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**

DEFENDANT ABRAXIS BIOSCIENCE, INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO COMPEL RESPONSES TO INTERROGATORIES AND PRODUCTION OF DOCUMENTS REFERRING TO ABRAXIS OR ABRAXANE

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NATURE AND STAGE OF PROCEEDINGS

Over a year ago, on July 19, 2006, Elan filed suit against Abraxis alleging infringement of U.S. Patent Nos. 5,399,363 and 5,834,025 (the "Patents-In-Suit"). (*See* Declaration of Diana Kruze in Support of Abraxis's Motion to Compel Responses to Interrogatories and Production of Documents ("Kruze Decl."), Exs. 1, 2, filed herewith.) While alleging generally that Abraxane infringes the Patents-In-Suit, Elan's Complaint did not set forth the basis for its allegations. Accordingly, Abraxis served document requests and interrogatories on Elan designed to elicit this information. Despite countless meet and confers and several "supplements," Elan's responses to Abraxis's interrogatories and document requests remain woefully deficient. Discovery closes on August 13, 2007, and Abraxis still does not know most of Elan's contentions about this case. The parties have briefed and argued claim construction, and the Court's claim construction order is expected within several weeks.

SUMMARY OF ARGUMENT

The Patents-In-Suit claim small particles of crystalline drugs. As stated in the Patents themselves, crystalline is the opposite of amorphous.[1] When this case began, Abraxis explained to Elan that it did not have a valid claim for infringement because the drug in Abraxane is amorphous, not crystalline. Over a year into the lawsuit, Elan has yet to produce a single piece of evidence which shows that Abraxane is crystalline. [redacted]

[1] Crystalline solids have an ordered arrangement of atoms or molecules in a space lattice. An example of a crystalline solid is a diamond. By contrast, examples of amorphous solids are a ball of candle wax or cotton candy. (*See, e.g.*, D.I. 115, at 18-20 (Abraxis's opening claim construction brief).)

With discovery substantially complete, Elan still refuses to articulate any valid theory of infringement or produce supporting evidence. Elan's failure is comprehensive:

- Elan has not provided Abraxis with responses to interrogatories which seek, among other things, Elan's position regarding infringement.
- Elan has resisted production of all documents referring to Abraxis or Abraxane. The few documents that Elan has produced confirm that Elan employees, including the named inventors of the Patents-in-Suit, believe that [redacted]
- Elan has also withheld documents reporting its testing of Abraxane – perhaps because these tests were negative, or perhaps because Elan wants to wait until the last possible moment to produce them to prevent meaningful follow-up discovery.

Elan's comprehensive failure is inexcusable. The close of discovery is less than one week away, and Elan still has not provided Abraxis with its contentions or supporting evidence. This is highly prejudicial to Abraxis's ability to prepare its defenses to Elan's claims. Even if Elan were to provide this information tomorrow, Elan's delay has foreclosed any opportunity for Abraxis to conduct meaningful follow-up discovery. The Court should not allow Elan to unfairly surprise Abraxis at trial with new contentions or evidence. Therefore, Abraxis seeks an Order compelling a final and complete response to its interrogatories, as well as production of all documents that refer to Abraxane or Abraxis. In the alternative, Abraxis seeks an Order precluding Elan from relying at trial or during motion practice on any theories or evidence other than what is listed in Elan's current discovery responses.

STATEMENT OF FACTS

A. Technological Background Of The '363 And '025 Patents.

These patents are about nanoparticles (less than 1000 nanometers in size[2]) of water-insoluble drugs. The alleged innovation of the '363 patent was to make nanoparticles containing crystalline anti-cancer drugs and "surface modifiers." (*See, e.g.*, Kruze Decl., Ex. 1, 7:5-45.) The '025 patent purports to solve the alleged problem that intravenously administering nanoparticles can cause certain unwanted cardiovascular-related side-effects (referred to in the patent as "adverse hemodynamic effects"). (*See, e.g.*, *id.*, Ex. 2, 1:48-65.) The '025 applicants stated that they solved this problem by administering the nanoparticulate drug substance composition at a slow infusion rate ("not exceeding 10 mg/min"). Both the '363 and the '025 applicants stressed that their crystalline nanoparticles were different from, and superior to, nanoparticles having drugs in their amorphous form. (*Id.*, Ex. 1, 2:28-34 ("The crystalline phase differs from an amorphous, i.e., non-crystalline phase . . . ."); Ex. 2, 7:28-31 (same).)

B. The Accused Product – Abraxane.

Abraxane, the accused product, is a drug approved by the FDA for the treatment of breast cancer. Abraxane is a nanoparticulate composition of amorphous paclitaxel and [redacted] human albumin. (*See, e.g.*, *id.*, Ex. 3 (paclitaxel in Abraxane is amorphous); Ex. 4 (albumin in Abraxane has crosslinkages).) Abraxis instructs doctors to reconstitute each vial of Abraxane with saline to form a suspension, and to administer that composition intravenously over 30 minutes. For the vast majority of patients, Abraxis recommends a dose of 260 mg of paclitaxel per one square meter of body surface area.

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[2] One thousand nanometers equals one micron, which is one thousandth of a millimeter.

C. Abraxis's Interrogatories And Elan's Inadequate Responses.

In November 2006, Abraxis served Elan with its First and Second Set of Interrogatories. (Kruze Decl., Exs. 5, 6.) These interrogatories request, among other things, Elan's contentions and supporting evidence regarding infringement, conception and reduction to practice of the inventions claimed in the patents-in-suit, and damages. (*Id.*) Elan first answered these interrogatories in December 2006. Complete copies of Elan's original responses to the Interrogatories are attached as Exhibits 7 and 8 to the Kruze Declaration. Although Elan has purported to "supplement" its responses several times, two of Elan's four "amended" responses provided no new information. Elan's first amended responses, served on January 18, 2007, only corrected minor typos contained in its original responses. (*Id.*, Exs. 9, 10.) Similarly, Elan's third "supplement" added a one-line contention regarding infringement by intermediates, but again included no new substantive information or evidence. (*Id.*, Exs. 13, 14.) Elan's first through third amended responses are attached hereto as Exhibits 9-14 to the Kruze Declaration. Elan's operative responses, its Fourth Amended Responses served on June 8, 2007, are attached as Exs. 15 and 16 to the Kruze Declaration.

Abraxis served its Third Set of Interrogatories (Nos. 10-13) in May 2007. (*Id.*, Ex. 17.) These interrogatories seek, among other things, Elan's contentions regarding validity, enforceability and standing. (*Id.*) Elan served its operative responses to these requests in June 2007. (*Id.*, Ex. 18.)

Abraxis has written Elan several times, pointing out the multiple deficiencies in Elan's responses. (*Id.*, Exs. 19-22.) The parties have also met and conferred close to a dozen times about Elan's responses. (*Id.*, ¶ 2.) Nonetheless, over a year into the case, Elan still has not provided its contentions or supporting evidence on the vast majority of issues in the case.

D. Abraxis's Document Requests Regarding Abraxis Or Abraxane And Elan's Belated Production Of Documents That Undermine Its Position In This Litigation.

In its First Set of Requests for Production, served in November 2006, Abraxis requested that Elan produce all documents that refer to Abraxis or Abraxane. (Kruze Decl., Ex. 23, at Document Request No. 74; *see also* Document Request Nos. 3,4, 55, 66-67, 69, and 77.) Elan objected to this request on several grounds but nonetheless agreed to produce documents responsive to the request regarding Abraxane or Abraxis. (*Id.*, Ex. 24 at 40-41.)

In the past few weeks, Elan has produced documents that have grave implications for this lawsuit. Although Abraxis requested documents regarding Abraxane or Abraxis in its First Set of Requests, Elan produced most of these highly relevant documents in mid-July, less than a month before the close of discovery. The documents Elan produced are only the tip of the iceberg, and fall in the following categories:

[redacted]

[redacted]

[redacted]

Abraxis's counsel has written Elan numerous times requesting that Elan provide the test results. (*Id.*, Exs. 30-33.) Elan has refused to do so. In all of these letters, Abraxis also requested that, if Elan was withholding any testing documents on the basis of privilege or work-product, Elan provide Abraxis with a detailed description of the documents and the basis for the non-production. Elan's counsel has failed to offer any reason for withholding the documents, other than vague and generalized statements of "privilege" or "work-product." Moreover, as of the date of this motion, Elan has not provided Abraxis with a privilege log, frustrating Abraxis's ability to determine whether Elan's non-disclosure is proper.

[redacted]

[redacted] Elan has not produced many documents that refer to Abraxane or Abraxis. A search of Elan's production reveals that Elan has only produced approximately 240 documents that refer to "Abraxane" or "Abraxis." (Kruze Decl., ¶ 3.) Out of these 240 documents, many are public documents: journal articles, presentations about Abraxane, Abraxis's financial documents filed with the SEC, Abraxis's publicly filed patents, and multiple copies of Abraxane's package insert. (*Id.*)

Upon noticing this discrepancy in the amount of material that Elan produced, Abraxis wrote Elan and requested all documents that refer to Abraxis or Abraxane. (*Id*, Ex. 42.) The parties met and conferred about this issue on August 1, 2007. (*Id.*, ¶ 4.) Although Elan's attorneys stated that they believed that they had produced all of these materials, Elan's counsel also promised that they would consult with Elan and re-check its production. (*Id.*) Additionally, Abraxis requested the number of documents originally culled by the terms "Abraxis" and "Abraxane" from Elan's e-discovery, to confirm that Elan's attorneys were not withholding any documents. (*Id.*) As of the date of this motion, Elan has not provided Abraxis with any additional information. Abraxis therefore brings this motion to compel Elan to produce all relevant information referring to Abraxis or Abraxane.

ARGUMENT

A. The Relevance Of Discovery Is Interpreted Broadly Under The Federal Rules.

Federal Rule of Civil Procedure 26(b)(1) provides that a party "may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party." Fed. R. Civ. P. 26(b)(1). Relevance under Rule 26 is interpreted broadly, and encompasses not only information that would be admissible at trial, but also information "reasonably calculated to lead

to the discovery of admissible evidence," Fed. R. Civ. P. 26(b)(1); Wright, Miller & Marcus, FEDERAL PRACTICE & PROCEDURE: CIVIL 2D § 2008 (2004) (noting that, even after the 2000 amendment to Rule 26(b)(1), the standard "is still a very broad one"). In the Third Circuit, "it is well recognized that the federal rules allow broad and liberal discovery." *Corning Inc. v. SRU Biosystems*, LLC, No. 03-633 JJF, 2004 U.S. Dist. LEXIS 14831, at *3 (D. Del. July 7, 2004) (citing *Pacitti v. Macy's*, 193 F.3d 766, 777-78 (3d Cir. 1999)).

Where a party objects, fails to answer an interrogatory, or fails to respond to a request for production, the party propounding discovery may move for an order compelling discovery under Rule 37(a). *See* Fed. R. Civ. P. 33(b)(5), 34(b). Under Rule 37(a), "an evasive or incomplete disclosure, answer, or response is to be treated as a failure to disclose, answer, or respond." Fed. R. Civ. P. 37(a)(3).

B. The Court Should Compel Elan To Provide A Substantive And Final Response To Abraxis's Interrogatories.

Abraxis's interrogatories have been outstanding since November 2006. Although Elan has purported to "supplement" its responses four times, Elan still has not explained its contentions or listed any evidence on which it relies for most of these contentions. Elan's delay has significantly prejudiced Abraxis's ability to prepare for depositions and pursue any needed follow-up discovery. Discovery will close in less than one week from the date of this motion. Moreover, Elan possesses all of the information it would need to adequately respond to Abraxis's requests. This Court should therefore grant Abraxis's motion to compel complete responses to its interrogatories, or preclude Elan from relying on any evidence other than what is cited in its current responses.

1. Elan Bears The Burden Of Showing Full and Complete Responses to Abraxis's Interrogatories Should Not Be Allowed.

Contention interrogatories, at issue here, are used to obtain evidence regarding the factual and legal bases for a specific contention of an opposing party. Fed. R. Civ. P. 33(c). Contention interrogatories are especially useful in ferreting out and narrowing the issues in a case, saving the parties and the Court the time and expense of discovery and litigation over uncontested or irrelevant issues. Fed. R. Civ. P. 33(c) advisory committee's note on 1970 Amendment Subdivision (b); *see also Lexington Ins. Co. v. Commonwealth Ins. Co.*, No. C 98-3477 CRB, 1999 U.S. Dist. LEXIS 23428, at *23 (N.D. Cal. Sept. 17, 1999) ("The purpose of contention interrogatories . . . [is to] narrow the issues that will be addressed at trial and to enable the propounding party to determine the proof required to rebut the respondent's position."); *Scovill Mfg. Co. v. Sunbeam Corp.*, 357 F. Supp. 943, 948 (D. Del. 1973) (finding that an interrogatory is proper if it "might refine the actual issue of fact") (citation omitted); *Montecatini Edison, S.p.A. v. Rexall Drug and Chem. Co.*, 288 F. Supp. 486, 489 (D. Del. 1968) (granting motion to compel plaintiff's responses to contention interrogatories regarding patent claims). "Th[is] court will prevent a party from raising a claim or defense at trial that was not adequately described in a response to a contention interrogatory . . . ." *Thorn EMI N. Am., Inc. v. Intel Corp.*, 936 F. Supp. 1186, 1191 (D. Del. 1996), *aff'd,* 157 F.3d 887 (Fed. Cir. 1998).

2. Interrogatories Regarding Infringement.

Abraxis's first and second interrogatories ask for Elan's direct and indirect infringement contentions and the evidence supporting those contentions. Despite the fact that the close of discovery is one week away, Elan still has not provided Abraxis with many of its infringement contentions for the patents-in-suit or any evidence. A defendant in a patent infringement action is entitled to know the basis for the plaintiff's allegation of infringement. *Refac Int'l, Ltd. v.*

Hitachi, Ltd., 921 F.2d 1247, 1255 (Fed. Cir. 1990) (It is a fundamental obligation of a plaintiff in a patent infringement action to "spell out a proper basis for charging infringement."). Vague and conclusory interrogatory responses are inadequate. *Id.*; *Carver v. Velodyne Acoustics, Inc.*, 202 F.R.D. 273, 274 (W.D. Wash. 2001) ("Velodyne is entitled to know what led the Carvers to file their patent infringement suit.") Flouting this basic principle, Elan has refused to provide a substantive response to Abraxis's interrogatories seeking Elan's infringement allegations.

3. Abraxis's First Interrogatory (Infringement).

Abraxis's first interrogatory states:

> Please explain in detail why Elan contends that Abraxis infringes U.S. Patent Nos. 5,399,363 and 5,834,025. Please provide an element-by-element claim chart including your contentions and references to the documents and other evidence on which Elan relies.

(Kruze Decl., Ex. 5 at 1.) Elan has not adequately answered this interrogatory with respect to either of the two patents-in-suit.

a. The '363 Patent.

Elan's responses to Abraxis's interrogatory regarding infringement of the '363 patent are deficient in at least four respects:

1. Elan has not provided Abraxis with any evidence for its infringement allegation.

2. Elan has not provided Abraxis with many of its contentions regarding infringement by Abraxane.

3. Elan has not provided any contentions or analysis regarding its theory that Abraxane infringes under the Doctrine of Equivalents.

4. Elan has not provided any analysis or evidence regarding its belief that "reconstituted Abraxane or an unknown "intermediate" infringe.

Abraxis therefore requests an Order compelling Elan to provide a full and complete response to this Interrogatory, including correction of the four specific deficiencies discussed

above. In the alternative, Abraxis requests an Order that precludes Elan from relying on any contentions or evidence other than what is cited in its interrogatory responses to date.

First, on many essential limitations of the '363 patent, Elan provides little or no evidentiary support for its contentions. The patentee, however, bears the burden of proving by a preponderance of the evidence that every limitation in the patent is present in the accused product. *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir. 1991); *Novartis Pharms. Corp. v. EON Labs Mfg.*, 234 F. Supp. 2d 464, 467 (D. Del. 2002). More than a year into a case and with discovery substantially complete, a plaintiff should be able to identify the evidence that supports its claims.[3] Elan has failed to do so.

For example, Elan's only support for its allegation that [redacted] These three pages in no way support Elan's contention. Moreover, Elan has cited no test results, nor any other evidence gathered by Elan in support of its contention.

Abraxis has been requesting any evidence that Elan may have regarding its contention that the paclitaxel in Abraxane is crystalline since the inception of this lawsuit. (*See, e.g.*, Kruze Decl., Exs. 43 at 3, 44.) Before discovery even began, Abraxis informally provided Elan with several letters attaching evidence that shows that Abraxane does not meet the crystalline limitation of the patents. Indeed, the documents that Elan has produced indicate that [redacted]

[3] Indeed, a plaintiff must be able to show "why it believed before filing the claim that it had a reasonable chance of proving infringement." *View Eng'g, Inc. v. Robotic Vision Sys.* 208 F.3d 981, 986 (Fed. Cir. 2000) (emphasis added).

[redacted] Absent from Elan's production is a single document indicating that Abraxane is crystalline.

During a meet and confer, when Abraxis asked Elan to provide factual support for its contentions, Elan stated that this information is protected by work product, and may be produced during expert discovery. As to privilege and work product, Elan should not be allowed to use these doctrines as both a sword and a shield. *In re Echostar Commc'ns Corp.*, 448 F.3d 1294, 1301-02 (Fed. Cir. 2006), *cert. denied*, 127 S. Ct. 846 (2006) ("[S]elective waiver of the privilege may lead to the inequitable result that the waiving party could waive its privilege for favorable advice while asserting its privilege on unfavorable advice."); *Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340, 1349 (Fed. Cir. 2005), *cert. denied*, 126 S. Ct. 1768 (2006) (Out of fairness, "a party is prevented from disclosing communications that support its position while simultaneously concealing communications that do not."). Here, Elan has not established that these documents are privileged, nor even provided Abraxis with a privilege log to enable Abraxis to make that determination. Abraxis also has no access to the evidence Elan says supports its case. In addition, waiting until expert reports are served to provide this evidence is not acceptable. With the close of discovery less than one week away, Elan has already effectively precluded Abraxis from engaging in any follow-up discovery that may be needed.

A year into this litigation, Elan can cite no evidence or test results that indicate that Abraxane is crystalline. [redacted] (*See, e.g.*, Kruze Decl., Exs. 34 & 35.) If Elan has any evidence that the paclitaxel in Abraxane is crystalline, it should be forced to disclose it.

Second, Elan's contentions as to infringement are deficient. For many limitations, Elan simply parrots the language of the patent claims. For example, Elan states that the human serum albumin in Abraxane is a "non-crosslinked surface modifier adsorbed on the surface of the paclitaxel," echoing the claim language without any analysis. (Kruze Decl., Ex. 15 at 12.) The mere repetition of claim elements, without any explanation as to what specific component or feature of the accused product practices each claim element, falls far short of the disclosure requirements required of a plaintiff in a patent infringement action. *Housey Pharms., Inc. v. Abbott Pharm. Corp.*, No. 01-401-SLR, 2002 U.S. Dist. LEXIS 24080, at *2 (D. Del. Nov. 20, 2002) (plaintiff must provide "more than conclusory allegations of infringement" in response to a defendant's contention interrogatory). In *Network Caching Tech., LLC v. Novell, Inc.*, the district court was faced with disclosures similar to Elan's responses. 67 U.S.P.Q.2d 1034, 1039 (N.D. Cal. 2002). As the court put it, the plaintiff's disclosures in that patent infringement case "simply mimic[ked] the language of [the] claim." *Id.* The court held that this was not adequate: "In essence, [the plaintiff] has provided no further information to defendants than the claim language itself. This is plainly insufficient." *Id.*

Third, Elan's interrogatory response fails to articulate any doctrine of equivalents theory. Elan contends that Abraxis infringes claims 1 and 15 of the '363 patent, stating only that, if the limitations are not literally met, Abraxane is "insubstantially different" from the claims. (Kruze Decl., Ex. 15 at 4.) There is no substantive application of the legal standard to this case, nor any evidence cited in support. To determine the basis of Elan's argument and prepare its response, Abraxis needs more information than the generalized claims of similarity put forth by Elan. *See Refac*, 921 F.2d at 1251, 1255 (affirming sanction of dismissal where plaintiff failed to identify which elements of its claims were present in each accused device under the doctrine of

equivalents); *Carver*, 202 F.R.D. at 274 (requiring patentee to provide detailed answers to interrogatory regarding doctrine of equivalents, claimed inability to examine defendant's discovery responses notwithstanding).

Elan's generalized contention that crystalline drugs can be equivalent to amorphous drugs is contrary to law and fact. (Kruze Decl., Ex. 15 at 4.) Elan not only disclosed amorphous, non-crystalline medicaments in its patents, Elan disclaimed them to overcome the prior art. (*See, e.g.*, D.I. 115, at 8-11, 18-20 (Abraxis's opening claim construction brief).) This is an absolute bar to asserting infringement of amorphous medicaments under the doctrine of equivalents. *See, e.g., Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 951-52 (Fed. Cir. 1993) ("The essence of prosecution history estoppel is that a patentee should not be able to obtain, through the doctrine of equivalents, coverage of subject matter that was relinquished during prosecution to procure issuance of the patent.").

Fourth, Elan has not provided its contentions as to "Abraxane as reconstituted" and any unknown "intermediates created during the manufacturing of Abraxane." (Kruze Decl., Ex. 15 at 4.) In two conclusory sentences, Elan alleges that these products, "upon information and belief," infringe. (*Id.*) Elan does not provide a single explanation for these assertions, nor a single citation to evidence. (*Id.*) Instead, in a footnote to its claim chart, Elan states that the term "Abraxane" refers to: (1) the actual product; (2) reconstituted Abraxane; and (3) an unknown intermediate product (created at some unknown point during the manufacture of Abraxane). (Kruze Decl., Ex. 15 at Ex. A, n.1.) This statement, however, ignores the fact that "reconstituted Abraxane" and an "unknown intermediate" include different components and may have different physical characteristics than Abraxane. For example, "reconstituted Abraxane" also contains saline. [redacted]

[redacted] Moreover, Elan has not identified any "intermediate" with specificity, nor even advised Abraxis of when during the manufacture of Abraxane a product may exist that, "on information and belief," infringes. This is insufficient.

Abraxis therefore respectfully requests an Order compelling Elan to provide a complete and substantive response to this Interrogatory. Specifically, Abraxis seeks an Order compelling Elan to: (1) identify all evidence that supports its contentions that Abraxis infringes, including any evidence that the paclitaxel in Abraxane is crystalline; (2) provide a detailed explanation of all of Elan's contentions regarding how and why Abraxane meets each and every limitation of the patents-in-suit; (3) provide Elan's contentions and supporting evidence for its doctrine of equivalents theories, including (a) a detailed explanation of why amorphous drugs are equivalent to crystalline drugs, and (b) a detailed explanation of why Elan is not estopped from asserting such a theory; (4) identify any "intermediate" that Elan contends infringes with specificity (including a reference to a specific point during the manufacture of Abraxane), as well as a detailed explanation as to why Elan contends any such intermediate meets each and every limitation of the claims of the patents-in-suit; and (5) provide claim charts with contentions and all supporting evidence for "reconstituted Abraxane" and all intermediates that Elan contends infringe.

b. The '025 Patent.

Elan's direct infringement response regarding the '025 patent is facially insufficient. Elan's complaint, as currently filed, alleges direct infringement by Abraxis of the '025 patent. (Kruze Decl., Ex. 46.) But Elan's infringement chart and contentions are wholly devoid of any analysis on direct infringement, save the following footnote:

> Elan is not presently aware of facts or circumstances indicating direct infringement of the '025 patent by Abraxis because our present understanding is that Abraxis supplies Abraxane to medical care providers

> to administer to patients, and does not itself administer Abraxane to patients. Elan reserves the right to amend or supplement its contentions if new facts warrant doing so.

(*Id.*, Ex. 15 at 6, n.1.) In other words, Elan admits that it has never had any claim of direct infringement of the '025 patent. *See Refac*, 921 F.2d at 1255 (affirming sanction of dismissal entered against plaintiff that failed to articulate its basis for infringement, commenting that its failure to do so "more than a year after bringing suit highlights its willfulness.")

Abraxis therefore respectfully requests that the Court order Elan to voluntarily dismiss this claim. Alternatively, Abraxis requests that the Court compel Elan to respond to this Interrogatory with its contentions and supporting evidence, including a description of: (1) any "new facts" that would support a claim for direct infringement of the '025 patent; (2) the date(s) upon which Elan became aware of these "new facts"; and (c) Elan's contentions as to why any administration by Abraxis of Abraxane would not be exempt from infringement under 35 U.S.C. § 271(e). *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) ("[S]ection 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information" to the FDA.) (citation omitted).

4. Abraxis's Second Interrogatory (Indirect Infringement).

Abraxis's second interrogatory states:

> Please explain in detail why Elan contends that Abraxis induces infringement and/or contributorily infringes each claim of the Patents-In-Suit. Please state facts and identify documents and other evidence on which Elan relies.

(Kruze Decl., Ex. 6 at 1.)

To prevail on its inducement claim, Elan "has the burden of showing" that Abraxis "possessed specific intent to encourage another's infringement and not merely that [Abraxis] had

knowledge of the acts alleged to constitute inducement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc) (citation and quotations omitted); *Tristrata Tech., Inc. v. Mary Kay, Inc.*, 423 F. Supp. 2d 456, 465 (D. Del. 2006). Elan's responses to Interrogatory No. 2 as to the '363 patent merely paraphrase its direct infringement contentions. The deficiencies in those responses are discussed above. *See, supra*, pp. 11-16. With regard to the '025 patent, Elan's contentions also are inadequate. For example, Elan has not stated the time periods in which it alleges indirect infringement, despite Abraxis's specific requests for this information since January 2007. As another example, on the 10 mg/min limitation of the '025 patent, Elan only cites numerous copies of Abraxis's package insert, but does not explain why Abraxis's recommended dosing of 260 mg/m2 of paclitaxel over 30 minutes would meet the claim limitation, which does not include any measure of body weight nor time of administration.

More than a year after filing its lawsuit, Elan cannot further prolong its refusal to articulate the basis for its allegation of infringement. *See Refac*, 921 F.2d at 1255. There is no excuse for these deficiencies. Abraxis therefore respectfully requests that the Court compel Elan to provide a detailed explanation of why Elan contends that Abraxis induces infringement and/or contributorily infringes each claim of the Patents-In-Suit, including: (1) a description of all specific products that Elan accuses; (2) the time periods in which Elan alleges indirect infringement; (3) for the '025 patent, an explanation of how Elan contends that Abraxis instructs doctors to administer at a rate of "less than 10 mg/min," including any mathematical calculations upon which Elan's contention is based; and (4) the identity of documents and other evidence on which Elan relies.

5. Abraxis's Third Interrogatory (Conception and Reduction to Practice).

Abraxis's third interrogatory states:

> For each claim of the Patents-In-Suit, describe the dates and circumstances of its conception, design, development, actual reduction to practice, first written description, first disclosure to another, first offer for sale, and first public use.

(Kruze Decl., Ex. 6 at 1.) Despite the fact that this Interrogatory has been outstanding for over nine months, Elan still has not provided circumstances or dates of: (1) conception, design, development; (2) actual reduction to practice; (3) first written description; (4) first disclosure to others; (5) first offer for sale; or (6) first public use.

Instead, Elan only states that these six separate events occurred [redacted] In other words, Elan responded to this interrogatory by offering some nebulous date that could be anytime [redacted] Abraxis, however, requested actual and specific dates, as well as a description of the relevant circumstances. This information is critical to Abraxis's section 102 and 103 defenses.[4] *See, e.g., Pfaff v. Wells Elecs.*, 525 U.S. 55, 67-68 (1998) (precise dates of conception and reduction to practice are essential to determining defendant's section 102 defense). Moreover, Elan is in sole possession of this information.

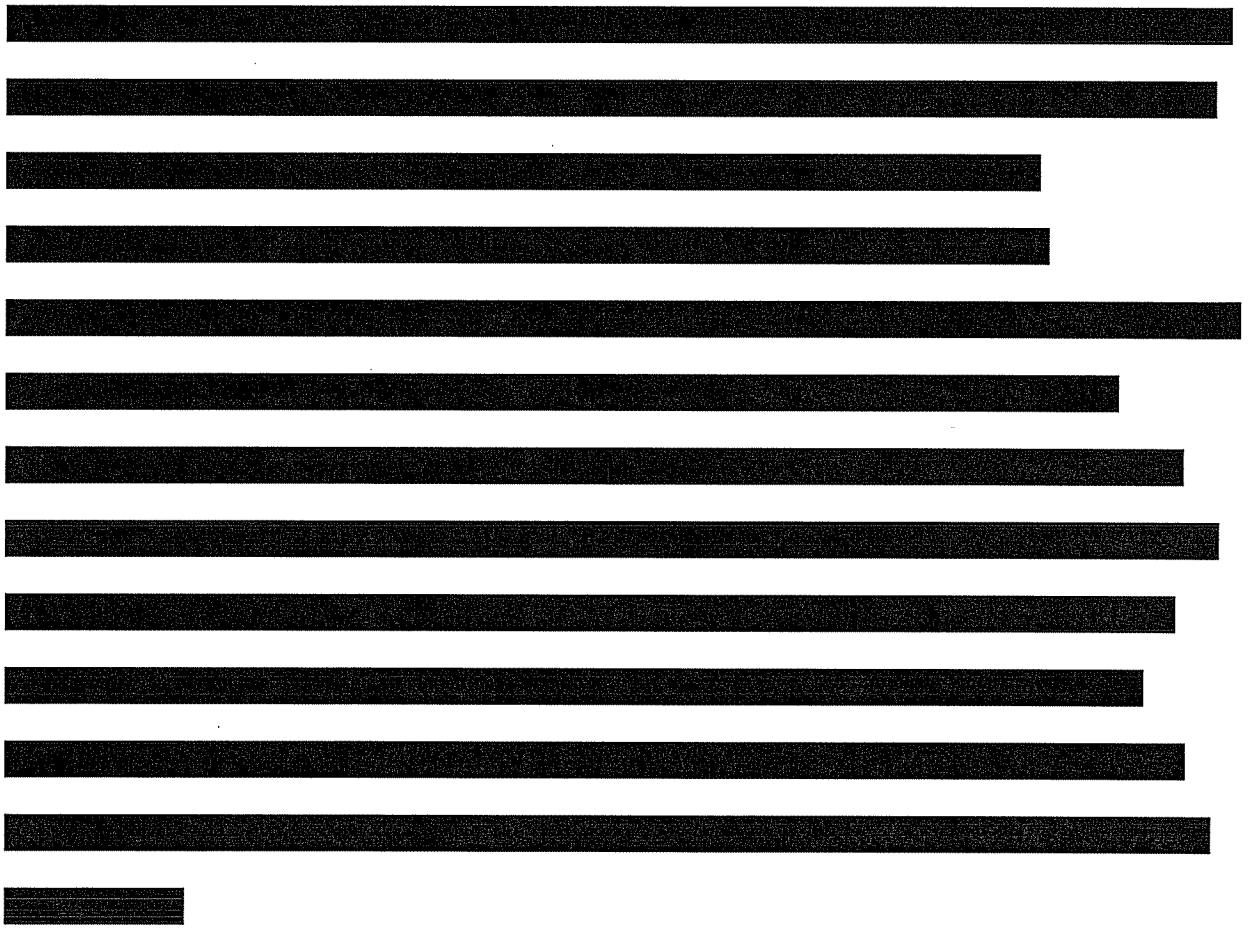
Second, Elan's identification of documents relating to these contentions is not a substitute for its actual contentions.

Third, Elan's identification of documents is not a proper use of Rule 33(d), as the notebooks and other documents in no way provide the information requested. For example,

[4] For example, under section 102, a patent is invalid as anticipated if another person's conception and reduction to practice of the invention occurred prior to the patentee's. *New Idea Farm Equip. Corp. v. Sperry Corp.*, 916 F.2d 1561, 1566-67 (Fed. Cir. 1990).

Elan's notebooks have nothing to do with the first disclosure to another, first offer for sale, or first public use. Nor do these documents explain Elan's contentions as to conception, reduction to practice or first written description of the inventions claimed. Saying "go fish" is not a proper response.

Worse still, the vast majority of the documents that Elan cites are heavily redacted. One need only look at the first section of documents that Elan cites for its conception response.



Finally, although Elan's answer to this interrogatory spans multiple pages, the vast majority of Elan's cites are to the same redacted and irrelevant documents, repeated over and

over again. (Kruze Decl., Ex. 16 at 8-16.) Elan's referral of Abraxis to redacted and irrelevant documents is no response at all.[5]

The Court should therefore compel Elan to describe the specific dates and circumstances of Elan's conception, design, development, actual reduction to practice, first written description, first disclosure to another, first offer for sale, and first public use for each of the Patents-In-Suit separately. Abraxis also respectfully requests that the Court order Elan to provide Abraxis with actual and specific dates responsive to this interrogatory, as opposed to any ranges of time.

6. Abraxis's Fourth Interrogatory (Willfulness).

Abraxis's fourth interrogatory states:

> Please explain in detail why Elan contends that Abraxis's infringement of the Patents-In-Suit has been "willful and deliberate." Please state facts and identify documents and other evidence on which Elan relies.

(Kruze Decl., Ex. 6 at 2.) To establish willful infringement, Elan must prove by clear and convincing evidence that the defendant acted without a reasonable belief that its conduct avoided infringement. *E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1440 (Fed. Cir. 1988) (affirming finding of non-willfulness where plaintiff failed to produce adequate evidence of willfulness); *W.R. Grace & Co. v. Intercat, Inc.*, 60 F. Supp. 2d 316, 333 (D. Del. 1999). Again, Elan cites almost no evidence in support of its contentions. (Kruze Decl., Ex. 16 at 17-20.) Instead, Elan regurgitates its responses to Abraxis's first and second interrogatories regarding infringement. (*Id.*) Moreover, despite the fact that Elan objects to this very interrogatory on the grounds that the two patents-in-suit are "separate and distinct" from one another (*id.* at 17), Elan's sole support for its contention that Abraxis knew of the '025 patent is

[5] Moreover, Elan is again using privilege as both a sword and a shield. If Elan is going to affirmatively rely on these documents to prove its conception and reduction to practice dates, Elan should produce unredacted versions of the documents. *Echostar Commc'ns Corp.*, 448 F.3d at 1301-02; *Fort James Corp.*, 412 F.3d at 1349.

based on alleged knowledge of the '363 patent. (*Id.* at 19-20.) The Court should compel a proper response to this interrogatory, including a detailed description of: (1) why Elan contends that Abraxis's infringement was willful; (2) the date that Elan alleges that Abraxis became aware of each of the Patents-In-Suit; (3) the circumstances, if any, of Abraxis's awareness of the Patents-In-Suit; and (4) the identity of documents and other evidence on which Elan relies. *Fresenius Med. Care Holding, Inc. v. Baxter Int'l, Inc.*, 224 F.R.D. 644, 652 (N.D. Cal. 2004) (motion to compel response to willful infringement interrogatory granted).

7. Abraxis's Fifth Interrogatory (Injunction).

Abraxis's fifth interrogatory states:

> Please explain in detail why Elan contends that it has suffered "irreparable harm" and "is entitled to temporary, preliminary, and/or permanent injunctive relief." Please state facts and identify documents and other evidence on which Elan relies.

(Kruze Decl., Ex. 6 at 2.) [redacted] Elan has also failed to identify a single license that supports its contention that it has suffered irreparable harm and is entitled to temporary, preliminary, and/or permanent injunctive relief. Abraxis therefore respectfully requests that the Court compel Elan to provide a detailed description of why and how Elan alleges it has suffered irreparable harm and is entitled to injunctive relief, including the identification of all licenses, communications and any other documents that support Elan's belief.

8. Abraxis's Sixth Interrogatory (Damages).

Abraxis's sixth interrogatory states:

> Please explain in detail why Elan contends that it is entitled to an award of monetary damages. Please provide:

a. a detailed description of the specific damages alleged, including whether they are based on a lost profits theory, reasonable royalty theory, or any other theory;

b. the mathematical computations(s) used to calculate the amount of damages alleged, and all of the dates upon which such calculations are based; and

c. the identity of documents and other evidence that support the calculations set forth in a. and b. above.

(Kruze Decl., Ex. 6 at 2.)

Elan has not explained its damages contentions or identified a single piece of evidence that supports its contention that it is entitled to damages. The only statement is that "Elan is entitled to a reasonable royalty."[6] (Kruze Decl., Ex. 16 at 22.) This is plainly deficient. *See Zenith Elecs. Corp. v. WH-TV Broad. Corp.*, 395 F.3d 416, 420 (7th Cir. 2005) (affirming district court's exclusion of damages evidence based on failure of proponent party to respond to an "interrogatory with a description of its damages theory and the proof to be employed").

As such, the Court should compel Elan to provide its specific contentions and evidence regarding its reasonable royalty theory, including: (1) the rate Elan contends it is entitled to; (2) the mathematical computations used to calculate the amount of damages alleged; (3) all of the dates upon which such calculations are based; and (4) the identity of documents, including licenses or offers to license, that support Elan's contentions. *Trio Process Corp. v. L. Goldstein's Sons, Inc.*, 612 F.2d 1353, 1358 (3d Cir. 1980) ("[T]he actual license rate is an important factor in the determination of a reasonable royalty, at least when those royalties prove or tend to prove an established royalty.")

[6] Elan should be precluded from relying on any theories other than a reasonable royalty rate. *Design Strategies, Inc. v. Davis*, 367 F. Supp. 2d 630 (S.D.N.Y. 2005) (striking claim for lost profits for failure to comply with discovery rules).

9. Abraxis's Seventh Interrogatory (Communications regarding Patents).

Abraxis's seventh interrogatory asks Elan to:

> Please identify each instance in which Elan has communicated with another party regarding either of the Patents-In-Suit or the '684 Patent, including an identification of each instance in which Elan has offered a license under, or threatened or instituted legal action based upon, any claim of the Patents-In-Suit or the '684 Patent. For each communication, please describe (1) the date and form of the communication, (2) the participants in the communication, and (3) the content of the communication, including any allegations of invalidity, unenforceability, and/or non-infringement, and Elan's response, if any. Please identify any documents or other evidence constituting or referring to such communications.

(Kruze Decl., Ex. 6 at 2-3.) Elan has not provided any information regarding offers for licenses of these patents. (Kruze Decl., Ex. 16 at 24.) Instead, Elan has provided Abraxis with a list of licensees and a log of documents withheld from production on confidentiality grounds. (*Id.*) But Elan has failed to provide the requested information regarding communications with those companies. Moreover, Elan has resisted production of its licenses as well. The few licenses that Elan has produced typically have the financial portions redacted. (Kruze Decl., Exs. 48, 49.) This information bears directly on the analysis of damages under a reasonable royalty theory, which Elan has asserted in this case. *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), *aff'd,* 446 F.2d 295 (2d Cir. 1971); *Unisplay, S.A. v. Am. Elec. Sign Co.*, 69 F.3d 512, 517 n.7 (Fed. Cir. 1995). Moreover, Elan cannot rely on Rule 33(d), because Elan failed to identify any documents. (Kruze Decl., Ex. 16 at 24.)

Abraxis therefore requests an Order compelling Elan to identify all communications with a third party regarding the Patents-In-Suit or the '684 Patent, including a description of: (1) the date and form of the communication; (2) the participants in the communication; (3) the content of the communication; and (4) any documents constituting or referring to such communications.

10. Abraxis's Tenth Interrogatory (Enforceability and Invalidity).

Interrogatory number 10 states:

> Please explain in detail why Elan contends that the Patents-In-Suit are enforceable and not invalid. In answering this interrogatory, please address specifically all the unenforceability and invalidity contentions, arguments, and prior art set forth in Abraxis's responses to Elan Interrogatory No. 4, and include references to the documents and other evidence on which Elan relies.

(Kruze Decl., Ex. 17 at 1.) Elan has not provided any substantive response to this request. (*Id.*, Ex. 18 at 3-5.) Instead, Elan lodged three pages of objections, and answered: "Elan contends that the Patents-in-Suit are enforceable and not invalid." (*Id.* at 5.)

Elan has two principal objections to this interrogatory. First, Elan objects that, because Abraxis has so many affirmative defenses, responding to this interrogatory would be unduly burdensome. (*Id.* at 4.) Abraxis, however, should not be prejudiced because it provided a very complete and thorough response to Elan's interrogatory requesting the basis for Abraxis's defenses.[7] Elan also objects that this interrogatory attempts to shift the burden of proving invalidity from Elan to Abraxis. (*Id.*) Although it is true, as Elan argues, that Abraxis bears the burden on this issue, Abraxis needs to know if and how Elan will contest invalidity. Therefore, Abraxis seeks an Order compelling Elan to explain in detail why it contends that the Patents-In-Suit are enforceable and not invalid, including: (1) its contentions in response to all the unenforceability and invalidity contentions, arguments, and prior art set forth in Abraxis's current responses to Elan Interrogatory Nos. 2 and 4, and (2) the identity of any documents on which Elan will rely.

[7] Indeed, after Elan complained about Abraxis's initial response to Elan's contention interrogatory regarding invalidity and unenforceability, Abraxis supplemented its response with detailed claim charts and more than fifty pages of Abraxis's contentions and supporting evidence. Elan should be compelled to provide the same level of detail.

11. Abraxis's Eleventh Interrogatory (Standing).

Interrogatory number 11 seeks Elan's contentions regarding its standing to sue. Is asks Elan to:

> Please explain in detail why Elan believes it has standing to sue for infringement of the Patents-In-Suit by any paclitaxel-containing composition or its use. In answering this interrogatory, please identify all instruments or other agreements that Elan contends transfers any rights in the Patents-In-Suit to any entity and identify the rights transferred, the date of transfer, and the parties to any such instruments or other agreements.

(Kruze Decl., Ex. 17 at 2.) Elan, of course, bears the burden of proving that it has standing, and should have determined this prior to filing suit. *See, e.g., Danvers Motor Co. v. Ford Motor Co.*, 432 F.3d 286, 291 (3d Cir. 2005); *Ortho Pharm. Corp. v. Genetics Inst.,* 52 F.3d 1026, 1032-33 (Fed. Cir. 1995). Nonetheless, Elan again provides no substantive response, merely referring Abraxis to nine agreements that Elan cites. (Kruze Decl., Ex. 18 at 6.) Documents are no substitute, however, for Elan's contentions.

Moreover, this is not a proper use of Rule 33(d). Under Federal Rule of Civil Procedure 33(d), a party may respond to an interrogatory by specifying the records from which the relevant information may be obtained. Fed. R. Civ. P. 33(d). Rule 33 authorizes this response only in situations where the burden of deriving the answer from the documents is "substantially the same." *Id.* Generally, the responding party's familiarity with its records and methods of organization will facilitate review of the documents in ways unavailable to the opposing party. *See Govas v. Chalmers*, 965 F.2d 298, 302 (7th Cir. 1992) (if the information sought is contained in the responding party's files and records, she is under a duty to search the records and provide the answers). Therefore, the greater burden usually falls on the propounding party. *See Al Barnett & Son, Inc. v. Outboard Marine Corp.*, 611 F.2d 32, 35 n.8 (3d Cir. 1979); *Fresenius Med. Care*, 224 F.R.D. at 652; *Sabel v. Mead Johnson and Co.*, 110 F.R.D. 553, 556-57 (D.

Mass. 1986) (where company's employees generated the documents and were responsible for maintaining them, "it [was] simply absurd [for the company] to contend that it [was] equally burdensome for the plaintiff to derive [the requested] information").

Here, the burden is not the same, as these are Elan's corporate transfer agreements. Moreover, the transfer documents that Elan cites are unclear. [redacted] Elan and its employees are much better situated to look through these documents and provide its contention that it has standing to bring this lawsuit. The Court should therefore compel Elan to provide a detailed description of why Elan believes it has standing to sue for infringement of the Patents-In-Suit by any paclitaxel-containing composition, including a detailed description of: (1) the documents that Elan contends transfers any rights in the Patents-In-Suit to any entity; (2) the rights transferred; (3) the date of transfer; and (4) the parties to any such agreements.

12. Abraxis's Twelfth Interrogatory (Nanoparticulate Paclitaxel).

Interrogatory No. 12 requests that Elan:

> Please describe in detail Elan's attempts to develop a nanoparticulate paclitaxel composition. In answering this interrogatory, please describe all attempts to make and/or test such a composition, the dates of such attempts, the people involved in such attempts and their roles, the methods used for such attempts, the results of such attempts, and identify the documents reflecting such attempts.

(Kruze Decl., Ex. 17 at 2.) [redacted] is highly relevant to enablement and other key defenses.[8] Instead of offering a substantive response to this Request, Elan refers Abraxis to thousands of pages of documents produced by Elan. (*Id.*, Ex. 18 at 7-13.) Again, the burdens on the parties of identifying the information from these documents are not the same, as these are [redacted] Moreover, even when allowed, a Rule 33(d) response must identify the nature and organization of the documents sufficiently to allow the interrogating party to "locate and to identify, as readily as can the party served, the records from which the answer may be ascertained." Fed. R. Civ. P. 33(d). Plaintiff's citation to thousands of pages fails Rule 33(d)'s requirements. *In re Fine Paper Antitrust Litig.*, 685 F.2d 810, 823 (3d Cir. 1982) (affirming district court sanction of a party who merely directed the party seeking discovery to a mass of business records); *Bowoto v. Chevron Corp.*, No. C 99-02506 SI, 2006 U.S. Dist. LEXIS 65135, at **10-11 (N.D. Cal. Aug. 29, 2006) (defendants abused Rule 33(d) by referring plaintiffs to thousands of pages of technical documents). As such, Abraxis respectfully requests an Order compelling Elan to [redacted]

[8] As explained in further detail below, Elan's response to this Interrogatory is also important because documents produced in this case indicate that [redacted]

13. Abraxis's Thirteenth Interrogatory (Contribution to Patents).

This interrogatory states:

> Please describe in detail the timing and specific content of contributions to the Patents-In-Suit and the '684 Patent by the named inventors of those patents, and identify the evidence reflecting those contributions. In answering this interrogatory, for each named inventor, please identify the claims of those patents as to which Elan contends that inventor made an inventive contribution.

(Kruze Decl., Ex. 17.) Again, Elan provides no substantive response, instead referring Abraxis to its Response to Interrogatory No. 3. (*Id.*, Ex. 18 at 14.) The deficiencies with that response are discussed above. *See, supra*, pp. 18-21. Moreover, the response to Interrogatory No. 3 in no way identifies the named inventors' contributions to the Patents-in-Suit. Therefore, the Court should compel the Plaintiff to provide a full and complete response to this Interrogatory, including a detailed description of: (1) each named inventor's contribution to the Patents-In-Suit and the '684 Patent, on a claim-by-claim basis, (2) the timing of those contributions; and (3) the identity of any documents reflecting those contributions.

* * *

More than a year into the case and with fact discovery coming to a close, Elan is still unwilling to divulge its contentions and evidence. Elan's refusal to reveal its contentions and supporting evidence has prejudiced Abraxis by preventing Abraxis from conducting any follow-up discovery into Elan's theories and support. A plaintiff should not be permitted to hide from the defendant the reasons behind a lawsuit. For example, if Elan has any evidence of infringement, it should have produced that information months ago. Abraxis therefore respectfully requests that the Court order Elan to provide Abraxis with a final, complete, and substantive response to its interrogatories. Failing that, Elan should be precluded from relying

on any undisclosed evidence or contentions that is not listed in its operative responses as of August 13, 2007.

C. The Court Should Compel Elan To Produce All Documents Referring To Abraxis Or Abraxane.

Before formal discovery even began, Abraxis explained to Elan that it did not have a valid claim for infringement based on the crystalline limitation of the patent-in-suit. Over a year into the lawsuit, Elan has yet to produce a single piece of evidence which shows that Abraxane is amorphous. Indeed, documents recently produced by Elan indicate the opposite. Elan's employees, including the inventors of the patents-in-suit, know that Abraxane does not meet this limitation. Although Elan has produced a few dozen internal documents, Elan has not produced all documents in its possession. Specifically, the documents that Elan has produced refer to other documents, including testing of Abraxane, that have not been produced. Abraxis respectfully requests and Order compelling Elan's production of these highly relevant documents.

1. Elan Bears the Burden of Justifying its Non-Production.

Federal Rule of Civil Procedure 34 provides that a party may serve on another party a request specifying documents or categories of documents that the serving party wishes to inspect. Fed. R. Civ. P. 34. The responding party must state any objections to document requests with specificity. The burden is on the party resisting document production to explain why its objections are proper given the broad and liberal construction of the discovery rules found in the Federal Rules of Civil Procedure. *Willemijn Houdstermaatschaapij BV v. Apollo Computer Inc.*, 707 F. Supp. 1429, 1442 (D. Del. 1989) (compelling production of documents in patent case because resisting party's generalized objections were insufficient).

2. Elan Cannot Meet Its Burden and Should Produce All Documents Referring to Abraxis or Abraxane.

In November 2006, Abraxis's propounded its first set of document requests and asked that Elan produce "Documents referring to Abraxis or Abraxane."[9] (Kruze Decl., Ex. 23 at 15.) Nearly a year later, [redacted]

The Court should grant Abraxis's motion to compel for three reasons. First, Elan has not produced all documents that refer to Abraxis or Abraxane. Second, Elan does not have any valid basis for withholding these documents. Finally, if Elan plans to rely on evidence that refers to Abraxis or Abraxane at trial or during motion practice, Abraxis is entitled to these documents.

First, Abraxis has good reason to believe that Elan has not produced all documents that are responsive to this Request. Elan has only produced approximately 240 documents that refer to Abraxis or Abraxane. (Kruze Decl., ¶ 3.) Many of these documents are public articles, presentations, and patents. (*Id.*) The few internal documents that Elan did produce confirm that there are many more documents that Elan has not produced.

[redacted]

9 [redacted]

[redacted]

[redacted]

Abraxis's belief that more documents exist is not just speculation: it is confirmed by the few documents that Elan has, in fact, chosen to produce.

Second, Elan has no valid basis for withholding these documents. In its responses, Elan objected on privilege and/or work-product grounds.[11] No attorney-client privilege can possibly attach to testing information regarding Abraxane. *See Upjohn Co. v. United States,* 449 U.S. 383, 395-96 (1981) ("The privilege only protects disclosure of communications; it does not protect disclosure of the underlying facts by those who communicated with the attorney… The protection of the privilege extends only to communications and not to facts. A fact is one thing and a communication concerning that fact is an entirely different thing."); *Monsanto Co. v. Mycogen Plant Science, Inc.*, 61 F. Supp. 2d 133, 175 (D. Del. 1999) (citation omitted). Moreover, even if some parts of the documents reflect protectable communications, which Abraxis denies, the law forecloses Elan's attempt to make blanket claims of privilege regarding the facts contained in the subject documents. *See Henry v. Champlain Enters., Inc.*, 212 F.R.D.

[11] Elan also objected on relevance grounds. Documents referring to Abraxis or Abraxane are unquestionably relevant to the claims and defenses of this suit. Information is relevant so long as it is reasonably calculated to lead to the discovery of admissible evidence. Fed. R. Civ. P. 26(b)(1). The documents already produced establish relevance. [redacted]

73, 90-91 (N.D.N.Y. 2003) (holding that "privileges do not protect the client's knowledge of the relevant facts, whether they were learned from counsel or facts learned from an attorney from independent sources"); *cf. Bogosian v. Gulf Oil Corp.*, 738 F.2d 587, 595 (3d Cir. 1984) ("where the same document contains both facts and legal theories of the attorney, the adversary is entitled to discovery of the facts").

Nor is Elan entitled to any presumption of privilege. Instead, Elan must carry the burden of proving the attorney-client privilege is applicable. *See, e.g., Maine v. United States Dep't of the Interior*, 298 F.3d 60, 71 (1st Cir. 2002); *In re Grand Jury Investigation*, 918 F.2d 374, 385 n.15 (3d Cir. 1990) ("[I]n this Circuit . . . a party who asserts a privilege has the burden of proving its existence and applicability."). Elan has failed to provide even a privilege log to support its claim of privilege. Considering Elan's burden to prove infringement and the paramount importance of seeking the truth in our justice system, Elan's generalized and unsupported assertion of attorney-client privilege is not sufficient to immunize either the documents themselves or the facts reflected in the subject documents from discovery in this case. *See, e.g.*, Fed. R. Civ. P. 26(b)(5) ("When a party withholds information otherwise discoverable under these rules by claiming that it is privileged or subject to protection as trial-preparation material, the party shall make the claim expressly and shall describe the nature of the documents, communications, or things not produced or disclosed in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the applicability of the privilege or protection"); *Blaser v. Mt. Carmel Regional Med. Ctr., Inc.*, No. 06-2422-JAR, 2007 U.S. Dist. LEXIS 36421, at **6-9 (D. Kan. May 17, 2007) (overruling objections as to attorney-client privilege and work product protection because the party failed to provide a

privilege log and "a 'blanket claim as to the applicability of the privileges/work product doctrine does not satisfy the burden of proof").

Similarly, if Elan is claiming work-product immunity, it bears the burden of showing that the materials in question "were prepared in the course of preparation for possible litigation." *Holmes v. Pension Plan of Bethlehem Steel Corp.*, 213 F.3d 124, 138 (3d Cir. 2000) (citations omitted). Work product prepared in the ordinary course of business is not shielded from discovery. *Id.* Again, Elan's generalized objections are insufficient to meet this burden.[12] Fed. R. Civ. P. 26(b)(5); *Blaser*, 2007 U.S. Dist. LEXIS 36421, at **8-9. [redacted]

Third, and most importantly, if Elan plans to rely on any evidence regarding Abraxane that it has not yet produced, Elan should be precluded from sandbagging Abraxis with such evidence at trial. The close of discovery is less than one week away, yet Elan has provided no evidence that Abraxis meets several of the limitations of the patents-in-suit. Elan's non-production of these documents precludes any meaningful follow-up discovery that Abraxis may need to conduct. Moreover, Elan has not provided any testing results on the alleged crystallinity of Abraxane. If Elan has such evidence, it should be forced to produce such results.

In a case strikingly similar to the one at bar, defendants believed that plaintiffs intended to pursue a theory of infringement based on the presence of an abnormality within an anti-ulcer drug manufactured by defendants. *Glaxo, Inc. v. Torphram, Inc.*, No. 95 C 4686, 1996 U.S. Dist.

[12] Even if Elan is able to meet its burden, Abraxis would still be entitled to any documents if Abraxis could establish that there is a substantial need for the documents which cannot be readily obtained elsewhere. *Id.*

LEXIS 10139, at **6-7 (N.D. Ill. Jul. 17, 1996), *rev'd on other grounds*, 153 F.3d 1366 (Fed. Cir. 1998). The court granted the defendants' motion to compel production of the plaintiff's testing results, including infrared and x-ray studies. *Id.* The court compelled production of the plaintiff's testing because, among other reasons, the defendants were "entitled to receive a copy of the reference spectrum used to determine infringement." *Id.* at *8. Here, if Elan used testing results to determine infringement, Abraxis is entitled to those documents, including any x-ray diffraction test.

Elan's failure to articulate the documentary support for its infringement allegations is wholly inadequate. Elan has an obligation to point to actual evidence of infringement. *Laitram Corp.*, 939 F.2d at 1535; *Novartis Pharms. Corp.*, 234 F. Supp. 2d at 467. Yet, over a year into the lawsuit, Elan has not done so.

Abraxis respectfully requests that the Court compel production of all documents responsive to Document Request Nos. 74, 75, and 76, including any documents regarding testing of Abraxane. Abraxis also requests an Order from the Court overruling all of Elan's objections to Document Request Nos. 74, 75, and 76.

CONCLUSION

For the foregoing reasons, Abraxis respectfully requests that the Court grant its Motion to Compel and enter an Order substantially in the form of the Proposed Order attached hereto.

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Dated: August 8, 2007

CERTIFICATE OF SERVICE

I, Elena C. Norman, Esquire, hereby certify that on August 15, 2007, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on August 15, 2007, I caused a true and correct copy of the foregoing document to be served by e-mail on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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