**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| ELAN PHARMA INTERNATIONAL LIMITED, | § | **REDACTED PUBLIC VERSION** |
| Plaintiff, Counterdefendant | § | C.A. No. 06-438-GMS |
| vs. | § | |
| ABRAXIS BIOSCIENCE, INC., | § | |
| Defendant, Counterplaintiff. | § | |

**PLAINTIFF ELAN PHARMA INTERNATIONAL LIMITED'S REPLY IN SUPPORT OF ITS MOTION IN LIMINE NO. 2 TO PRECLUDE ABRAXIS FROM USURPING THE COURT'S AUTHORITY TO CONSTRUE THE PATENT CLAIMS AND BIFURCATE EQUITABLE DEFENSES**

*Of Counsel:*

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

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 Telephone

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
P.O. Box 1150
Wilmington, Delaware 19899-1150
(302) 654-1888 Telephone
sbalick@ashby-geddes.com
jday@ashby-geddes.com
lmaguire@ashby-geddes.com

*Attorneys for Plaintiff,*
*Elan Pharma International Limited*

Dated: April 7, 2008

Plaintiff Elan Pharma International Limited ("Elan") hereby respectfully submits its reply in support of its Motion In Limine No. 2 to preclude Abraxis Bioscience, Inc.'s ("Abraxis") from usurping the Court's authority to construe patent claims and determine equitable defenses.

## A. Abraxis's Should Not Be Permitted To Reargue Claim Construction Positions Already Ruled On By This Court

Abraxis asserts that it will not present evidence or argument inconsistent with the Court's claim construction . Abraxis then immediately proceeds to do just that, outlining a crystallinity-related limitation that the Court rejected. Specifically, the Court has already rejected Abraxis's contention that the patent applicants disclaimed all "amorphous" medicaments from the claim scope.

Further, Abraxis states that it intends to introduce testimony from experts on what the already-construed term "maintain" means. The Court has already supplied a meaning for this term, and the Court does not allow expert testimony on claim construction.

### 1. "particles consisting essentially of"

Elan requests that Abraxis be precluded from rearguing the meaning of the claim term "particles consisting essentially of." Abraxis opposes this request by advancing one of its flawed non-infringement positions, namely that there is not enough crystalline material in Abraxane as a whole (as opposed to in the claimed *particles* therein) in order for a jury to find infringement.

Elan's Motion In Limine seeks only to preclude Abraxis from rearguing precisely what this Court rejected during the *Markman* process. Specifically, Abraxis argued during claim construction that Elan disclaimed *any* amount of amorphous medicament from being present in the claimed medicament; and instead required that the crystalline medicament and surface modifier must combine to total 100% of the weight of every particle. *See* D.I. 105 at 16-18. The Court found as a matter of law that the prosecution history did not require this artificially

restrictive meaning of the claim language.. *See* D.I. 271 at 1 n.1. This being so, Abraxis should be precluded from making arguments on this issue of claim interpretation to the trier of fact, when it was properly rejected by the Court.

**2. "in an amount of 0.1-90% by weight and sufficient to maintain an average effective particle size of less than 1000 nm"**

Abraxis's position that it may present argument and evidence at trial in support of the contention that the term "maintain" is indefinite also cannot be reconciled with the Court's claim construction of the above referenced term, which includes a construction of the word "maintain." *See* D.I. 271 at 3 (construing "in an amount of 0.1-90% by weight and sufficient to maintain an average effective particle size of less than 1000 nm" to mean "an amount of surface modifier that maintains the size of the particles such that at least 90% of the particles have a number average particles size of less than about 1000 nanometers"). "A determination of claim indefiniteness is a legal conclusion that is drawn from the Court's performance of its duty as the construer of patent claims." *Praxair, Inc. v. ATMI, Inc.*, 231 F.R.D. 457, 461 (D. Del. 2005) (quoting *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 705 (Fed. Cir. 1998)). Having found the claim sufficiently definite to construe, the Court can and should exclude testimony from Abraxis purporting to be on definiteness "but essentially [aimed at] reargument of claim construction with a view towards its non-infringement defense." *Talecris Biotherapeutics, Inc. v. Baxter Int'l Inc.*, No. 05-349 (GMS), slip op. at 9 (June 18, 2007).

Further, . **REDACTED**

For the foregoing reasons, Abraxis should be precluded from arguing and presenting evidence at trial that the claim term "in an amount of 0.1-90% by weight and sufficient to maintain an average effective particle size of less than 1000 nm" is indefinite.

**B. Bifurcation Of The Equitable Affirmative Defenses Of Inequitable Conduct And Unclean Hands is Appropriate**

Rule 42(b) of the Federal Rules of Civil Procedure provides the Court with wide discretion to "separate issues and claims for trial, and [to] 'order a trial on unenforceability separate from an infringement trial that may involve an invalidity defense.'" *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 507 F. Supp.2d 870, 872 (N.D. Ill. 2007) (quoting *Gardco Manuf., Inc. v. Herst Lighting Co.*, 820 F.2d 1209, 1212 (Fed. Cir. 1987)).

District courts have often "opted for bifurcation of the issue of inequitable conduct" due to several considerations, including that "inequitable conduct is an issue for the court's determination, that patent cases are inherently complicated and confusing for a jury, and that evidence of inequitable conduct, essentially fraud, may very well prejudice the patentee in its case to the jury." *Trading Techs.*, 507 F. Supp.2d at 873 (citing cases). *See also Agfa Corp. v. Creo Prods. Inc.* 451 F.3d 1366, 1375 (Fed. Cir. 2006) ("a judge retains the discretion to conduct a bench trial on the equitable issue of unenforceability in the same case where invalidity is to be tried to a jury"). Abraxis's argument that presenting the equitable issues of inequitable conduct and unclean hands to the jury is appropriate because trial will be more efficient rings hollow. "It is the patent, not the patentee, on trial before the jury." *Trading Techs.*, 507 F. Supp.

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2d at 873. Bifurcation of equitable issues from cases in which invalidity is to be tried by a jury is common, particularly as the ultimate issue is one to be decided by the Court, and should be ordered in this case to prevent undue prejudice to Elan in presenting its case to the jury. *See id.*

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

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BAKER BOTTS L.L.P.
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910 Louisiana Street
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