IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

PLAINTIFF ELAN PHARMA INTERNATIONAL LIMITED'S MOTION IN LIMINE NO. 3 TO PRECLUDE ABRAXIS'S EXPERTS, DRS. JERRY L. ATWOOD AND MANSOOR AMIJI, FROM TESTIFYING ON SUBJECTS AS TO WHICH THEY ARE NOT QUALIFIED

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Plaintiff Elan Pharma International, Ltd. ("Elan") hereby respectfully moves in limine to preclude introduction of, or reliance upon, testimony from Defendant Abraxis Biosciences Corp.'s ("Abraxis") purported expert witnesses, Dr. Jerry Atwood and Dr. Mansoor Amiji, on subjects in which they lack adequate scientific grounding, for the reasons set forth below.

I. Relevant Legal Standard

The Federal Rules of Evidence contemplate that an expert witness may offer his informed opinions on technical matters outside the scope of what is presumed to be a jury's ordinary knowledge. *800 Adept, Inc. v. Murex Securities, Ltd.*, No. 6:02-cv-1354-Orl-28DAB, 2006 WL 5249727, at *1 (M.D. Fla. August 3, 2006) (citing Fed. R. Evid. 702). However, Fed. R. Evid. 702 provides that such a witness must first be qualified as an expert by knowledge, skill, experience, training or education:

> [A] witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

It is well-established that the District Court must act as a "gatekeeper" to "make certain that an expert, whether basing testimony on professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141, 152 (1999). As gatekeeper, the District Court is charged with screening out purported "experts" whose expertise is irrelevant or otherwise unhelpful. *See 800 Adept, Inc. v. Murex Securities, Ltd.*, 2006 WL 52459727, at *1 (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590-593 (1993)). It falls to the trial judge to determine whether a designated witness is qualified to give the expert

opinion he seeks to express. *Kumho*, 526 U.S. at 156; *Daubert*, 509 U.S. at 156. The burden rests on Abraxis to demonstrate that its designated experts are indeed qualified experts. *See Daubert*, 509 U.S. at 579. This is a heavy burden, and one that Abraxis has failed to meet.

II. Dr. Atwood Is Not Qualified To Testify About Solid-State Nuclear Magnetic Resonance Spectroscopy ("ssNMR") Or Issues Relating To ssNMR

Dr. Atwood is not qualified to testify or opine on issues pertaining to ssNMR techniques or ssNMR data. Dr. Atwood lacks the requisite knowledge, skill, experience, training, and education that would establish him as a competent technical expert for any issue relating to ssNMR. Accordingly, any testimony from Dr. Atwood on such matters would be unreliable and would fail to assist the jury.

Dr. Atwood is presently Curators' Professor at University of Missouri-Columbia. His research focuses on a field known as Supramolecular Chemistry, which is a discipline that focuses on particular types of bonding interactions between molecules, known as non-covalent bonding interactions. *See* Chiarini Decl. Exhibit 1, 2. Dr. Atwood's testimony and the public record make clear the following facts that illustrate his lack of expertise or qualification on issues relating to ssNMR.

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scientific literature search identified no publications or articles by Dr. Atwood that even mention ssNMR in the text. *See* Chiarini Decl. Exhibit 5.

- Dr. Atwood is a named inventor on 11 United States Patents, but not one of those patents relates to or mentions ssNMR. *See* Chiarini Decl. Exhibit 6.

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. it is difficult to imagine that Dr. Atwood's opinions regarding ssNMR will be of any assistance or have any probative value to the jury.

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Based on *Daubert* and in view of the above-cited facts, it is clear that any testimony from Dr. Atwood relating to ssNMR should be deemed inadmissible under Fed. R. Evid. 702. ssNMR is a very specialized branch of analytic physical chemistry, which requires considerable focused experience and training in order to be conducted and analyzed properly.

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His testimony could only be conjectural, coming essentially from a layman status, and his opinions on such points would be of no assistance to the jury, and ought therefore to be excluded.

III. Dr. Amiji Is Not Qualified To Testify About The Prior Art Nor About X-Ray Powder Diffraction ("XRPD") Or Issues Relating To ssNMR

Dr. Amiji is currently a Professor at Northeastern University, School of Pharmacy, Department of Pharmaceutical Sciences. The major focus of Dr. Amiji's research is synthesis of polymeric materials for medical and pharmaceutical applications. *See* Chiarini Decl. Exhibit 1.

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The invention of the '363 Patent relates to the delivery of drugs that pose unique issues because they do not dissolve well in water. The '363 Patent claims very tiny particles, known as nanoparticles, of stabilized anticancer agents that are essentially free of solvent contamination. Dr, Amiji has limited experience, if any, in formulating nanoparticulate systems of poorly water soluble anticancer agents.

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Based on *Daubert*, Dr. Amiji is not competent to testify regarding conclusions of obviousness and materiality, nor on XRPD issues, because he lacks meaningful background in the technical field that would aid the jury.

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