UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ELAN PHARMACEUTICAL INTERNATIONAL LIMITED, Plaintiff, v. ABRAXIS BIOSCIENCE, INC., Defendant.	Case No. 06-438-GMS **REDACTED –** **PUBLIC VERSION**

DEFENDANT'S OPPOSITION TO
PLAINTIFF'S MOTION TO MODIFY THE SCHEDULING ORDER

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I. INTRODUCTION

Seeking to justify a delay in the case schedule, Elan goes to great lengths to paint Abraxis in a bad light. Elan's allegations are unfounded. The real issue is that Elan made certain strategic choices in the litigation — including proposing an aggressive discovery schedule and then waiting to pursue certain discovery — and now does not wish to live with the consequences.

During the parties' discussion with the Court over the case management schedule, Abraxis noted that if Elan pursued its "crystalline" infringement claim against an amorphous drug like Abraxane, discovery could take more time than might otherwise be necessary. (D.I. 21, Nov. 6, 2006 Case Management Conference Tr. ("CMC Tr.") at 7:7-20.) Elan asked for a tight discovery schedule. The Court largely agreed with Elan, and set a July 30, 2007 cut-off. Abraxis has moved heaven and earth to meet that schedule.

Now, with its infringement case against Abraxane having collapsed, Elan seeks more time. It does so not to prove that Abraxane meets the claim limitations, such as that the medicament is crystalline (which it cannot do), but to continue to impose huge litigation costs on Abraxis and to forage ever more widely for something, *something*, on which Elan might hang its hat.

We ask that the Court hold to the case schedule it entered. The Court's determination to adhere to the ordered schedule is well-understood by litigants in Delaware, and was specifically referenced in the discussion of the applicable schedule during the case management conference.[1]

II. FACTUAL BACKGROUND

A. This Is The Schedule Elan Proposed.

Despite objection by Abraxis and its alternate proposal that fact discovery close in December, Elan sought the July 30, 2007 fact discovery cut-off adopted by the Court. (D.I. 11,

[1] "MR. JACOBS: …I know that the Court likes to stick to the deadlines. THE COURT: Yes." (CMC Tr. at 10:9-11.)

Oct. 30, 2006 Joint Status Rpt. at 7; CMC Tr. at 5:2-11:5.) Elan did so despite Abraxis's warning that the nature of this dispute might warrant additional time for discovery and the Court's warning that it would prefer to maintain the deadline entered. (CMC Tr. at 7:7-20, 10:9-11.) Mindful of the Court's desire to maintain its schedule, Abraxis has undertaken extraordinary efforts to complete discovery in this matter, including assembling a team of more than a dozen attorneys, an additional 3-6 contract attorneys, and several additional technical personnel and staff working long hours over the past months to meet Abraxis's discovery obligations. (July 11, 2007 Declaration of Emily A. Evans ("Evans Decl.") at ¶ 2.)

B. Abraxis Produced Its Key Documents On Or Before March 29, 2007.

Abraxis produced key documents regarding Abraxane, the accused product, to Elan on or before March 29, 2007. This early production was the result of a huge commitment of time and resources by Abraxis. These productions included virtually all of the documents that were submitted as the New Drug Application (NDA) to the FDA.[2] The FDA portion of the pre-March productions constitutes approximately 100,000 pages and contains detailed documents relating to Abraxane. (*See* Evans Decl., ¶ 3.) These are the most important infringement-related documents in this case. Additionally, the key laboratory notebooks were produced, which include information related to the most significant infringement issues in this case, crosslinking of the albumin and non-crystallinity of the paclitaxel in Abraxane. (*Id.* at ¶ 4.) In addition to the initial disclosures, these notebooks also gave insight into the key people involved in the development of Abraxane, for example, Dr. Neil Desai. In short, these documents comprehensively disclosed the structure and characteristics of Abraxane and suggested who to depose.

C. Elan Did Not Notice Key Depositions Until Late In The Discovery Period.

Despite having these critical documents and Abraxis's initial disclosures, Elan elected not to notice a single deposition of an individual until June 29, 2007. (*Id.* at ¶ 5.) And that was

[2] The sole exception was certain details regarding Abraxis's highly confidential manufacturing processes, discussed below.

prompted by Abraxis, which on June 27, 2007, took the unusual step of sending a letter to Elan providing available dates for key individuals so that discovery could be completed on time notwithstanding Elan's failure to notice the depositions. (*Id.* at ¶ 6, Ex. 1.) All of Elan's complaints regarding discovery must be considered in light of the fact that Elan has had the key information for months yet conducted none of the discovery it now claims is essential.

D. Elan's Demand To Review Cumulative And Irrelevant Notebooks Resulted In The Production Of Only Three Boxes Of Documents.

Although Elan makes much of the discovery of laboratory notebooks in this action, the facts tell a different story. Although the laboratory notebooks produced in March, together with the FDA documents, provided a complete description of Abraxane, Elan continued to request more notebooks. Finally, to end all issues relating to laboratory notebooks, Abraxis produced for inspection — *at Elan's request* — hundreds of laboratory notebooks, many of which had already been produced and many that were completely irrelevant (*i.e.*, did not relate to Abraxane), but which Elan nonetheless demanded to review. The process of complying with Elan's unreasonable demands was extremely burdensome to Abraxis. These notebooks were reviewed from June 13-15, 2007 at the two locations where they are kept and shortly thereafter, on July 2, 2007, Abraxis produced the small amount of material (approximately 3 boxes) that Elan had designated. (*See* Evans Decl., ¶ 7.) Due to an oversight, a small number of additional notebooks were produced for inspection on June 22, 2007. (*Id.*)

Elan complains that it will be unduly burdened in its review of these notebook documents produced by Abraxis because it could not take notes during the inspection. Elan's review of approximately 700 notebooks resulted in the production of approximately three boxes of documents. Elan's team of lawyers is capable of promptly reviewing these documents, particularly since they already reviewed them to designate them for production. Again, the information in the notebooks that Elan requested was largely duplicative or completely irrelevant. Of course, Elan's statement that the notebooks somehow undermine the fact that the

paclitaxel in Abraxane is amorphous (D.I. 166, Elan's Motion to Modify the Scheduling Order ("Mot.") at 2-3) is simply wishful thinking.

E. Abraxis's Production Of Electronic Documents Occurred Nearly Two Weeks Before Elan Produced Electronic Documents.

Rather than address the substantive contents of the Abraxane documents it has had for months, Elan argues that Abraxis only recently produced "more than half of its responsive documents" on June 14, 2007. (*Id.* at 5.) This is a red herring. These documents were electronic documents that the parties agreed would be produced closer to the discovery deadline due to the time-consuming nature of the production of such documents. Indeed, Elan concedes that it did not produce *its* electronic documents, totaling more than 65,000 pages, until June 27, 2007 (*Id.*), *after* Abraxis produced its electronic documents and the day before the deposition of one of the named inventors of the '363 patent. Nevertheless, Abraxis has been working diligently to review these documents so that discovery can close on July 30, 2007, as the Court ordered.

F. Elan Stipulated To The Order Governing Review Of Abraxis's Manufacturing Information.

Elan also complains that Abraxis has imposed conditions on Elan's review of the manufacturing documents. As the Court is aware, the manufacturing documents at issue are among the most sensitive documents within Abraxis and the Court has agreed that additional security precautions for those documents are warranted. Accordingly, the parties negotiated and the Court entered an "Interim Order Regarding Secret Abraxane Manufacturing Information" on June 12, 2007 (D.I. 135). The terms that Elan now claims are burdensome were negotiated by the parties and entered by the Court pursuant to stipulation. Elan's argument that Abraxis "unilaterally mandated" these discovery terms runs headlong into the facts.

Moreover, Elan has not been diligent in negotiating the terms of a permanent protective order that would address Abraxis's sensitive manufacturing information. Indeed, Abraxis sent a proposed amended protective order for Elan to consider on June 1, 2007, to which Elan failed to respond until nearly a month later, on June 26, 2007. (Evans Decl. at ¶¶ 13-15, Exs. 6 and 7.) And while Elan has repeatedly claimed it would need access to manufacturing information by

two experts, (D.I. 89, March 15, 2007 Hearing Tr. at 2:20-3:21; D.I. 128, May 23, 2007 Hearing Tr. at 31:16-32:2), Elan has only ever sought to designate one. As to documents for use in deposition, Abraxis is working with Elan to develop a procedure for the use of manufacturing documents at depositions, if those circumstances arise.

G. Abraxis Complied With Its Obligation To Search For And Produce Documents.

Based on statements from Abraxis's Rule 30(b)(6) witness, Elan asserts that Abraxis did not conduct an adequate search for documents. (Mot. at 4.) Elan cites passages from the deposition that 39 Abraxis employees were asked to search for documents, presumably to show that this is an inadequate number. Putting aside whether those inquiries satisfied Abraxis's discovery obligations, Elan failed to cite other pertinent testimony on this issue:

[redacted]

And Elan, having reviewed

these notebooks, is well-aware that more than 39 people searched for responsive documents. As this testimony makes clear, Abraxis's document search was comprehensive. Contrary to Elan's speculation, there is not a "substantial number" of additional relevant documents "that have yet to be gathered and processed by Abraxis' counsel."

III. ARGUMENT

The facts belie Elan's assertion that Elan has been diligent in its efforts to meet the scheduled discovery deadlines. Not only has Elan not been diligent in conducting discovery of Abraxis, it has not been diligent in producing its own documents. Initially, it was Elan who proposed the current schedule. And Abraxis has repeatedly attempted to work with Elan to set clear deadlines for the completion of document discovery. (*See, e.g.*, Evans Decl., Exs. 2-5, 1/16/07 Letter from Kruze to Glover; 1/19/07 Letter from Glover to Kruze; 4/27/07 Letter from Walters to Glover; 5/4/07 Letter from Glover to Walters.) Each time, Abraxis was rebuffed by Elan. (*Id.*) Moreover, any assertion that Elan has been diligent falls apart in light of the facts set forth above. The key individuals within Abraxis were identified in Abraxis' initial disclosures in November 2006 and the key documents were produced in March. Despite having the relevant information, Elan made virtually no effort to schedule depositions until near the close of discovery. In fact, Abraxis took the unusual step of sending a letter to Elan providing available dates for key individuals so that discovery could be completed on time notwithstanding Elan's failure to notice the depositions. Elan's failure to prosecute its case does not warrant dragging Abraxis through another two months of costly discovery.[3]

Elan cannot show good cause to modify the scheduling order to delay the close of discovery. Elan makes three arguments that it would be prejudiced by complying with the

[3] If the recent deposition of Dr. Michael Hawkins is any indication, Elan's request for additional discovery will lead to a fishing expedition. Elan's counsel asked numerous questions that have no relation to any of the issues in this lawsuit, such as [redacted]

current scheduling order: (1) it needs time to conduct analysis to confirm that Abraxane is amorphous rather than crystalline; (2) it has been hindered in its ability to determine who should be deposed in this matter; and (3) it needs to analyze the manufacturing process to assess the "potential for forming infringing intermediates." (Mot. at 6-7.) Elan's complaints regarding the existing schedule have nothing to do with discovery from Abraxis and everything to do with Elan's own strategic choices.

First, Abraxis produced detailed documentation regarding the amorphous nature of Abraxane in March. Specifically, Abraxis produced x-ray crystallography data evidencing that the paclitaxel in Abraxane is amorphous, TEM analyses of Abraxane, and myriad FDA submissions and other documents stating that Abraxane is amorphous. (*See* Evans Decl., ¶ 12.) It has been clear from the start that the fact that Abraxane is amorphous rather than crystalline would be one of the key issues in this case.[4] (*See, e.g.,* D.I. 11, Oct. 30, 2006 Joint Status Rpt. at 3, 5.) Indeed, this issue will likely be dispositive. The notion that Elan will be prejudiced because it has not had the opportunity to thoroughly investigate this issue can hardly be taken seriously. It is certainly not grounds for delay.

Second, despite Elan's assertion that it has no idea who to depose in this case, it has long been clear who within Abraxis has significant knowledge regarding Abraxane. Indeed, the key players were identified in Abraxis' initial disclosures in *November 2006*. Abraxis' initial disclosures identified Dr. Patrick Soon-Shiong and described his knowledge, in part, as follows: "Discovery, development, and commercialization of Abraxane; FDA approval of Abraxane." Dr. Neil Desai was also disclosed and his identified knowledge included "[d]iscovery and development of Abraxane; FDA approval of Abraxane." Dr. Michael Hawkins was also identified and his disclosed knowledge included "[d]evelopment, commercialization, and FDA approval of Abraxane." Abraxis also disclosed others with knowledge of Abraxane. (*See* Evans

[4] In fact, Elan has admitted its own testing was "inconclusive," yet it has refused to produce any records from that testing. (D.I. 86 Elan's Opposition to Abraxis's Motion for Sanctions, Ex. L at ¶¶ 3, 7-9.)

Decl., Ex. 8, Nov. 16, 2006 Abraxis Initial Disclosures.) Though these individuals were disclosed last year, Elan did not schedule these depositions.

Even if we pretend there were no initial disclosures identifying the key witnesses, their identities are clear from the documents that were produced months ago and from publicly-available sources. For example, the Abraxis website identifies many of the key scientists at Abraxis. Of course, Elan's professed concern that it did not want to waste limited depositions on individuals who were only tangentially involved does not explain its wholesale failure to notice the depositions of *any* of the individuals who were clearly heavily involved the development of Abraxane, *i.e.,* the key individuals identified in the November 2006 disclosures. Moreover, Abraxis already made available a Rule 30(b)(6) witness on the people involved with formulation development and the manufacturing process for Abraxane. Notably, Elan does not reveal any details regarding its supposed inability to identify appropriate deponents. Elan's failure to notice what it now calls the key technical depositions in this case reflects its lack of diligence, not lack of discovery from Abraxis. Elan's failure to diligently conduct discovery pursuant to the Court's schedule does not warrant delay.

Third, Elan's argument that it needs to analyze Abraxis's highly-confidential manufacturing information to see if it can cobble together a case regarding "infringing intermediaries" is both improper and factually incorrect. Abraxis produced the exact details of the manufacturing process on June 19, 2007. Much of this information was already known to Elan as of March 23, 2007, when Abraxis produced a detailed outline of the process. Moreover, as the Court is aware, Abraxis does not believe that the complaint in this action properly includes "intermediaries," nor, as Elan admitted to the Court, did it have a reasonable belief when it filed this lawsuit that any "intermediate" infringed. (D.I. 47, Tr. of Feb. 16, 2007 Discovery Conference at 8:12-17 ("We have good reason to believe that in the course of manufacturing, crystalline medicament may exist. But we have no way to know. We can speculate in conjunction with our experts. But all of our experts have told us that until they see how this stuff is made, they are really shooting in the dark.").)

Elan's claim that Abraxis will not be prejudiced by delay is wrong. This litigation is costly and it draws valuable resources from Abraxis's core business, developing biopharmaceuticals to meet the needs of critically ill patients. Additionally, despite Elan's suggestion to the contrary, the delay proposed by Elan will undoubtedly have collateral effects on the rest of the schedule. Instead of seven weeks between the close of fact discovery and opening expert reports, Elan's proposed schedule only provides two weeks. Similarly, the conference regarding summary judgment motions is scheduled for December 20, 2007, only five days after Elan's proposed new deadline for the close of expert discovery. The letter brief regarding these motions is currently scheduled for December 4, 2007, *before* the close of expert discovery. Thus, Elan's requested delay would create problems with the remaining deadlines in the schedule, would prejudice Abraxis, and would prejudice the Court because the parties would be unable to make a thorough presentation to the Court regarding issues that may be resolved by summary judgment.

IV. CONCLUSION

The discovery schedule in this matter was set on November 15, 2006. Abraxis has fully complied with its discovery obligations and, in fact, went above and beyond those obligations. Elan, on the other hand, has not diligently pursued discovery. There is no basis for delay in this case and delay will prejudice Abraxis. For these reasons, Elan's motion should be denied in its entirety.

Dated: July 11, 2007

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CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire, hereby certify that on July 19, 2007, 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 July 19, 2007, I caused a true and correct copy of the foregoing document to be served by e-mail on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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