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January 14, 2008

The Honorable Gregory M. Sleet
United States District Court
844 North King Street
Wilmington, DE 19801

REDACTED
PUBLIC VERSION

Re: *Elan Pharma International Ltd. v. Abraxis Bioscience, Inc.*,
C.A. No. 06-438-GMS

Dear Chief Judge Sleet:

Plaintiff Elan respectfully submits this reply letter in support of its January 2, 2008 request for permission to file and brief motions for summary judgment.

(1) Entry Of Judgment On The '025 Patent

The Court should grant partial summary judgment that Elan's infringement contentions as to the '025 Patent do not now raise a genuine issue of material fact because they were based on an alternative claim interpretation that the Court declined to enter. Rules 56(a) and (d) explicitly contemplate that summary judgment can and should in appropriate circumstances be entered as to "part of [a] claim," and that summary judgment will frequently resolve less than "the whole action." *See* Fed. R. Civ. P. 56. In such cases, the Court is instructed to "issue an order specifying what facts . . . are not genuinely at issue" – in this case, the fact that Elan does not intend to attempt proof of infringement on the current claim construction. Moreover, there is no reason to proceed with adjudicating Abraxis's invalidity allegations at this time. If the claims of the '025 Patent remain construed as they are now, Abraxis is free of any infringement exposure and need not attempt to invalidate the '025 Patent in order to secure peace. If a different construction is ultimately entered, this would require a different invalidity analysis. Thus, there is no "genuine need for trial" on any aspect of the '025 Patent at this time, and entry of summary judgment to this effect is therefore appropriate and efficient. *See* Rule 56 Advisory Committee Note, 1963 Amendment.

(2) Obviousness-Type Double Patenting

Abraxis inaccurately represents to the Court that it did not receive notice of the '363 Patent terminal disclaimer until Elan's response to Abraxis's letter brief seeking permission to move for summary judgment. This is simply not the case. Elan produced the terminal disclaimer to Abraxis *four days* after it was filed with the United States Patent and Trademark Office ("PTO") and informed Abraxis of the disclaimer in an interrogatory response on October

29, 2007.[1] Abraxis is also mistaken in stating that *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368 (Fed. Cir. 2005) stands for the proposition that a terminal disclaimer has a prospective effect only. In *Perricone*, there was no terminal disclaimer in evidence at all. Therefore, the Court *could not* reach the question of whether it would have a retrospective effect. *Id.* at 1375. Abraxis's reliance on *Southwest Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280 (Fed. Cir. 2000) is similarly misplaced. *Southwest* holds only that filing a certificate of correction – not a terminal disclaimer – is effective only for causes of action arising after the certificate issued. *Id.* at 1294.

Contrary to Abraxis's assertions, it is abundantly clear that a terminal disclaimer filed during litigation is not limited to its prospective effect. *See Taltech Ltd. v. Esquel Enters., Ltd.*, No. 04-974Z, 2006 WL 2459100 (W.D. Wash. Aug. 23, 2006) (granting plaintiff's motion for summary judgment dismissing double patenting defense when plaintiff filed terminal disclaimer during litigation); *Syngenta Seeds, Inc. v. Monsanto Co.*, No. 02-1331-SLR, 2004 WL 2790499 (D. Del. Nov. 19, 2004) (Robinson, J.) (denying defendant's motion for summary judgment of invalidity based on alleged double patenting, when plaintiff had filed terminal disclaimer during litigation); *accord Bayer AG. v. Barr Labs., Inc.* 798 F. Supp. 196, 197-198 (S.D.N.Y. 1992).

(3) Patent Misuse And Unclean Hands

Abraxis has failed to establish the existence of a genuine issue of material fact regarding its claims of patent misuse and unclean hands. There is not a scintilla of evidence that Elan brought this lawsuit for any purpose other than to legitimately protect its intellectual property rights.

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Elan's enforcement of its patents for fiscal gain relies on the right to exclude *unauthorized* competition – the very purpose of our patent system.

Abraxis's purported "evidence" that Elan has engaged in "sham" litigation rests on allegations that: (1) Elan advocated for certain claim constructions that were rejected by the Court; and that (2) Elan has asserted a claim of privilege over pre-suit testing. Neither allegation could establish that Elan's lawsuit is objectively baseless and subjectively motivated by bad faith as is required to show sham litigation. *See Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1305 (Fed. Cir. 2004) (finding that both prongs of the two-part test articulated by the Supreme Court in *Professional Real Estate Investors, Inc. v. Columbia Pictures, Inc.*, 508 U.S. 49 (1993), must be met to prove sham litigation). The reports of Elan's eight renowned experts establish that Elan's lawsuit could not, objectively, be void of any *ab initio* merit.

(4) Inequitable Conduct

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[1] *See* Exh. 1, 10/29/07 Elan letter enclosing document production, including terminal disclaimer (ELANP0319168-71); Exh. 2, Elan's First Amended Response To Abraxis's Third Set Of Interrogatories at 90.

Abraxis's inequitable conduct claims are ripe for summary adjudication. First, by Abraxis's own theories, *Domb* would be cumulative of *Haynes* (which *was* considered during prosecution of the '363 Patent) and the knowledge of a person of ordinary skill in the art. Abraxis's own expert argues that Haynes discloses "intra-tumor" administration of nanoparticles, and according to Abraxis's expert, this means that "anticancer drugs should be used." (*See* Exh. 5, Amiji Opening Report ¶ 77-78). Accordingly, everything allegedly taught in *Domb* is also taught by *Haynes*, and Abraxis cannot meet the threshold requirement of materiality by pointing to a cumulative reference. *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 1000 (Fed. Cir. 2007). Even if *Domb were* material, Abraxis presents no evidence of intent to deceive by Elan. The only "evidence" Abraxis can point to consists of Abraxis's citation of the deposition testimony of one attorney involved in prosecuting the '363 Patent. Such testimony, though, indicates only that counsel had no recollection of *Domb* whatsoever. "When the absence of a good faith explanation [of non-disclosure] is the only evidence of intent . . . that evidence alone does not constitute clear and convincing evidence warranting an inference of intent." *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc.*, 439 F.3d 1335, 1341 (Fed. Cir. 2006). Abraxis's citation to *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 917-18 (Fed. Cir. 2007), is misplaced. There, a finding of deceptive intent relied on both failure to disclose and "overwhelming circumstantial evidence," which has not been shown here. *Id.* at 919. Abraxis's assertion of deceptive intent lacks legal foundation and must be rejected.

With respect to alleged experimental evidence of non-enablement, Abraxis again fails to establish materiality or intent to deceive. It is undisputed that the '363 Patent, and its parent the '684 Patent, teach *screening procedures* to identify compatible drug-surface modifier combinations.

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"[T]he specification need only teach those aspects of the invention that one skilled in the art could not figure out without undue experimentation." *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1337 (Fed. Cir. 2005); *In re Wands,* 858 F.2d 731, 736-37 (Fed. Cir. 1988) ("Enablement is not precluded by the necessity for some experimentation such as routine screening.").

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This alone negates Abraxis's allegation of inequitable conduct. *See, e.g., Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1357-8 (Fed. Cir. 2003) ("[W]e need look no further than the district court's determination that TKT's [inequitable conduct] case was doomed because it was bereft of evidence of intentional deception.").

(5) Partial Summary Judgment Relating To Certain Claim Limitations

As to the claim limitations that the parties agree are met in Abraxane®, summary judgment is timely and appropriate. Abraxis's suggestion that these agreed-upon limitations can be "reflected in the pre-trial order" is vague and without merit. Rule 56(d) clearly provides that when certain facts "are not genuinely at issue," "[t]he facts so specified *must* be treated as established in the action" by way of summary judgment, so as to conclusively remove them from consideration. Fed. R. Civ. P. 56(d)(1) (emphasis supplied).

Respectfully,

/s/ *John G. Day*

John G. Day (I.D. #2403)

JGD/rbg
Enclosure
187305.v1

cc: Clerk of the Court (by hand; w/enc.)
Josy W. Ingersoll, Esquire (by hand; w/enc.)
William J. Sipio, Esquire (via electronic mail; w/enc.)
Steven Scheve, Esquire (via electronic mail; w/enc.)
Paul F. Fehlner, Esquire (via electronic mail; w/enc.)
Michael A. Jacobs, Esquire (via electronic mail; w/enc.)
Emily A. Evans, Esquire (via electronic mail; w/enc.)

EXHIBIT 1

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VIA FEDERAL EXPRESS AND EMAIL

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Re: *Elan Pharma International Limited v. Abraxis BioScience, Inc.*
In the United States District Court for the District of Delaware
Case No. 06-438-GMS

Dear Diana:

Enclosed please find imaged documents produced by Plaintiff bearing bates numbers: ELANP0319127-ELANP0319171.

Please let us know if you have any questions regarding these materials.

Very truly yours,

Jacqueline A. Lowe
Paralegal

:04826
Enclosure (1 CD)

cc: Steve Scheve
Paul F. Fehlner
William J. Sipio
Linda Glover

Atty. Dkt. No. 029318-0673

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Gary Liversidge et al.

Title: SURFACE MODIFIED ANTICANCER NANOPARTICLES

Patent No.: 5,399,363

Grant Date: 03/21/1995

Appl. No.: 07/908,125

Appl. Filing Date: 07/01/1992

TERMINAL DISCLAIMER AND FEE TRANSMITTAL FORM

Commissioner for Patents
Box NON-FEE AMENDMENT
Washington, D.C. 20231

Sir:

Transmitted herewith is a Terminal Disclaimer disclaiming the term of the above-identified patent. A credit card authorization form to cover the terminal disclaimer fee of $130.00 is also attached. The Commissioner is also authorized to charge any additional fee, or credit any overpayment to Deposit Account No. 19-0741.

Respectfully submitted,

Date Oct. 25, 2007

By

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Atty. Dkt. No. 029318-0673

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Gary Liversidge et al.

Title: SURFACE MODIFIED ANTICANCER NANOPARTICLES

Patent No. 5,399,363

Grant Date: March 21, 1995

Appl. No.: 07/908,125

Appln. Filing Date: July 1, 1992

TERMINAL DISCLAIMER FOR U.S. PATENT NO. 5,399,363

Commissioner for Patents
Box NON-FEE AMENDMENT
Washington, D.C. 20231

Sir:

Petitioner, Elan Pharma International Ltd., having its principal place of business at Monksland, Athlone, County Westmeath, Ireland (previously Wil House, Shannon Business Park, Shannon, Co. Clare, Ireland), represents that it is the owner of the entire right, title, and interest in and to U.S. Patent No. 5,399,363, for "Surface Modified Anticancer Nanoparticles," filed on July 1, 1992, as U.S. Patent Application No. 07/908,125, which is a continuation-in-part of U.S. Patent Application No. 07/647,105, filed on January 25, 1991, now U.S. Patent No. 5,145,684, by virtue of: (1) an Assignment from the inventors to Sterling Winthrop, Inc., recorded on July 1, 1992, at Reel/Frame 006228/0917; (2) an Assignment from Sterling Winthrop, Inc., to Eastman Kodak Co., recorded on October 21, 1994, at Reel/Frame 007175/0056; (3) an Assignment from Eastman Kodak Co. to Particulate Prospects, Corp. recorded on February 20, 1996, at Reel/Frame 007815/0409; (4) an Assignment from Particulate Prospects, Corp. to NanoSystems LLC, recorded on December 3, 2001, at Reel/Frame 012322/0261; (5) an Assignment from NanoSystems LLC to Elan

Corporation, plc, recorded on August 15, 2001, at Reel/Frame 012066/0732; and (6) an Assignment from Elan Corporation, plc, to Elan Pharma International Ltd., recorded on August 15, 2001, at Reel/Frame 012066/0747, in the United States Patent and Trademark Office.

Further, Petitioner represents that it is the owner of U.S. Patent No. 5,145,684, for "Surface Modified Drug Nanoparticles," filed on January 25, 1991, as U.S. Patent Application No. 07/647,105, by virtue of: (1) an Assignment from the inventors to Sterling Winthrop, Inc., recorded on March 21, 1991, at Reel/Frame 005647/0704; (2) an Assignment from Sterling Winthrop, Inc., to Eastman Kodak Co., recorded on October 21, 1994, at Reel/Frame 007175/0056; (3) an Assignment from Eastman Kodak Co. to Particulate Prospects, Corp. recorded on February 20, 1996, at Reel/Frame 007815/0409; (4) an Assignment from Particulate Prospects, Corp. to NanoSystems LLC, recorded on February 20, 1996, at Reel/Frame 007815/0404; (5) an Assignment from NanoSystems LLC to Elan Corporation, plc, recorded on April 12, 2000, at Reel/Frame 010742/0161; and (6) an Assignment from Elan Corporation, plc, to Elan Pharma International Ltd., recorded on April 12, 2000, at Reel/Frame 010742/0137, in the United States Patent and Trademark Office.

Petitioner hereby disclaims the terminal part of the term of U.S. Patent No. 5,399,363 which would extend beyond the full statutory term of U.S. Patent No. 5,145,684. In addition, Petitioner hereby agrees that U.S. Patent No. 5,399,363 shall be enforceable only for and during such period that the legal title to U.S. Patent No. 5,399,363 shall be the same as the legal title to U.S. Patent No. 5,145,684, this agreement to run with U.S. Patent No. 5,366,363 and to be binding upon the grantee, its successors, or assigns.

In making this disclaimer, Petitioner does not disclaim any terminal part of U.S. Patent No. 5,366,363, prior to the full statutory term of U.S. Patent No. 5,145,684 as defined in 35 U.S.C. §§ 154-156 and 173, in the event that U.S. Patent No. 5,145,684 expires for failure to pay a maintenance fee, is held unenforceable or is found invalid in a final judgment by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 C.F.R. § 1.321(a), has all claims canceled by a reexamination certificate or as a result of an interference proceeding, or is otherwise not deemed to provide the rights

EXHIBIT 2

REDACTED

EXHIBIT 3

REDACTED

EXHIBIT 4

REDACTED

EXHIBIT 5

REDACTED