IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

PLAINTIFF ELAN PHARMA INTERNATIONAL LIMITED'S REPLY IN SUPPORT OF ITS MOTION IN LIMINE NO. 5 TO EXCLUDE ARGUMENTS OR EVIDENCE BASED UPON THE REVERSE DOCTRINE OF EQUIVALENTS

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Dated: April 7, 2008

Plaintiff Elan Pharma International Limited ("Elan") hereby respectfully submits its reply in support of its Motion In Limine No. 5 to preclude Abraxis Bioscience, Inc. ("Abraxis") from making any references at trial to a theory or defense that Abraxis is not liable for infringement under the so-called reverse doctrine of equivalents.

A. Elan's Motion To Exclude Arguments Concerning The Reverse Doctrine Of Equivalents Is Justified Under Federal Circuit Precedent

The reverse doctrine of equivalents is a fabled (in the worst sense) legal doctrine, a unicorn of patent law. It is speculated to exist, but is in real life nowhere to be seen. Thus, it is appropriate for the Court to exclude testimony on this issue, especially as Abraxis's stated bases for invoking the defense suggest that no useful, relevant, or non-prejudicial evidence or argument is likely to be advanced on this alleged defense.

The Federal Circuit has affirmed a district court's grant of a motion in limine to exclude arguments regarding the reverse doctrine of equivalents. *Colassi v. Cybex Int'l, Inc.*, 221 Fed. Appx. 973, 976-77 (Fed. Cir. 2007) (unpublished table decision). In *Colassi*, the district court granted plaintiff's motion in limine to preclude evidence relating to a defense under the reverse doctrine of equivalents. *Id.* On appeal, defendant made the same argument as Abraxis makes in its Response, faulting the in limine order as supposedly tantamount to a summary judgment. *Id.;* Abraxis's Response to Elan's MIL No. 5 at 1. But the Federal Circuit affirmed the granting of the in limine application, noting that defendant had at trial proffered "only attorney argument" in support of the defense. *Colassi*, 221 Fed. Appx. 977. The logic of the *Colassi* court applies here.

B. The Reverse Doctrine Of Equivalents Is A Hypothetical Doctrine

Abraxis's Response fails to rebut Elan's statement that the reverse doctrine of equivalents is an outlier defense, if that. Abraxis's legal authorities support Elan's argument. As Abraxis

concedes, the court in *Amgen Inc. v. Hoechst Marion Roussel, Inc.* 314 F.3d 1313, 1351 (Fed. Cir. 2004) expressly declined to apply the reverse doctrine of equivalents. Abraxis does not dispute, either, what the court in *Ciena Corp. v. Corvis Corp.*, 334 F. Supp. 2d 598, 604 (D. Del. 2004) recognized: that the Federal Circuit has "never affirmed a decision applying the reverse doctrine of equivalents to find non-infringement of a claim otherwise literally infringed." A doctrine that rarely if ever finds real world application is not one that should be the vehicle for prejudicial lawyer argument, not evidence, to be introduced against Elan, and to the confusion of the jury, as more fully explained below.

C. Abraxis Has Not Identified And Will Not Be Prepared To Proffer Evidence, As Opposed To Argument, To Support The Defense

The reverse doctrine of equivalents clearly would not apply when the alleged infringer fails to demonstrate that "the accused component is [] dissimilar to those contemplated by the patentee." *Praxair, Inc. v. ATMI, Inc.*, 445 F. Supp. 2d 460, 467 (D. Del. 2006).

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Exhibit 2 to the March 27, 2008 Declaration of Lisa A. Chiarini in Support of Elan's MIL No. 5 at 12-13. Abraxis has the burden of proving that allegedly-amorphous medicaments behave substantially differently from crystalline medicaments in nanoparticle formulations, or that choice of particular surface modifiers affects drug effectiveness. However, Abraxis has offered no evidence specifically showing or suggesting either of these facts. If Abraxis is permitted to offer argument on a theory **REDACTED** it will be just that: unsubstantiated lawyer argument.

Abraxis's Response (at 5) contains conclusory phrases like "substantially different" and cites to testimony **REDACTED**

But Elan has asserted this all along: it is the nanoparticulate form of this product that provides this efficacy. None of this material provides any logical basis for the existence, assessment, or *comparison* of a significant functional, medical *difference* between Abraxane® and Elan's claimed crystalline medicament based upon: (a) the degree of crystallinity vs. "amorphousness" in each; (b) the type of surface modifier used in each; or (c) the manufacturing process chosen to produce the claimed end product. Instead, this material supports infringement.

Nor will Abraxis be able at trial to point to any specific disclosures in the '363 Patent vis à vis which it can present specific evidence that some physical parameter or therapeutic characteristic of Abraxane® differs not just specifically and quantifiably, but by so great a magnitude that a reasonable jury would have no choice but to enter one of history's first verdicts finding that literal infringement of a patent claim led to no liability under one of patent law's most obscure doctrines.

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/s/ *John G. Day*

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