least with respect to some of the individuals you listed. Based on Elan's review of the notebooks produced by Abraxsis, as well as our inspection of notebooks in Chicago and Los Angeles, the following individuals from your list have notebooks regarding Abraxane:

- Nino Alapishivili (e.g., notebook #s 23813, 23723, 23685, 23597, 23637, 23788)
- Maureen Connell (e.g., notebook #s 22500, 23876, 23938, 24076, 24251, 22489, 22500, 23938, 24076)
- Kevin Ferreri (e.g., notebook # 90)
- Jane Li (e.g., notebook # 21984)
- Kenney Nealy (e.g., notebook # 22476)
- Zhongyan Zhu (e.g., notebook #s 23741, 23815, 244)

With respect to the individuals listed in your June 12th letter, and specifically those listed above, Elan wishes to inspect any lab notebooks regarding Abraxane not already provided. If any such lab notebooks exist, please immediately provide a time and place for Elan's inspection.

Also, with respect to the individuals listed in your June 12th letter, and specifically those listed above, please confirm that Abraxis (1) either has already produced all lab notebooks regarding Abraxane, or (2) has already made such lab notebooks available for Elan's inspection.

Very truly yours,

/s/

Paul F. Fehlner, Ph.D.

cc: Steve Scheve
William J. Sipio
Jeffrey Sullivan
Linda Glover
Lisa Chiarini

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