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May 21, 2008

BY CM/ECF AND HAND DELIVERY

The Honorable Gregory M. Sleet
U.S. District Court District of Delaware
844 N. King Street, Lockbox 19
Wilmington, DE 19801

Re: *Elan Pharma International Limited v. Abraxis BioScience, Inc.*
Case No. 06-438-GMS

Dear Chief Judge Sleet:

Abraxis writes in response to Elan's May 20, 2008 letter to the Court regarding the form of order for Abraxis motions *in limine* no. 1 and 4.

Abraxis notes at the outset that the Court's order clarifying its claim construction should conclusively resolve infringement issues because even Elan's experts agree that the paclitaxel in Abraxane is overwhelmingly amorphous. Abraxis has written to Elan asking for confirmation that Elan no longer intends to pursue infringement at trial. Elan has not responded, but it would appear from Elan's letter to the Court that it intends to persist with its infringement case.

As we noted in our letter to the Court accompanying the proposed orders [DI 567], we proposed language we believed necessary to effectuate the Court's order. In particular, in addition to specifying that Abraxis could cross-examine Dr. Brittain using Dr. Brittain's testing document privilege log, we anticipated (correctly) that Elan might attempt to eviscerate this relief by not calling Dr. Brittain at trial and instead replacing him with another of its multiple experts. Accordingly, Abraxis also requested that the Court order Elan to produce Dr. Brittain, not another expert, at trial on the topic of Abraxis's XRPD testing.

Elan's letter reinforces the need for the requested relief. Elan now proposes not to call Dr. Brittain and to call Dr. Berkland instead to testify about XRPD. In doing so, it evidently hopes to hamstring Abraxis from cross-examining its expert regarding the withheld tests – which was the whole point of the relief Abraxis requested, and the Court was inclined to grant, at the pretrial conference. To the extent Elan chooses to introduce testimony at trial criticizing Abraxis's XRPD testing, Elan should be required to do so through Dr. Brittain.

Elan's effort to relitigate its underlying wrongdoing should be rejected. Elan withheld over 400 testing documents while falsely representing to the Court that it had (1) produced all non-privileged testing documents, (2) maintained the walls between testifying experts and consultants and (3) logged all testing documents it had withheld. When Abraxis attempted to explore Dr. Brittain's testing in deposition, he *admitted* he had conducted testing on Abraxane, but counsel instructed him not to answer questions regarding the type of studies he had performed, whether he had performed XRPD testing, and whether his studies concerned the question of whether XRPD was a reliable method for testing the paclitaxel in Abraxane. Brittain Depo. Tr. at 6:10-7:13, 11:3-10, 18:7-13, 18:20-19:9 (copy attached).

Elan newly cites *United States v. 215.7 Acres of Land, Situated in Kent County, State of Delaware*, 719 F. Supp. 273 (D. Del. 1989). But this case was based on the earlier, more restrictive version of Rule 26. *See Western Resources, Inc. v. Union Pac. R.R. Co., Inc.*, 2002 U.S. Dist. Lexis 1911 at *26 n. 10 (D. Kan. Jan. 11, 2002).

Elan's disagreement with our proposed adverse inference instruction ignores caselaw from this very Court. The absence of an explicit court order is not a bar to an adverse inference instruction. *Mosel Vitelic Corp. v. Micron Tech., Inc.*, 162 F. Supp. 2d 307, 311 (D. Del. 2000) (Sleet, J.) (adverse inference instruction ordered where party failed to preserve evidence). *See also* Fed. R. Civ. P. 37(c)(1)(B), (C) (sanctions for failure to produce information required under Rule 26(e) include "inform[ing] the jury of the party's failure" and other appropriate sanctions, including those listed in Rule 37(b)(2)). Indeed, "adverse inference instructions are one of the least severe sanctions which the court can impose ...." *Mosel Vitelic*, 162 F. Supp. 2d at 315. In any event, as the Court noted at the October 2007 hearing, Elan "understands from this discussion ... that it is the Court's order. That is inherent, before we ever convened on this once." Tr. 92:18-21 [D.I. 365].

Respectfully submitted,

Elena C. Norman (No. 4780)

ECN:mm
Enclosure

cc: Clerk of Court (by CM/ECF)
John G. Day, Esq. (by CM/ECF and hand delivery)
Steven J. Balick, Esq. (by CM/ECF and hand delivery)
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Diana B. Kruze, Esq. (by electronic mail)

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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

- - - - - - - - - - - - - -x

ELAN PHARMA

INTERNATIONAL LIMITED,

Plaintiff,

Case No. 06-438-GMS

vs.

ABRAXIS BIOSCIENCE, INC.,

Defendant.

- - - - - - - - - - - - - -x

DEPOSITION OF HARRY G. BRITTAIN

New York, New York

November 16, 2007

Reported by:

MARY F. BOWMAN, RPR, CRR

JOB NO. 14024

BRITTAIN

A. Good morning.

Q. The Center for Pharmaceutical Physics is your center?

A. Yes, it is.

Q. Do you have any employees?

A. No.

Q. Is it located in your house?

A. Yes.

Q. Do you have equipment in your house to perform studies?

A. I do.

Q. Did you use that equipment to perform any studies on Abraxane?

A. Yes.

Q. When did you do that?

A. Early in 2007, probably -- certainly before April. My recollection is the last study I performed ended in April of 2007.

Q. And what did you -- what studies did you perform?

MR. SCHEVE: Don't answer that question, privileged, objection.

Q. Are you going to follow that instruction?

BRITTAIN

A. I suppose, yes.

Q. Was Abraxane the target of your studies?

MR. SCHEVE: Objection, that's privileged. If you are talking about which time period?

MR. JACOBS: I think the record is clear.

MR. SCHEVE: Then I object to the form of the question, but I also instruct you not to answer as privileged under the consulting attorney work product doctrine.

Q. When were you first retained by Elan or its counsel in connection with this litigation?

A. My recollection, it was in August of 2007.

Q. Meaning only three or four months ago, two months ago?

A. Yes, I think so.

Q. So the studies you did in April '07 were not at the request -- were not part of your retention by Elan or its counsel?

A. No, that's correct.

BRITTAIN

Q. In what capacity did you do those studies?

A. I was retained as a consulting expert by a lawyer named William Sipio.

Q. And who is Mr. Sipio representing?

MR. SCHEVE: If you know?

A. I don't. He said he was working for Elan I suppose but I really don't -- I think so but I'm not sure.

Q. He told you he was working on behalf of Elan?

A. I'm not sure whether he said he was working on behalf of Elan or he would be working on behalf of Elan. Mr. Sipio was apparently works for himself and so I'm not sure of his business arrangements.

Q. But you understood you were doing studies in connection with a dispute between Elan and Abraxis?

A. My understanding at the time was there might be a dispute. I wasn't sure at the time whether there would be one or not.

Q. When did Mr. Sipio retain you?

A. Oh, that's a good question. I'm not

BRITTAIN

sure whether it was the beginning of 2007 or at the end of 2006, but it was somewhere around there.

Q. When did you first become aware of the existence of Abraxane?

A. I would say probably halfway through the time period when I was working with Mr. Sipio.

Q. What was his first assignment to you?

MR. SCHEVE: Don't answer that question, objection, privileged.

Q. Are you going to follow that instruction?

A. Yes.

Q. Do you have retainer agreement, written agreement with Mr. Sipio?

A. I thought I did. I have been looking for it. I haven't been able to find it.

Q. Where have you looked?

A. Well, I have a binder in which I keep all retainer agreements that I have signed and there is not one in there, which -- I said I thought I signed one, but if it is not in my binder, then I really don't know where. That's

BRITTAIN

the only way I can keep track of things is to keep them all in this one binder.

Q. Did you send invoices to Mr. Sipio?

A. Yes, I did.

Q. How did you address them? What was the -- next to the "To," what did it say?

A. Oh, we probably since my arrangement was with Mr. Sipio, it probably said invoice to William J. Sipio, Esquire.

Q. At what address?

A. I sent them by e-mail, so I presume it went to -- I'm not -- I don't know whether he has an office or whether he works out of his home, but wherever that is, that's where they would go. I sent it to an e-mail address.

Q. Did you have some kind of identifier for the project or the title of the engagement?

A. No, I only had this one project working with Mr. Sipio.

Q. And what was that project called?

A. We never called it anything. It was just working on these compounds.

Q. What compounds were you working on?

MR. SCHEVE: Objection, work product,

BRITTAIN

don't answer the question.

Q. Did you do x-ray crystallography studies on the unnamed compounds?

MR. SCHEVE: Objection, privileged, instruct you not to answer the question.

MR. JACOBS: Can we have a standing stipulation that he will be following, for the purposes of --

MR. SCHEVE: Sure.

MR. JACOBS: For the purposes of establishing the record on the privilege assertion, so that I don't have to ask him each time, are you following counsel's instruction? Can you and I have an instruction that he will be following this, following your instruction?

MR. SCHEVE: Absolutely. For the record, Michael, anything that he has reviewed, looked at, considered for the purposes of forming his opinions, you have got a copy of. My objection goes to any consultation that he did in terms of his relationship with Mr. Sipio prior to his agreeing and being asked to serve as an

BRITTAIN

expert witness in this lawsuit for testifying purposes. I think he said that was in August of this past year, so you have a clear sense of where I am coming from.

MR. JACOBS: It is your -- it is your view that Mr. Sipio was acting on behalf of Elan in retaining him?

MR. SCHEVE: I'm not privy to exactly what Mr. Sipio's relationship was. In other words, I don't know the parameters or the extent or the details. I didn't participate in all of those. I've never seen whatever engagement letter he has with Elan.

Clearly, Mr. Sipio was providing consultative services to Elan as an attorney and this doctor was hired by Bill Sipio to provide advice and consultation with Mr. Sipio up until a point in time when he was asked whether or not he would be willing to serve as an expert on behalf of Elan. My objection goes and will consistently go to any questions that seek to inquire into his consultative efforts with Mr. Sipio.

MR. JACOBS: And maybe so we can don't

BRITTAIN

have to ask him a zillion questions, that began and ended when?

MR. SCHEVE: The word "that" means?

MR. JACOBS: The relationship with Mr. Sipio as to which you are asserting privilege?

MR. SCHEVE: I can't testify for him and I will let you ask that.

The relationship, first time I met this gentleman and asked him whether or not he would be willing to serve as an expert, I believe was on around -- it was in the middle of August of 2007.

I don't know the extent to which he has had any conversations with Mr. Sipio since then, but his contact has been three people within the firm of Baker Botts since that date and anything that he has reviewed or looked at, reviewed, relied upon for the purposes of the opinions or reports in this case, we have given that to you.

Q. And so just to make had clear, sir, the beginning date of your relationship with Mr. Sipio?

BRITTAIN

Mr. Sipio?

A. I am trying to remember.

I don't -- I mean I really don't recall any such discussions and nothing comes to mind.

Q. Did any of your work, the work that you did on behalf of Mr. Sipio, bear on the question whether Abraxane paclitaxel is crystalline or amorphous?

MR. SCHEVE: I am going to object that that invades the attorney work product doctrine and instruct him not to answer.

Q. Did any of your work with, on behalf of Mr. Sipio bear on the question whether the HSA in Abraxane is cross-linked or not?

MR. SCHEVE: Same objection, violates the attorney work product doctrine and instruct the witness not to answer.

Q. Did any of your work with Mr. Sipio bear on the question whether x-ray crystallography or x-ray powder diffraction are reliable techniques for testing whether the paclitaxel in Abraxane is crystalline or amorphous?

BRITTAIN

MR. SCHEVE: Objection, attorney work product privilege and instruct the witness not to answer. And I do need to have it read back, read that back. Did you include the words "Mr. Sipio" in that question.

MR. JACOBS: Yes.

MR. SCHEVE: Then I have a standing objection.

Q. Do you consider yourself a scientist?

A. Yes.

Q. And when you use that word, "a scientist," what does that mean to you?

A. A scientist is an individual who is in -- becomes interested in determining underlying causes for some physical phenomenon. All of my science is physically oriented, so I am primarily interested in the physical phenomena and a scientist would be one who, in seeking to understand scientific phenomena, determines answers to the questions that he is trying to understand, either through experimentation or through consultation with the published literature, ultimately taking all of these facts, observations and deducing

BRITTAIN

conclusions from these.

And then in the process, it usually works out that if possible, sometimes, that work then is written up in the form of a publication that becomes peer reviewed and published in the literature.

Q. Does being a scientist mean applying the scientific method?

A. It certainly should, yes.

Q. What do you understand the scientific method to mean?

A. The scientific method usually begins with the development of a -- first there is a statement of the problem. From the statement of the problem, then comes the procedure of developing perhaps a hypotheses or multiple hypotheses as ways to understand how to investigate the nature of the problem.

From my personal research then, there is -- usually involves the conduct of experimental studies to either approve or disprove the hypothesis, accumulate observations, and from the accumulation of observations, to then deduct results which

BRITTAIN

hopefully turn into conclusions. The conclusions either support the initial hypothesis or they don't.

Q. How is the scientific method validated over time as to any particular problem? How is the quality of the science tested?

A. The -- well, there is a number of ways you can test the quality of science. If you are conducting experimental work, it is -- one of the criteria is always to make sure that whatever instrumentation you use is indeed capable of providing reliable results. So we refer to that as validation.

Assuming all the work has been obtained by methods that are verifiable and validatable, then if true science is then typically written up in the form of a publication and submitted to, if it is original research, would be submitted to a journal where it would undergo review by those who have knowledge in that particular area. If the science is good, then it will withstand the peer review process and ultimately be published.

Q. One of the tests for whether the