UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

DEFENDANT'S REPLY BRIEF IN SUPPORT OF DEFENDANT'S MOTION FOR SANCTIONS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 11

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FEDERAL RULE

Fed. R. Civ. P. 11 ..... *passim*

I. INTRODUCTION

Elan's Opposition brief confirms the unfortunate necessity of Abraxis's Rule 11 Motion. Elan persists in turning the Federal Rules of Civil Procedure on their head, seeking extensive trade secret information from Abraxis in the vain hope Elan will be able to find a basis for its allegation that Abraxis infringes the '363 patent. That is not the way our legal system works.

Elan asks the Court to find its investigation reasonable even though at the time it filed this action the evidence ran counter to its allegations. Elan does not dispute that the requirements of Rule 11 are ongoing, but it ignores the additional evidence of noninfringement Abraxis voluntarily produced months ago, as well as more recently in discovery. Elan does not dispute that it must demonstrate why it was objectively reasonable for it to assert the '363 patent against Abraxis, both at the time of filing and now, but Elan has not done so. How many more hundreds of thousands—even millions—of dollars must Abraxis spend to litigate this demonstrably frivolous claim?

Elan's 38-page Opposition attempts to obfuscate, in a sea of red herrings, its failure to address substantively its obligations under Rule 11. Elan devotes much of its brief to complaining of supposed discovery misconduct by Abraxis, which even if true, would have no bearing on whether Elan had or has a good faith basis for asserting infringement of the '363 patent. (*See, e.g.*, Plaintiff's Answering Brief in Opposition to Defendant's Motion for Sanctions Pursuant to Fed. R. Civ. P. 11 ("Opp.") at 1-5, 10-13, 18-19, 30-31.) Elan also argues Abraxis makes an end-run around the Court's scheduling order by seeking the same "death-penalty" sanctions it would get via early summary judgment, even though Abraxis's motion seeks

dismissal *without* prejudice. (*See, e.g.*, Opp. at 4, 18.) Elan further declares that Abraxis seeks to usurp the Court's authority to construe claims, ignoring that Elan itself was required to construe the claims reasonably before filing suit. (*See, e.g., id.* at 4, 20-21.) Elan spends two pages of its Opposition arguing that the '363 patent is "important" and "pioneering," which is not an issue here. (*See id.* at 7-8.) These exercises in misdirection do not meet Elan's burden in responding to Abraxis's Rule 11 Motion to explain the bases for its '363 patent infringement allegations.

II. ELAN'S INFRINGEMENT THEORIES ARE OBJECTIVELY BASELESS.

In responding to Abraxis's motion, Elan bears the burden of "demonstrat[ing] to both the court and the alleged infringer exactly 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). Elan does not contest that it bears this burden or that this burden requires it to construe its claims reasonably. Yet despite the length of Elan's Opposition, Elan fails to identify an objectively reasonable basis for why it believed that the "crystalline" limitation of the '363 patent claims was met under any theory.

Elan is asserting numerous baseless theories, each of which is sanctionable. Elan relies on a frivolous construction of the claim term "crystalline" that would encompass "amorphous," the very antithesis of crystalline. (Opp. at 20-23.) Elan then states four more frivolous theories to explain why the "crystalline" limitation of the '363 patent claims is met if not construed literally to mean "amorphous."

First, Elan has not shown it had a basis for asserting direct, literal infringement by Abraxane, because the publicly available documents

overwhelmingly suggested that the paclitaxel in Abraxane is amorphous and Elan's test results were inconclusive. Second, Elan has not shown it had a basis for asserting direct infringement by Abraxane under the doctrine of equivalents, because that argument was precluded by three independent legal bars. Third, Elan has not shown it had a basis for asserting direct, literal infringement by intermediates created during the manufacture of Abraxane, admitting the argument was speculative. Fourth, Elan has not shown it had a basis for asserting indirect infringement by reconstituted Abraxane,[1] failing even to address the argument substantively.

A. Elan's Construction Of The "Crystalline" Limitation To Include "Amorphous" Was Objectively Unreasonable.

Throughout its Opposition, Elan argues that this Motion is premature because the Court has not yet construed the "crystalline" limitation. (Opp. at 1, 3-5, 19-21.) Elan is wrong. While it is true that the Court ultimately construes the asserted claims, the Federal Circuit "has construed Rule 11, in the context of patent infringement actions, to require that an attorney interpret the pertinent claims of the patent in issue before filing a complaint alleging patent infringement." *Antonius v. Spalding & Evenflo Cos.*, 275 F.3d 1066, 1072 (Fed. Cir. 2002) (citing cases). The "attorney's proposed claim construction is subject to the Rule 11(b)(2) requirement that all legal arguments be nonfrivolous." *Id.* Elan does not dispute these requirements, but never shows it met them.

[1] Elan's reference to "reconstituted Abraxane" is to a liquid pre-administration form of Abraxane. (*See* Opp., Ex. 1 at 1.) Abraxane is sold as a dry powder. Before intravenous administration it is reconstituted in saline solution. (*Id.*)

While Elan's counsel avers in conclusory fashion that they construed the claims, they do not reveal their construction. (Opp., Ex. L at ¶ 7, Ex. U at ¶ 6, Ex. V at ¶ 3.) Elan nonetheless argues that its secret construction would permit the "crystalline medicament" limitation to encompass "amorphous medicament." (Opp. at 20-21.) As we show below, there is no objectively reasonable construction of "crystalline medicament" that would cover an "amorphous medicament."

A non-frivolous litigant would have construed the claims in light of the patent specification and file history. *See, e.g., Eon-Net, L.P. v. Flagstar Bancorp, Inc.*, 239 F.R.D. 609, 617-618 (D. Wash. 2006) (citing cases) ("The specification exposes the frivolity of [plaintiff's] claim construction position."). Here, one need only look to the specification of the '363 patent, which confirms that "crystalline medicament" cannot possibly be construed to encompass its polar opposite: "[t]he crystalline phase differs from an amorphous, i.e., non-crystalline phase . . . ." (Declaration of Diana B. Kruze in Support of Defendant's Reply Brief in Support of Defendant's Motion for Sanctions Pursuant to Federal Rule of Civil Procedure 11 ("Kruze Decl."), Ex. A at 2:29-30.)

The prosecution history confirms that crystalline is the opposite of amorphous. Throughout the prosecution of the '363 patent, the applicants distinguished one reference after another on the grounds that the prior art described amorphous, non-crystalline particles. (Kruze Decl., Ex. B [10/29/92 Information Disclosure Statement Pursuant to 37 C.F.R. 1.97-1.99] at 3 ("U.S. Patent No. 4,826,689 discloses a method of making uniformly sized noncrystalline amorphous particles from water-insoluble organic compounds wherein the organic compound is

dissolved in an organic solvent."); *see also id.*, Ex. B [Rule 132 Declaration by G. Liversidge] at 2 ("U.S. Patent No. 5,049,322 discloses a solvent precipitation technique for preparing nanocapsules. Solvent precipitation techniques ordinarily result in the formation of noncrystalline or amorphous particles.").)

Elan's contention that the crystalline limitation can encompass its very antithesis—which was expressly disclaimed to obtain allowance of the asserted claims—is objectively unreasonable.[2] *Eon-Net,* 239 F.R.D. at 618 (sanctioning plaintiff because "[t]o the extent [the patentee] went through the motions of a claim construction exercise, it recklessly defined terms to suit its purposes in spite of the specification's language"). Filing suit based on this frivolous construction violates Rule 11. *Id.*; *see also Antonius*, 275 F.3d at 1075 ("[S]anctions may be based on a single invalid legal or factual theory, even if other asserted theories are valid.").

B. At No Point Could Elan Reasonably Have Believed That The Crystalline Limitation Of The Asserted Claims Is Met Literally By Abraxane.

1. Elan's Pre-Filing Investigation Did Not Support Its Claims.

As a preliminary matter, Elan has improperly cherry-picked what it deems to be helpful information from its pre-filing investigation, while simultaneously hiding everything else under the veil of attorney-client privilege and work-product

[2] Contrary to Elan's suggestion, this case is nothing like *Q-Pharma, Inc. v. Andrew Jergens Co.*, in which the patentee's pre-filing claim "interpretations comport[ed] with the plain meaning of the claim language and d[id] not appear to be inconsistent with the patent's written description and prosecution history." 360 F.3d 1295, 1301 (Fed. Cir. 2004) (finding pre-filing claim interpretation not frivolous because it "followed the standard canons of claim construction and was reasonably supported by the intrinsic record.").

immunity. This is impermissible: a litigant may not use the attorney-client privilege and work product immunity 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.").

Elan's offer of an *in camera* inspection of selected documents does not solve this problem. (Opp. at 36.) Elan was required to explain "to both the court and the alleged infringer exactly why it believed" it had reasonable basis for suing. *View Eng'g*, 208 F.3d at 986. *In camera* inspection hides that explanation from Abraxis and asks the Court to "go fish" for a basis among the documents Elan produces.

a. Publicly available information demonstrated that the paclitaxel in Abraxane is not crystalline.

Elan could not have reasonably concluded that the paclitaxel in Abraxane was crystalline in the face of myriad publications available to Elan confirming that the paclitaxel in Abraxane was amorphous, not crystalline. For example, *PR Newswire* reported twice in 2003 that Abraxis's technology "integrates biocompatible proteins with drugs to create the amorphous, nanoparticle form of the drug." (Declaration of Emily A. Evans in Support of Defendant's Motion for Sanctions Pursuant to Federal Rule of Civil Procedure 11 ("Evans Decl."), Ex. A.) In 2004, *Pharmaceutical Innovation* published an article on Abraxane, similarly

explaining that the "paclitaxel [in Abraxane] is amorphous." (*Id.*) Elan's characterization of these documents as "self-serving" (Opp. at 12) misses the mark; at least eight such documents pre-date this litigation by years. (Defendant's Opening Brief in Support of Its Motion for Sanctions Pursuant to Federal Rule of Civil Procedure 11 ("Mot.") at 4.) And Elan does not dispute that it was aware of these documents at the time it filed suit. (Opp. at 24; Evans Decl., Ex. N at 8:19-22.)

Elan, in turn, cites only one publication that it avers characterizes the paclitaxel in Abraxane as crystalline. (Opp., Ex. T.)[3] That publication, however, simply characterizes three broad categories of nanoparticles—"solid drug nanoparticles," "solid lipid nanoparticles," and "polymeric nanoparticles"—as "crystalline materials formed by precipitation." (Opp., Ex. T at Table 2.) Abraxane is just a bullet point under one of those broad categories. (*Id.*) Not only does the publication present no data and cite no support for the proposition that the paclitaxel in Abraxane is crystalline, but, as we note above, the prosecution history of the '363 patent makes clear that Elan knew nanoparticles could be either crystalline or amorphous. A reasonable litigant in Elan's position would not have relied on this publication to file suit.

Elan's decision to ignore all evidence contrary to its allegations runs counter to the very cases upon which it relies. For example, in *Hoffman-La Roche, Inc. v. Invamed, Inc.*, the Federal Circuit affirmed the denial of sanctions only where "at the end of the plaintiff's pre-suit investigation it had neither evidence of infringement

[3] Elan does not contend that it was even aware of, much less relied upon, this publication at the time it filed suit.

nor non-infringement...." 213 F.3d 1359, 1364 (Fed. Cir. 2000).[4] Conversely, here, Elan filed suit despite being aware of substantial evidence of non-infringement.

b. Abraxis's patents covering Abraxane suggest the paclitaxel therein is not crystalline.

Elan also argues that the patents listed in the Orange Book for Abraxane support its position that the paclitaxel in Abraxane is crystalline, because for example, U.S. Patent Nos. 6,537,579 (claim 13) and 6,749,868 (claim 4) indicate that the particles covered by the patent claims are "amorphous, crystalline, or a mixture thereof." (Opp. at 20, n.50, Ex. L ¶ 4, Ex. U ¶ 4.) This argument makes no sense, because if the patents cover particles that are amorphous, crystalline, or a mixture thereof, then they simply do not inform the analysis – such claims would cover Abraxane regardless of whether the paclitaxel therein was crystalline or amorphous.

Moreover, Elan ignores that both of these patents disclose an amorphous drug as the preferred embodiment: "While it is recognized that particles produced according to the invention can be either crystalline, amorphous, or a mixture thereof, it is generally preferred that the drug be present in the formulation in an amorphous form." (*Id.*, Ex. R at 6:25-28; Ex. S at 7:13-16.) After reviewing these patents, Elan could not have believed before filing the '363 patent claim that it had a reasonable chance of proving infringement.

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[4] In *Cambridge Prods., Ltd v. Penn Nutrients, Inc.*, there was no mention of evidence contrary to the infringement allegations, and the patentee procured "chemical analyses and acquired documentary evidence that appeared to confirm that the product alleged to infringe fell within the chemical specifications of the patented method." 962 F.2d 1048, 1050 (Fed. Cir. 1992). In *Q-Pharma*, there was also no evidence that would have led the patentee away from concluding the accused product infringed. 360 F.3d at 1302.

c. Elan's tests of Abraxane were at best inconclusive.

In the face of the extensive public documentation suggesting that the paclitaxel in Abraxane is amorphous, a reasonable litigant would only have filed suit with contrary test results in hand. Here, one is left with the inescapable conclusion that Elan's pre-suit testing was at best "inconclusive," as admitted by Elan's counsel. (*See* Opp., Ex. L at ¶¶ 3, 7-9 (providing no test results but stating that at least some were "inconclusive").) Nothing in the declarations of Elan's counsel suggests that any pre-suit testing of Abraxane supported the allegation that the paclitaxel therein is crystalline. (*See generally* Opp., Exs. L, U and V.)

Unlike *Hoffman-La Roche*, in which no analytical test existed that would support or undermine the infringement allegation, 213 F.3d at 1363-64, Elan lists in its brief many analytical tests that it says would demonstrate whether the paclitaxel in Abraxane is amorphous, (Opp. at 12-13). Elan argues that if Abraxane does not infringe, Abraxis would have produced exculpatory results of its own such testing. (*Id.*) This argument turns patent litigation on its head.

The burden of proving infringement is Elan's, as was the burden of conducting the pre-filing investigation. That Elan argues it needs Abraxis's test results provides further confirmation that Elan did not do its own testing, as it was obligated to do under Rule 11. In any event, Abraxis has produced documentation of its test results, which were submitted to the FDA, showing that the paclitaxel in Abraxane is amorphous. *See* Part II.B.2, *infra*.

d. The Abraxane label coupled with public statements by Abraxis does not support Elan's position.

Elan last cites the Abraxane label, which discloses that the raw ingredient paclitaxel "is a white to off-white crystalline powder," and Elan's unsupported allegation that "paclitaxel is typically found as a crystalline material." (Opp., Ex. L at ¶ 6, Ex. U at ¶ 5.) Elan relies on this in conjunction with a statement in an ODAC Briefing Package that Abraxane is formed without altering the paclitaxel and human albumin. (Opp. at 22, Ex. G.) Elan contends that a pre-filing review of these documents together supported a reasonable basis for Elan's mistaken belief that Abraxane infringes. This is objectively incorrect.

First, Elan could not have relied on the ODAC Briefing Package during its pre-filing review, because it is dated two weeks *after* Elan filed its complaint. (Opp., Ex. G at 2.) Second, this document only discusses chemical alteration of paclitaxel into other compounds, not a change in its physical form from crystalline to amorphous. Elan should have known this. "Paclitaxel raw material is usually present as needle shaped crystals … typically between 5-500 microns [(5,000 to 500,000 nm)]." (Opp., Ex. S at col. 31:64-65.)[5] Conversely, Abraxane is only 130 nm. (Opp., Ex. 1 at 1.) This drastic reduction in size between the raw ingredient and the final product is an obvious change in physical form.[6]

[5] As Elan itself states, this patent formed part of its basis for filing suit.

[6]

* * *

In sum, Elan had the following information available to it at the time it filed suit: (1) "inconclusive" test results; (2) one publication characterizing, without support, all nanoparticles as "crystalline materials;" (3) the Abraxane label characterizing the raw ingredient paclitaxel as crystalline; (4) at least eight publications confirming that the paclitaxel in Abraxane is amorphous; and (5) at least two patents covering Abraxane, in which the preferred embodiment contains an amorphous drug. No reasonable litigant could have believed the crystalline limitation is met by Abraxane, when the only available evidence pointed so overwhelmingly to the contrary.

2. The Evidence Produced In This Case Further Undermines Elan's Claim.

Elan does not contest that it has a continuing duty under Rule 11 to dismiss its claims if Elan discovers during the course of the litigation that its claims were unfounded. Elan's case has only grown worse since it was filed. Early in the litigation, Abraxis voluntarily produced numerous documents evidencing that the paclitaxel in Abraxane is amorphous. (Mot. at 4-5; Evans Decl., Exs. A, B and D; Declaration of Paul F. Coyne in Support of Defendant's Motion for Sanctions Pursuant to Federal Rule of Civil Procedure 11 ("Coyne Decl."), Ex. A.) Documents produced more recently in the course of discovery strengthen that showing. Elan's Opposition simply ignores or mischaracterizes this evidence.

As noted in Abraxis's opening brief, Abraxis voluntarily produced the results of an X-ray diffraction analysis of Abraxane that was submitted to the FDA before this suit was filed. (Mot. at 5.) This document explains that the paclitaxel in

Abraxane is amorphous. (Coyne Decl., Ex. A.) Rather than acknowledging the import of this document, Elan in its Opposition mischaracterizes it as "regarding an uncharacterized material." (Opp. at 12.) This argument is without merit. Even the letter from Elan's counsel cited as support for this statement admits that this document "report[s] results of a physical analysis of Abraxane®...." (Opp., Ex. I at 6.)[7] Moreover, at the time Elan filed its Opposition, Abraxis had already produced the entire report containing the X-ray diffraction analysis of Abraxane, entitled "Characterization of ABI-007." (Kruze Decl. ¶ 2.)

Elan also mischaracterizes the document attached to its Opposition as Exhibit Q, as suggesting that the question of whether the paclitaxel in Abraxane is crystalline is ambiguous. (Opp. at 20, n.50 ("Abraxis describes the paclitaxel in Abraxane as 'ambiguous noncrystalline.'").) This is a gross misstatement of the document, which clearly identifies the paclitaxel in Abraxane as amorphous: "Because the two components are joined together to form tiny spheres of albumin encapsulating ***paclitaxel in the amorphous (ambiguous noncrystalline) state,*** paclitaxel will readily dissolve." (Opp., Ex. Q at 3 (emphasis added).) That this non-scientific "Sales Training Book" also uses the inartful phrase "ambiguous noncrystalline" is of no moment. Indeed, if any confirmation were necessary, Figure 7-1 on that very page says Abraxane contains "Amorphous Paclitaxel." (*Id.*)

[7] Elan apparently seeks to obfuscate the import of this document, which refers to Abraxane as ABI-007, by suggesting that Elan does not know if ABI-007 is Abraxane. Any ambiguity was resolved when Elan served a request for admission that ABI-007 is Abraxane, which Abraxis admitted on January 25, 2007. (Kruze Decl., Ex. C at 3.) Abraxis has also produced documents submitted to the FDA stating that ABI-007 is the same as Abraxane. (Kruze Decl., Exs. D and E.)

C. Elan's Allegation That Amorphous Paclitaxel Meets The Crystalline Limitation By Equivalents Ignores Law And Fact.

Elan's desperation to show its claim was brought in good faith is most apparent in Elan's argument that it reasonably believed there was infringement under the doctrine of equivalents. (Opp. at 22-23.) Elan simply tosses this argument out in half-a-page of its 38-page tome, as a specious attempt to deflect criticism from its deficient pre-filing investigation. As we show below, under well-established law, no reasonable litigant could have believed that amorphous paclitaxel was equivalent to crystalline paclitaxel as claimed in the '363 patent.

Notably, Elan did not allege infringement under the doctrine of equivalents in its Complaint. Moreover, in its operative, twice-amended response to Abraxis's infringement contention interrogatory (an interrogatory that was served more than five months ago), Elan did not allege the crystalline limitation is met equivalently. (Kruze Decl., Ex. G [Ex. A to Elan's second amended response to Abraxis Interrogatory No. 1] at 1.) Elan did, however, allege in its response that other limitations were met equivalently. (*Id.* at 11.)

It is well-established law that the doctrine of equivalents cannot be used to capture that which is disclosed in the specification, but not claimed. Indeed, the Federal Circuit addressed this issue *en banc*. *Johnson & Johnston Assoc., Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054-55 (Fed. Cir. 2002) (*en banc*). As the Federal Circuit made clear,

> when a patent drafter discloses but declines to claim subject matter, as in this case, this action dedicates that unclaimed subject matter to the public. Application of the doctrine of equivalents to recapture subject matter deliberately left unclaimed would conflict with the

> primacy of the claims in defining the scope of the patentee's exclusive right.

Id. at 1054 (internal quotation omitted). In this case, every asserted claim is limited to a particulate composition containing a "crystalline medicament," while the specification discloses both crystalline anti-cancer agents and amorphous, non-crystalline anti-cancer agents. (Kruze Decl., Ex. A at 2:29-33.)

The facts of this case are even worse than those of *Johnson & Johnston*, because Elan not only disclosed amorphous, non-crystalline medicaments, it disclaimed them to overcome the prior art. (Kruze Decl., Ex. B [9/13/93 Amendment] at 4.) This too 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.").

Moreover, because the patent itself makes clear that the amorphous, non-crystalline state is the antithesis of the crystalline state, a finding that "amorphous" is the equivalent of "crystalline" is legally barred under the doctrine of vitiation. *See, e.g., Moore, U.S.A., Inc. v. Std. Register Co.*, 229 F.3d 1091, 1106 (Fed. Cir. 2000) (refusing to permit claim element "majority" from encompassing a minority under the doctrine of equivalents).[8]

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[8] The Federal Circuit stated, "First, to allow what is undisputedly a minority (i.e., 47.8%) to be equivalent to a majority would vitiate the requirement that the 'first and second longitudinal strips of adhesive . . . extend the majority of the lengths of said longitudinal marginal portions.' '464 patent, col. 10, ll. 56-60. . . .

(Footnote continues on next page.)

To argue that the amorphous paclitaxel in Abraxane could meet the crystalline limitation of the asserted claims under the doctrine of equivalents, Elan had to ignore each of these three legal bars to the doctrine of equivalents. Ignoring this controlling authority is a violation of Rule 11. It is also a prime example of just how egregious Elan's conduct is.

D. Elan Still Has Nothing To Support Infringement By Intermediates.

Elan admits it has no basis for believing that an intermediate created during the manufacture of Abraxane infringes any claim of the '363 patent, and that it was just "'shooting in the dark.'" (Opp. at 13-14, 30.) In its Opposition, Elan even tries to minimize the impact of its counsel's admission during the February 16, 2007 discovery conference by "clarifying" that his speculation regarding infringement "applies solely to potentially infringing intermediates." (*Id.* at 13.) Despite its admissions, Elan baldly posits that it "reasonably believed that manufacturing Abraxane® would result in products that infringe the '363 Patent. Short of filing suit and conducting discovery, Elan had no way of verifying or disputing that belief." (*Id.* at 30.)

This is unacceptable, and a clear violation of Rule 11. In arguing to the contrary, Elan relies on only one inapposite case: *Cambridge Prods, Ltd. v. Penn Nutrients, Inc.*, 962 F.2d 1048 (Fed. Cir 1992). In that case, the patent claimed a method of manufacture. *Id.* at 1049. The patentee there conducted a pre-filing

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(Footnote continued from previous page.)

Second, it would defy logic to conclude that a minority -- the very antithesis of a majority -- could be insubstantially different from a claim limitation requiring a majority, and no reasonable juror could find otherwise." *Moore*, 229 F.3d at 1106.

investigation "that appeared to confirm that the product alleged to infringe fell within the chemical specifications of the patented method." *Id.* at 1050. The Federal Circuit noted that "[w]ithout the aid of discovery, any further information was not practicably obtainable." *Id.*

In this case, the entirety of Elan's argument is that because the raw ingredient paclitaxel is crystalline and the final product is amorphous, it must transform at some point during the manufacturing process. (Opp. at 36.) Elan offers nothing to support a belief that at the time right before such a transformation occurs, there is an intermediate product meeting every limitation of any asserted claim.[9] By its own admission, Elan asserted this theory on nothing more than a guess—a far cry from the patentee in *Cambridge Prods.*

But even if the Court accepts Elan's position that this shot in the dark did not violate Rule 11 when Elan filed suit, Elan's continued pressing of this argument is such a violation. As noted above, Elan filed its Opposition while in possession of documents showing the contours of Abraxis's manufacturing process.

Elan cannot argue that there exists an intermediate "particulate composition" meeting the limitations of the asserted claims.

[9] For example, individual particles, smaller than 1000 nm, comprising a crystalline medicament and a non-crosslinked surface modifier adsorbed thereon.

E. Elan Does Not Even Attempt To Justify Its Assertion of Infringement By Reconstituted Abraxane.

In hearings before the Court, Elan has asserted that Abraxane, when reconstituted prior to patient administration, may infringe the '363 patent. (*See, e.g.*, Evans Decl., Ex. N at 9:5-7.) Elan reiterated this allegation in its Opposition, alleging "indirect and/or contributory infringement through the reconstituted Abraxane®," stating that in making this allegation Elan was not "'speculating' or 'shooting in the dark.'" (Opp. at 14.) Despite Elan's obligation in opposing Abraxis's Motion to explain exactly why Elan believed reconstituted Abraxane infringed, those conclusory fragments are Elan's sole mention of this allegation in its brief. (*See generally* Opp.)

None of the supporting declarations submitted by Elan's counsel even suggests that Elan counsel tested reconstituted Abraxane to determine if the crystalline limitation was met. (*See generally* Opp., Exs. L, U and V.) Elan has never offered anything to suggest that this allegation was made in good faith. Indeed, in its operative twice-amended response to Abraxis's infringement contention interrogatory (which, again, was served more than five months ago), Elan does not allege infringement of any claim of the '363 patent by reconstituted Abraxane, let alone provide support for that allegation. (*See generally* Kruze Decl., Ex. G [Elan's second amended response to Abraxis Interrogatory No. 1].)

Elan has steadfastly refused to explain the basis for this infringement allegation, and it therefore should be sanctioned under Rule 11. *View Eng'g*, 208 F.3d at 986.

III. ELAN BROUGHT THIS CLAIM FOR AN IMPROPER PURPOSE.

Elan's sophistry does not obscure its improper purpose in asserting infringement of the '363 patent. Elan does not dispute that its requests for admission seek information pertinent to Elan's pending patent applications.[10] Nor does Elan dispute that it could file new patent applications or tailor the claims of its existing applications. It instead attempts to justify its requests for admission by tying them to Abraxis's patent applications. (Opp. at 32-35.) This argument misses the mark because what is at issue here is Elan's '363 patent, not Abraxis's patent applications.

With respect to Elan's requests for Abraxis's manufacturing documents, Elan argues that they do not evidence an improper purpose because Elan needs those documents to determine infringement by an intermediate. (*Id.* at 35.) Even if true, as explained above and in Abraxis's opening brief, using discovery to find a basis for an otherwise groundless claim *is* an improper purpose. Because Elan has no reasonable basis to believe that any intermediates in the manufacture of Abraxane infringe, Elan's continued pursuit of these trade secrets supports an inference of improper purpose.

With respect to the "stability" requests, Elan concedes that this term appears nowhere in the claims, instead arguing it is "implicit." With respect to the "carrier protein" requests, Elan does not even make the feeble argument that this limitation is "implicit." Again, these requests support an inference of improper purpose.

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[10] Elan mischaracterizes Abraxis's argument as suggesting that Elan should be sanctioned for its discovery requests. (Opp. at 31.) Abraxis did not so argue. Rather, as explained by Abraxis, Elan's discovery requests evidence Elan's improper purpose in bringing this suit.

IV. CONCLUSION

Elan has set forth five separate allegations, each of which alone warrants sanctions under Rule 11.[11] Together, they demonstrate the cavalier attitude with which Elan has approached this litigation—Elan chose to shoot first and ask questions later, or not at all. And for this, Abraxis seeks only relatively modest sanctions: (1) costs and attorneys' fees incurred in defending against Elan's baseless claims and in bringing this motion, and (2) a dismissal *without* prejudice subject to documenting a *prima facie* basis for its allegations. These are not the "death penalty" sanctions of which Elan so vehemently complains, and they are not the same as the dismissal with prejudice that would flow from an order granting summary judgment.

The Court should thus grant Abraxis's motion, and spare Abraxis the continued harassment of litigating these baseless claims. As the Federal Circuit has stated, a party's failure to explain why it had a reasonable pre-filing basis for

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[11] Contrary to Elan's assertion, Abraxis's mere mention of its Rule 11 motion during the March 15, 2007 discovery conference does not preclude sanctions. Not one case upon which Elan relies suggests otherwise. In every one, the moving party failed to serve the Rule 11 motion on the opposing party before filing it with the court. *First Bank v. Hartford Underwriters Ins. Co.*, 307 F.3d 501, 511 (6th Cir. 2002) (service of summary judgment motion that did not mention Rule 11 was not equivalent to service of a safe harbor letter); *Elliott v. Tilton*, 64 F.3d 213, 216 (5th Cir. 1995) ("plaintiffs did not serve their motion for sanctions on the defendants and defense counsel prior to filing"); *Ridder v. City of Springfield*, 109 F.3d 288, 296-97 (6th Cir. 1997) (same); *Hadges v. Yonkers Racing Corp.*, 48 F.3d 1320, 1328 (2d Cir. 1995) (same); *United Food & Commercial Workers Union Local No. 576. v. Four B Corp.*, 893 F. Supp. 980, 987 (D. Kan. 1995) (same). Such is not the case here, as evidenced by the certificate of service. (Kruze Decl., Ex. H.) In this case Abraxis's counsel only invited the Court to permit the motion to be filed earlier, which is contemplated by Rule 11. Fed. R. Civ. P. 11(c)(1)(A) ("21 days after service of the motion (or such other period as the court may prescribe)"); (*see* Opp., Ex. F at 6:12-13.)

believing it could establish infringement "should ordinarily result in the district court expressing its broad discretion in favor of Rule 11 sanctions, at least in the absence of a sound excuse or considerable mitigating circumstances." *View Eng'g*, 208 F.3d at 986.

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CERTIFICATE OF SERVICE

I, Josy W. Ingersoll, Esquire, hereby certify that on April 17, 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 April 17, 2007**,** I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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