UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ELAN PHARMACEUTICAL INTERNATIONAL LIMITED, Plaintiff, v. ABRAXIS BIOSCIENCE, INC., Defendant.	)	C. A. No. 06-438-GMS

DEFENDANT'S ANSWERING BRIEF IN OPPOSITION TO PLAINTIFF'S MOTION FOR CLARIFICATION OF ORDER CONSTRUING THE TERMS OF U.S. PATENT NO. 5,834,025

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I. INTRODUCTION

Although Elan styles its motion a "motion for clarification," Elan's motion is actually a thinly-disguised motion to reconsider. As it candidly concedes, however, Elan cannot meet the standard for a motion to reconsider. The motion should be denied on that basis alone.

Even if the Court entertains the motion, it is without merit whether it is characterized as a motion for clarification or a motion to reconsider. If it is a motion for clarification, it fails because the *Markman* order is clear. If it is a motion to reconsider, Elan cannot meet the standard for such a motion. *First*, there is no ambiguity in the Court's construction and Elan's fig leaf — a professed concern that the jury might not understand the Court's construction — is baseless. *Second*, Elan ignores all of the intrinsic evidence in favor of extrinsic evidence of the worst kind: non-patent materials dated approximately a decade after the filing of the patent application. Worse, this irrelevant intrinsic evidence contradicts the plain language of the claims. It is black-letter law that extrinsic evidence cannot be considered where, as here, the intrinsic evidence provides a clear meaning for the claims. *Third*, Elan now proposes a brand new construction that contradicts its previous proposed construction.

Because the Court's construction is fully supported by the intrinsic evidence and Elan's motion is improper, the motion should be denied.

II. ELAN'S MOTION IS IMPROPER

A. There is No "Ambiguity" to Clarify

The Court's *Markman* order is clear. The Court construed the term "at an infusion rate not exceeding 10 mg/min" as "intravenously administering the *composition* at a rate not exceeding 10 milligrams per minute" and clarified that "the *plain language of the claim* states that it is the nanoparticulate drug *composition* that is administered, not the nanoparticles." (D.I. 271 August 17, 2007 Order Construing the Terms of U.S. Patent Nos. 5,399,363 and 5,834,025 at 4 and n.9 ("*Markman* Order")) (emphasis added). The Court thus made clear that the 10 mg/min was not limited to just to the nanoparticles. Accordingly, the *Markman* Order cannot be read to mean that the 10 mg/min refers to just the drug (a component of the nanoparticles).

Although Elan asserts there is an ambiguity in the *Markman* Order, the Court plainly rejected Elan's argument.

As the Court noted, the claim itself defines the "composition." The relevant portion of the claim states:

> wherein said *drug composition comprises*: (a) *particles* consisting essentially of from about 0.1 to about 99.9% by weight of a crystalline organic drug substance having a solubility in water of less than 10 mg/ml; (b) a *surface modifier* adsorbed on the surface of the drug substance in an amount of from about 0.1 to about 99.9% by weight and sufficient to maintain an effective average particle size of from about 50 nm to about 1000 nm; and (c) a pharmaceutically acceptable *carrier* therefor.

Thus, according to the plain language of the claim, the "composition" contains at least the particles, the surface modifier, and the carrier. The "*composition*" is administered "at a rate not exceeding 10 milligrams per minute." Notwithstanding the plain language of the claim explicitly referenced in the *Markman* Order, Elan seeks to manufacture an "ambiguity." Because there is no conceivable way one can read the *Markman* Order as referring only to the weight of the drug, there is no "ambiguity."

B. Elan's Motion is an Improper Motion to Reconsider

Likely because it cannot come close to meeting the standard for a motion to reconsider, Elan has captioned its motion a "motion for clarification."[1] However, simply calling a motion to reconsider a "motion for clarification" does not make it so. As even a cursory review of Elan's brief demonstrates, Elan wants reconsideration, not clarification. To maintain the façade of reconsideration, Elan is forced to argue that it "understands" the Court's construction to mean that "mg" somehow refers only to the "active pharmaceutical ingredient" (*i.e.*, the drug), a construction flatly contradicted by the *Markman* Order. Elan then disingenuously asks to Court to "confirm than Elan's understanding of the Order is correct." (*See* D.I. 308 at 3 ("Elan Br.")). Elan cannot bypass the requirements of a motion to reconsider by employing semantic games.

[1] The declaration submitted with the motion, however, is styled a declaration in support of Elan's "Motion for Clarification and/or Partial Reconsideration."

Even if Elan's motion were construed to be a motion for "clarification," Elan notes that a motion for clarification is properly granted when there has been a misapprehension of law or fact. *See* Elan Br. at 2. There is nothing to suggest that the Court misapprehended either the law or the facts.

The purpose of a motion for reconsideration is to correct manifest errors of law or fact or to present newly discovered evidence. *Harsco Corp. v. Zlotnicki*, 779 F.2d 906, 909 (3d Cir. 1985). Accordingly, a court may only grant a motion for reconsideration if the moving party shows one of the following: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court issued its order; or (3) the need to correct a clear error of law or fact or to prevent a manifest injustice. *Max's Seafood Café by Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999). As this Court has stated:

> As a general rule, motions for reconsideration should be granted only "sparingly." In this district, these types of motions are granted only if it appears that the court has patently misunderstood a party, has made a decision outside the adversarial issues presented by the parties, or has made an error not of reasoning, but of apprehension. Moreover, even if the court has committed one of these errors, there is no need to grant a motion for reconsideration if it would not alter the court's initial decision. Finally, motions for reconsideration should not be used to rehash arguments already briefed.

Becton Dickinson & Co. v. Tyco Healthcare Group LP, No. 02-1694 GMS, 2006 WL 890995, at *2 (D. Del. Mar. 31, 2006) (citations and internal quotations omitted).

Elan admits that it cannot meet the standard for a motion to reconsider, as it concedes that has been no change in controlling law, no new evidence has recently become available, and Elan does not "believe that the Order is erroneous as such." Elan Br. at 5. The Court has not "patently misunderstood a party." Elan is not concerned about a supposed ambiguity in the *Markman* Order, it is concerned because the Court's construction means that the claims cannot possibly read on the administration of Abraxane. As Abraxis has stated from the start, under a proper construction of the claims of the '025 patent, Abraxane cannot infringe. That issue will be addressed in due course. What's really happening here is that Elan lost on a crucial claim

construction issue and now would like the opportunity to present its second-tier arguments to the Court. The Court should not countenance Elan's attempt to present serial claim construction arguments.

III. EVEN IF CONSIDERED, ELAN'S ARGUMENTS ARE UNPERSUASIVE

A. Elan's Proposed Construction is Legally Improper

Remarkably, Elan fails to cite any evidence from the claim language or the patent itself. Rather, Elan cobbles together, for the first time, an assortment of documents unrelated to the patent and dated long after the patent was filed. *See* Elan Br. at 6-9. Elan's arguments thus rely exclusively on extrinsic evidence that contradicts the intrinsic record.

The claim plainly defines the "composition" as including the particles, the surface modifier, and the carrier. Nevertheless, Elan asserts that it is well-known "that infusion rates refer only to the mass or weight of the active pharmaceutical ingredient (or drug) in a given formulation" but there is no support for this proposition, let alone evidence sufficient to contradict the plain language of the claim and the intrinsic evidence. The Federal Circuit has repeatedly stated that extrinsic evidence cannot be used to contradict the intrinsic evidence. *See, e.g., On-Line Techs., Inc. v. Bodenseewerk Perkin-Elmer GmbH*, 386 F.3d 1133, 1139 (Fed. Cir. 2004) ("Extrinsic evidence, however, cannot be used to alter a claim construction dictated by a proper analysis of the intrinsic evidence"); *Novartis Pharm. Corp. v. Abbott Labs*, 375 F.3d 1328, 1335 (Fed. Cir. 2004) ("Although extrinsic evidence may be used by the court to help understand the disputed limitation, it may not be used to vary, contradict, expand, or limit the claim language from how it is defined, even by implication, in the specification or file history.").

Indeed, considering extrinsic evidence when a meaning is clear from the patent can be reversible error. *See, e.g., Vitronics Corp. v. Conceptronic*, 90 F.3d 1576, 1584-85 (Fed. Cir. 1996) (district court committed reversible error in considering extrinsic evidence where meaning of claim term was clear from the patent itself); *see also Southwall Techs. v. Cardinal IG Co.*, 54 F.3d 1570, 1578 (Fed. Cir. 1995) ("A patentee may not proffer an interpretation for the purposes of litigation that would alter the indisputable public record consisting of the claims, the

specification and the prosecution history, and treat the claims as a 'nose of wax.'").[2] Elan's proposed construction is precluded by Federal Circuit case law.

B. Elan's "Evidence" is Irrelevant

Even putting aside the fact that Elan invites legal error by proposing a construction based exclusively on extrinsic evidence that contradicts the intrinsic evidence, the supposed support for Elan's construction is completely irrelevant to the claim construction issue. Elan cites to the Abraxane package insert (from 2007), which is not part of the extrinsic evidence and was created years after the patent was filed, for a different purpose. The Abraxane package insert is legally irrelevant. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1319 (Fed. Cir. 2005) (en banc), *cert. denied*, 546 U.S. 1170 (2006) ("undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the 'indisputable public records consisting of the claims, the specification and the prosecution history,' thereby undermining the public notice function of patents") (citation omitted). Like the rest of its extrinsic evidence, the package insert also sheds no light on the phrase actually used in the claim: "at an infusion rate not exceeding 10 mg/min." Elan also cites to the insert for another drug, AmBisome (from 2005), but that citation is just as irrelevant as the Abraxane insert. Finally, Elan cites to FDA guidelines regarding prescription drug labels. Like the package inserts, these guidelines are in no way relevant to the claim construction issues at hand. Of course, all of this new claim construction "evidence" was available when the initial briefing was filed.

The *Phillips* Court identified several reasons why extrinsic evidence is "less reliable" than the intrinsic record. *Phillips*, 415 F.3d at 1318. Two are particularly noteworthy here. First, "extrinsic evidence by definition is not part of the patent and does not have the

[2] Reliance on extrinsic evidence is improper because the public is entitled to rely on the patent itself when it clearly defines the scope of the invention. As the Court explained in *Vitronics,* "[C]ompetitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention and, thus, design around the claimed invention. Allowing the public record to be altered or changed by extrinsic evidence . . . would make this right meaningless." 90 F.3d at 1583 (internal citation omitted).

specification's virtue of being *created at the time of patent prosecution* for the purpose of explaining the patent's scope and meaning." *Id.* (emphasis added). And second, "there is a virtually unbounded universe of potential extrinsic evidence of some marginal relevance that could be brought to bear on any claim construction question. In the course of litigation, each party will naturally choose the pieces of extrinsic evidence most favorable to its cause, leaving the court with the considerable task of filtering the useful extrinsic evidence from the fluff." *Id.* The supposed support for Elan's construction consists of hand-picked documents created long after the patent was filed for purposes other than explaining the patent's scope and meaning. As such, it is simply irrelevant to the claim construction issues. Although Elan plainly wishes it drafted a different claim, it did not and no amount of extrinsic evidence can change the clear text of the claim itself. *See, e.g., Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) ("[I]n accord with our settled practice we construe the claim as written, not as the patentees wish they had written it.").[3]

C. Elan Improperly Raises a Completely New Construction

Finally, Elan now suggests that the term "at an infusion rate not exceeding 10 mg/min" refers "to the mass of active pharmaceutical ingredient infused" and that it excludes "the mass of inert dilutant in which the nanoparticles, *i.e.*, active pharmaceutical agent and surface modifier are carried." Elan Br. at 3. In other words, Elan now argues that the term refers to *just the drug*. Elan had previously argued that the term meant the "weight of the nanoparticles," meaning the *drug and the surfaced modifier*. (*See* Elan Reply Br. at 28-32; D.I. 99 April 20, 2007 Joint Claim Chart at 28). Thus, not only is the motion a poorly disguised motion for reconsideration, it seeks a construction that Elan has now proposed for the very first time. Regardless, because the Court's construction is correct, Elan's latest argument fares no better than the first argument.

[3] Elan also recycles an argument from its initial papers, contending that mass is typically measured in mg. *Compare* (D.I. 148 June 22, 2007 Plaintiff Elan Pharma International Limited's Answering Claim Construction Brief at 29-30 ("Elan Reply Br.")). This argument was unpersuasive the first time and it is no more persuasive this time.

IV. CONCLUSION

The Court properly construed the phrase "at an infusing rate not exceeding 10 mg/min" in the *Markman* Order. The construction properly considered the claim language and the relevant extrinsic evidence. Elan's improper motion does nothing to change the correctness of that construction, as it ignores the relevant evidence and focuses exclusively on extrinsic evidence that contradicts the intrinsic evidence and was created long after the patent was filed and for different purposes. Elan's motion should be denied in its entirety.

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Dated: September 17, 2007

CERTIFICATE OF SERVICE

I, Elena C. Norman, Esquire, hereby certify that on September 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 September 17, 2007, I caused a true and correct copy of the foregoing document to be served by hand delivery and e-mail on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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