IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

ELAN PHARMA INTERNATIONAL LIMITED'S REPLY IN SUPPORT OF PLAINTIFF'S MOTION FOR CLARIFICATION OF ORDER CONSTRUING THE TERMS OF U.S. PATENT NO. 5,834,025

ASHBY & GEDDES
Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
Lauren E. Maguire (I.D. #4261)
500 Delaware Avenue, 8th Floor
Wilmington, Delaware 19899-1150
(302) 654-1888
sbalick@ashby-geddes.com
jday@ashby-geddes.com
lmaguire@ashby-geddes.com

Attorneys for Plaintiff
Elan Pharma International Limited

Of Counsel:

Stephen E. Scheve
Linda M. Glover
BAKER BOTTS L.L.P.
One Shell Plaza
910 Louisiana Street
Houston, Texas 77042-4995
(713) 229-1659

Paul F. Fehlner
Jeffrey D. Sullivan
Lisa A. Chiarini
BAKER BOTTS L.L.P.
30 Rockefeller Plaza
New York, New York 10112-4498
(212) 408-2527

William J. Sipio
1375 Brentwood Road
Yardley, Pennsylvania 19067
(215) 801-3625

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TABLE OF CONTENTS

A. Physicians and Pharmacologists Administer Compositions At A Rate Based On The Amount Of Active Pharmaceutical Agent Present. 1

B. The Intrinsic Evidence Supports An Interpretation Of 10mg/min As Referring Only To The Active Pharmaceutical Agent. 3

C. Conclusion 4

TABLE OF AUTHORITIES

CASES

Phillips v. AWH Corp.,
415 F.3d 1303 (Fed. Cir. 2005).....4

Pitney Bowes, Inc. v. Hewlett-Packard Co.,
182 F.3d 1298 (Fed. Cir. 1999).....3

Wilson Sporting Goods Co. v. Hillerich v. Bradsby,
442 F.3d 1322 (Fed. Cir. 2006).....2

Once again, Abraxis ascribes questionable motives to Elan that simply do not exist. Abraxis erroneously claims that Elan is asking the Court to reconsider its *Markman* Order and issue a new construction of the claim term "at an infusion rate not exceeding 10mg/min." Elan's motion and this reply, however, seek clarification on a single issue only: Does "mg" [milligrams], as it appears in the above claim term and in the Court's construction of that term, refer to the entire drug composition, or only to the active pharmaceutical agent in the drug composition?

A. Physicians and Pharmacologists Administer Compositions At A Rate Based On The Amount Of Active Pharmaceutical Agent Present.

The Court has construed the term "at an infusion rate not exceeding 10mg/min" to mean "intravenously administering the composition at a rate not exceeding 10mg/min." D.I. 271. Through its construction, the Court may have intended "mg" to refer to the weight or mass of the entirety of the drug composition. Because "mg" is undefined in the interpretive phrase provided by the Court, however, it could have just as easily intended that "mg" refer only to the weight or mass of the active pharmaceutical agent in the drug composition. To avoid confusion, Elan seeks clarification as to the construction of this single claim term.

Elan has supplied intrinsic and extrinsic evidence supporting its position that "mg" in claim 1 of the '025 Patent means milligrams of nanoparticles (i.e., the active pharmaceutical agent and surface modifier). It is worth noting, as Elan's opening brief (D.I. 308) in support of its motion for clarification points out, that one of ordinary skill in the art would understand "mg" in *any* claim limitation that refers to the rate of administration of a drug composition as referring only to milligrams of the active pharmaceutical agent, i.e., drug substance. Indeed, Abraxis does not — and cannot — deny that its own instructions to physicians to administer Abraxane® at 260mg/m2 explicitly state that "[d]ose levels of mg/m2

refer to mg of paclitaxel in ABRAXANE." *See* D.I. 308, Exh. 1 at 17. Notably, Abraxis does not state that 260mg/m2 refer to the entirety of the composition, i.e., the paclitaxel, human serum albumin surface modifier, and the saline inert carrier or dilutant

The fact that Abraxis's instructs physicians to interpret "mg" as referring only to the active pharmaceutical agent when calculating the rate at which Abraxane® is to be administered should carry considerable weight in clarifying the meaning ascribed to "mg" in the '025 Patent. In *Wilson Sporting Goods Co. v. Hillerich v. Bradsby*, 442 F.3d 1322, 1326-27 (Fed. Cir. 2006), the Federal Circuit instructs that claim construction should take place in the context of the accused product:

> . . . the legal function of giving meaning to claim terms always takes place in the context of a specific accused infringing device or process. While a trial court should certainly not prejudge the ultimate infringement analysis by construing claims to include or exclude an accused product or process, knowledge of that product or process provides meaningful context for the first step of the infringement analysis, claim construction.

Thus, according to Federal Circuit case law, the fact that Abraxis, one of ordinary skill in the art, understands "mg" as referring to only milligrams of the active pharmaceutical agent in a drug composition should provide context for the Court's construction of the '025 Patent. *See id.*

Elan might have stood silent and then offered substantial evidence and attorney argument at trial that one skilled in the art would understand the Court's interpretive phrase "intravenously administering the composition at a rate not exceeding 10mg/min" to mean that the composition should be infused at 10 milligrams of active pharmaceutical agent per minute — thereby effectively asking the jury to construe the claim again. Because that would have violated the entire point and spirit of the *Markman* process, however, Elan seeks clarification instead.

B. The Intrinsic Evidence Supports An Interpretation Of 10mg/min As Referring Only To The Active Pharmaceutical Agent.

Abraxis also erroneously claims that there is no intrinsic support in the '025 Patent for a finding that "mg" refers only to the weight or mass of the pharmaceutically active agent in the drug composition, and that Elan's reference to highly relevant extrinsic evidence in its Motion For Clarification violates fundamental claim construction principles.

As a threshold matter, Abraxis has clearly lost sight of the fact that its own claim construction briefing included *extensive* citation to extrinsic evidence. Indeed, Abraxis relied on no fewer than twenty exhibits that were extrinsic, including an expert declaration, to support its claim construction positions. *See generally* D.I. 144. Remarkably, one of the exhibits upon which Abraxis relied was the "FDA Guideline for Submitting Supporting Documentation in Drug Applications for Manufacture of Drug Substances (1987)." *See id.* at tab 48. Nevertheless, Abraxis now claims that Elan's submission of FDA guidelines regarding prescription drug labels, which require pharmaceutical companies to describe administration rates in terms of milligrams of active pharmaceutical agent, are "irrelevant" to any claim construction issues. *See* Abraxis Answering Brief (D.I. 342) at 5. To the contrary, the Federal Circuit is clear that extrinsic evidence is always allowed for the purpose of providing a background understanding of the invention. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309 (Fed. Cir. 1999). Here, Elan has provided extrinsic evidence to apprise the Court of the understanding that would be held by one of ordinary skill in the art in reading the claims of the '025 Patent.

Abraxis itself has routinely submitted documentation to FDA in which drug dosing instructions were expressed only in terms of milligrams of active pharmaceutical agent, and not in terms of gross quantity of a composition containing an active pharmaceutical agent combined with an additional amount of pharmaceutically inert (and thus irrelevant) dilutant, such

as a saline carrier. *See e.g.* D.I. 308, Exh. 1 at 17. Abraxis cannot possibly contend that it may make one representation as to how dosages are expressed before one federal agency, and a diametrically opposed representation to this Court.

Phillips v. AWH Corp., 415 F.3d 1303, 1319 (Fed. Cir. 2005) (*en banc*) endorses the use of extrinsic evidence as a complement to intrinsic evidence when it serves as an aid in "determin[ing] what a person of ordinary skill in the art would understand claim terms to mean." Thus, Elan was well within the confines of controlling authority when it pointed to extrinsic evidence supporting the proposition that one of ordinary skill in the art would understand "mg" to refer to the weight or mass of the active pharmaceutical agent in a drug composition. Moreover, the extrinsic evidence offered by Elan is entirely consistent with the '025 patent, which provides that "hemodynamic effects of suspensions [or drug compositions] can be eliminated or at least substantially reduced by controlling the rate of infusion and/or the concentration of the *active drug in the suspensions*. Col. 1, lns 62-65 of the '025 Patent (emphasis added). Thus, Abraxis's claim that Elan's Motion For Clarification lacks a proper legal foundation is without merit.

C. Conclusion

Elan seeks only clarification of that part of the Court's Order which construes the claims of the '025 Patent so as to avoid any confusion that might result if the term "mg" were not expressly defined. Elan has presented ample and legally sufficient evidence to support its position that one of ordinary understanding in the art would interpret "mg" as referring to the weight or mass of only the active pharmaceutical agent in a drug composition. Accordingly, Elan requests that the Court clarify its construction of the term "at an infusion rate not exceeding 10 mg/min" by modifying the interpretive language in the Court's Order to the following:

"[A]t an infusion rate not exceeding 10 mg/min" is construed to mean "intravenously administering the nanoparticulate composition at a rate not exceeding 10 milligrams of active pharmaceutical agent per minute."

ASHBY & GEDDES

/s/ John G. Day

Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
Lauren E. Maguire (I.D. #4261)
500 Delaware Avenue, 8th Floor
Wilmington, Delaware 19899-1150
(302) 654-1888
sbalick@ashby-geddes.com
jday@ashby-geddes.com
lmaguire@ashby-geddes.com

Attorneys for Plaintiff
Elan Pharma International Limited

Of Counsel:

Stephen E. Scheve
Linda M. Glover
BAKER BOTTS L.L.P.
One Shell Plaza
910 Louisiana Street
Houston, Texas 77042-4995
(713) 229-1659

Paul F. Fehlner
Jeffrey D. Sullivan
Lisa A. Chiarini
BAKER BOTTS L.L.P.
30 Rockefeller Plaza
New York, New York 10112-4498
(212) 408-2527

William J. Sipio
1375 Brentwood Road
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(215) 801-3625

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