IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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

REPLIES IN SUPPORT OF
MOTIONS IN LIMINE OF DEFENDANT ABRAXIS BIOSCIENCE, INC.

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INDEX OF MOTIONS IN LIMINE

I. REPLY IN SUPPORT OF ABRAXIS' MOTION REQUESTING EXCLUSION OF ELAN TESTIMONY AND ARGUMENT RE: XRPD TESTING.....1

II. REPLY IN SUPPORT OF ABRAXIS' MOTION REQUESTING EXCLUSION OF ELAN'S TESTIMONY AND ARGUMENT RE: SSNMR TESTING. 4

III. ABRAXIS' REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE EVIDENCE OF THE [redacted] 7

IV. ABRAXIS' REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE THE UNTIMELY AND CUMULATIVE SUPPLEMENTAL REPORT OF DR. BYRN. 10

V. ABRAXIS' REPLY IN SUPPORT OF MOTION IN LIMINE NO. 5. 13

I. REPLY IN SUPPORT OF ABRAXIS' MOTION REQUESTING EXCLUSION OF ELAN TESTIMONY AND ARGUMENT RE: XRPD TESTING.

Elan's response to Abraxis' motion to exclude XRPD testing evidence confirms that Elan intentionally withheld hundreds of documents from its testifying expert's testing of Abraxane's crystallinity. Elan argues that the documents may be withheld because they concern a different subject, but it never even identifies that subject, offering only its expert's conclusory statement that it concerned unrelated matters. Elan's argument that its expert only "consulted for" attorney William Sipio, who is not with Baker Botts (Resp. at 2.) is a classic red herring: Sipio is Elan's counsel *in this lawsuit*. Most disturbingly, Elan does not even attempt to explain its representations to this Court -- in response to our request for an order compelling production -- that it had produced all documents from its "testifiers."

Compared to the magnitude of the wrong, the sanctions sought are modest. Having withheld its own testing evidence, which undoubtedly is harmful to its infringement case, Elan should not be permitted to challenge similar experiments by Abraxis.

A. ELAN'S JUSTIFICATIONS FOR FAILING TO PRODUCE DR. BRITTAIN'S TESTING DOCUMENTS ARE FRIVOLOUS

As Abraxis explained and Elan does not contest, Elan bears the burden of proof that the withheld documents from its testifying expert, Dr. Harry Brittain, do not concern his testimonial subject. "'[T]his burden cannot generally be satisfied by the expert's representations alone.'" (MIL 1 at 4.) Significantly, Elan never contests Abraxis' showing that the withheld documents concern XRPD testing of Abraxane, which is one of the subjects of his report. (MIL 1 at 1, 3-4.)

Elan nonetheless argues that Brittain's work concerned a different subject and therefore was not "considered" by him in analyzing Abraxis XRPD tests. (Resp. at 2; *id.*, Brittain Decl. ¶¶4, 6.) Elan's reliance on a conclusory declaration from Brittain that the subjects were "separate and distinct" without even identifying the other subject (*id.*, Brittain Decl. ¶¶2, 4.) is not nearly sufficient. Elan's case, *B.C.F. Oil Refining, Inc. v. Consol. Edison Co. of New York, Inc.*, 171 F.R.D. 57, 61 (S.D.N.Y. 1997) does not help it. There, the court held that "documents *having no relation* to the expert's role as an expert need not be produced but that any ambiguity

as to the role played by the expert when reviewing or generating documents should be resolved in favor of the party seeking discovery." *Id.* (emphasis added). Here, Elan's silence on the purportedly separate subject reinforces Elan's failure to meet its burden of proof.

Elan cites this Court's opinion in *Dyson Tech. v. Maytag Corp.*, 241 F.R.D. 247, 251 (D. Del. 2007), but ignores the holding that all documents "reviewed, reflected upon, read and/or used in formulating [the expert's] opinions" be produced. Elan's argument guts that decision, turning expert disclosures into a game of "red-light/green light" based on arbitrary lines between when consulting ended and expert opinion formation began. *Dyson's* limitations on disclosure involved a regular employee who was also offering expert testimony that do not apply here.

That Dr. Brittain was originally retained by Sipio, rather than Baker Botts, is irrelevant. Not surprisingly, Elan has no authority that a party can avoid expert disclosure by the artifice of having one lawyer retain the expert as a "consultant" and another lawyer for the same client later hire the same expert as a testifier. In any case, Sipio is counsel of record and an integral member of Elan's litigation team. (*E.g.*, D.I. 1, p. 6). At his request (Kruze Ex. 1), he was routinely copied on case correspondence, and Elan designated him to review Abraxis information under the Protective Order, which allowed access only for purposes of the litigation. (D.I. 135.)

Moreover, although Elan claims that Dr. Brittain "met Elan's lead attorney Stephen E. Scheve for the first time" on August 21, 2007 (Resp. at 2), Elan fails to mention that Sipio earlier shared Dr. Brittain's information with Scheve. Responding to Abraxis Rule 11 motion, Scheve declared that Sipio "briefed me on the testing of Abraxane® done by an independent expert at the request of counsel." (D.I. 88, Ex. T, ¶ 3.) That expert was undoubtedly Dr. Brittain.

B. ELAN DOES NOT DEFEND ITS FALSE STATEMENTS TO THE COURT

The most telling feature of Elan's opposition is its deafening silence on the damning record of false representations to the Court that we adduced in our opening brief. Elan makes no effort to justify its representation that "*At the direction of counsel, we had consulting experts,* ***not testifiers,*** *consult with us and do testing before we filed this lawsuit.*" (MIL 1 at 2-3.) Nor has

Elan attempted to explain its assurances to this Court that it "preserved all the walls between consultants and testifiers" (*id.* at 3) and that it had logged all testing documents it claimed as work product when it was secretly withholding more than 400 unlogged documents. (*Id.*)

The reason for Elan's stunning silence is clear: There is no conceivable justification for Elan's conduct. Elan's brief confirms that there is no "I didn't know" excuse; *six weeks before the October 2 hearing, Elan's lead counsel had retained Brittain as a testifying expert and was well aware of his work for Sipio.* (Resp. at 2.) The Court had informed the parties that this was the last discovery conference, and thus the last opportunity for Abraxis to obtain the Court's assistance in obtaining these documents. (Kruze Ex. 2 at 111:21-112:2.) The stakes were clear, and Elan chose to dissemble rather than permit Abraxis access to its test results.

C. PRECLUSION OF XRPD EVIDENCE IS APPROPRIATE

Contrary to Elan's contention, the remedy we request is modest compared to the wrong and prejudice. The only reasonable conclusion is that the withheld evidence damages Elan's case, and confirms Abraxis test results. Permitting Elan to challenge Abraxis' testing while hiding its own would be unfair. And allowing it to simply substitute one expert for another, after having been caught red-handed withholding critical evidence, would reward its misconduct.[1]

[1] Elan cites testimony from Dr. Berkland, another expert, regarding alleged improper techniques Abraxis used in conducting its XRPD tests. These opinions were not the subject of Dr. Berkland's report (Evans Decl. Ex. 17), and hence are inadmissible regardless of the outcome of this motion.

II. REPLY IN SUPPORT OF ABRAXIS' MOTION REQUESTING EXCLUSION OF ELAN'S TESTIMONY AND ARGUMENT RE: SSNMR TESTING.

Elan has no response to, indeed does not even *address*, most of the deficiencies in Elan's ssNMR testing that render its evidence unreliable and hence inadmissible. As our opening brief demonstrated, Elan's expert Dr. Munson's opinion that Abraxane contains over 10% crystallinity was rank speculation supported by cherry-picked evidence. We also demonstrated that Elan's disclosed experts did not perform the tests nor know important details of the tests' performance, and did not produce an experimental record sufficient for replication and verification.

Elan's response goes no deeper than "trust our experts." Elan argues that its experts routinely worked with the individuals who actually performed the tests, but this does nothing to address the deficiencies in its experts' opinions or Elan's inadequate disclosure of their basis, much less the experts' lack of knowledge of the very tests on which they opine.

Elan argues that exclusion would be unfair because it will be left with no infringement case. That Elan brought this suit with no infringement evidence and maintained it with unreliable tests does not give Elan license to ignore the rules. *Daubert* is designed to ensure that science in the courtroom is as reliable as it is in the world at large. This is a textbook case for this Court to serve as gatekeeper and keep out "junk science." Elan should not be permitted to mislead the jury into accepting opinions based solely on expert qualifications, when its expert's key opinions appear to have been made up out of whole cloth, and Elan has not provided sufficient evidence to allow Abraxis cross-examination on the full depth of flaws in the tests.

A. ELAN HAS FAILED TO REBUT ABRAXIS PROOF OF THE DEFECTS IN ITS SSNMR TESTING EVIDENCE.

Abraxis' motion demonstrated that the ssNMR testing evidence underlying Dr. Munson's opinion was unreliable for a host of reasons. Elan does not contest, and therefore admits, most deficiencies in Dr. Munson's opinion. Elan does not rebut, for example, that a critical underpinning of Dr. Munson's opinion is that a third peak "appeared" when he performed deconvolution, but that discovery revealed that Dr. Munson arbitrarily placed this peak into the results himself. Thus, Dr. Munson's opinion of *any crystallinity at all* depends on a

manufactured peak, which even Elan's own expert Brittain testified was contrary to accepted practice. (MIL 2 at 6, 10; Atwood Decl. ¶¶51-61.)

Nor does Elan challenge that Dr. Munson's numerical calculations reflect layer on layer of speculation. Dr. Munson initially determined that Abraxane had 3.5%-4% crystallinity. This was far below even the 10% crystallinity Elan says is required, but Dr. Munson never explained how he came up with these figures. (MIL 2 at 10.) Dr. Munson then added another layer of guesswork by doubling the 3.5%-4% to 7-8% based on the speculation that Abraxane contained a new form of crystalline paclitaxel unknown in the annals of science. (*Id.* at 6-7.) This still was not sufficient, so Dr. Munson tacked on *a 50% error rate*. (*Id.* at 7.) Aside from the obvious defect in using the error rate to inflate the number, the error rate was pulled out of thin air: Dr. Munson admitted it was no more than a "best guess estimate." (*Id.*)

Elan contests *none* of this, undoubtedly hoping its silence will lead the Court to ignore the record. In fact, these admitted deficiencies alone justify exclusion of Dr. Munson's ssNMR opinions. As Abraxis explained and Elan does not contest, courts should not accept subjective, unverifiable opinions. (MIL 2 at 10); *see also Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 322 (3d Cir. 2003) (affirming exclusion of opinion as "speculative and unreliable.").

But there is much more. Elan does not contest that Dr. Munson cherry-picked the results of 6 out of 34 tests, never explained or justified the exclusion of the other data, and failed to keep records of the excluded 28 runs that would permit Abraxis or the jury to analyze the omitted results. (MIL 2 at 5.) Nor does it contradict the showing that the control and test samples' purity is unknown because Drs. Shi and Barich never tested for purity and Dr. Winkler *destroyed* the results of the only purity test he performed.[2] (*Id.* at 10.)

Elan argues that its experts ordinarily collaborate and did not keep detailed records because the work was "routine." Elan's explanation fails to grapple with the gaping holes in the

[2] Indeed, Elan has not even attempted to rebut the substance of Dr. Atwood's declaration documenting the scientific flaws with Elan's evidence.

experimental record arising from these supposedly "routine" practices. Elan does not contest that it maintained no records of the preparation conditions for the Abraxane test sample or of the critical parameters for displaying and analyzing the ssNMR test runs. (MIL 2 at 8.) Nor does Elan contest that the samples were discarded and the data collected on sample purity and characterization actually *destroyed.* (*Id.* at 8, 10.) Elan's reliance on scientific collaboration is no excuse for these astonishing evidentiary chasms.

Elan attempts to justify Winkler's declaration by claiming that when he said "*I* prepared amorphous paclitaxel…" he meant that *others who worked for him* prepared it. (Resp. at 4 n.3.) Far from negating our claim of falsity, Elan's cited deposition excerpts confirm that Dr. Winkler did not perform the experiments as he stated; indeed, Bihovsky, one of the two scientists who did so was not even a scientist in Winkler's lab. (*Id.* Ex. 13; Kruze Decl. Ex. 3 at 49:2-50:16.) Moreover, Elan's argument does not solve Elan's fundamental problem: Dr. Winkler lacked personal knowledge of the work and hence his statements, on which Dr. Munson relies, are themselves unreliable.

Thus, magnifying the unreliability of Dr. Munson's speculative and conclusory opinions on crystallinity, Elan's testing evidence also has "no demonstrated indicia of reliability" because Elan failed to produce an adequate experimental record. (MIL 2 at 9.) Because Elan failed to keep and in some cases destroyed evidence, there is no way to reconstruct how it performed those experiments and repeat them, a hallmark of the scientific method. (*Id.*) Unless barred, Elan will present crystallinity data to the jury that may well be the result of contamination, improper experimental procedures, or other defects beyond the flaws already discovered. The rules are designed to prevent precisely this sort of unreliable evidence in the guise of science.[3]

[3] Elan's ssNMR evidence should be excluded under Rule 37 in addition to the rules of evidence. Elan has no response to our showing that its experts' reports failed to adequately disclose the basis for their opinions. (MIL 2 at 6, 7, 9.) Elan claims that its violations were not willful (Resp. at 4), but this defense is belied by Elan's persistent pattern of obstruction, documented in the Evans declaration, which was unchallenged by Elan.

III. ABRAXIS' REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE EVIDENCE OF THE [redacted]

Elan's response to this motion contains no decision from any court that admits similar evidence in any case, let alone as probative evidence of infringement in a patent case. To our knowledge, no such decision exists. Elan's response, moreover, implicitly concedes the premise of our motion – [redacted] And while Elan attempts to throw mud at Abraxis, Elan makes no effort to explain why it would not be error to admit this evidence, or why the prejudicial effect of this evidence does not outweigh whatever conceivable probative value the evidence might have.

A. Elan Has Not Shown That The [redacted] Evidence Has Any Probative Value

Elan itself recognizes that the [redacted] gave no reasons for its decision, and that the best anyone can do is draw inferences and make guesses: [redacted]

The obvious fallacy in Elan's construct, and the reason the prejudicial effect of the evidence far outweighs any probative value, [redacted] that decision cannot be probative of anything, much less of Abraxis' alleged patent infringement.

Elan, moreover, sets forth no evidence that would support its fanciful hypothesis that the [redacted] – coupled with an FDA regulatory scheme entirely unrelated to patent infringement constructs – is precisely the reason other courts have refused to admit similar evidence. As noted in more than one of the decisions cited in our motion, allowing Elan to argue infringement based on the FDA actions will "cause undue delay and a waste of time because the parties would litigate the meaning of the FDA regulatory system and the difference between that and the standards for the claims before the jury." *Cardiovention, Inc. v. Medtronic, Inc.*, 483 F. Supp. 2d 830, 840 (D. Minn. 2007). Elan never disputes this decision or the cases upon which it was based.

B. The [redacted] Evidence Is Highly Prejudicial

Rather than substantively address Abraxis' arguments as to the prejudicial nature of the [redacted] evidence, Elan asserts that the [redacted] evidence should be admissible because "Abraxis created this evidence; it is only fair for Abraxis to live with this evidence at trial." (Resp. at 5.) This is not the standard that the Federal Rules of Evidence employ for determining what is admissible evidence.

The official comment to Federal Rule of Evidence 403 states that "Unfair prejudice" means "an undue tendency to suggest decision on an improper basis . . . ." (emphasis added). Elan's response, in an attempt to demonstrate the probative value of the [redacted] evidence, does

nothing but set forth a number of improper bases on which a jury could make a decision. Such improper bases include Elan's assertion that the [redacted] an assertion that Elan concedes it cannot confirm.

Additionally, for the jury to decide infringement based on Elan's argument that the [redacted] would be improper. Nor is Elan's argument that Abraxis wanted to "hide its tracks" (Resp. at 4) probative of any issue in this litigation. Even willful infringement is to be decided as of the date the complaint was filed, not by post-complaint conduct of the defendant. *See In re Seagate Tech., LLC*, 497 F.3d 1360, 1374 (Fed. Cir. 2007). Even if "hiding its tracks" were probative of something in the case, Elan still does not explain why the probative value of the [redacted] evidence outweighs its prejudicial effect on the jury and the fact-finding process. As Elan's response demonstrates, the jury could infer an endless number of things from the [redacted] evidence, none of which is made "any more probable", Fed. R. Evid. 401, by the [redacted] evidence, or even has any basis in fact. Without such a basis in fact, and in light of the corresponding prejudice, all of these inferences are improper to present to a jury.

Finally, the only reason Elan does give for why the [redacted] evidence is not prejudicial – that it [redacted] essentially amounts to an argument by Elan that the [redacted] evidence should be admissible as evidence of Abraxis' "character" or evidence of a "subsequent remedial measure," either of which would be inadmissible under Rules 404 and 407 in addition to Rule 403.

For all of these reasons, Abraxis' Motion to Exclude [redacted] evidence should be granted.

IV. ABRAXIS' REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE THE UNTIMELY AND CUMULATIVE SUPPLEMENTAL REPORT OF DR. BYRN.

Elan's opposition to Abraxis' motion to exclude the supplemental report of Dr. Byrn (the "Byrn Report") does not dispute the factual basis for the motion: Byrn's report, served the evening before Dr. Byrn's deposition, addressed new issues unrelated to his earlier report; it was based on information available to Elan months before the Court's deadline for opening reports; and all of the issues it addressed could have been anticipated when the opening reports were served – indeed, other Elan experts addressed the same issues in their opening reports.

Rather, Elan's opposition establishes that it thinks the Court's deadlines and rules just don't apply to it. Indeed, compounding its multiplication of motions in limine in its opening papers in violation of the Court's limitations,[4] Elan's opposition adds yet another motion. Elan now seeks to exclude the supplemental report of Abraxis' expert Dr. Atwood (the "Atwood Report") and to distract the Court from the tardiness of the Byrn Report.

But Elan's attempt at misdirection only highlights why the Byrn Report should be excluded. Unlike the Byrn Report, Dr. Atwood's supplemental report, which address Elan's ssNMR testing, *could not* have been offered earlier. As summarized in the Declaration of Emily Evans filed in support of Abraxis' motion in limine no. 2, which Elan did not rebut, Elan repeatedly attempted to block Abraxis' efforts to get to the bottom of Elan's evidence, which Elan had inadequately disclosed. The Atwood Report itself documents that the information he relies on was *not available* to him in time for his rebuttal expert report or deposition and only trickled in as Abraxis extracted it from Elan. (Resp., Ex. 2 at ¶¶ 2-3.) The contrast between the untimely and cumulative Byrn Report and the Atwood Report could not be more stark.

[4] As we noted in our oppositions to Elan's motions in limine, Elan engaged in various stratagems to avoid the Court's limit of 5 motions per side. We counted a total of at least 8 motions in Elan's opening papers.

A. Elan Offers No Justification for Failing to Timely Serve the Byrn Report

Elan cites Fed. R. Civ. P. 26(e)(2) to argue that the Byrn Report was timely because an expert has a "duty" to supplement. (Resp. at 2.) But of course the duty to "supplement" is not a license to raise new issues after Court-imposed deadlines. As our motion noted, Fed. R. Civ. P. 26(e)(1), which Elan fails to address, allows supplementation only where the original report becomes "*incomplete or incorrect* and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing." (MIL 4 at 19 (emphasis added).) Elan concedes that Dr. Byrn raised "*new* and *additional* opinions" (Resp. at 2 (emphasis added).). As the cases we cited confirm, Dr. Byrn had no legal basis to "supplement" a report that was previously limited to invalidity by adding a completely unrelated analysis on infringement. (MIL 4 at 19 n.4.) And that Dr. Amiji reported noticing Dr. Byrn on an Internet search (Resp. at 2) does not change that result. (*Id.*, Ex. 1)

B. Abraxis Will Be Prejudiced If the Byrn Report Is Admitted

Elan's opposition does not rebut the prejudice that Abraxis will incur if the Byrn Report or related testimony is admitted. Abraxis did not have sufficient time to prepare to examine Dr. Byrn on the new opinions that were offered just hours before his deposition. The first hint that Dr. Byrn would be opining on infringement came with service of his new report on the eve of his deposition. As the court stated in *Praxair*[5], it should not have been Abraxis' burden to analyze at the last minute a report that should have been produced months earlier.

C. The Atwood Supplemental Report Was Justified Under Rule 26

In contrast to the Byrn Report, the Atwood Report contains "supplemental opinions" that fall squarely within Rule 26(e). The Atwood Report further opines on Elan's ssNMR testing

[5] 445 F. Supp. 2d 460 (D. Del. 2006).

evidence and analysis, which Dr. Atwood's earlier rebuttal report addressed extensively based on the limited ssNMR testing information provided in Elan's expert reports.[6] And, unlike Byrn's Report, the Atwood Report did not emerge out of the blue: it is based on new information that Elan improperly withheld during discovery. Elan does not dispute that the Atwood Report covers materials and testing data that were provided to Abraxis after the due date for rebuttal expert reports. (Resp., Ex. 2 at ¶ 2.) Elan's obstructive discovery tactics – which went as far as Elan filing motions for protective orders in disparate district courts to block depositions of those who actually did its ssNMR testing (Evans Decl. at ¶ 24, 31-32) – prevented earlier access to the information necessary for Dr. Atwood to complete his opinion. (*See, e.g.* Ex. A at 11 n.1) (Dr. Atwood mentioned in earlier report that he would need to supplement opinion when testing data became available.) Far from showing why Atwood's Report should be excluded, Elan's response highlights an astounding pattern of discovery abuse and manipulation.

[6] Dr. Atwood is in fact qualified to opine on these issues as set forth in Abraxis' Response to Elan's Motion in Limine No. 3 to Exclude the Expert Testimony of Drs. Amiji and Atwood.

V. REPLY IN SUPPORT OF MOTION IN LIMINE NO. 5.

As set forth in Abraxis' Motions in Limine Nos. 1-2, and the Evans Declaration in Support of Abraxis' Motions in Limine 1-2, throughout this litigation Elan has withheld evidence and information in contravention of this Court's rules, attempting to force Abraxis to prepare its case without full disclosure from Elan. Elan's opposition to Motion in Limine No. 5 – in which Elan *admits* that it did not fully disclose its cases regarding invalidity and inequitable conduct when it made its pretrial disclosures regarding infringement – only highlights Elan's latest effort to hold back information in violation of this Court's rules. Elan must not be allowed to make up its own rules for pretrial disclosures. Its exhibits and deposition designations relating to invalidity and inequitable conduct should be precluded because they were not timely disclosed.

A. Elan Has Failed to Comply With the Rules Regarding Pretrial Disclosures.

Elan cannot, and does not even attempt to, controvert certain key facts:

First, Elan did not disclose to Abraxis its exhibits and designations relating to invalidity and inequitable conduct when its made its other pre-trial disclosures on March 7, 2008[7];

Second, the pre-trial order *drafted* by Elan and *served* by Elan on March 7, 2008 provided, in bold text, that Elan would provide "its draft exhibit list" on March 7:

> (d) List of exhibits, except for rebuttal exhibits, in the form required by the Court, are attached as follows: **[Elan to provide its draft exhibit list on 3/7; Abraxis to provide its draft exhibit list on 3/21.]**

[7] Elan identified more than 250 additional documents and added several additional deposition designations after March 7, 2008, the day Elan's pre-trial submissions were due. Specifically, Elan added 17 new exhibits of March 16, 165 new exhibits on March 28, 70 new exhibits on April 1, and 14 new exhibits on April 4. Despite repeated requests, Elan's counsel has refused to disclose whether these additional documents and designations comprise everything that Elan will rely upon at trial, or whether Elan plans to further supplement its lists.

(Sullivan Decl. Exh. 1.) Elan did not state or imply on or before March 7 that it would not serve its invalidity exhibits on that date. Elan made no mention at that time of any right or desire to hold back portions of its invalidity and inequitable conduct cases. It did not mention this orally or in writing to Abraxis' counsel. It did not file an objection with the Court.

Third, Elan advances inconsistent positions: although Elan failed to disclose its invalidity exhibits and designations on March 7, the witness list that it served on March 7 included both its invalidity and inequitable conduct witnesses. (Ex. B.) Elan also served other pretrial submissions on March 7, including its Proposed Statement of Uncontested Facts, Statement of Contested Issues of Law and Fact, Proposed Jury Instructions and Proposed Verdict Form. Each of these drafts included references to Elan's invalidity and unenforceability positions. (Ex. C.) This directly contradicts Elan's after-the-fact assertion that waiting to serve its invalidity and inequitable conduct materials is "contemplated by" the Scheduling Order and Local Rules.

Elan argues that its disclosure obligations did not include its case regarding invalidity and inequitable conduct. But neither the plain language of the rules nor the ordinary practice of this District support that position. Both Local Rule 16.3(d)(1) and paragraph 12 of the Scheduling Order expressly provide that "*plaintiff*" – Elan – was required to serve Abraxis with the "information *plaintiff* proposes to include in the draft [pretrial order]." Both provide that plaintiff "*shall*" make its disclosures 30 days before the Pre-Trial Order is due.

Elan proposes a definition of "plaintiff" that would redefine that term as "plaintiff, but only with respect to issues on which plaintiff bears the burden of proof, along with counterclaim plaintiff". Neither the Local Rules nor the Scheduling Order contemplate Elan's definition. Indeed, Elan points to no decision that would support this interpretation, even though many patent and other cases in this Court frequently involve counterclaims. Moreover, Elan's self-

serving interpretation is contradicted by other provisions of the Local Rules. Local Rule 16.3(c)(10), for example, provides that "counterclaimants" are required to include in the pre-trial order "[s]tatements . . . comparable to that required *of the plaintiff*." This language is inconsistent with Elan's argument that when the L.R. 16.3(d) refers to the "plaintiff," the rule really means "plaintiff . . . and counterclaimant."

B. The Prejudice to Abraxis Is Great.

Elan does not dispute that the proper remedy for failing to disclose pre-trial materials is exclusion at trial. Rather, Elan seems to say that because it disclosed its materials earlier than parties had done in other written decisions, its violation of the Local Rules and Scheduling Order should be excused. The Local Rules and the Scheduling Order set forth an orderly process for preparation of the Pre-Trial Order to ensure that the Court and the parties can properly prepare complex cases for trial. The Manual for Complex Litigation describes the pre-trial process and exchange of materials as "essential". 32-11 MANUAL FOR COMPLEX LITIGATION 11.6 (4th Ed. 2007). Failure to comply with the rules can significantly impact an opponent's trial preparation. That is why exclusion is the appropriate remedy. Here, Abraxis has incurred prejudice as a result of Elan's late and incomplete pretrial disclosures. With just days remaining before the pre-trial order was due, Elan has effectively forced Abraxis to review over 200 new exhibits and over 132 new deposition designations. Failure to do this work accurately and thoroughly carries significant consequences, as objections not made in the Pre-Trial Order may not be made at trial. And it is not clear whether all of the rebuttal exhibits and designations on which Elan intends to rely have now been produced. It simply is not fair to allow Elan to unilaterally change the rules, and to thereby prejudice Abraxis. Elan should be precluded from relying on any exhibits and deposition designations that were not produced in accordance with the rules of this Court.

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Dated: April 7, 2008

CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire, hereby certify that on April 15, 2008, 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 April 15, 2008, 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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Attorneys for Defendant
ABRAXIS BIOSCIENCE, INC.

EXHIBIT A

REDACTED IN ITS ENTIRETY

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

EXHIBIT 11: PLAINTIFF ELAN'S WITNESS LIST

Plaintiff Elan identifies the following witnesses that will be called to testify at trial. The order of the presentation of evidence of witnesses is not indicative of the order in which the witnesses will be called at trial.

1. Gary G. Liversidge
Elan Drug Delivery, Inc.
3500 Horizon Drive
King of Prussia, PA 19406
(live)

2. John C. Jarosz
Analysis Group
1899 Pennsylvania Ave., N.W.
Suite 200
Washington, D.C. 20006
(live)

Mr. Jarosz will testify about the methodology to determine damages for patent infringement. Mr. Jarosz will testify as to reasonable royalty damages arising from Abraxis's past infringement of the '363 Patent and the appropriate reasonable royalty to

license the '363 Patent to Abraxis. Mr. Jarosz will testify as to the methods, assumptions, and conclusions of Mr. Musika.

Mr. Jarosz will testify as to the topics addressed in his report.

3. Eric J. Munson Ph.D.
1324 Lawrence Ave.
Lawrence, KS 66049
(live)

Dr. Munson will testify about analytical testing of pharmaceutical formulations using Solid-State Nuclear Magnetic Resonance Spectroscopy (SSNMR). He will also testify about how SSNMR compares with other analytical testing of pharmaceutical formulations. Dr. Munson will testify that particles of crystalline paclitaxel exist in Abraxane® and reconstituted Abraxane®. Dr. Munson will testify as to the particles within Abraxane® and reconstituted Abraxane® meeting the crystalline medicament useful for treating cancer limitation of the asserted claims.

Dr. Munson will testify as to the topics addressed in his report.

Plaintiff Elan identifies the following witnesses that may be called to testify at trial. The order of the presentation of evidence of witnesses is not indicative of the order in which the witnesses may be called at trial.

1. All witnesses listed by defendant Abraxis (Ex 12) (live and/or by deposition).

2. Elaine Liversidge
Elan Drug Delivery, Inc.
3500 Horizon Drive
King of Prussia, PA 19406
(live and/or by deposition)

3. Nancy Peltier
Elan Drug Delivery, Inc.
3500 Horizon Drive
King of Prussia, PA 19406
(live and/or by deposition)

4. David Czekai
NanoSystems Div., Elan Pharmaceuticals
3500 Horizon Drive
King of Prussia, PA 19406
(live and/or by deposition)

5. Seamus O'Loan
Elan Drug Technology
3500 Horizon Drive
King of Prussia, PA 19406
(live)

6. Pramod P. Sarpotdar
3981 Gaffney Court
San Diego, California 92130
(live and/or by deposition)

7. Lawrence de Garavilla
909 Noble Drive
Downingtown, PA 19335
(live and/or by deposition)

8. Eugene Cooper
2621 Crum Creek Dr.
Berwyn, PA 19312
(live and/or by deposition)

9. Lianjun Shi, Ph.D.
150318 Doolittle Drive
Bridgewater, NJ
(live and/or by deposition)

10. Dewey Barich, Ph.D.
University of Kansas
Lawrence, KS 66045
(live and/or by deposition)

11. Jeffrey D. Winkler, Ph.D.
University of Pennsylvania
Philadelphia, PA 19104
(live and/or by deposition)

12. Mark C. Manning, Ph.D.
1826 Monarch Circle
Loveland, CO 80538
(live and/or by deposition)

Dr. Manning will testify about human albumin in pharmaceutical formulations and about crosslinking. Dr. Manning will testify that human albumin on the particles within Abraxane® and reconstituted Abraxane® is essentially free of intermolecular crosslinkages. He will further testify that the particles within Abraxane® and reconstituted Abraxane® meet the non-crosslinked limitation in the asserted claims. Dr. Manning will testify as to the deficiencies of Abraxis's analytical testing.

Dr. Manning will testify as to the validity and enforceability of the '363 Patent. Dr. Manning will testify as to the understanding of the '363 Patent by one of ordinary skill in the art, including that the specification enables one of ordinary skill in the art to practice the invention of the asserted claims without undue experimentation; that the specification adequately describes the limitations of the asserted claims; and that one of ordinary skill in the art would understand the scope of the asserted claims when read in light of the specification. Dr. Manning will testify that no material information was withheld from the Patent Office during examination of the patent application that issued as the '363 Patent.

Dr. Manning will testify as to the topics addressed in his expert reports.

13. Harry G. Brittain, Ph.D.
10 Charles Street
Milford, NJ 08848
(live and/or by deposition)

Dr. Brittain will testify about limitations of using X-Ray Powder Diffraction (XRPD) to characterize Abraxane®. Dr. Brittain will testify as to the deficiencies in the XRPD testing commissioned by Abraxis. Dr. Brittain will testify that particles within Abraxane® and reconstituted Abraxane® meet the non-crosslinked surface modifier limitation of the asserted claims. Dr. Brittain will testify that Abraxane® and reconstituted Abraxane® infringe the asserted claims under the doctrine of equivalents.

Dr. Brittain will testify as to the methods, assumptions, and conclusions of Dr. Atwood.

Dr. Brittain will testify as to the topics addressed in his reports.

14. Samuel J. Danishefsky, Ph.D.
Memorial Sloan-Kettering Cancer Institute
1275 York Avenue
New York, NY 10065
(live and/or by deposition)

Dr. Danishevsky will testify about the nature of paclitaxel, the synthesis of paclitaxel, and the role of formulation in effective delivery of paclitaxel. Dr. Danishevsky will testify as to the inventive achievements described in the '363 Patent. Dr. Danishevsky will testify as to the chemical nature of paclitaxel in particles within Abraxane® and reconstituted Abraxane® with respect to literal infringement and infringement under the doctrine of equivalents.

Dr. Danishevsky will testify as to the non-obviousness of the '363 Patent in view of the Haynes Patent.

Dr. Danishevsky will testify as to the topics addressed in his reports.

15. Cory Berkland, Ph.D.
18329 Northwind Drive
Lawrence, KS 66044
(live and/or by deposition)

Dr. Berkland will testify as to the isolation of particles within reconstituted Abraxane®. Dr. Berkland will testify that particles within Abraxane® and reconstituted Abraxane® meet the non-crosslinked surface modifier limitation of the asserted claims. Dr. Berkland will testify as to deficiencies of Abraxis's analytical testing. Dr. Berkland will testify about TEM and cryo-TEM testing to determine crystallinity. Dr. Berkland will testify as to the TEM and cryo-TEM images commissioned by Abraxis.

Dr. Berkland intends to testify as to the topics addressed in his report.

16. Manoj Maniar, Ph.D.
375 Pheasant Run
Newtown, PA 18940
(live and/or by deposition)

Dr. Maniar will testify about drug development, including compliance with guidelines promulgated by the United States Food and Drug Administration. Dr. Maniar will testify as to the validity and enforceability of the '025 Patent, if necessary. Dr. Maniar will testify that no material information was withheld from the Patent Office during examination of the patent application that issued as the '025 Patent, if necessary.

Dr. Maniar will testify as to the topics addressed in his expert report.

17. David Robert Taft, Ph.D.
Division of Pharmaceutical Sciences
Long Island University
Brooklyn, NY 11201
(live)

Dr. Taft will testify as to preclinical studies of Elan's nanoparticulate

paclitaxel formulations and preclinical studies of Abraxane®, both involving comparisons to paclitaxel dissolved in Cremophor™. Dr. Taft will testify that the preclinical studies demonstrate that the efficacy of paclitaxel is increased by administering it as surface modified nanoparticles. Dr. Taft will testify that the reduction of particle size and use of a surface modifier increased efficacy and reduced toxicity in both Elan's formulations and Abraxane®. Dr. Taft will testify that the preclinical studies demonstrate that particles within reconstituted Abraxane® perform substantially the same function in substantially the same way with substantially the same result as the particles of the asserted claims.

Dr. Taft will testify as to the topics addressed in his report.

18. David J. Haidak, M.D.
Oncology-Hematology Associates, P.A.
8926 Woodyard Road, Suite 201
Clinton, MD 20735
(live)

Dr. Haidak will testify about use of Abraxane® in treating cancer patients. He will testify as to the use and administration of Abraxane® to treat cancer patients.

Dr. Haidak will testify as to the topics addressed in his report.

19. Stephen R. Byrn, Ph.D.
Purdue University
West Lafayette, IN 47906
(live)

Dr. Byrn will testify about formulation of pharmaceutical solids. Dr. Byrn will testify about nanoparticles, crystallinity, amorphousness, and analytical techniques for characterizing pharmaceutical solids. Dr. Byrn will testify about XRPD. Dr. Byrn will testify as to the deficiencies of Abraxis's XRPD testing. Dr. Byrn will testify that

Abraxane® and reconstituted Abraxane® literally infringe the asserted claims.

Dr. Byrn will testify about the state of the prior art with respect to the '363 Patent and, if necessary, the '025 Patent. Dr. Byrn will testify as to what a person of skill in the art would understand from the prior art. Dr. Byrn will testify that the '363 Patent claims are non-obviousness. Dr. Byrn will testify that the Domb Patent is immaterial to the '363 Patent claims.

Dr. Byrn will testify as to the topics addressed in his reports.

20. Patrick Soon-Shiong
c/o counsel for Abraxis
(live and/or by deposition)

21. Neil Desai
c/o counsel for Abraxis
(live and/or by deposition)

22. Michael Hawkins
c/o counsel for Abraxis
(live and/or by deposition)

23. Richard E. Maroun
c/o counsel for Abraxis
(live)

24. Mitchall Clark
c/o counsel for Abraxis
(live)

25. Bruce Wendell
c/o counsel for Abraxis
(live and/or by deposition)

26. Carlo Montagner
c/o counsel for Abraxis
(live)

27. Chunlin Tao
c/o counsel for Abraxis
(live and/or by deposition)

28. Leslie Louie
c/o counsel for Abraxis
(live and/or by deposition)

29. Ulagaraj Selvaraj
c/o counsel for Abraxis
(live and/or by deposition)

30. Julie Lisano
c/o counsel for Abraxis
(live and/or by deposition)

31. Henry Lee
MedComm Solutions
1900 Powell Street, Suite 880
Emeryville, CA 94608
(live and/or by deposition)

32. Johnson Tai Wong, M.D.
c/o counsel for Abraxis
(live and/or by deposition)

33. Edmund A.C. Crouch, Ph.D.
c/o counsel for Abraxis
(live and/or by deposition)

34. Mansoor M. Amiji, Ph.D.
c/o counsel for Abraxis
(live and/or by deposition)

35. Michael R. Hamrell, Ph.D.
c/o counsel for Abraxis
(live and/or by deposition)

36. Jerry L. Atwood, Ph.D.
c/o counsel for Abraxis
(live and/or by deposition)

37. Terry L. Musika
c/o counsel for Abraxis
(live and/or by deposition)

EXHIBIT C

REDACTED IN ITS ENTIRETY