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**

MOTIONS IN LIMINE OF DEFENDANT ABRAXIS BIOSCIENCE, INC.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

Josy W. Ingersoll (#1088)
Elena C. Norman (#4780)
Karen E. Keller (#4489)
Michele Sherretta Budicak (#4651)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, DE 19801
(302) 571-6672 Telephone
jingersoll@ycst.com
enorman@ycst.com
kkeller@ycst.com
mbudicak@ycst.com

Attorneys for Defendant
ABRAXIS BIOSCIENCE, INC.

OF COUNSEL:

Michael A. Jacobs
MORRISON & FOERSTER, LLP
425 Market Street
San Francisco, CA 94105-2482
(415) 268-7000 Telephone

Emily A. Evans
MORRISON & FOERSTER, LLP
755 Page Mill Road
Palo Alto, CA 94304-1018
(650) 813-5600 Telephone

Dated: April 11, 2008

INDEX OF MOTIONS IN LIMINE

I. MOTION IN LIMINE TO STRIKE PORTIONS OF ELAN EXPERT HARRY BRITTAIN'S EXPERT REPORT REGARDING TESTING OF ABRAXANE AND TO BAR RELATED TESTIMONY AND ARGUMENT.....1

II. MOTION IN LIMINE TO EXCLUDE EVIDENCE OF ELAN'S SSNMR TESTING OF ABRAXANE.....6

III. MOTION IN LIMINE TO BAR ELAN FROM INTRODUCING EVIDENCE OF [redacted].....11

IV. MOTION IN LIMINE TO PRECLUDE ELAN FROM INTRODUCING EVIDENCE AND TESTIMONY REGARDING BYRN'S UNTIMELY SUPPLEMENTAL EXPERT REPORT ON INFRINGEMENT.....16

V. MOTION IN LIMINE TO PRECLUDE ELAN FROM INTRODUCING INTO EVIDENCE AT TRIAL ANY EXHIBIT OR OTHER EVIDENCE, ARGUMENTS OR CONTENTIONS, THAT ELAN HAS NOT PROVIDED TO ABRAXIS AS OF THE DATE OF THIS MOTION – TWENTY DAYS AFTER ELAN'S PRETRIAL DISCLOSURES WERE DUE.....21

I. MOTION IN LIMINE TO STRIKE PORTIONS OF ELAN EXPERT HARRY BRITTAIN'S EXPERT REPORT REGARDING TESTING OF ABRAXANE AND TO BAR RELATED TESTIMONY AND ARGUMENT

INTRODUCTION

Elan's expert Harry Brittain is expected to testify regarding two different tests that the parties used to assess the alleged crystallinity of Abraxane: X-ray Powder Diffraction ("XRPD") and solid-state Nuclear Magnetic Resonance ("ssNMR"). Specifically, in his expert report, Brittain criticizes XRPD, which Abraxis used to test Abraxane, while adopting the results of Elan's ssNMR testing of Abraxane performed by another Elan expert, Eric Munson.

The Court should bar Brittain's testimony critiquing Abraxis's XRPD testing and related evidence and argument because Elan violated Rule 26 by withholding the results of Brittain's own testing of Abraxane under an improper assertion of work product, after falsely representing to the Court during the fourth and final discovery conference that it was not withholding testing documents. To prevent Elan from benefiting from its failure to produce highly relevant testing documents that are clearly not work product, Elan should be barred from introducing evidence or argument contending that Abraxis's XRPD is not an appropriate method for testing the crystallinity of Abraxane.

I. ELAN'S FAILURE TO PRODUCE ITS TESTIFYING EXPERT'S TESTING OF ABRAXANE RENDERS BRITTAIN'S TESTIMONY INADMISSIBLE

Although Brittain opines in his expert report on the various tests used by others to evaluate Abraxane, Elan has withheld the tests Brittain himself performed. This is a clear violation of Rule 26, which mandates disclosure of "the data or other information considered by the witness" in forming his opinions. Fed. R. Civ. P. 26(a)(2)(B)(ii). As explained below, Elan's failure to produce its expert's testing evidence is prejudicial to Abraxis and warrants

striking the affected portions of Brittain's report and excluding any related evidence and argument.

That Brittain—a testifying expert—performed testing on Abraxane for the purposes of this litigation came to light only the day before his November 16, 2007 deposition, when Elan produced an astounding 34-page privilege log listing *over 400* undated entries styled vaguely as "Test Data," "Lab Notebook," "Test Report," "Presentation," or "Image" "prepared in conjunction with the Elan-Abraxis litigation at request of counsel," with the purported basis for privilege identified as "Attorney Mental Impression Work Product." (Evans Decl., Ex. 6 (Brittain log dated Nov. 15).)[1]

Elan's withholding of data from tests performed by its testifying expert was completely unexpected. Abraxis had earlier moved to compel production of all documents reflecting testing of Abraxane in Elan's possession, custody or control. (Evans Decl., Ex. 1 at 82:10-86:5 (Oct. 2, 2007 Hearing Tr.).) In response, Elan represented to the Court that it had produced all non-privileged testing documents and informed the Court that the testing documents it was withholding were from consultants, not its testifying experts:

> [Mr. Scheve]: Now, what is really happening here is a veiled effort to get at my work product. Your honor entered an order denying the Rule 11 motion. We did testing before we filed this lawsuit. We met our obligations under Rule 11.
>
> *At the direction of counsel, we had consulting experts,* ***not testifiers,*** *consult with us and do testing before we filed this lawsuit.* And this is nothing but a veiled effort now of trying to pierce these privileges. (*Id.* at 87:15-22 (emphasis added).)

Abraxis expressed concern that Elan's then-current privilege log did not appear to reflect the testing conducted on behalf of Elan by its so-called "consultants." (*Id.* at 89:7-11.) The

[1] All references to the "Evans Decl." is to the Declaration of Emily A. Evans in Support of Abraxis's Motion in Limine Nos. 1 and 2.

Court directed Elan to respond directly to that concern. (*Id.* at 89:22-23). In response, Elan represented to the Court that it had "preserved all the walls between consultants and testifiers" (*Id.* at 90:4-9), that the testing evidence it was withholding *was* on the log, and reiterated that the testing evidence from its testifying experts was not being withheld:

> You know, it's called Presentation. It's on the privilege log. All I can tell you, Judge, is it's there. Constantly, every day, "You didn't do this, [ ] you didn't do that."
>
> It's there.
>
> Clearly, if one of our witnesses comes in and talks about some testing that he has done, he is going to testify to it. He is going to get all the testing he did on that topic. *There is no ands, ifs or buts about that.* (*Id.* at 89:24-90:7 (emphasis added); *see also id.* at 90:15-18.)

The Court "accept[ed] [Mr. Scheve's] representation as an officer of the Court." (*Id.* at 91:21-22, 92:18-20.)

There is no way to square Elan's representations to the Court with what we later learned. Brittain confirmed at his deposition that he had tested Abraxane (Evans Decl., Ex. 8 at 6:10-7:2), and his privilege log produced the day before his deposition reflects hundreds of documents containing test data that were withheld by Elan without a colorable work product claim. Moreover, the testing documents that Elan withheld do not appear to have been earlier identified on its privilege log, contrary to Elan's earlier representations that the log was complete. (Evans Decl. ¶ 8.)

At his deposition, Elan's counsel repeatedly instructed Brittain not to answer any questions about his testing of Abraxane, on the ground that Brittain had performed the testing when he was a consultant before formally being designated a testifying expert. (*See, e.g.*, Evans Decl., Ex. 8 at 6:13-7:13, 9:10-15, 10:24-13:22, 14:20-24, 18:7-19:7.) As a result, Abraxis was unable to inquire about the contents of the privilege log it had received just the day before, let

alone the full bases for Brittain's opinions criticizing certain test methods and whether Brittain's testing might controvert his opinions.

A recent decision by this Court makes abundantly clear that Elan has no justification for its non-compliance with Rule 26(a)(2)(B), which mandates disclosure of all data or other information considered by an expert witness in forming the opinions expressed in his report:

> [P]utting privilege considerations aside, a testifying expert must disclose all information that he or she reviewed, reflected upon, read and/or used in formulating his or her opinions.

Dyson Tech. v. Maytag Corp., 241 F.R.D. 247, 251 (D. Del. 2007) (Sleet, J.); *see also In re Pioneer Hi-Bred Int'l, Inc.*, 238 F.3d 1370, 1375 (Fed. Cir. 2001) ("Indeed, we are quite unable to perceive what interests would be served by permitting counsel to provide core work product to a testifying expert and then to deny discovery of such material to the opposing party."). Once Elan designated Brittain as a testifying expert to opine on testing Abraxane, any privilege that might have attached to his own Abraxane testing was waived and all evidence should have been produced.

Furthermore, even if Brittain's claim that he did not rely on his own testing of Abraxane in forming his opinions were credited, it is of no moment. (*See, e.g.*, Evans Decl., Ex. 8 at 215:2-6.) "[T]he 1993 amendments to Rule 26 . . . make clear that documents and information disclosed to a testifying expert in connection with his testimony are discoverable by the opposing party, whether or not the expert relies on the documents and information in preparing his report." *Pioneer Hi-Bred*, 238 F.3d at 1375 (emphasis added). Rather, Elan, as the party resisting disclosure, "bears the burden of showing that an expert did not consider certain documents in forming his opinion; this burden cannot generally be satisfied by the expert's representations alone." *See, e.g., Schwab v. Philip Morris USA, Inc.*, 2006 U.S. Dist. LEXIS 11047, at *11 (E.D.N.Y. March 20, 2006). Not only has Elan failed to carry its burden, it affirmatively and repeatedly blocked Abraxis's inquiries. (*See, e.g.*, Evans Decl., Ex. 8 at 18:7-19:7.) In any event, it would be nonsensical for Elan to argue that Brittain never even *considered*, i.e.,

"reviewed, reflected upon, read and/or used" (*Dyson,* 241 F.R.D. at 251) his own testing when considering the appropriate method for testing Abraxane.

Abraxis has been prejudiced by Elan's withholding of Brittain's own testing of Abraxane. That evidence may tend to controvert Brittain's "general opinion" that the XRPD testing methodology Abraxis used was unsuitable; it may, moreover, corroborate Abraxis's own XRPD testing results. Indeed, it is hard to imagine evidence that bears more directly on Brittain's expert opinion, and that could have been more prejudicial to Abraxis to withhold. Abraxis and its experts should have had access to Brittain's test results to fully evaluate Brittain's opinions regarding the testing Elan and Abraxis performed. *See, e.g.*, *Schwab*, 2006 U.S. Dist. LEXIS 11047 at *13 ("Adverse material reviewed and rejected by an expert bears on his credibility, the soundness of his techniques, and the weight to be given his conclusions. It may be relevant to the court's decision whether to qualify under *Daubert.*"). Elan should be prevented from offering Brittain's testimony that Abraxis's XRPD data is problematic while hiding the results of Brittain's own tests from Abraxis and the jury, and it should be prevented from introducing related evidence or argument from any other source as well.

CONCLUSION

For the reasons set forth above, Abraxis respectfully requests that the Court grant its motion to exclude Elan from introducing evidence and testimony contending that Abraxis's XRPD testing methods were an inappropriate method for testing for crystallinity in Abraxane.

II. MOTION IN LIMINE TO EXCLUDE EVIDENCE OF ELAN'S SSNMR TESTING OF ABRAXANE

In support of its infringement theory, Elan offers its expert Eric Munson to testify that the paclitaxel in Abraxane is more than 10% crystalline.[2] Discovery revealed, however, that Elan engaged in an elaborate shell game to mask its "junk science." Neither Munson, nor the Elan expert who supposedly supplied him with samples (Cory Berkland), actually performed the work underlying their reports. Moreover, Munson relied on a false declaration from another scientist, Winkler, who claimed to have done work that was actually performed by others and for which he had no personal knowledge. Elan cherry-picked results of 6 out of 34 test runs, systematically failed to maintain adequate records, and discarded test samples. These egregious violations of Rule 26 warrant exclusion of the Elan's crystallinity tests. In addition, Munson's testimony is unreliable. Munson's claim of *any* crystallinity relies on his assertion that a "third peak" allegedly "appeared" during his analysis, but Munson himself arbitrarily placed this third peak into the test results. To derive a percentage crystallinity that exceeded 10%, Munson then engaged in a series of unfounded and speculative assumptions that render his opinions unreliable. The Court should bar Elan's testing evidence under F.R.C.P. 37 and F.R.E. 702.

II. ELAN FAILED TO MAINTAIN AND DISCLOSE TESTING EVIDENCE

Elan disclosed only two experts whose reports set forth its tests—Berkland and Munson. Berkland's report said he prepared Abraxane test samples and sent them to Munson. (Evans Decl., Ex. 17 ¶ 14 (Berkland Rep.).) Munson said that he tested the Abraxane samples against paclitaxel controls and concluded that Abraxane contained 3.5%-4% crystallinity. He then doubled the measured value based on the speculative hypothesis that Abraxane contained a new

[2] As Abraxis will explain in its trial brief, even if Elan's evidence were accepted, this small amount of crystallinity in an otherwise amorphous drug is insufficient to prove infringement.

form of crystalline paclitaxel unknown in the annals of science. (*Id.*, Ex. 9 ¶¶ 21- 22; Atwood Decl. ¶¶ 21-26.) The resulting 7-8% range was still too low, so based on a claimed 50% error rate he admitted was no more than a "best guess estimate," he opined that Abraxane particles had as much as 12% crystallinity. (Evans Decl., Ex. 22, 234:10-235:11 Atwood Decl. ¶ 26.)

Rule 26 requires full disclosure of Elan's tests, mandating not only "a complete statement of all opinions the witness will express and the basis and reasons for them," but also "the data or other information considered by the witness in forming them." Fed. R. Civ. P. 26(a)(2)(B). Instead, as the Court found in another context, Elan engaged in "hide the ball behavior" (*See* D.I. 437 at n.2 (Dec. 6, 2007 Order.) to mask serious shortcomings in its expert opinions.[3]

Berkland and Munson's reports do not specify most experimental conditions or adequately explain each step of the derivation of the crystallinity percentage. (Atwood Decl. ¶¶ 6-13.) At their depositions, they acknowledged that two other scientists, Shi and Barich, actually prepared the samples and performed the tests, which involve a method known as solid state Nuclear Magnetic Resonance ("ssNMR"). (Evans Decl., Ex. 18 at 200:12- 207:15 (*see also* errata); Ex. 22 at 33:3-4 (Munson Dep.).) Elan's expert reports did not disclose Shi or Barich's involvement, and Elan never produced expert reports from them.

Abraxis eventually learned that Barich collected data for 34 ssNMR runs, although Munson chose to rely on only 6. (*Id.*, Ex. 9 at Appendix C-H (Munson Report).) No Elan expert disclosed the existence of the excluded data or supported the selection of only 6 of 34 runs. (Atwood Decl. ¶¶ 27-32.). Because of Elan's inadequate recordkeeping, it is impossible to reconstruct the other 28 runs to analyze their consistency with Munson's opinion.

[3] Elan resisted Abraxis's efforts to get to the bottom of Elan's testing. Elan's obstruction is detailed in the Evans Decl.

This is just the tip of the iceberg. Shi testified that he prepared the Abraxane test samples, but did not maintain records of the preparation conditions. (Evans Decl., Ex. 21 at 143:18-144:13; 106:3-11.) Barich confirmed that he actually ran the ssNMR tests, and assisted Munson in deconvoluting the results. He admitted that both he and Munson failed to record the parameters used for displaying and analyzing the ssNMR test runs. (*Id.*, Ex. 26 at 71:10-17, 80:10-81:9.) These parameters are critical to Munson's conclusions. (Atwood Decl. ¶¶ 44-56.)

Moreover, the integrity and origin of the control samples cannot be confirmed. Elan submitted a declaration with Munson's report, from Winkler, purporting to describe the preparation of Elan's controls. Winkler declared: "I prepared amorphous paclitaxel…" (Evans Decl., Ex. 16 ¶ 7.) But Winkler admitted that he did not do so. Rather, two *other* scientists, Riichero Tsuji and Ron Bihovsky, did. (*Id.*, Ex.14 at 47:4-48:8.) And once again, the samples were discarded. (*See, e.g.*, *id.* at 295:18-296:13.) Data collected on purity and characterization of the samples was also destroyed. (*Id.* at 203:21-204:18; 206:16-207:5; 225:21-226:17.)

We summarize the missing information on Elan's ssNMR experiments in paragraph 3 of the Atwood Declaration. Elan's asserted ssNMR crystallinity results could well be attributable to error, impurities, artifacts, or induced crystallization, but Elan failed to maintain records of, and in some cases suppressed, information necessary for Abraxis to fully analyze Elan's results.

III. ELAN'S NON-DISCLOSURE MANDATES EXCLUSION UNDER RULE 37

Elan repeatedly violated applicable rules governing expert disclosure. Elan submitted reports from two experts (Berkland and Munson) who did not do the work, and failed to include reports of those who actually did (Shi, Barich, Tsuji, Winkler and Bihovsky). It submitted a false declaration from Winkler. Elan's experts consistently failed to keep records, making it impossible to analyze the ssNMR results in Munson's report, much less the 28 out of 34 runs that

were inexplicably excluded. Elan thus violated Rule 26's requirement to produce expert reports with a complete basis for all opinions, as well as all "data or other information considered."

These violations prejudiced Abraxis by preventing it from being able to fully analyze and explain to the jury the experimental conditions under which the testing occurred, and the potential impact on the test results. Without sufficient records, there is no way to put Elan's ssNMR Humpty Dumpty back together again; Abraxis is forever precluded from fully analyzing Elan's asserted ssNMR results. Elan's violations and the resulting prejudice are thus incurable.

Elan's ssNMR evidence should be excluded under Fed. R. Civ. P. 37(c)(1). *See, e.g., Hagans v. Henry Weber Aircraft Distribs., Inc.*, 852 F.2d 60, 64 (3rd Cir. 1988) (affirming exclusion where information was fabricated or deliberately or recklessly withheld); s*ee also, Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1376 n.4 (Fed. Cir. 2008) ("Conclusory expert reports, eleventh hour disclosures, and attempts to proffer expert testimony without compliance with Rule 26 violate both the rules and principles of discovery, and the obligations lawyers have to the court. Exclusion and forfeiture are appropriate consequences to avoid repeated occurrences of such manipulation of the litigation process.").

IV. ELAN'S SSNMR TESTING IS ALSO INADMISSIBLE UNDER RULE 702

Elan's ssNMR evidence should also be excluded under F.R.E. 702, which requires expert testimony to be "based upon sufficient facts or data." Munson and Berkland are relying on other scientists who did not provide them with sufficient facts or data to draw reliable conclusions. This dooms Elan's claim of reliability. *See, e.g., In re TMI Litig.*, 193 F.3d 613, 705-706 (3d Cir. 1999) (affirming exclusion where expert relied on summaries prepared by non-testifying consultants but no evidence produced on preparation of summaries). Without records detailing the work, Elan's testing "ha[s] no demonstrated indicia of reliability." *Id.* at 705.

Rule 702 also requires that the testimony be "the product of reliable principles and methods," but as even high school students are taught, proper experimental documentation is critical to good scientific practice. (Atwood Decl. ¶¶ 5-13); *Cf.* Manual for Complex Litigation, Fourth, § 23.33 at 499 (Fed. Jud. Center 2004) ("The court should impress on counsel *the critical importance of Rule 26(a)(2)(B) requirements to the judge's gatekeeping obligations*, and the seriousness of the disclosure requirement ....") (emphasis added). Absent proper experimental records, Elan's testimony is inherently unreliable and should be excluded.

In addition to the gross defects in Munson's analysis described above, Elan's ssNMR testing evidence suffers from many other substantive defects, including:

- The control and test samples' purity is unknown. Shi and Barich never tested for purity. (Evans Decl., Ex. 21 at 98:15-25; Ex. 26 at 117:4-7). Winkler destroyed the results of the only purity test he performed. (*Id.*, Ex. 14 at 225:21-226:17.)
- Munson's crystallinity opinion relied on his deconvolution analysis generating three peaks for the test samples but only two peaks for the control. (*Id.*, Ex. 9 ¶¶ 21-22.) Even Brittain agreed, however, that the third peak is superfluous. "From the date that was seen here, it doesn't look like it is necessary." (*Id.*, Ex. 8 at 129:18-131:5).
- Munson never explained how he calculated the third peak's area to be 3.5%-4%, which is essential to his opinion. (*Id.*, Ex. 9 ¶¶ 21-22.)

Because Munson did not substantiate his subjective method, it should be excluded. *In re TMI*, 193 F.3d at 704 n.145 ("[I]t is impossible to test a hypothesis generated by a subjective methodology because the only person capable of testing or falsifying the hypothesis is the creator of the methodology."). Courts need not admit "opinion evidence which is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

CONCLUSION

Abraxis respectfully requests that the Court exclude evidence and testimony regarding Elan's ssNMR testing. If necessary, Abraxis requests that the Court hold a *Daubert* hearing and an evidentiary hearing regarding Elan's non-compliance with Rule 26(a)(2)(B).

III. MOTION IN LIMINE TO BAR ELAN FROM INTRODUCING EVIDENCE OF [redacted]

Counsel for Elan questioned Abraxis' witnesses in depositions about the [redacted] This questioning suggests that Elan will attempt to introduce both the [redacted] to support its argument that the paclitaxel in Abraxane is, in fact, crystalline rather than amorphous, which is an ultimate issue of fact. The risk of prejudice, jury confusion and wasted time in admitting the [redacted] evidence substantially outweighs its probative value. Abraxis therefore seeks an order under F.R.E. 403 barring Elan from introducing such evidence at trial.

A. Factual Background.

In 2006, Abraxis [redacted] *See* Email dated 1/9/07 from Cross to Batra (attached as Exhibit A). [redacted] *See* Email dated 1/17/07 from Batra to Cross (attached as Exhibit B). [redacted]

During the deposition of Abraxis' Vice President, Research and Development, Elan asked a series of questions around the [redacted]

Q: [redacted]

A: Yes.

Q: [redacted]

A: [redacted]

* * *

Q: [redacted]

A: Yes, I guess so.

Q: [redacted]

A: Yes.

Transcript of Deposition of Neil Desai at 139:9 – 140:22; 148:11-22 (attached as Exhibit C).

B. The [redacted] Should Be Excluded Under Rule 403.

Rule 403 provides that otherwise relevant evidence "may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury . . . ." Fed. R. Evid. 403. This Court has wide discretion to exclude evidence where the risk of prejudice substantially outweighs evidentiary worth. *Betterbox Comms. Ltd. v. BB Techs., Inc.*, 300 F.3d 325, 330 (3d Cir. 2002). Because the [redacted] is not probative of the issue of infringement and would be prejudicial and cause jury confusion it should be excluded under Rule 403.

1. [redacted] The determination of whether the [redacted] and the determination of whether the paclitaxel in Abraxane is crystalline or amorphous for purposes of infringement are different analyses. There is no reason to think [redacted]

[redacted] *See Conaway v. Smith*, 1989 U.S. Dist. LEXIS 3903, at *7 (D. Kan. Mar. 17, 1989) (administrative decision "was devoid of any probative value" regarding the issues before the court because the issues faced by the agency were "completely different than the issues that the jury faced in the present action.").

Just as an infringement decision likely would not be considered probative to [redacted]

[redacted]

Federal courts have recognized the differences between [redacted] and the requirements of proving infringement. *See Cardiovention, Inc. v. Medtronic, Inc.*, 483 F. Supp. 2d 830, 840 (D. Minn. 2007) (citing cases). In *Cardiovention*, the court refused to admit defendant's submissions to the FDA to prove misappropriation of trade secrets on grounds that the submissions were "misleading and unfairly prejudicial" because they appeared to contain conclusions on factual issues. The court explained that "[i]t would also 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." *Id. See also Univ. of Fla. Research Found., Inc. v. Orthovita, Inc.*, 1998 U.S. Dist. LEXIS 22648, at *80 n.23 (N.D. Fla. Apr. 20, 1998) ("[T]he Court cannot use the FDA [submission] in considering infringement by equivalence, since in addition to comparing the commercial embodiment of the . . . invention, instead of the patent claims, . . . the FDA filing is controlled by a separate regulatory scheme.").

Indeed, because of the differences between the requirements of the FDA and the standards for proving infringement, one district court recently issued sanctions against a plaintiff for arguing to the jury that statements to the FDA regarding "substantial equivalents" were relevant to infringement under the doctrine of equivalents. *See Medtronic Navigation, Inc. v.*

BrainLAB Medizinisch, 2008 U.S. Dist. LEXIS 13483, *24-26 (D. Colo. Feb. 12, 2008) (such an argument to jury was "egregious" and basis for a finding of litigation misconduct).

There is no basis for concluding that [redacted] *Everest Capital, Ltd. v. Everest Funds Mgmt. LLC*, 393 F.3d 755, 764 (8th Cir. 2005) (agency decision had "little probative value" because it was not "based upon an adequate record.").

2. [redacted] also would create a substantial risk of unfair prejudice and jury confusion. The decision of an administrative body carries with it "a certain imprimatur, which creates a substantial risk that the jury will give its conclusions undue deference," and thereby also creates a substantial risk of prejudice to the party against whom it is offered. *PharmaStem Therapeutics, Inc. v. Viacell Inc.*, 2003 U.S. Dist. LEXIS 17137, at *8-9 (D. Del. Sept. 30, 2003). "Even if the jury is instructed to consider the opinion for its limited purposes, there is a strong likelihood that the jury would be confused as to its relevance." *Id.* at *9. *See also John McShain, Inc. v. Cessna Aircraft Co.*, 563 F.2d 632, 636 (3d Cir. 1977) (affirming exclusion of agency decision under Rule 403).

The likelihood of jury confusion is particularly strong where, as here, [redacted] *See Angelo v. Bacharach Instrument Co.*, 555 F.2d 1164, 1176 (3d Cir. 1977) (affirming exclusion of EEOC report under Rule 403 and noting the "dangers of unfair prejudice and misleading the jury inherent in an ex parte EEOC evaluation of the ultimate factual issue in the case."); *Kyle v. City of New York*, 2006 U.S. Dist. LEXIS 61396, at *3-5 (E.D.N.Y. Aug. 7, 2006) (excluding

evidence, on grounds of prejudice and jury confusion, of administrative decision "containing factual conclusions, that, if taken at face value, might reasonably be construed as foreclosing deliberation on an element of [a party's] case . . . .") (citations and quotations omitted).

Further, where the [redacted] the risk for prejudice is increased because the jury could assume the decision is an official government position on a central factual issue in the case. *See Everest Capital*, 393 F.3d at 765 (affirming exclusion of "tentative opinion" of USPTO under Rule 403; opinion "had the potential to unfairly prejudice the defendants if the jury mistakenly viewed it as an official government position on the critical . . . issue that the jury had to decide.").

Admission of [redacted] would likely mislead the jury by suggesting that [redacted] Admission of this evidence also risks complication of the trial and wasted time in that Abraxis will need to put on rebuttal evidence to show that [redacted] Because of the risk of jury confusion and the associated prejudice to Abraxis, [redacted] should be excluded.

Elan should also be precluded from offering into evidence [redacted] is not probative of infringement, and there is a substantial risk that these submissions, combined with [redacted] Because of the risk of unfair prejudice and jury confusion, any [redacted] should be excluded pursuant to Rule 403.

IV. MOTION IN LIMINE TO PRECLUDE ELAN FROM INTRODUCING EVIDENCE AND TESTIMONY REGARDING BYRN'S UNTIMELY SUPPLEMENTAL EXPERT REPORT ON INFRINGEMENT

Abraxis moves for an order *in limine* to exclude the "Supplemental Expert Report" of Dr. Stephen R. Byrn. The report was served 11 weeks after the deadline for serving opening expert reports, after the close of business on the evening before Bryn's deposition, and just one day before the close of expert discovery. Despite its title, Byrn's Supplemental Report did not supplement any previous opinions Byrn provided in this litigation; rather, it offered opinions on topics that were, for Bryn, wholly new. Based on Elan's unjustifiable delay in serving Byrn's Supplemental Report, and the consequent prejudice to Abraxis, Abraxis seeks an order barring Elan from relying on Byrn's report or testimony related to that report at trial.

A. Dr. Byrn's "Supplemental" Report Prohibited By Scheduling Order

The amended scheduling order agreed to by the parties and ordered by the Court required opening expert reports to be served by September 28, 2007. Answering expert reports, in turn, were due on October 29, 2007. The expert discovery cut-off was December 14, 2007. (D.I. 295)

Elan timely served eight opening expert reports. These reports included *seven* reports on infringement and one report on damages. Elan did not serve an opening expert report from Byrn. Elan timely served five answering expert reports. Among Elan's answering reports was one by Byrn, entitled "Dr. Stephen R. Byrn's Answering Report to Dr. Mansoor Amiji's Expert Report of September 27, 2007" ("Byrn Ans. Report"). Dr. Amiji's Expert Report, and Dr. Byrn's Answering Report, addressed the "validity and enforceability" of the '363 and '025 patents. Neither report addressed the issue of infringement. *See* Byrn Ans. Report, ¶ 1 (Exhibit D) ("I have been asked by Elan Pharma International Limited to provide my opinions concerning the validity and enforceability of U.S. patent number [5,399,363] and U.S. patent number [5,834,025].").

Expert depositions commenced after the exchange of answering expert reports. Byrn attended the depositions of two of Abraxis's experts, Drs. Amiji and Atwood. (*See* Byrn Supplemental Report, ¶ 2 (Exhibit E); *see also* Byrn Tr. 281:21-282:5 (Exhibit F)). Each of these experts had provided an opening report on the issue of invalidity and enforceability, and a rebuttal report on the issue of non-infringement. These depositions occurred before the service of Byrn's Supplemental Report.

On December 13, 2007, one day before the close of expert discovery, Elan served a report entitled "Dr. Stephen R. Byrn Supplemental Report on Infringement" (the "Supplemental Report"). The Supplemental Report was served via e-mail following the close of business on the day before Byrn's scheduled 9:00 a.m. deposition (D.I. 416). The Supplemental Report was served 11 weeks after the deadline for opening expert reports and 6 ½ weeks after the deadline for answering expert reports.

Abraxis's counsel did not have sufficient opportunity to review the Supplemental Report and exhibit thereto in advance of Byrn's deposition. Nor did Abraxis's counsel have sufficient opportunity to select exhibits and prepare a cross-examination on the new opinions in Byrn's Supplemental Report. Abraxis therefore did not question Byrn about the substance of the Supplemental Report. Abraxis's counsel stated on the record at Byrn's deposition that "this supplemental expert report was received by me at 7:00 last night. It is – it is beyond the deadline set by the court, and Abraxis considers it to be a non-event." (*See* Byrn Tr. at 282:6-11 (Exhibit F).

Elan has confirmed it may call Dr. Byrn to testify at trial regarding his opinions in this Supplemental Report. (*See* E-mail from S. Scheve dated March 5, 2008) (Exhibit G). Abraxis therefore moves to exclude Byrn's cumulative and late-served Supplemental Report.

B. Dr. Byrn's Supplemental Report Should Be Excluded Under Rule 37

Federal Rule of Civil Procedure 37 allows the Court to sanction a party for abusing the discovery process, including precluding evidence when a party's conduct is neither substantially justified nor harmless. Fed. R. Civ. P. 37(c)(1). This Court has excluded untimely expert reports under Rule 37. In *Praxair, Inc. v. ATMI, Inc.*, 445 F. Supp. 2d 460 (D. Del. 2006), for example, defendants moved for a new trial arguing that the Court erred in excluding one of their supplemental expert reports. The expert report at issue had been served after the close of expert discovery, on the morning of the expert's deposition. The new report contained "new testing, conclusions and theories" that had not been set forth in the original report. *Id.* at 470. In denying the motion for a new trial, the Court found that there had been no "substantial justification" for defendants' delay in producing the report. It concluded that the "burden should not be shifted to Praxair to study and analyze the supplemental expert report overnight to redeem ATMI's flawed discovery strategies." *Id.* at 470-71.

As in *Praxair,* Elan's late production of the Supplemental Report was neither substantially justified nor harmless. It was not justified to serve a late expert report after the clear deadline for doing so simply because the expert formulated additional opinions on issues not addressed in his earlier report, after attending the depositions of other experts. The issue on which he opines – infringement – is central to the case and an issue Elan was obligated to address in its initial expert reports. Moreover, the information relied on by Byrn to formulate his infringement opinion was known at the time of his initial report. There was no excuse for the failure of Elan to serve an opening expert report by Byrn on infringement if they wanted to. The noninfringement evidence that Bryn addresses in his report had been disclosed in Abraxis's interrogatory responses. Although Byrn premised his new report on his attendance at Drs.

Atwood's and Amiji's depositions, he does not rely on that testimony in the Supplemental Report. (Supplemental Report, ¶ 2 (Exhibit E); Byrn Tr. 281:19-24 (Exhibit F)). What Byrn does rely on are Abraxis documents produced in March, June and August of 2007 (one document was produced after the opening reports and that was related to Dr. Atwood's report). (Supplemental Report, Appx. A (Exhibit E)).

The fact that Byrn's report is styled as a "supplemental report" does not save it. Under the Scheduling Order, Elan was obligated to serve expert reports on the issues for which it bore the burden of proof on September 28, 2007. In addition, the Scheduling Order did not provide for the service of "supplemental reports"'. Even if it had, Byrn's report is not a supplement of his earlier opinion within the meaning of the Federal Rules. Fed. R. Civ. P. 26(e)(1) provides that a party is under a duty to supplement if the information is "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." That subsection further provides that "with respect to testimony of an expert from whom a report is required under subdivision (a)(2)(B) the duty extends both to information contained in the report and to information provided through a deposition of the expert." These provisions do not apply here. The Supplemental Report does not correct errors or supplement Byrn's original report. As Byrn admits, it is an "additional opinion" that covers an entirely new topic – infringement – that was not addressed in the original report, which was limited to the issues of invalidity and unenforceability of the patents in suit. (*See* Supplemental Report, ¶ 2 (Exhibit E)). Nor was the Supplemental Report – which occurred prior to Byrn's deposition – necessary to correct an aspect of his deposition testimony.[4]

[4] In addition to the *Praxair* case, courts systematically exclude untimely expert reports that purport to be "supplements" of the expert's earlier opinions. *Akeva L.L.C. v. Mizuno Corp.*, 212 F.R.D. 306, 310 (M.D.N.C. 2002) (granting defendants' motion to exclude supplemental expert

The late service of the Supplemental Report further prejudiced Abraxis because it did not allow Abraxis any time for follow-up discovery in response to the opinion, including obtaining a rebuttal report from one of its own experts. *See, e.g.*, *Transclean Corp.* 101 F. Supp. 2d at 796 (party would be prejudiced by opponent's late-disclosure of expert report because untimely disclosure "effectively denies [party] the opportunity to depose [expert] on the new opinions which were added to his initial report, much less develop rebuttal expert opinion evidence, in view of the rapidly approaching Trial date.").

C. Dr. Byrn's Supplemental Report and Testimony Is Cumulative

The Supplemental Report should also be stricken because it is cumulative of Elan's other expert reports. Footnote 5 of this Court's Final Pretrial Order limits the parties to "[o]nly one expert witness on each subject for each party. . . absent good cause shown." Elan has not and cannot show good cause for the cumulative testimony. Elan served *seven* redundant opening expert reports that, like the Supplemental Report, address the issue of infringement. Because Byrn's testimony on infringement is cumulative of Elan's other experts, it should not be allowed. Allowing such cumulative testimony would waste judicial resources and the jury's time. This provides a separate reason that Byrn's testimony on infringement should not be allowed.

For the above reasons, Abraxis respectfully requests that this Court issue an order *in limine* excluding the Supplemental Report and precluding any testimony relating to the report.

---

report containing new opinions and testing and disclosed after the exchange of expert reports and discovery deadline; "[t]o construe supplementation to apply whenever a party wants to bolster or submit additional expert opinions would reek (*sic*) havoc in docket control and amount to unlimited expert opinion preparation."). *See also Transclean Corp. v. Bridgewood Servs.*, 77 F. Supp. 2d 1045 (D. Minn. 1999) (excluding supplemental expert report containing new theories where all materials relied upon were available to expert prior to discovery cut-off and at early stages of litigation); *Transclean Corp. v. Bridgewood Servs.*, 101 F. Supp. 2d 788 (D. Minn. 2000) (excluding supplemental report of expert containing new opinions and disclosed after the close of discovery and one month before trial).

V. MOTION IN LIMINE TO PRECLUDE ELAN FROM INTRODUCING INTO EVIDENCE AT TRIAL ANY EXHIBIT OR OTHER EVIDENCE, ARGUMENTS OR CONTENTIONS, THAT ELAN HAS NOT PROVIDED TO ABRAXIS AS OF THE DATE OF THIS MOTION – TWENTY DAYS AFTER ELAN'S PRETRIAL DISCLOSURES WERE DUE.

Contravening Local Rule 16.3(d)(1), as well as the purpose of pretrial procedure, and this Court's own Form Order, Elan has refused to disclose, in the pretrial order, any of the exhibits or other evidence it intends to rely on at trial in response to Abraxis' invalidity and unenforceability claims. Elan's refusal to disclose the evidence it plans to rely on has prejudiced Abraxis by leaving it unable to adequately prepare for trial. To ensure a fair trial and an even playing field, Abraxis requests that the Court bar Elan from introducing into evidence at trial any exhibits or other evidence not included in the pretrial submissions it provided to Abraxis as of the date of this motion – 20 days after they were due.

A. Factual Background.

On March 7, 2008, a date specified by Local Rule 16.3(d)(1) and agreed to by the parties, Elan forwarded to Abraxis Elan's portions of the pretrial order, including Elan's trial exhibit list (the "Exhibit List"). (Exhibit H.) On reviewing the Exhibit List, Abraxis realized that there appeared to be no listed exhibits relating to Elan's response to Abraxis's invalidity and unenforceability claims. Abraxis contacted Elan to inquire whether Elan's Exhibit List included all of the exhibits that Elan might use in its defense of Abraxis' invalidity and unenforceability claims, in addition to the exhibits Elan might use in its case-in-chief. (Email from Budicak to Day dated Mar. 20, 2008) (Exhibit I). Elan responded that it "ha[d] not provided Abraxis with rebuttal documents, in accordance with Chief Judge Sleet's form pretrial order." (Email from Maguire to Budicak dated Mar. 26, 2008, Exhibit J).

Having received only partial disclosures from Elan, Abraxis was forced to prepare its exhibit list and other disclosures without the benefit of having Elan's full exhibit list to respond to. In its pretrial submissions, Abraxis fully disclosed to Elan all of the evidence it intends to rely on at trial, including evidence it intends to introduce in defense of Elan's infringement case.

Upon further review of Elan's pretrial submissions, it appears that Elan has also failed to provide Abraxis with deposition designations for testimony it will offer by deposition in support of its defense of Abraxis' invalidity and unenforceability cases. Abraxis cannot determine whether the remaining parts of Elan's pretrial submissions disclose all of the evidence, arguments and contentions that Elan intends to rely on at trial.

Because Elan has taken the position that it is not required to disclose the exhibits or deposition testimony it will use in response to Abraxis' invalidity and unenforceability cases, Abraxis is unable to fully prepare for trial.

B. Elan Should Be Precluded From Introducing Into Evidence At Trial Any Exhibit Or Other Evidence, Arguments, Or Contentions That Elan Has Not Provided To Abraxis As Of The Date Of This Motion – Twenty Days After Elan's Pretrial Disclosures Were Due To Be Served.

1. This Court's Pretrial Disclosure Expectations Are Clear.

It is beyond peradventure that the purpose of a pretrial order is to enable each party to prepare for trial by requiring full disclosure of evidence, theories, and defenses. *Becton Dickinson & Co. v. Tyco Healthcare Group LP*, 2006 U.S. Dist. LEXIS 14999 (D. Del. 2006) ("The Federal Rules of Civil Procedure were adopted, in part, to eliminate the element of 'surprise' in litigation."). The Delaware Local Rules reflect and effectuate that purpose. *See* Local Rule 16.3. Accordingly, a party's failure to fully disclose all evidence, theories, and defenses will result in preclusion of that material at trial. *See Philips Elecs. N. Am. Corp. v. Contec Corp.*, 2005 U.S. Dist. LEXIS 3718, at *14-17 (D. Del. Mar. 8, 2005), *aff'd*, 177 Fed.

Appx. 981 (Fed. Cir. 2006) (stating that "courts have repeatedly held that the pretrial order limits the evidence that may be presented at trial," and holding that a theory not included in the pretrial order was waived); *Rockwell Int'l Corp. v. United States*, 127 S. Ct. 1397, 1409 (2007) ("[C]laims, issues, defenses, or theories of damages not included in the pretrial order are waived even if they appeared in the complaint") (quoting *Wilson v. Muckala*, 303 F.3d 1207, 1215 (10th Cir. 2002)); *Tristrata Tech., Inc. v. ICN Pharms., Inc.*, 2004 U.S. Dist. LEXIS 6559, at *6 (D. Del. Apr. 7, 2004) ("[Plaintiff] waived its right to request an accounting by not including it in its Pretrial Order."); *Dean v. Brandywine Studios*, 2003 U.S. Dist. LEXIS 2299, at *4 (D. Del. Feb. 10, 2003) ("Having failed to raise the issue in the pretrial order and having failed to address it at trial, defendants have waived any right they might have had to assert a statute of limitations defense.").

The Local Rules state what must be included in the pretrial order. For example:

> [C]ounsel for all parties shall meet and confer in order to premark and exchange *all trial exhibits* and otherwise discuss the contents of the proposed pretrial order, which *shall* include the following:
>
> > (6) A list of premarked exhibits which each party *intends to offer* at trial . . . .
> >
> > (7) The names of *all* witnesses a party *intends to call* to testify, whether the witness will testify in person or by deposition and, if by designation, a list of deposition designations

Local Rule 16.3(c) (emphasis added). The inclusion of the word "shall" and the reference to "all" trial exhibits and witnesses plainly conveys that disclosure be complete. All exhibits a party "intends to offer" at trial must be disclosed, and all witnesses a party "intends to call" at trial must be disclosed. This encompasses all exhibits and testimony a party intends to offer in

its defense, and Abraxis has accordingly listed all such exhibits in its pretrial submissions. Elan, in contrast, has attempted to hide the ball.

To further guide parties in preparing pretrial submissions, this Court has issued a form Pretrial Order ("Form Order"). The Form Order directs the parties to include the following in their final pretrial order:

> (c) *except for rebuttal exhibits*, schedules in the form set out in the attached Schedule (c) of;
> 1) all exhibits [], including documents, summaries, charts and other items expected to be offered into evidence
> (f) a list of all depositions, or portions thereof, to be read into evidence . . . .

Form Order at (2)(c)(emphasis added). The provisions of the Form Order are obviously not intended to relieve the parties of the pretrial disclosure requirements of the Local Rules, but rather to provide parties with an example of how it expects the Local Rules to be applied.

Additionally, the Court has made its expectations with regard to the comprehensiveness of pretrial disclosures known on multiple occasions. In fact, as recently as March 18, 2008, at a CLE presented jointly by this Court and the Delaware Chapter of the Federal Bar Association, the Judges of this Court discussed the need for and timing of disclosure of exhibits, expressing generally its anticipation of full disclosure to avoid surprise at trial. (CLE titled "Federal Practice in the District of Delaware: Openings, Closings, and Case Themes," Judicial Roundtable, Mar. 18, 2008) (discussing the timing and need for the disclosure of Powerpoint demonstrative exhibits, as well as discussing the use of impeachment exhibits during trial).

2. Elan's Interpretation of This Court's Form Order is an Attempt to Avoid Full Disclosure and Gain an Unfair Advantage at Trial.

Elan's position that the Form Order's reference to the exclusion of "rebuttal exhibits" permits it to not disclose any exhibits it will be using in responding to Abraxis' invalidity and

unenforceability cases intentionally misinterprets this Court's words in an attempt to gain an unfair advantage at trial. This Court has already made it clear to Elan that it will not put up with such "hide the ball" tactics, yet Elan continues to employ them. (*See* Order Granting Abraxis' Motion to Dismiss Newly Added Infringement Contentions dated December 6, 2007 at n.2) ("[I]t appears that Elan takes the position it does in order to gain some tactical advantage over Abraxis, and the court will not tolerate this type of hide the ball behavior.")

Elan's interpretation of the Form Order's reference to "rebuttal exhibits" is specious. It is not credible to argue that the Court's intention is for parties to disclose only some of the evidence on which they intend to rely at trial, and to keep other evidence a surprise. Furthermore, the interpretation of the Form Order that is consonant with the Local Rules and in keeping with the spirit and purpose of pretrial procedure, is that "rebuttal exhibits" refers to only those exhibits that, at the time the pretrial order was prepared, a party could not have reasonably expected or anticipated that it might rely on at trial. Here, Elan has the benefit of Abraxis' detailed interrogatory responses and expert testimony; it cannot credibly claim it does not know what case Abraxis will put on at trial.

That this is the correct interpretation of the phrase "rebuttal exhibits" is made clear by the Court's other use of the word "rebuttal" in the Form Order, relating to "rebuttal witnesses." Footnote 4 of the Form Order states: "Any witness not listed will be precluded from testifying absent good cause shown, except that each party reserves the right to call such *rebuttal witnesses* (*who are not presently identifiable*) as may be necessary, without prior notice to the opposing party." (emphasis added). To read the Court's Form Order's reference to "rebuttal exhibits" to be significantly broader than that defeats the purpose of the pretrial order: full disclosure.

Dated: April 4, 2008

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ *Karen E. Keller*

Josy W. Ingersoll (#1088)
Elena C. Norman (#4780)
Karen E. Keller (#4489)
Michele Sherretta Budicak (#4651)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, DE 19801
(302) 571-6672 Telephone
(302) 576-3301 Facsimile
kkeller@ycst.com

Attorneys for Defendant

Of Counsel:

MORRISON & FOERSTER, LLP

Michael A. Jacobs
425 Market Street
San Francisco, CA 94105-2482
(415) 268-7000 Telephone
(415) 268-7522 Facsimile
MJacobs@mofo.com

Emily A. Evans
755 Page Mill Road
Palo Alto, CA 94304-1018
(650) 813-5600 Telephone
(650) 494-0792 Facsimile
EEvans@mofo.com

CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire, hereby certify that on April 11, 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:

Steven J. Balick, Esquire
ASHBY & GEDDES
500 Delaware Avenue, 8th Floor
Wilmington, DE 19801

I further certify that on April 11, 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:

BY E-MAIL

Linda Glover, Esquire
Stephen Scheve, Esquire
BAKER BOTTS L.L.P.
One Shell Plaza
910 Louisiana Street
Houston, TX 77002-4995
steve.scheve@bakerbotts.com

Paul F. Fehlner, Esquire
BAKER BOTTS L.L.P.
30 Rockefeller Plaza
New York, NY 10112-4498
paul.fehlner@bakerbotts.com

William J. Sipio, Esquire
1375 Brentwood Road
Yardley, PA 19067
sipz25@aol.cm

YOUNG CONAWAY STARGATT
& TAYLOR, LLP

/s/ Karen E. Keller

Josy W. Ingersoll (No. 1088)
jingersoll@ycst.com
Elena C. Norman (No. 4780)
enorman@ycst.com
Karen E. Keller (No. 4489)
kkeller@ycst.com
Michele Sherretta Budicak (No. 4651)
mbudicak@ycst.com
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19899
(302) 571-6600

Attorneys for Defendant
ABRAXIS BIOSCIENCE, INC.

EXHIBITS A-C

REDACTED IN THEIR ENTIRETY

EXHIBIT D

Elan Pharma International Ltd.

Plaintiff

v.

Abraxis Bioscience, Inc.

Defendant

Dr. Stephen R. Byrn Answering Report To

Dr. Mansoor Amiji's Expert Report of September 27, 2007

I. Background

1. I have been asked by Elan Pharma International Limited to provide my opinions concerning the validity and enforceability of U.S. patent number 5,399,363 ("the '363 patent," attached as Exhibit 1) and U.S. patent number 5,834,025 ("the '025 patent," attached as Exhibit 2) and I am prepared to testify as an expert witness if called to do so. I have focused my attention on prior art. I understand that Dr. Mark Manning will address issues of enablement, written description, indefiniteness, and materiality of certain data raised in the Expert Report of Dr. Mansoor Amiji dated September 27, 2007.

2. Specifically, I have been asked to consider and respond to the opinions concerning obviousness, and materiality with respect to the Domb reference and the '363 patent. I have also been asked to consider and respond to the opinions concerning the teaching or knowledge by one of ordinary skill in the art of the particles in claims 1 to 3 and 13 to 15 of the '025 patent by 1995.

3. I am compensated for my services in this case at the rate of $600.00 per hour. During the last four years I have provided expert testimony in nine litigations. A listing of those litigations is attached as Exhibit 3. I attach as Exhibit 4 my current curriculum vitae, which lists my publications during the last ten years.

4. I received a Ph.D. in Chemistry from the University of Illinois in 1970 and was a post-doctoral fellow at UCLA from 1970 to 1972. In 1972, I became a professor of Pharmacy at Purdue University. I was Head of the Department of Medicinal Chemistry and Pharmacology at Purdue University in the School of Pharmacy and Pharmaceutical Sciences form 1988-1994. I was the Director of the Center for AIDS Research at Purdue form 1988 until 1998, and since 1994, I have been the Head of the Department of Industrial and Physical Pharmacy. I became the Charles B. Jordan Professor of Medicinal Chemistry in 1992. I am familiar with the curriculum taught to all students in the Department of Industrial and Physical Pharmacy from 1992 to present.

EXHIBIT E

Elan Pharma International Ltd.

Plaintiff

v.

Abraxis Bioscience, Inc.

Defendant

D. Del.

06-438 GMS

Dr. Stephen R. Byrn

Supplemental Report on Infringement

I. Background

1. I am the same Stephen R. Byrn who filed an Expert Report on October 29, 2007 concerning issues of validity and enforceability of US Patent Nos. 5,399,363 and 5,834,025 in this matter. My professional experience and credentials are outlined in that Expert Report, which I incorporate in this Supplemental Report by reference.

2. I only recently attended the depositions of Abraxis's designated experts, Jerry Atwood and Mansoor Amiji, from which I have now formulated additional opinions, and in particular, opinions about infringement of the '363 Patent. I also learned during the deposition of Dr. Amiji that he recommended me to Abraxis's counsel as an expert in crystal analysis. My other qualifications are outlined in my CV attached to my report dated October 29, 2007. Thus, I am prepared to testify as an expert witness on issues of infringement as well as validity, if called to do so.

3. I am also prepared to give a tutorial to the Judge and/or jury on issues relating to the formulation of pharmaceutical solids including topics such as nanoparticles, crystallinity, amorphousness, X-ray powder diffraction techniques, TEM, and cryo-TEM techniques, solvent precipitation, and solvent evaporation processes, if called to do so.

4. In connection with my opinions regarding issues of infringement I have reviewed the reports of Dr. Atwood dated September 28, 2007 and October 29, 2007, Dr. Amiji's report dated October 29, 2007, in addition to being present at their respective depositions. I have also reviewed Dr. Brittain's report dated September 28, 2007 and Dr. Munson's report dated September 28, 2007. I have also reviewed the XRPD testing and TEM testing conducted by Abraxis on ABI-007, which I understand to be Abraxane. A complete list of the materials that I have reviewed and relied upon in connection with this supplemental report is attached as Exhibit A.

II. Technological Background

5. Typically, a solid is characterized as "crystalline" when it has molecules which are arranged in an orderly pattern and a solid is characterized as "amorphous" when it has molecules randomly arranged such that the molecules are disordered.

6. There are methods for determining presence of crystalline material. These methods include conventional X-ray powder diffraction (XRPD) and solid state NMR (ssNMR). XRPD has several limitations in its ability to determine crystallinity. Some of the limitations include XRPD's inability to detect crystallinity in mixtures and in nanosized materials.

7. The limitations of XRPD in detecting crystallinity in nanosized materials is well-recognized. S. Bates et al., Pharmaceutical Research, 23, 2333-2349 (2006). To detect crystallinity with conventional XRPD, the sample must contain many planes to diffract the X-rays. ssNMR has been used to overcome the limitations of XRPD. It can detect crystallinity in a broader range of samples. Accordingly, for detecting crystallinity in nanosized materials ssNMR is a more powerful analytical technique.

8. Electron Microscopy (EM) is a subjective technique used by some to detect crystallinity, but it requires the viewer to make a subjective determination based on the shape or morphology of the particle. Because crystalline materials can exist without sharp edges, particularly at the nanoscale, EM is not a reliable tool for establishing crystallinity. Further, EM is even more unreliable because it views a limited number of particles, which is not a statistically significant sample.

III. The '363 Patent

9. The '363 Patent is directed to stable nanoparticles that have a poorly water-soluble crystalline anticancer agent stabilized by surface modifier. The '363 patent teaches enhanced efficacy of anticancer agents as a feature of the nanoparticles. The inventiveness of the '363 Patent involves, in part, the stabilization of the submicron anticancer agents by preventing or reducing agglomeration/aggregation and/or Ostwald Ripening of the particles to large sizes.

IV. The Claims of the '363 Patent and the Order Construing the Terms

10. The claims of the '363 patent recite "particles consisting essentially of 99.9-10% by weight of a crystalline medicament useful in treating cancer." The claim language further recites "wherein said medicament is selected from the group consisting of . . . taxol . . . ."

11. The Court construed the phrase "particles consisting essentially of" to mean "the particles, composed of crystalline medicament and surface modifier, may also include other ingredients that do

not affect their basic and novel properties, and are essentially free of solvent and other contaminants." In my opinion, the novel and basic properties of the particles of the '363 patent include particle size stability, reduced toxicity, and enhanced efficacy. Based on the Court's construction of the phrase "particles consisting essentially of," the particles may include materials in addition to crystalline medicament and non-crosslinked surface modifier.

12. The Court construed the phrase "crystalline medicament useful in treating cancer" to mean "a medicament suitable for treating cancer that has a regular arrangement of atoms or molecules in a space lattice, as distinguished from amorphous." The Court's construction of this phrase includes crystalline solids with ordered atoms or molecules, as distinguished from an amorphous solid, which have, as Dr. Atwood opines on page 1 of this Rebuttal Report, a "complete lack of ordering of the molecules." A solid material that is a mixture having both ordered and disordered phases would fall within the Court's construction because a regular arrangement of atoms or molecules in a space lattice would exist in such solid material.

13. Claim 1 of the '363 patent further recites "and having a non-crosslinked surface modifier adsorbed on the surface thereof in an amount of 0.1-90% by weight and sufficient to maintain an average effective particle size of less than 1000 nm." The Court construed the term "non-crosslinked" to mean that "the individually adsorbed molecules of the surface modifier are essentially free of intermolecular crosslinkages." Intermolecular crosslinkages are linkages between two or more different surface modifier molecules. Thus, for adsorbed surface modifier molecules to be essentially free of intermolecular crosslinkages there should not be linkages between most of the individually adsorbed surface modifier molecules. This means that the surface modifier molecules are free to dissociate from the particle and allow for delivery of the medicament. Accordingly, the adsorbed surface modifier molecules should not entrap or form a shell around the particle through linkages between the adsorbed surface modifier molecules.

14. The Court also construed the phrase "adsorbed on the surface" to mean "a molecule retained at the surface of the crystalline medicament that does not chemically bond with such medicament." Thus, a surface modifier may be adsorbed on the surface through any interaction other than a chemical bond.

15. The Court also construed the phrase "in an amount of 0.1-90% by weight and sufficient to maintain an average effective particle size of less than 1000 nm" to mean "an amount of surface modifier that maintains the size of the particles such that at least 90% of the particles have a number average particle size of less than about 1000 nanometers." The Court's construction is based on the definition provided in the '363 patent at col. 4, ll. 65-68. "By 'an effective average particle size of less than about 1000 nm' it is meant that at least 90% of the particles have a number average particle size of less than about 1000 nm when measured by the above-noted techniques." The "above-noted techniques" referenced in the patent refer to "conventional particle size measuring techniques well known to those skilled in the art, such as sedimentation field flow fractionation, photon correlation spectroscopy, or disk centrifugation." Col. 4, ll. 60-64. In my opinion, the Court's claim construction indicates that the particles of the '363 patent have a particle size distribution such that 90% of the particles have a particle size less than 1000 nm (for claim 1), less than 400 nm (claim 2), and less than 300 nm (claim 3). Such particle size distributions are commonly referred to in the art as D_{90} distribution.

V. Legal Standards of Infringement

16. To determine "literal infringement" I have been asked to compare Abraxane to the asserted claims of the '363 patent. It is my understanding based on information from counsel and my experience with patents that an accused product literally infringes a claim of a patent when every element or limitation of the asserted claim is present in the accused product.

17. I have been informed by counsel that a party who actively induces infringement of a patent shall be liable as an infringer. Active inducement of infringement occurs when a party, such as a product manufacturer, provides the necessary material and information to allow another party, such as an end-user, to infringe a patent. The inducer must have actual knowledge of the patent at issue.

18. I have been informed by counsel that one can be liable for "contributory infringement" when a party sells a material component of a patented invention for which there is no substantial non-infringing use for the component.

19. I have been informed by counsel that if a patent claim is not literally infringed, the claim may be infringed under the doctrine of equivalents. Infringement under the doctrine of equivalents occurs

where the accused product or process contains an element that performs substantially the same function in substantially the same way to achieve substantially the same result as that of a claim limitation, or if there is an insubstantial difference between the claim limitation and a corresponding element in the accused product or process.

VI. Abraxis's Testing of Abraxane is Flawed

20. I have reviewed the X-Ray Powder Diffraction (XRPD) testing performed by Abraxis, which was submitted to the FDA as part of the NDA 21-660 for Abraxane, including the underlying raw data collected by Micron, Inc. In my opinion, this testing is not reliable to establish that Abraxane is purely amorphous. The reasons for the unreliability include the following:

- The XRPD did not follow USP standards. Nor was the XRPD performed with the experimental rigor and detail I would expect for a pharmaceutical product.
- The XRPD samples were "homogenized" and/or "chopped," which is known to induce phase transformations in solids. The samples tested were neither Abraxane nor the nanoparticles as formulated and sold for administration to humans.
- The XRPD paclitaxel standards were inappropriate because their crystal size was on the order of 5 to 500 microns.

VII. The Appropriate Test of Crystallinity

21. While XRPD is typically useful in detecting crystallinity of bulk active pharmaceutical ingredients (APIs), submicron materials are better tested by alternative techniques like ssNMR. Abraxane is claimed to be composed entirely of submicron nanoparticles and free HSA.

22. Abraxane is a 9:1 ratio of amorphous HSA to paclitaxel; thus, Abraxane is only 10% paclitaxel. The commonly accepted crystalline detection limits of conventional XRPD is about 10%. Thus, even if all the paclitaxel in Abraxane were crystalline, I would expect XRPD to be limited in its ability to detect it.

23. XRPD's limitations are compounded when dealing with submicron particles. As particle size is reduced, the XRPD peak-width increases and peak-height decreases. Additionally, submicron

particles are smaller and more likely to include regions of disorder, making detection of crystallinity more difficult.

24. The majority of HSA in the formulation is not associated with the nanoparticle, and the majority of paclitaxel in the formulation is in the nanoparticle. Thus, the free HSA effectively dilutes the paclitaxel present in the nanoparticles. Such dilution was observed in XRPD differences between the raw paclitaxel standard and the physical mixture of raw pacltiaxel and HSA. Specifically, the peak at ~12 degrees 2θ in the physical mixture showed peak-height reduction and peak-width broadening as compared to the raw paclitaxel standard.

25. Abraxis's XRPD method is not reliable for determining whether paclitaxel in Abraxane is crystalline or amorphous.

26. I have reviewed the documents cited in Dr. Atwood's Rebuttal Report concerning XRPD and TEM/cryo-TEM. None of these documents establish that the paclitaxel in Abraxane is amorphous.

VIII. Abraxane Contains Particles That Infringe The '363 Patent

27. According to Abraxis, Abraxane is a 9:1 ratio of HSA to paclitaxel. The formulation is free of solvent. The nanoparticles in Abraxane have a mean size of 120 to 150 nm, and contain nanoparticles of about 82% paclitaxel and 18% HSA.

28. Dr. Munson, an expert in ssNMR characterization of nanoparticles, has reported that Abraxane contains particles that meet the 99.9-10% crystalline medicament limitation of the '363 Patent.

29. Nothing in the CMC section of Abraxis's FDA filing suggests that the HSA present on the surface of the nanoparticles in Abraxane are crosslinked. In fact, Abraxis has represented to FDA that the HSA is "unmodified."

30. Furthermore, in Dr. Amiji's rebuttal report he concludes that the nanoparticles in Abraxane contain 45% HSA monomer. Even if I accept Dr. Amiji's conclusion as true, the nanoparticles in Abraxane meet the non-crosslinked surface modifier limitation of the '363 Patent:

Nanoparticle: 18:82 HSA to Paclitaxel

82% (percent of particle that is paclitaxel)
45% x 18 = 8.1% (percent of particle that is monomeric albumin)
55% x 18 = 9.9% (percent of particle that is non-monomeric albumin)

8.1% clearly falls within the range of 0.1-99.9%.

31. Thus, the Abraxane formulation contains particles consisting essentially of 99.9-10% of a crystalline medicament useful in treating cancer, 90-10% of a surface modifier, other ingredients that do not affect the basic and novel properties of the invention, and are essentially free of solvent and other contaminants.

32. Abraxis reported to the FDA that the HSA is a stabilizing agent that maintains the size of the nanoparticles. Therefore, the HSA is a substance that modifies the surface properties of the paclitaxel in Abraxane, and as such is a surface modifier as recited in the claims of the '363 Patent.

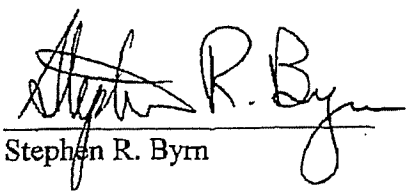
33. Abraxis represented to the FDA that the HSA is "adsorbed" to the surface of the paclitaxel. Thus, the nanoparticles in Abraxane have a surface modifier adsorbed to the surface.

34. The particles of Abraxane are reported to have a mean average particle size of 120 to 150 nm. Further, I understand that Abraxis has admitted that at least 90% of the particles have a number average particle size of less than 300 nm. Thus, the effective average particle size recited in claims 1 (1000 nm), 2 (400 nm), and 3 (300 nm) of the '363 patent is present in the nanoparticles of Abraxane.

35. Abraxis represented to the FDA that HSA is a stabilizing agent. The term "surfactant" was construed by the Court to mean "a stabilizing agent that reduces interfacial tension between oil and water." Accordingly, the HSA adsorbed on the surface nanoparticles in Abraxane is a surfactant.

36. Based on the analysis above, it is my opinion that all of the elements of claims 1, 2, 3, 5, 8, and 12 are present in the Abraxane formulation.

December 13, 2007



Stephen R. Byrn

Appendix A

Documents Reviewed and Relied Upon

ABRX 0117420

ABRX 0148746

ABRX 0150544

ABRX 0151403

ABRX 0151417

ABRX 0151449

ABRX 0151479

ABRX 0151512

ABRX 0151528

ABRX 0151586

ABRX 0151935

ABRX 0151951

ABRX 0153042

ABRX 0153298

ABRX 0153316

ABRX 0284194

ABRX 0378983-9036

ABRX 0532454

ATWOOD 0000159

ABRX 0224829

ABRX 0123712

EXHIBIT F

UNITED STATES DISTRICT COURT

FOR THE DISTRICT

OF DELAWARE

C.A. No.: 06-438 GMS

ELAN PHARMA INTERNATIONAL, LTD.,

Plaintiff,

vs.

ABRAXIS BIOSCIENCE, INC.,

Defendant.

~~~~~~

The deposition upon oral examination of STEPHEN R. BYRN, Ph.D., a witness produced and sworn before me, Linda Mayo Baynes, Notary Public, RPR, CSR, in and for the County of Marion, State of Indiana; taken on the 14th day of December, 2007, at the offices of Baker & Daniels, 300 North Meridian Street, Suite 2700, Indianapolis, Marion County, Indiana; pursuant to Notice. This deposition was taken on behalf of the Plaintiff in the above-captioned matter.
~~~~~~

Q. Since signing your report, have you discovered anything in there that is incorrect?
A. No, not that I can think of. I mentioned some things here today that might have been slight elements that were -- led to confusion, but I haven't found anything other than what we talked about today.
Q. Now, when in your -- if you can tell from your invoice, when did the work on preparing your expert report begin with your involvement?
A. Well, I think it began at that October 8th meeting.
Q. I see. On Page 2517 through 2518, what is that?
A. That's the tally of my hours at the time I produced the documents since November 15th. And then, there's -- this is just boilerplate stuff below that came through some other invoices I had. So, the trip to Chicago, those are not real charges. The correct numbers are just those tables, the 11/18, 11/22, 11/23 and 11/26.
Q. I'm sorry, I don't -- where are you

-- where are you pointing to? I don't see --
A. This (indicating).
Q. What page are you -- if you give me --
A. I'm on --
Q. -- the Bates number, that might be helpful.
A. I'm on 2517.
Q. All right.
So, the trip to Chicago was for another matter?
A. Yeah -- no. I have a boilerplate document that I just paste in, and then, I put the hours in.
Q. Okay.
A. And unfortunately, I see now that it said, trip to Chicago --
Q. Okay.
A. -- but I didn't add anything to it.
And these numbers below here are also just boilerplate and should be ignored.
Q. I see. Well, this is a draft invoice; you haven't sent this out yet?
A. I'm just tallying the doc -- the

hours.
Q. Understood.
A. I'll tally the hours after this meeting and -- and send a second invoice out.
Q. Understood.
Now, on the -- Page 25 -- well, actually, at the bottom of 2517, it states, "Dr. Stephen Byrn, Improved Pharma, LLC."
Do you see that?
A. Yes.
Q. What is Improved Pharma, LLC?
A. That's a consulting company that my wife and I set up to handle my consulting, my consulting work that I do.
Q. And why did you set up a company for --
A. It's --
Q. -- your consulting?
A. -- much easier to handle travel and expenses, and so on, if you have a company.
And in some occasions, we're -- I'm asked to do experiments. And so, it -- the company can take in payments for experiments, and then pay out experimental -- pay

contractors, and so on.
Q. Doctor, does your report that is marked as Byrn Exhibit 1 reflect all the opinions relating to invalidity, validity for materiality to which you expect to testify at trial?
A. I haven't -- I have a supplemental report, and I haven't gone through it in the detail to answer that question. There might be some -- some issues related to those topics that are in my supplemental report.
But other than my supplemental report and this report, that's all the opinions I have right now, but my attorneys may ask me to give other opinions at trial.
Q. So, this is the supplemental report that was served yesterday?
A. Yes.
Q. When were you told you would be preparing a supplemental report, Doctor?
A. Well, there was ongoing discussion -- from the time I attended Mr. -- Dr. Atwood's report, there was ongoing discussion about whether or not I would do that.
Q. Is that why you were asked to attend

Page 282

Dr. Atwood's deposition, because it was contemplated you would do a supplemental expert report?

A. I -- I don't know. I have no idea. I don't think so, but I have no idea.

MS. EVANS: Well, I want to state for the record that this supplemental expert report was received by me at 7:00 last night. It is -- it is beyond the deadline set by the court, and Abraxis considers it to be a non-event.

With that said, I will take one last break. I believe I'm probably done, but I want to just look at some materials and confirm that in my own mind.

So, let's go off the record.

THE VIDEOGRAPHER: We are now going off record in the deposition of Stephen Byrn.

Time is 5:26 P.M..

(AT THIS TIME THERE WAS A BRIEF RECESS TAKEN, AFTER WHICH THE FOLLOWING PROCEEDINGS WERE HAD:)

THE VIDEOGRAPHER: We're back on record in the deposition of Stephen Byrn.

Time is 5:37 P.M..

Page 283

Q. Dr. Byrn, what other litigation matters are you working on at this time?

A. That was -- I think I provided that in my curriculum vitae.

Do you want me to try to do what I can from memory or -- it's in my -- I -- I don't mean in my curriculum vitae. I think I provided the cases I've served on in my -- at some point in my expert report, and maybe I didn't.

Q. So, let's -- I think it's Tab 3; is that right? Although that's --

A. Yes, that's the tab.

Q. Are there cases in addition to what's listed at Tab 3 of your report in which you have consulted but not yet testified?

A. There's one -- at least one that is -- that's correct. That's correct.

Q. Which is that one?

A. It's a -- actually, there may be two. Trying to remember. I'm sorry, my memory -- one I know I testified, so let me give you that one. I think there's only one that I can remember right now.

It's a matter involving Kirkland. I

Page 284

work with a firm -- law firm Kirkland, and it involves the drug called Azalasting (phonetic).

Q. What is the general nature --

A. It's -- Azalasting's a nasal spray. It's a -- it's a formulation and solid state chemistry case.

Q. What is the general nature of the subject matter that you are -- have been retained to opine on in that case?

A. Validity of the patent, and stability issues are involved.

Q. Now, what --

A. That's probably about as far as I could go.

Q. All right.

Because of confidentiality issues, sir?

A. I think it's confidential. I think the only thing in the public is the law firm and the name of the material.

Q. All right.

So, looking at the list of lawsuits on -- at Tab 3 of your report, in how many of those were you testifying on behalf of

Page 285

the patent holder?

A. In these -- in all of these, I testified on behalf of the patent holder.

In other cases that are not within the last four years, I've also testified against the patent holder.

Q. Can you just tell me in general for each of these matters listed at Tab 3 what was the subject matter of your testimony?

A. I can in general. It's --

Q. Just very in general. I don't want you to --

A. All right.

Q. -- breach any protective orders.

A. Well, I -- I am not -- some of these I -- I'll -- many of these are public, so I can talk about one of them. I don't think I could -- two of them I can't talk about, but the rest of them I can.

So, Prevacid dealt with a formulation. That went to -- there was a trial in Delaware about a month ago, month and a half ago. It's a formulation case.

Q. And what was the nature of your testimony?

EXHIBIT G

From: Steve.Scheve@bakerbotts.com
Sent: Wednesday, March 05, 2008 7:08 PM
To: Evans, Emily A.
Subject: Re: Abraxis: Dr. Byrn

Emily,

Please excuse my tardiness in getting back to you. The flu knocked the legs out from under me beginning last week and I am now forced to travel. My current sense is that Dr. Byrne will be listed in Elan's pre-trial submission provided to you on Friday as a "may call" witness on all topics disclosed in his reports. Final review and decisions, of course, have not yet been made.

Best personal regards.

Steve

----- Original Message -----
From: Evans, Emily A. <EEvans@mofo.com>
To: Scheve, Steve
Cc: Sullivan, Jeffrey D.; Fehlner, Paul F.; Glover, Linda; Riddle, Robert; Chiarini, Lisa
Sent: Mon Mar 03 17:58:15 2008
Subject: RE: Abraxis: Dr. Byrn

Dear Steve,

I have not yet heard back from you on this. Could you please respond?

Thanks,

Emily

From: Evans, Emily A.
Sent: Friday, February 08, 2008 8:00 PM
To: Steve.Scheve@bakerbotts.com
Cc: 'Jeffrey.Sullivan@bakerbotts.com'; PAUL.FEHLNER@bakerbotts.com; linda.glover@bakerbotts.com; Robert.Riddle@bakerbotts.com; Lisa.Chiarini@bakerbotts.com

Subject: Abraxis: Dr. Byrn

Dear Steve:

Please let us know whether Elan intends to call Dr. Byrn to testify on the topics of his supplemental expert report submitted on December 13, 2007, eleven weeks after the due date.

Regards,

Emily

Emily A. Evans
Morrison & Foerster, LLP
755 Page Mill Road
Palo Alto, CA 94304
Tel.: (650) 813-5625
Fax: (650) 494-0792
eevans@mofo.com

==========

To ensure compliance with requirements imposed by the IRS, Morrison & Foerster LLP informs you that, if any advice concerning one or more U.S. Federal tax issues is contained in this communication (including any attachments), such advice is not intended or written to be used, and cannot be used, for the purpose of (i) avoiding penalties under the Internal Revenue Code or (ii) promoting, marketing or recommending to another party any transaction or matter addressed herein.

For information about this legend, go to http://www.mofo.com/Circular230.html

==========

This message contains information which may be confidential and privileged. Unless you are the addressee (or authorized to receive for the addressee), you may not use, copy or disclose to anyone the message or any information contained in the message. If you have received the message in error, please advise the sender by reply e-mail @mofo.com, and delete the message.
==========

EXHIBIT H

REDACTED IN ITS ENTIRETY

EXHIBIT I

From: Budicak, Michele Sherretta
Sent: Thursday, March 20, 2008 3:16 PM
To: 'jday@ashby-geddes.com'
Cc: Ingersoll, Josy; Norman, Elena
Subject: Elan/Abraxis - Exhibits exchanged

John,

I write to confirm our conversation of this morning in which you indicated that you understood Elan's pretrial submissions to Abraxis on March 7th included all of the exhibits that Elan may rely on in its case in chief, as well as all exhibits it intends to use in its defense of Abraxis' invalidity case (excluding "impeachment exhibits" - those in response to what we include in our Exhibit List, which you will receive tomorrow.)

Please let me know if this is incorrect.

Regards,
Michele

Michele Sherretta Budicak
Young Conaway Stargatt & Taylor, LLP
The Brandywine Building
1000 West Street, 17th Floor
P.O. Box 391
Wilmington, DE 19899-0391
Phone: 302-571-6661
Facsimile: 302-576-3446
MSherrettaBudicak@ycst.com

This message may contain confidential attorney-client communications or other protected information. If you believe you are not an intended recipient (even if this message was sent to your e-mail address), you may not use, copy, or retransmit it. If you believe you received this message by mistake, please notify us by return e-mail, and then delete this message. Thank you for your cooperation.

EXHIBIT J

From: LMaguire [lmaguire@ashby-geddes.com]
Sent: Wednesday, March 26, 2008 12:17 PM
To: Budicak, Michele Sherretta; JDay
Cc: Ingersoll, Josy; Norman, Elena; SBalick
Subject: RE: Elan/Abraxis - Exhibits exchanged

Michele,

With respect to your inquiry regarding the scope of exhibits Elan has produced, Elan has not provided Abraxis with rebuttal documents, in accordance with Chief Judge Sleet's form pretrial order.

Best regards,
Lauren

-----Original Message-----
From: Budicak, Michele Sherretta [mailto:MSherrettaBudicak@ycst.com]
Sent: Monday, March 24, 2008 5:27 PM
To: JDay
Cc: Ingersoll, Josy; Norman, Elena; SBalick; LMaguire
Subject: RE: Elan/Abraxis - Exhibits exchanged

John,

Thank you for the clarification. Have you been able to speak with your co-counsel about this yet?

Regards,
Michele

-----Original Message-----
From: JDay [mailto:jday@ashby-geddes.com]
Sent: Thursday, March 20, 2008 3:34 PM
To: Budicak, Michele Sherretta
Cc: Ingersoll, Josy; Norman, Elena; SBalick; LMaguire
Subject: RE: Elan/Abraxis - Exhibits exchanged

Good afternoon Michele. Actually, your confirmation is not correct.
The purpose of my call this morning was to clarify what you meant when you used the terms "rebuttal" exhibits, as opposed to providing a substantive response to either of the questions you asked in our earlier call this morning. I did indicate my understanding that Elan was complying with what Judge Sleet requires in paragraph 2(c) of the form Final Pretrial Order that is posted on his webpage, but I also said that I needed to confirm the specifics of what exhibits Elan has produced to date with my co-counsel before I could answer your questions.

Regards,

John

-----Original Message-----
From: Budicak, Michele Sherretta [mailto:MSherrettaBudicak@ycst.com]
Sent: Thursday, March 20, 2008 3:16 PM
To: JDay
Cc: Ingersoll, Josy; Norman, Elena
Subject: Elan/Abraxis - Exhibits exchanged

John,

I write to confirm our conversation of this morning in which you indicated that you understood Elan's pretrial submissions to Abraxis on March 7th included all of the exhibits that Elan may rely on in its case in chief, as well as all exhibits it intends to

use in its defense of Abraxis' invalidity case (excluding "impeachment exhibits" - those in response to what we include in our Exhibit List, which you will receive tomorrow.)

Please let me know if this is incorrect.

Regards,
Michele

Michele Sherretta Budicak
Young Conaway Stargatt & Taylor, LLP
The Brandywine Building
1000 West Street, 17th Floor
P.O. Box 391
Wilmington, DE 19899-0391
Phone: 302-571-6661
Facsimile: 302-576-3446
MSherrettaBudicak@ycst.com

This message may contain confidential attorney-client communications or other protected information. If you believe you are not an intended recipient (even if this message was sent to your e-mail address), you may not use, copy, or retransmit it. If you believe you received this message by mistake, please notify us by return e-mail, and then delete this message. Thank you for your cooperation.