IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELAN PHARMA INTERNATIONAL LIMITED, Plaintiff, vs. ABRAXIS BIOSCIENCE, INC., Defendant.	§ § § § § § § § § § §	Case No. 06-438-GMS

PLAINTIFF ELAN PHARMA INTERNATIONAL LIMITED'S MOTION FOR JUDGMENT AS A MATTER OF LAW ON CERTAIN UNSUBSTANTIATED ABRAXIS DEFENSES AND COUNTERCLAIMS

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Plaintiff Elan Pharma International Limited ("Elan") hereby respectfully moves, pursuant to Fed. R. Civ. P. 50(a), for judgment as a matter of law ("JMOL") that: (a) none of claims 1, 3, 5, 10, or 11 of its '363 Patent, or claims 1-3 or 13-15 of its '025 Patent, are invalid on grounds of lack of enablement; (b) these claims are also not invalid for lack of an adequate written description; (c) these claims are also not invalid for indefiniteness; (d) these claims are not obvious under 35 U.S.C. Section 103; (e) obviousness-type double patenting does not apply to limit the validity or available damages for the '363 Patent; (f) the reverse doctrine of equivalents does not preclude or limit Elan's ability to recover for defendant Abraxis Bioscience Inc.'s ("Abraxis's") infringement; (g) neither the '363 Patent nor the '025 Patent is unenforceable due to inequitable conduct by Elan; (h) there is no evidence that would support barring Elan's recovery of damages based on the equitable defense of unclean hands; and (i) Elan's evidence of its damages from Abraxis's infringement is undisputed and accordingly no alternate theory of Abraxis's should be considered in reaching the damages determination.

I. Standards For Judgment As A Matter Of Law

Federal Rule of Civil Procedure 50 governs motions for judgment as a matter of law in jury trials. It allows the trial court to remove cases or issues from the jury's consideration 'when the facts are sufficiently clear that the law requires a particular result.'" *Weisgram v. Marley Co.*, 528 U.S. 440, 448-49 (2000) (citing 9A C. Wright & A. Miller, FEDERAL PRACTICE AND PROCEDURE § 2521, p. 240 (2d ed. 1995)); *see also Buskirk v. Apollo Metals* 307 F.3d 160 (3d Cir. 2002) ("[A] directed verdict is mandated where the facts and the law will reasonably support only one conclusion.") (quoting *McDermott Int'l, Inc. v. Wilander,* 498 U.S. 337, 356 (1991)).

Under Rule 50(a)(1), specifically, a court may render judgment as a matter of law after the moving party is fully heard on an issue at trial, if "there is no legally sufficient evidentiary

basis for a reasonable jury to find for that party on that issue." Fed. R. Civ. P. 50(a)(1); *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, No. C.A. 02-148 GMS, 2004 WL 2127192, *2 (D. Del. Sept. 15, 2004). All evidence is to be viewed in the light most favorable to the party opposing the motion. *Walter v. Holiday Inns, Inc.*, 985 F.2d 1232, 1238 (3d Cir. 1993).

To prevent the Court from entering judgment as a matter of law, Abraxis would need to show there is evidence upon which a jury could properly find a verdict for it; the evidence must be substantial, that is, more than just a scintilla of evidence. *See Walter*, 985 F.2d at 1238 (citing *Patzig v. O'Neil*, 577 F.2d 841, 846 (3d Cir. 1978)).

Defendant Abraxis has had the opportunity to be fully heard on all of its affirmative defenses and declaratory judgment counterclaims during this trial, but has failed to set forth a legally sufficient evidentiary basis upon which the jury could reasonably find that Abraxis had satisfied its burden of proving by clear and convincing evidence that the '363 Patent or '025 Patent is invalid for any reason or unenforceable, or that Abraxis had established the applicability of the reverse doctrine of equivalents, or that Elan's unrefuted damages evidence should not be taken as established by the jury. Judgment as a matter of law in Elan's favor on all these points is accordingly timely and justified.

II. Jury Cannot Reasonably Find For Abraxis On Many Defenses Or Counterclaims

A. Abraxis Has Not Met Its Burden Of Showing That The Claims In Suit Lack Enablement

At trial Abraxis asserted that claims 3, 5, 10, and 11 of the '363 Patent, and claims 1-3 and 13-15 of the '025 Patent, lack enablement. The only evidence proffered by Abraxis's experts concerned: (a) the assertion that Elan's '363 and '025 Patents did not provide sufficient explanation for how to combine particular medicaments with particular surface modifiers for stabilization; and (b) the suggestion that Elan did not adequately teach how to avoid

unacceptable contamination of the claimed stable nanoparticles of the '363 Patent.

35 U.S.C. § 282 provides that a "patent shall be presumed valid." To "overcome the presumption of validity, the party challenging a patent must prove facts supporting a determination of invalidity by clear and convincing evidence." *Apotex USA v. Merck*, 254 F.3d 1031, 1036 (Fed. Cir. 2001).

The courts have strongly indicated that to meet this burden, a defendant should present competent and comprehensive expert testimony. *Koito Mfg. v. Turn-Key-Tech*, 381 F.3d 1142, 1152, fn.4 (Fed. Cir. 2004) ("'Typically, testimony concerning [invalidity] must be testimony from one skilled in the art and must identify each claim element, state the witnesses' interpretation of the claim element, and explain in detail how each claim element" [affects the invalidity analysis]. The testimony is insufficient if it is merely conclusory.' General and conclusory testimony, such as that provided by Dr. Kazmer in this case, does not suffice as substantial evidence of invalidity.") (citing *Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1315-16 (Fed. Cir. 2002)). *In re Omeprazole Patent Litigation*, 490 F. Supp. 2d 381, 535 (S.D.N.Y. 2007) (holding claims valid when "[n]o expert witness addressed the validity of the process claims" and stating that, "[w]here a patent challenger fails to set forth persuasive evidence of invalidity, the very existence of the patent satisfies the burden on the validity issue.").

In this case, the Elan Patents themselves speak eloquently to the enablement of the claims. The '363 Patent describes in detail a screening procedure for matching medicament substances with surface modifiers, and provides numerous examples of successful combinations arrived at using this screening procedure. '343 Patent, col. 7, lns. 5-45. The Patent (through incorporation by reference of the '684 parent patent) further teaches that any level of zirconium

residue is at an "acceptable" level. '684 Patent, col. 6, ln. 44.

The intrinsic teaching of the Patent is confirmed by the testimony at trial. Dr. Gary Liversidge of Elan gave uncontroverted testimony that none of the multiple licensees of the '363 Patent had ever complained to Elan that the '363 Patent was incapable of being practiced or that it did not provide an adequate written description. Tr. 1613:2-10. He also supplied unrefuted testimony that no medically-significant contamination had ever been reported in drug particles prepared in accordance with the teachings of the '363 Patent, including during the stringent impurity measurements made by Elan and its licensees and reported to the Food and Drug Administration. Tr. 303:12-304:2 ("[T]he FDA agreed with us, you can just drop that test for that material in the product because you never detected it.").

It would be pointless for the jury to be permitted to entertain speculation about the presence of hypothetical contamination in '363 nanoparticles, when review by FDA based upon actual detailed testing has never established any medically significant heavy metal contamination.

Dr. Mark Manning provided expert confirmation of the '363 Patent's compliance with the enablement requirement. He agreed that "[t]here is sufficient description, detail, that allows someone of ordinary skill in the art to teach them to make and use that invention described in the '363 Patent." Tr. 1580:14-17.[1]

Abraxis argued at trial that so-called "failed" experiments within Elan's screening process demonstrate non-enablement of the invention. This argument misconceives the law of enablement and overlooks entirely the uncontroverted testimony establishing that Elan is

[1] The shifting nature of Abraxis's affirmative defenses makes it difficult to ascertain whether Abraxis intended to put on a case of lack of enablement for the '025 Patent. To the extent that Abraxis may maintain that it has made such an allegation, there is no expert testimony for Abraxis of record on this point, whereas Dr. Manning clearly opined that the '025 Patent contained "more than sufficient" enabling detail. Tr. 1581:10-13. Accordingly, there is no substantive basis for entertaining a defense of non-enablement as to the '025 Patent, and judgment to this effect is justified and timely.

generally successful in finding suitable surface modifiers in 98% of the many screens it performs. Tr. 491:1-5 (E. Liversidge) ("And in addition to that, over the last ten years doing this screen in my laboratory, we have had basically a 98 percent success rate. In almost any new chemical entity that comes into my shop that is poorly water soluble, we can generate a stable nanoparticle formulation.").

Abraxis's contentions on enablement are contradicted by the law as well as these facts. Especially in the context of patents including screening procedures, the Federal Circuit has made plain that the "screening out" of some incompatible candidates is not determinative of non-enablement. See, *e.g.*, *Atlas Powder Co. v. E.I. DuPont De Nemours*, 750 F.2d 1569, 1576-77 (Fed. Cir. 1984):

> Du Pont argues that the patent disclosure lists numerous salts, fuels, and emulsifiers that could form thousands of emulsions but there is no commensurate teaching as to which combination would work. The disclosure, according to Du Pont, is nothing more than "a list of candidate ingredients" from which one skilled in the art would have to select and experiment unduly to find an operable emulsion.
>
> The district court held it would have been impossible for Bluhm to list all operable emulsions and exclude the inoperable ones. Further, it found such list unnecessary, because one skilled in the art would know how to select a salt and fuel and then apply [a well known chemical principle] to determine the proper emulsifier.
>
> * * *
>
> Du Pont argues that of some 300 experiments performed by Atlas . . . Atlas' records indicated that 40 percent failed 'for some reason or another.' The district court agreed that Atlas's records showed 40 percent "failed," but found that Atlas' listing of an experiment as a "failure" or "unsatisfactory" was misleading. Experiments were designated "failures," the district court found, in essence because they were not optimal under all conditions, but such optimality is not necessary for a valid patent. The district court also found that one skilled in the art would know how to modify slightly many of those "failures" to form a better emulsion.

See also In re Wands, 858 F.2d 731, 740 (Fed. Cir. 1988), whose detailed discussion of enablement in the context of a biochemical screening procedure is highly instructive:

> The nature of monoclonal antibody technology is that it involves screening hybridomas to determine which ones secrete antibody with desired characteristics. Practitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody. No evidence was presented by either party on how many hybridomas would be viewed by those in the art as requiring undue experimentation to screen. However, it seems unlikely that undue experimentation would be defined in terms of the number of hybridomas that were never screened. Furthermore, in the monoclonal antibody art it appears that an "experiment" is not simply the screening of a single hybridoma, but is rather the entire attempt to make a monoclonal antibody against a particular antigen. This process entails immunizing animals, fusing lymphocytes from the immunized animals with myeloma cells to make hybridomas, cloning the hybridomas, and screening the antibodies produced by the hybridomas for the desired characteristics. Wands carried out this entire procedure three times, and was successful each time in making at least one antibody that satisfied all of the claim limitations. Reasonably interpreted, Wands' record indicates that, in the production of high-affinity IgM antibodies against HBsAG, the amount of effort needed to obtain such antibodies is not excessive. Wands' evidence thus effectively rebuts the examiner's challenge to the enablement of their disclosure.

See also id. at 739 n. 29 (suggesting that even a screening "success rate" as low as 2.8% would not be dispositive evidence of undue experimentation or lack of enablement).

The evidence of the patent, and the clear testimony of the inventors and Dr. Manning, further weigh against a finding of non-enablement on the factors enumerated in case law, including the time and cost of any necessary experimentation; how routine any necessary experimentation would be to those of ordinary skill in the art; whether the '363 and '025 Patent discloses specific working examples of the claimed invention; the amount of guidance presented in the '363 Patent and/or '025 Patent; the nature and predictability of the technical field of the invention; and the level of ordinary skill in the field. *See In re Wands*, 858 F.2d at 737.

All that Abraxis submits in the face of the legal and factual factors weighing against its affirmative defense is the conclusory testimony of its expert witness Dr. Amiji -- an interested witness who has tried to sell his technology to Abraxis (Tr. 1442:18-1443:10) and whose fundamental experience with surface modifiers had to do not with drug particles, but with applying surface modifiers to glass and plastic beads (Tr. 1450:6-16).

In summary, the jury could not reasonably find that Abraxis has met its heavy burden of proving lack of enablement by clear and convincing evidence, and judgment against Abraxis on this defense is appropriate.

B. Abraxis Has Not Met Its Burden Of Showing That The Claims In Suit Lack Adequate Written Description

Abraxis put on little if any proof that would even tend to establish that Elan failed in its obligation to provide a written description evidencing that it was in possession of the claimed inventions of the '363 and '025 Patents as required by law.

Pursuant to the first paragraph of 35 U.S.C. § 112, the specification of a patent must contain a written description of the invention. "[I]nvalidating a claim [based upon this defense] requires a showing by clear and convincing evidence that the written description requirement has not been satisfied." *Invitrogen Corp. v. Clonotech Laboratories, Inc.*, 429 F.3d 1052, 1072 (Fed. Cir. 2005). Notably, "[t]he written description requirement does not require the applicant to 'describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.'" *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000).

The requirement "ensures that, as of the filing date, the inventor conveyed with reasonable clarity to those of skill in the art that he was in possession of the subject matter of the claims." *Id.* "A challenger must provide clear and convincing evidence that persons skilled in

the art would not recognize in the disclosure a description of the claimed invention." *Boston Scientific Scimed, Inc. v. Cordis* Corp., 392 F. Supp. 2d 676, 683 (D. Del. 2005).

Abraxis's own expert witness Dr. Amiji confirmed that Elan met the written description requirement. Tr. 1424:22-25 ("Q. At the time the patent was filed, did the patent convey that Elan was actually in possession of the full scope of the patent claims? A. Yes."). For this reason and all the reasons earlier set forth in Section (A) above, it is clear that Elan communicated through its Patents extensive information regarding what it had invented. And unlike a "paper patentee" who merely describes so-called "prophetic examples" of how an imagined invention might work, Elan provided 23 distinct examples of '363 nanoparticle applications in the '363 patent specification (in addition to 13 additional examples in the parent '684 Patent, incorporated by reference in the '363 Patent). Additionally, Dr. Manning opined that the inventors were "clearly in possession" of the claimed inventions of the '363 and '025 Patents. Tr. 1580:18-:1582:4.

Against all of this stands only (once again) the conclusory and unelaborated-upon bare opinion of Dr. Amiji, who offered an opinion on the ultimate issue of written description adequacy without any discussion of the facts and circumstances that could speak to whether the inventors were "in possession" of what they claimed.

For this reason, the jury could not reasonably hold for Abraxis on this defense, as to which it bears a burden of clear and convincing evidence, and the Court can and should enter judgment as a matter of law.

(C)-(E) Abraxis Has Failed To Put On Any Case At All On Three Of Its Previously Asserted Affirmative Defenses

Abraxis has previously asserted, and has not formally withdrawn, defenses based upon (C) alleged invalidity for indefiniteness of the '363 and '025 Patents; (D) alleged obviousness of

the '363 and '025 Patent claims under 35 U.S.C. Section 103; and (E) obviousness-type double patenting of the '363 Patent (based on the '684 "mother" Patent from which it claimed priority).

Within the past several days, counsel for Abraxis has notified counsel for Elan that Abraxis would not pursue any of these affirmative defenses, and indeed, Abraxis put on no proof at all at trial regarding these defenses. Further, the parties have now agreed upon jury instructions and a verdict form that omit all reference to these defenses. However, Elan submits that entry of final judgment as a matter of law memorializing that Abraxis's declaratory judgment counts asserting these defenses are dismissed is necessary and appropriate to make the record in this case.

F. Abraxis Has Not Met Its Burden Of Showing That Elan's Infringement Recovery Is Barred By The Reverse Doctrine Of Equivalents

Abraxis has asserted that Elan should not be able to recover for Abraxis's infringement based upon the so-called "reverse doctrine of equivalents," a legally-dubious doctrine that had its genesis in dicta from a long-ago Supreme Court case, *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605 (1950). In that opinion, the Court mentioned circumstances (not at issue on the facts of the case) that could lead to denial of a finding of literal infringement.

> [W]here a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement.

Id. at 608-609. The reverse doctrine of equivalents would apply only when the accused product is "sufficiently different from that which is patented." *Texas Instruments, Inc. v. United States Int'l Trade Comm'n,* 846 F.2d 1369, 1371 (Fed. Cir. 1988).

As district courts and the Federal Circuit have recognized, the theoretical availability of the defense does not translate into many real world situations in which a defendant can

successfully assert it:

> Although long-recognized as a defense to infringement, the reverse doctrine of equivalents is rarely offered as a defense. According to the Federal Circuit, "because products on which patent claims are readable word for word often are in fact the same, perform the same function in the same way, and achieve the same result, as the claimed invention, a defense based on the reverse doctrine of equivalents is rarely offered."

Monsanto Co. v. Mycogen Plant Science, Inc. 61 F. Supp. 2d 133, 185 (D. Del. 1999) (quoting *SRI Int'l v. Matsushita Elec.* Corp. of Am., 775 F.2d 1107, 1123 n.19 (Fed. Cir. 1985) and entering judgment as a matter of law that the reverse doctrine of equivalents did not apply).

As further confirmation that the reverse doctrine of equivalents is, at best, an outlier defense, the Federal Circuit has gone so far as to note that "[n]ot once has this court affirmed a decision finding noninfringement based on the reverse doctrine of equivalents." Tate Access Floors, Inc. v. Interface Architectural Resources, Inc. 279 F.3d 1357, 1368 (Fed. Cir. 2002). Commentators confirm that while "[n]umerous court decisions . . . acknowledge the vitality of the reverse doctrine of equivalents," most honor it principally in the breach and "find it inapplicable on the particular facts of the case." Donald S. Chisum, Chisum On Patents § 18.04[4](c) (2007). Other authors suggest that the doctrine, because so rarely applied, "probably [has] no vitality." Carl Moy, 4 Moy's Walker On Patents § 13.44 (2007).

Against this backdrop, the court in Ciena Corp. v. Corvis Corp., 334 F. Supp. 2d 598, 609 (D. Del. 2004), provided a well-reasoned analysis of the requirements of the doctrine holding that: "in determining whether the reverse doctrine of equivalents applies to preclude a finding of literal infringement, the Court must consider four criteria: (1) the principle of the claimed invention; (2) the principle of the accused product; (3) the degree of change in the principle of the accused product from that of the claimed invention; and (4) whether the accused product performs in a substantially different way." Id. at 605. On this standard, nothing Abraxis

has presented at trial would give a jury a reasonable basis to rule in Abraxis's favor on a reverse doctrine of equivalents defense.

Applying the Ciena principles to the facts of record in this case demonstrates that this defense should be dismissed. A chief principle of the claimed '363 nanoparticles is the provision of stable (non-aggregating) particles of a nano-sized anti-cancer drug (allowing them to be delivered to a tumor site to have anti-tumor activity). Nanoparticles of paclitaxel in Abraxane demonstrate the very same principle. The principles of nanoparticles of paclitaxel in Abraxane are identical to those of the '363 paclitaxel nanoparticles. Dr. Danishefsky gave unrepudiated testimony that in comparing the paclitaxel particles of Abraxane to those of the '363 Patent, he concluded that the respective forms of paclitaxel had the same molecular weight; the same chemical formula; the same chemical structure; the same purity level; the same starting materials; the same solubility in blood (within experimental error); and the same recognition by tumor cells. Tr. 733:13-736:2.

As Dr. Danishefsky concisely summed it up: "Paclitaxel is paclitaxel. There is only one paclitaxel." Tr. 734:7-16; *see also* Tr. 951:1-17 (C. Berkland) (opining that TEM images of Abraxane nanoparticles were consistent with claimed crystalline '363 nanoparticle). Dr. Danishefsky's testimony regarding the tumor cells' inability to distinguish between Abraxane paclitaxel particles and '363 nanoparticles confirms that the respective particles perform in substantially if not identically the same way. And Abraxis has not presented any fact or expert evidence specifically drawn to a showing of the factors enumerated in the case law discussing the reverse doctrine of equivalents.

For all these reasons, the Court should enter judgment as a matter of law that Abraxis's purported reverse doctrine of equivalents defense is unsupported by the law and the facts of

record.

G. Abraxis Has Not Met Its Burden Of Showing That The Claims Are Unenforceable

Abraxis has failed to put forth even a prima facie case of inequitable conduct to support its allegation that the '363 and '025 Patents are unenforceable (principally based on the same alleged failure to inform the PTO of supposed "failures" in matching surface modifiers and drugs using the screening process, of alleged (but unsubstantiated) "contamination," and of supposed failure to inform the PTO that hemodynamic effects addressed in the '025 Patent were "species specific."). For the reasons set forth in Section (A) above, neither of the first two of these allegations rises to the level of materiality, as required by the standard for inequitable conduct.

The third issue -- "species specific" -- also fails to rise to the level of materiality as defined by 37 C.F.R. Section 1.56(b) ("[I]nformation is material to patentability when it . . . (1) establishes by itself or in combination with other information, a prima facie case of unpatentability of a claim; or it refutes, or is inconsistent with, a position the applicant takes in: (i) opposing an argument of unpatentability relied on by the Office; or (ii) asserting an argument of patentability."). Abraxis put on no evidence as to: (a) the factual basis for asserting that in properly-monitored experiments, hemodynamic effects were not present in particular animals; (b) the rationale under which such information, if existent, would establish a prima facie case of unpatentability; (c) Elan's supposed relying on characterizations of animal tests as a basis for patentability. Absent such proof, the record holds no basis for determining that any material omission of disclosure took place.

Even more damagingly for Abraxis's defense, it put on absolutely no evidence of intent to deceive by Elan. The only evidence of record on intent is the consistent testimony of Gary and Elaine Liversidge to the effect that they never knowingly deceived or misled the Patent

Office. Tr. 467:9-20; Tr. 499:14-18.

An accused infringer's defense of inequitable conduct requires that it establish threshold factual showings both that the applicant submitted material false information to, or withheld material information from, the PTO during examination of the patent, and that the applicant acted with the intent to deceive the Examiner into granting the patent. *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1326 (Fed. Cir. 2000). "[I]nformation is material if there 'is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.'" *PerSeptive Biosystems, Inc. v. Pharmacia Biotech,* Inc., 225 F.3d 1315, 1321 (Fed. Cir. 2000) (quoting *Baxter Int'l v. McGaw. Inc.*, 149 F.3d 1321, 1327 (Fed. Cir. 1998)).

The accused infringer must establish each element of its defense by clear and convincing evidence. *Fiskars*, 221 F.3d at 1326. "It was to mitigate the 'plague' whereby every patentee's imperfections were promoted to 'inequitable conduct' that [the Federal Circuit] reaffirmed that both materiality and culpable intent must be established." *Allied Colloids, Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1578 (Fed. Cir. 1995). If both materiality and intent have been established by clear and convincing evidence, the Court must weigh the facts, including all evidence of the patentee's good faith, to determine the ultimate question of inequitable conduct and whether that conduct renders the patent unenforceable. *Id.*; *Kingsdown Med. Consultants v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (requiring consideration of any evidence of patentee's good faith).

In weighing materiality and intent, the more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa. *Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1261 (Fed. Cir. 2001). However,

if either materiality or intent is not found, then no further analysis need be performed. "[G]ross negligence or gross recklessness alone, absent culpable intent, does not provide sufficient basis for a holding of inequitable conduct." *Tool-O-Matic v. Proma Produkt-Und Mktg. Gessellschaft M.B.H.*, 945 F.2d 1546, 1553 (Fed. Cir. 1991), *overruled on other grounds by Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995); *see also CFMT, Inc. v. YieldUp Int'l Corp.*, 349 F.3d 1333, 1342-43 (Fed. Cir. 2003) ("However, even gross negligence does not alone suffice to establish intent . . . Instead, 'the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.'"). "While lack of deceptive intent, as a negative, may be hard for a patentee to prove . . . good faith is presumed in the absence of a persuasive showing of deceptive intent." *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 n.4 (Fed. Cir. 1998).

Because there is absolutely no showing of intent to deceive, and because materiality has only been insinuated, not clearly shown, as to the alleged non-disclosures, the Court should enter judgment dismissing Abraxis's inequitable conduct counterclaim and defense.

H. The Doctrine Of Unclean Hands Is Not A Defense And Has Not Been Established

Elan has consistently argued that Abraxis's "unclean hands" defense is not properly submitted to the jury, as it is a purely equitable doctrine. Further, there is no evidence of record that would support a finding that Elan has acted improperly in the assertion of its patents and the prosecution of this lawsuit.

"The basis of the unclean hands 'defense' is the 'equitable principle that '[n]o court will lend its aid to a man who founds his cause of action upon an immoral or illegal act.'"). *Sears, Roebuck & Co. v. Sears plc*, 744 F. Supp. 1297, 1309-10 (D. Del. 1990) (citing *American Bell, Inc. v. Federation of Telephone Workers* of *Pennsylvania,* 736 F.2d 879, 886 (3d Cir. 1984))

(citation omitted). "In actuality, a defendant's claim of unclean hands on the part of a plaintiff is not a defense at all." *Sears*, 744 F. Supp. at 1309. "When presented with a claim of unclean hands, the court is primarily concerned with protecting its own integrity, and in not abetting the inequitable conduct of a plaintiff with respect to the matter in litigation." *Id.*

Abraxis's unclean hands allegations are also likely redundant in view of its inequitable conduct arguments based on the prosecution of the patents in suit. "While bringing a lawsuit brings the contested issue before the court, the act of bringing suit is not, itself, the matter concerning which a plaintiff seeks relief. Thus, the Court must focus on alleged inequitable conduct in the gaining or the use of the right being contested, not alleged inequitable conduct in the bringing of the lawsuit. Accordingly, PLC cannot maintain a claim of unclean hands based on Roebuck's alleged intent in bringing this action as based on Roebuck's alleged litigation strategy." *Id.* at 1310.

Further, the Court can readily determine that Elan's claims -- which are about to be submitted to the jury, and which have survived multiple attempts by Abraxis seeking dismissal and limitation -- are far from baseless. Abraxis's positions supposedly supporting its "unclean hands" theory are either based upon a tendentious assumption that Abraxis will prevail on all disputed issues, or on incorrect allegations that Elan knew its contentions had no merit. Merely asserting the claims of an issued and presumptively valid United States Patent against a product reasonably believed to infringe cannot be the basis for denying Elan a hearing on or recompense for such claims.

The Court should accordingly disregard Abraxis's "unclean hands" defense, should not submit it to the jury, and should enter judgment that Abraxis cannot prevail on such a defensive theory.

H. Abraxis Cannot Prove Damages On Any Theory Other Than Elan's

Elan tendered an expert report of Mr. John Jarosz on the issue of damages. Abraxis tendered an expert report of Mr. Terry Musika. Mr. Jarosz testified at trial, setting forth his theory of damages. Neither Mr. Musika nor any other witness appeared at trial to contest Mr. Jarosz's opinion or set forth a different factual or expert basis for calculating damages.

For this reason, while the jury generally has discretion to assess damages independently, the Court should enter judgment as a matter of law that Mr. Musika's theory of damages cannot be the basis of a damages award, but that instead, Mr. Jarosz's opinion on damages should be adopted by the Court as conclusive of the economic damages caused to Elan by Abraxis's infringement, and judgment should be entered as a matter of law to this effect.

CONCLUSION

For the forgoing reasons, this Court should enter judgment as a matter of law on the respective counterclaims and defenses of Abraxis set forth hereinabove.

ASHBY & GEDDES

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