UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

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

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FEDERAL RULES

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

We recognize that Rule 11 motions are a last resort. We are at the point, however, where we need to bring to the Court's attention in a formal way the violation of the Federal Rules of Civil Procedure represented by Elan's continued pursuit of its infringement claim on the '363 patent. We have tried to persuade Elan that it had and has no viable claim for infringement based on the "crystalline" limitation of the '363 patent claims. Elan has nonetheless persisted in the lawsuit. Now we know for certain — from admissions by Elan's counsel — what we suspected all along: this case is not about the pursuit of meritorious claims for infringement; it is instead about the abuse of the litigation process to obtain discovery and then determine whether there is a viable claim on either of the patents-in-suit or other soon-to-issue patent applications. That is not how our legal system works.

All of the claims of the '363 patent require a "crystalline medicament." That the paclitaxel in Abraxane is amorphous, not crystalline, is a matter of public record; indeed, Elan's counsel has acknowledged that Elan was aware of public reports of this fact. Elan's rank speculation that the paclitaxel in Abraxane nonetheless is crystalline (speculation which its own testing failed to confirm) is legally insufficient to impose on Abraxis the significant expense of defending against a patent infringement suit. Nor does it justify Elan's quest for Abraxis's most closely held trade secrets. Elan should be sanctioned for its failure to conduct a reasonable inquiry into its allegations of patent infringement, and its refusal to abandon its baseless claim in the face of all contrary evidence. Abraxis requests reimbursement of its fees and costs incurred in bringing this motion and defending against Elan's

groundless claims. Abraxis also requests that Elan's claim of infringement of the '363 patent be dismissed and that Elan not be permitted to file an amended complaint absent a prima facie showing of a non-frivolous basis for its allegations.

NATURE AND STAGE OF PROCEEDINGS

On July 19, 2006, Elan filed suit against Abraxis in this Court, alleging infringement of U.S. Patent Nos. 5,399,363 and 5,834,025. Abraxis answered the Complaint on August 22, 2006, denying the allegations of patent infringement. The parties are currently engaged in fact discovery, during which Elan made statements confirming it had no basis for believing Abraxis infringed the '363 patent prior to filing suit (or, for that matter, now), as required by Fed. R. Civ. P. 11.

SUMMARY OF ARGUMENT

1. It is well-established that filing a claim of patent infringement without conducting a proper pre-filing investigation constitutes a violation of Fed. R. Civ. P. 11, for which sanctions are appropriate. It is also a violation of Rule 11 to file suit for an improper purpose, such as to cause harassment, undue delay, or needless increase in litigation expense.

2. In the context of patent infringement, before filing suit plaintiff's counsel must compare the accused product to the claims of the asserted patents, and determine that there is a reasonable basis for finding infringement of at least one claim of each patent asserted.

3. In this case, every claim of the '363 patent requires a "crystalline medicament." Elan admits that it has no basis for contending that the paclitaxel in the accused product, Abraxane, is crystalline, and that it is seeking discovery in the hope of finding a basis for an infringement claim.

4. Because Elan has subjected Abraxis to suit without a good faith basis that Abraxane infringes any claim of the '363 patent, and with the improper purpose of gaining access to Abraxis's highly confidential, trade secret information, Elan's cause of action for infringement of the '363 patent should be dismissed and Abraxis should recover its costs and fees for bringing this motion and for defending against this baseless claim.

BACKGROUND

Abraxis is an integrated, global biopharmaceutical company dedicated to meeting the needs of critically ill patients. Abraxis invented and sells the drug product Abraxane, which has been approved by the FDA for the treatment of breast cancer in certain patients. (Answer, ¶¶ 9-11 [Docket No. 7].) Abraxane is a particulate formulation of paclitaxel. (*Id.* at ¶ 10.)

Paragraph 13 of Elan's Complaint states:

> On information and belief, Abraxis has been, and currently is, directly and/or indirectly infringing the '363 patent by making, using, selling, and/or offering for sale Abraxane®; contributing to the use of Abraxane® by others; and/or inducing others to use Abraxane®.

(Compl., ¶ 13 [Docket No. 1].) The '363 patent has 17 claims; Claim 1 is an independent claim from which all other claims depend. (*Id.*, Ex. A, '363 patent, cols. 14-16.) Claim 1 of the'363 patent requires particles "consisting essentially of" "a non-crosslinked surface modifier" and "a crystalline medicament." (*Id.*, col. 14, lines 7-11.) Thus, every claim of the '363 patent also has those limitations.

On October 30, 2006, the parties submitted a Joint Status Report to the Court. (Joint Status Rpt. [Docket No. 11].) In that Report, Abraxis explained that Abraxane

could not infringe any claim of the '363 patent because the paclitaxel in Abraxane is amorphous, not crystalline – a fact that is public knowledge. (*Id.* at 3, 5.) At the November 6, 2006 Scheduling Conference, Elan's counsel refused to concede this fact. Elan's counsel instead stated, "I think we are prepared to say that we don't agree with those flat-out statements. I think that's why we are here, ***to determine that information.***" (*See* Declaration of Emily A. Evans in Support of Defendant's Motion for Sanctions Pursuant to Federal Rule of Civil Procedure 11 ("Evans Decl."), Ex. M at 3:2-4 [Tr. of Nov. 6, 2006 Scheduling Conference] (emphasis added).)

In an effort to resolve this dispute quickly, on November 8, 2006, Abraxis's counsel sent Elan's counsel myriad publicly available documents reporting that the paclitaxel in Abraxane is amorphous. (*Id.*, Ex. A.) Four of the six documents enclosed were created years before this litigation was commenced. (*Id.*) Elan refused to abandon its claims.

Again seeking an early resolution of this issue, on December 1, 2006, Abraxis's counsel provided Elan with another four documents confirming that the paclitaxel in Abraxane is not crystalline, all of which were created in 2004 or earlier. (*Id.*, Ex. B.) Elan nevertheless continued to pursue its infringement claim.

On December 4, 2006, Elan served its infringement contentions.[1] (*Id.*, Ex. C.) For the crystalline claim limitation, Elan stated, "Abraxane® comprises roughly 100 mg (10% by weight) of paclitaxel, a crystalline medicament useful in treating

[1] Elan made a non-substantive amendment to its infringement contentions on January 18, 2007.

cancer." (*Id.*, Ex. C, Claim Chart, at 1.) Elan cited no factual support for this statement. (*Id.*)

Abraxis again sought to resolve this issue on January 31, 2007, by providing counsel for Elan with the results of an X-ray diffraction analysis of Abraxane that Abraxis had filed with the U.S. Food and Drug Administration showing that the paclitaxel in Abraxane is not crystalline. (*Id.*, Ex. 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.) Elan again failed to withdraw its claim.

On February 16, 2007, the parties participated in a discovery conference before the Court. (*See generally,* Evans Decl., Ex. N [Tr. of Feb. 16, 2007 Discovery Conference].) During that conference, attempting to justify Elan's quest for Abraxis's manufacturing trade secrets, Elan alleged three theories of infringement with respect to the crystalline limitation: (1) the possibility of an infringing intermediate product formed during the process of manufacturing Abraxane, (2) the possibility that the paclitaxel in Abraxane may become crystalline when Abraxane is reconstituted prior to patient-administration, and (3) the only theory that was set forth in its Complaint and infringement contentions, the possibility that the paclitaxel in Abraxane might be crystalline. (*See, e.g.*, *id.* at 2:14-20, 9:2-10.)

Regarding the first theory, Elan's counsel admitted on the record that it had no basis for asserting infringement against an intermediate:

> We have good reason to believe that in the course of manufacturing, crystalline medicament may exist. But ***we have no way to know. We can speculate*** in conjunction with our experts. But all of our experts have told us that until they see how this stuff is made, they ***are really shooting in the dark.***

(*Id.* at 8:12-17 (emphasis added).) Elan's counsel reiterated this position during the conference, stating, "nor can we know whether an intermediate in the manufacturing process infringes our product claim." (*Id.* at 13:8-10.)

Regarding the second theory, Elan again spoke only in terms of possibilities: "The reconstitution process ***provides another opportunity*** for more amorphous material if it is indeed amorphous to convert to crystalline material." (*Id.* at 9:5-7 (emphasis added).)

Regarding all three of its infringement theories, Elan reiterated that these theories were speculative: "So there are three points at which we are ***potentially looking at crystalline material*** with respect to that limitation." (*Id.* at 9:8-10 (emphasis added).) During the conference, both counsel for Abraxis and the Court expressed concern that Elan was using discovery to find a basis for a claim that was otherwise unfounded. (*Id.* at 12:15-13:12.) Nevertheless, Elan made clear that it would persist in asserting its claims. (*Id.* at 13:7-17.)

Elan made further admissions regarding its third infringement theory on February 21, 2007, when Elan's counsel and counsel for Abraxis met and conferred regarding several discovery issues. (Evans Decl., ¶ 6; Coyne Decl., ¶ 2.) During that call, counsel for Elan acknowledged, for the first time, that Elan had previously conducted tests of Abraxane to determine whether the paclitaxel therein was crystalline. (Evans Decl., ¶ 6; Coyne Decl., ¶ 2.) According to counsel for Elan, the results of these tests were "***inconclusive***." (Evans Decl., ¶ 6; Coyne Decl., ¶ 2.)

ARGUMENT

I. ELAN VIOLATED RULE 11.

A. Applicable Legal Standard.

Rule 11 plays a particularly important role in patent cases, because "[d]efending against baseless claims of infringement subjects the alleged infringer to undue costs – precisely the scenario Rule 11 contemplates." *View Eng'g, Inc. v. Robotic Vision Sys.*, 208 F.3d 981, 986 (Fed. Cir. 2000). If challenged, a patent holder "must be prepared to demonstrate 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." *Id.*; *see also Antonious v. Spalding & Evenflo Cos.*, 275 F.3d 1066, 1072 (Fed. Cir. 2002) (requiring a patentee to conduct an infringement analysis before filing suit). If it cannot, absent mitigating circumstances or a legitimate excuse, a district court should ordinarily express its "broad discretion in favor of Rule 11 sanctions." *View Eng'g, Inc.*, 208 F.3d at 986.[2]

Rule 11(b)(3) requires an attorney to certify that "the allegations and other factual contentions have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery." Fed. R. Civ. P. 11(b)(3). The test is not whether the Complaint, taken as a whole, is non-frivolous. *Antonius*, 275 F.3d at 1075 ("The current version of the rule makes clear that sanctions may be based on a single

[2] To determine whether Rule 11 sanctions are warranted, the Federal Circuit applies the law of the relevant regional circuit. *Antonius*, 275 F.3d at 1072. In the Third Circuit, "[t]he court determines the reasonableness of an inquiry by applying an objective standard." *Garr v. U.S. Healthcare, Inc.*, 22 F.3d 1274, 1278 (3d Cir. 1994).

invalid legal or factual theory, even if other asserted theories are valid.") Rather, as Rule 11 itself states, "the claims, defenses and other legal contentions" and "the allegations and other factual contentions" in any pleading must be warranted under existing law and have evidentiary support. Fed. R. Civ. P. 11(b)(2) and (b)(3).

B. Elan Did Not Sufficiently Investigate the Substantive Basis for Its Claims.

Elan's claim that Abraxis meets the crystalline limitations of the '363 patent is unfounded.[3] Prior to filing its claim for infringement of the '363 patent, Elan only had the Abraxane package insert describing raw paclitaxel as crystalline, test results of the paclitaxel as it exists in Abraxane that were at best, "inconclusive," and rank speculation. Moreover, Elan was aware of the many publicly available documents reporting that the paclitaxel in Abraxane is amorphous. (Evans Decl., Ex. N at 8:19-22 [Tr. of Feb. 16, 2007 Discovery Conference].)

Counsel for Elan's recent statements to the Court and to Abraxis's counsel confirm this. Elan recently admitted that it could only "speculate" that this limitation is met; it has "no way to know" and is "really shooting in the dark." (*Id.* at 8:12-17.) Elan claims it has "opportunit[ies]" for "potentially" finding that this limitation is met (*id.* at 9:5-10), but admits that the only analysis it actually conducted was "inconclusive." (Evans Decl., ¶ 6; Coyne Decl., ¶ 2.) With nothing to support its claims, and publicly available information to the contrary, Elan has come to this

[3] Although this motion is directed at Elan's improper claim for infringement of the '363 patent, its claims under the '025 patent are similarly infirm. If the Court grants this motion, Abraxis believes that the '025 patent infringement claim readily can be resolved either by Elan withdrawing the claim, or by summary judgment.

Court on a fishing expedition to "determine that information." (Evans Decl., Ex. M at 3:2-4 [Tr. of Nov. 6, 2006 Scheduling Conference].)[4]

The possibility of "potentially" finding infringement is not a sufficient basis for bringing suit. In *Judin v. United States*, the patentee based its suit on viewing the accused devices at a distance. 110 F.3d 780, 781 (Fed. Cir. 1997) ("find[ing] a clear violation of Rule 11" and vacating trial court decision denying motion for sanctions).[5] In reviewing this pre-filing analysis, the Federal Circuit stated:

> That may have been sufficient to put Judin on inquiry about whether the Government was using a device that infringed his patent. But Rule 11 requires more. It requires that the inquiry be undertaken *before* the suit is filed, not after. Defendants have no choice when served with a complaint if they wish to avoid a default. They must undertake a defense, and that necessarily involves costs. Rule 11 prohibits imposing those costs upon a defendant absent a basis, well-grounded in fact, for bringing the suit.

Id. at 784 (emphasis in original).

The Federal Circuit reached a similar result in *View Engineering*, where the patentee based counterclaims for patent infringement solely on knowledge of the patents, the accused infringer's advertising, and statements made by the accused infringer to its customers. 208 F.3d at 985 (affirming district court's imposition of

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[4] Not only did Elan violate Rule 11 by pressing baseless claims, it has misused the discovery process by using this suit to force Abraxis to divulge its manufacturing trade secrets. *Micro Motion, Inc. v. Kane Steel Co.*, 894 F.2d 1318, 1327 (Fed. Cir. 1990) ("The discovery rules are designed to assist a party to prove a claim it reasonably believes to be viable *without discovery*, not to find out if it has any basis for a claim.") (emphasis in original).

[5] *Judin* addressed Rule 11 of the Rules of the Court of Federal Claims, which the Federal Circuit noted was "patterned after Rule 11, Fed. R. Civ. P." *Id.* at 783.

sanctions under Rule 11). In *View Engineering*, as in this case, the patentee filed claims to gain access to the accused infringer's trade secrets. *Id.* at 985-986. Moreover, this case is even more extreme than *View Engineering* because here the public record indicates that Abraxane is amorphous, Elan has admitted knowledge of that fact, and its own testing failed to show the contrary.

"A shot in the dark is a sanctionable event, even if it somehow hits the mark." *Garr*, 22 F.3d at 1279 (internal quotation omitted). And here, where the amorphous paclitaxel in Abraxane is the antithesis of the crystalline medicament required by the claims, Elan's shot in the dark could not be further from the mark. Elan should be sanctioned for averring in its Complaint that, on information and belief, Abraxis infringes the '363 patent. Elan was neither informed nor reasonably believed that the "crystalline medicament" limitation was met. Its persistence in advancing its claim even after being put on notice of the concerns of Abraxis and the Court is further evidence of Elan's violation of Rule 11. (*See* Evans Decl., Ex. N at 12:16-13:17 [Tr. of Feb. 16, 2007 Discovery Conference]); *see also Phonometrics, Inc. v. Economy Inns of Am.*, 349 F.3d 1356, 1361 (Fed. Cir. 2003) ("[O]ral statements that 'later advocate[e]' untenable contentions made in previously-filed papers are sanctionable under Rule 11.") (quoting adv. comm. note).

C. Elan Filed Its Complaint For An Improper Purpose.

Rule 11 also requires counsel to certify that its pleading is not being used for an improper purpose, such as to cause harassment, undue delay, or needless increase in litigation expense. Fed. R. Civ. P. 11(b)(1). "That test, too, is an objective one." *Lieb v. Topstone Indus.*, 788 F.2d 151, 157 (3d Cir. 1986). Elan's baseless infringement allegations and dogged pursuit of Abraxis's most sensitive trade secrets

suggest that Elan has another agenda for maintaining this suit – competitive advantage.

First, several of Elan's Requests for Admission seek information irrelevant to the patents-in-suit, but highly relevant to several of Elan's pending patent applications – applications that Elan may seek to assert against either Abraxane or other products in Abraxis's pipeline. For example, in Requests for Admission Nos. 15 and 21 through 23, Elan asked about the stability of Abraxane. (*See* Evans Decl., Ex. E, at 5-6.) Stability is not a limitation of any of the claims of the patents-in-suit. Several of Elan's pending patent applications, however, deal with the stability of nanoparticulate compositions. (*See, e.g.*, Evans Decl. Ex. F, ¶ 20 (invention "encompasses a process for *stabilizing* paclitaxel") (emphasis added); Ex. G (a nanoparticulate angiogenesis inhibitor composition comprising particles of paclitaxel and at least one "surface stabilizer"); Ex. H (a composition comprising paclitaxel particles and at least one water soluble peptide "surface stabilizer"); Ex. I (a composition comprising: particles of docetaxel or an analogue thereof and at least one "surface stabilizer"); Ex. J (a nanoparticulate tacrolimus formulation comprising particles of tacrolimus and at least one "surface stabilizer"); Ex. K (injectable nanoparticulate formulation comprising particles of tacrolimus and at least one "surface stabilizer"); Ex. L (a stable nanoparticulate cyclosporine composition comprising particles of a cyclosporine and at least one "surface stabilizer")). Moreover, in other Requests for Admission, Elan asked about the meaning of the term "proteins," whether Abraxane contains a "carrier protein," and whether, in a hypothetical nanoparticulate composition not at issue in this case, "bovine serum

albumin could be used as a carrier protein." (*See* Evans Decl., Ex. E at 5-6.) But having a protein is similarly not a limitation of any of the claims of the patents-in-suit. Indeed, the word "protein" is nowhere to be found in the patents-in-suit. Proteins, however, are highly relevant to Elan's pending patent applications. (*See, e.g.,* Evans Decl., Ex. H, ¶¶ 8-11, 19-24 ("polypeptides" as "surface stabilizers" for nanoparticles).) Elan therefore appears improperly to be seeking irrelevant admissions in the instant suit to bolster later claims against Abraxis should one or more of these Elan applications issue as a patent. *In re Intel Sec. Litig.*, 791 F.2d 672, 675 (9th Cir. 1986) (Rule 11 sanctions proper where attorney's goal was to gain an advantage in another case).

Second, Elan persists in seeking access to Abraxis's confidential manufacturing process information, despite this information's irrelevance to the claims and defenses in this suit. Abraxane's manufacturing process is a highly confidential trade secret. (Evans Decl., Ex. N at 4:12-5:1 [Tr. of Feb. 16, 2007 Discovery Conference].) As Abraxis has explained to Elan, Abraxis would be irreparably harmed if its trade secret manufacturing process documents were disclosed to Elan, Elan's licensees, or others in contact with Elan's experts. Nonetheless, Elan insists that it is entitled to discovery regarding this process, even after Abraxis provided Elan with data evidencing that the paclitaxel in Abraxane is amorphous. There are only two explanations. Elan may be seeking this information in the vain hope that it will find support for an infringement contention that it did not have prior to filing suit. Or, Elan filed suit specifically to gain access to this

confidential information for commercial advantage. Both motivations are improper; both are sanctionable under Rule 11.

II. BECAUSE ELAN DID NOT ADEQUATELY INVESTIGATE ITS CLAIM AND FILED SUIT FOR AN IMPROPER PURPOSE, ELAN MUST REIMBURSE ABRAXIS FOR ITS FEES AND COSTS.

Because Elan had no basis for its claim for infringement of the '363 patent at the time it filed its Complaint, because it continues to assert the claim notwithstanding this failure, and because it filed its claim for an improper purpose, Elan should be sanctioned under Rule 11. Fed. R. Civ. P. 11(c)(2). "The best way to control unjustified tactics in litigation is to ensure that those who create costs also bear them." *In re TCI Ltd.*, 769 F.2d 441, 446 (7th Cir. 1985). This should be particularly true for patent litigation, "an expensive proposition." *View Eng'g*, 208 F.3d at 986 (affirming monetary sanction based on calculation of attorneys' fees and costs). As the Federal Circuit has recognized, "[d]efending against baseless claims of infringement subjects the alleged infringer to undue costs–precisely the scenario Rule 11 contemplates." *Id.*

CONCLUSION

Abraxis requests that the Court order Elan to reimburse Abraxis for its costs and attorneys' fees incurred in bringing this motion and in defending against the allegations of infringement of the '363 patent. Abraxis also requests that Elan's cause of action for infringement of the '363 patent be dismissed, and that Elan be permitted to re-file only if and when it can establish and document, in the Complaint, a prima facie basis for its allegations. These are appropriate sanctions here, where Elan pressed its baseless allegations for half a year even in the face of mounting

evidence to the contrary, and where such a requirement will not altogether bar Elan from the courthouse.

Dated: March 20, 2007

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